# 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: **iBeta LLC**
**The lab uses iBeta Quality Assurance also.**

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.

**The Quality Management System covers this area.**

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.

**One laboratory location.**

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.

**Quality assurance testing is the business of iBeta.**

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

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

**4.1.5** The laboratory shall:

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

**The organizatonal chart defines roles; they are further defined in Paragraph 4.1.5 of the iBeta "Quality Policies of the iBeta Quality Management System" which is called the "iBeta – Quality Policy."**

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;

**4.1.5 b) in the "iBeta Quality Policy" covers this as does the Employee Handbook**

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;

**4.1.5 c) in the "iBeta Quality Policy"**

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

**4.1.5 d) in the "iBeta Quality Policy"**

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;

**4.1.5 e) in the "iBeta Quality Policy"**

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;

**4.1.5 f) in the "iBeta Quality Policy"**

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;

**4.1.5 g) in the "iBeta Quality Policy"**

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;

**4.1.5 h) in the "iBeta Quality Policy"**

Name of person: **Carolyn Coggins - QA Director**
Area of responsibility: **Voting Division - reports to Earl Wing, VP/CFO**
Repeat as necessary: **Gail Audette -Quality Manager**

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: **Gail Audette -Quality Manager**

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

Name(s): **Carolyn Coggins - Quality Assurance Director**

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.

**Reviewed two personnel files, a signed and dated form was in the files indicating they had knowledge of the "Introducton to the Quality Management System"**

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

X♦ **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.

**Not addressed in the Quality Policy**

## 4.2 Management system

**4.2.1**

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

**Sharepont – Configuration Management System; Quality Policy**

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.

**iBeta Quality Policy plus Procedures cover this area**

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

**The documentation is available through the electronic servers of iBeta.**

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

Date of most recent quality manual: **11/21/06**

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

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

**"Our Corporate Philosophy" is contained in the employee handbook**

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

**"Our Corporate Philosophy" is contained in the employee handbook**

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

**"Our Corporate Philosophy" is contained in the employee handbook**

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

**"Our Corporate Philosophy" is contained in the employee handbook**

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

**No words in the quality policy statement nor the employee handbook to address this at the top level**

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

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

**Not addressed in the "ibeta Quality Policy"**

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

**Every employee was introduced to the Quality Mangement System as was evidenced by inspecting two personnel files**

**4.2.5**

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

**Business vertical procedures need to be added to 2.3 of the Quality Policy which is referenced in 4.2.5 of the Quality Policy**

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

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

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.

## 4.3 Document control

### 4.3.1 General

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

**Reviwed Document Control Procedure – Version 1.1**

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

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

### 4.3.2 Document approval and issue

**4.3.2.1**

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

**ok**

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

**The Master List is available on the home page of the QMS; it includes the Quality Policy and 12 Quality Procedures**

**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;

**Available electronically**

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

**ok**

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

**ok**

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

**ok**

**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,

OK b) page numbering,

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

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.

**The document "Creating or Modifying a Procedure" covers this topic.**

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

**Sharepoint automatically retains earlier versions of the appropriate documents.**

**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**

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

**Allowable under non-standard testing; see 4.3.3.3 of the Quality Policy**

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

**SharePoint**

## 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:

**150-22 - 4.4.1** The procedures for review of contracts shall include procedures to ensure that the customer understands that its products and systems must meet the requirements of HAVA, the VSS-2002, and the EAC. **Covered in paragraph 6.1.2 in the Project Management Voting . Sharepoint has a procedure called "Review of Contracts" that covers this.**

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

**Covered under "Review of Contracts"**

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

**Covered under "Review of Contracts"**

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

**Covered under "Review of Contracts"**

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.

**Covered under "Review of Contracts"**

**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.

**150-22 4.4.2** The review shall include (but is not limited to): laboratory competencies and resources to provide the service, vendor-supplied documentation, tests to be conducted, test requested in addition to Qualification/National Certification Testing, and the requirements for subcontracting Covered under "Review of Contracts"; all records and e-mail discussions are archived.
**Covered in 6.1.2 of Project Management Voting Procedure.**

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

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

**150-22 4.4.3 The laboratory may conduct one or more state's Certification Testing for products and systems for which it previously conducted Qualification/National Certification Testing.**
**NOTE: Procedures for the review of requests, tenders, and contracts should include provisions to ensure that any State Certification Testing does not replace or dilute the Qualification/National Certification Testing requirements.**

**Covered under "Review of Contracts" procedure and 6.1.2 in Project Management Voting Procedure**

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

**Covered under "Review of Contracts"**

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.

**Covered under "Review of Contracts"**

## 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.

**Clause 6.1.2 of the iBeta procedure "Subcontracting" states the term "independent subcontractor or contractor" where subcontractor is not consistent with 17025/150. The term "contractor" is defined in the iBeta procedure "Subcontracting" and is appropriate for clause 6.1.2 but "subcontractor" is defined as an "accredited lab' and is not appropriate for clause 6.1.2.**

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.

**P aragraph 4.5.2 of the iBeta Quality Policy covers this issue**
**150-22 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.
**This is covered in the voting subcontractor list plus 4.5.1 of the iBeta Quality Policy.**

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

**Paragraph 4.5.3 of the iBeta Quality Policy covers this issue**
**4.5.3** If the VSTL subcontracts voting system testing that is outside of its scope of accreditation, the subcontracted laboratory must be:

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).

c. accredited under the appropriate scope of accreditation for the testing which is subcontracted.

**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.

**The list of subcontracted labs contains only labs in the USA and they are A2LA Accredited for the appropriate subcontracted tests.**

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

**There is a list of potential United States subcontractors for voting issues; in the Voting Vertical in Sharepoint. The plan is to use accredited subcontactors and two specific potential subcontracted labs have been contacted by phone and pre-qualified.**

**150-22 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.

**The FCA environmental test case assures that the equipment tested is the same as the equipment that is provided for certification testing. The Operational Status check is covered in the FCA environmental test case. Responsibility for the testing is covered under Paragraph 4.5.3 of the iBeta Quality Policy.**

## 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.

**Software services are purchased. Reagents and lab consumable materials are not relevant for election. Equipment Procuring, Handling, and Validation Procedure is relevant.**

**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.

**Equipment Procuring, Handling, and Validation Procedure is relevant.**

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

**Equipment Procuring, Handling, and Validation Procedure is relevant.**

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

**Equipment Procuring, Handling, and Validation Procedure is relevant.**

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

**4.6.4**

OK a) The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and

**Paragraph 4.6.4 of the Quality Policy is pertinent.**

X b) shall maintain records of these evaluations and list those approved.

**No evidence of an approved vendor list was available.**

## 4.7 Service to the customer

C **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.

**The procedure called "Review of Contracts" covers this issue as well as Paragraph 4.7.1 in the Quality Policy. The 2005 version of ISO/IEC 17025 changed the word "client" to "customer " and this is consistent with NIST Handbook 150 (2006 version) where the term customer is defined but client is not defined.**

**NOTE 1** Such cooperation may include:

a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer;

b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

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

OK♦ **4.7.2** The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.

**Feedback is solicited from customers via phone calls or e-mail. The feedback can be either positive or negative. Positive feedbacks are fed back to the employees who were involved with the project. Three examples of positive feedbacks were examined.**

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

## 4.8 Complaints

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

**The appropriate policy is found in Paragraph 4.8 of the Quality Policy. The procedure is "Handling Complaints" and it refers to an Action Plan which is initiated in some of the complaints.**

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

**One complaint from an external customer in the last 12 months.**

## 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:

**The appropriate policy is found in Paragraph 4.9 of the Quality Policy. The appropriate procedures are "Handling Complaints", "Test Project Management",**

150-22 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.

**Paragraph 6.2.2 of VSTCA Test Planning Procedure covers this issue.**

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;

**Paragraph 4.9 of the Quality Policy**

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

**Paragraph 4.9 of the Quality Policy**

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

**Paragraph 4.9 of the Quality Policy**

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

**Paragraph 4.9 of the Quality Policy**

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

**Action Plans in Paragraph 4.9 of the Quality Policy cover this issue.**

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

OK **4.9.2** Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.

**Paragraph 4.9.2 of the Quality Policy covers this issu.**

## 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.

**The iBeta Quality Policy covers this issue in paragraph 4.10 – Improvement. The Audit and Management Review Procedure is used as a technique to improve the overall operations.**

## 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.

**The iBeta Quality Policy covers this topic in paragraph 4.11 – Corrective Actions. The appropriate procedure is called "Action Plans – Corrective, Improvement and Proactive"**

**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.

**Paragraph 6.2.1 of the procedure "Action Plans – Corrective, Improvement and Proactive" covers this issue**

**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.

**Paragraph 6.2.2 of "Action Plans – Corrective, Improvement and Proactive" covers this issue.**

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

**Paragraph 6.2.2 of "Action Plans – Corrective, Improvement and Proactive" covers this issue.**

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

**Paragraph 6.2.3 – Implement the Action Plan of "Action Plans – Corrective, Improvement and Proactive" covers this issue.**

### 4.11.4 Monitoring of corrective actions

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

**A pass/fail criteria is used; pass means the achievements or milestones of the action plan have been met; see Paragraph 6.3 of the iBeta procedure "Action Plans – Corrective, Improvement and Proactive".**

### 4.11.5 Additional audits

OK 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.

**Paragraph 4.11.5 of the iBeta Quality Policy covers this issue. The iBeta procedure "Audit and Management Review" covers this topic in Paragraph 6.1.2.**

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

## 4.12 Preventive action

### 4.12.1

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

**Paragraph 4.12.1 of the "iBeta Quality Policy" covers this topic. The Audit and Management Review procedure is relevant.**

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

**Paragraph 4.12.1 of the "iBeta Quality Policy" covers this topic. The Audit and Management Review procedure is relevant**

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

**Paragraph 4.12.2 of the "iBeta Quality Policy" covers this topic. The Audit and Management Review procedure is relevant. One example was discussed about improving the operations through an "end of project" form.**

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

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

## 4.13 Control of records

### 4.13.1 General

OK **4.13.1.1** The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of

quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

**Paragraph 4.13.1.1 of the "iBeta Quality Policy" covers this topic. The appropriate iBeta procedure is "Document Control."**

**4.13.1.2**

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

**Records are stored electronically for at least three years.**

OK b) Retention times of records shall be established.

**3 to 5 years is used.**

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

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

**Records are stored electronically in a secure and protected environment.**

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

**Okay for 150 purposes.**

**150-22 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.

### 4.13.2 Technical records

**4.13.2.1**

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

**Covered in paragraph 4.13.2.1 of the iBeta Quality Policy and Paragraph 6.2.4 of the procedure "Test Planning, Execution, and Recording of Results"**

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

**Covered in paragraph 4.13.2.1 of the iBeta Quality Policy and Paragraph 6.2.4 of the procedure "Test Planning, Execution, and Recording of Results"**

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.

**Covered in paragraph 4.13.2.1 of the iBeta Quality Policy and Paragraph 6.2.4 of the procedure "Test Planning, Execution, and Recording of Results"**

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

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

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

**Covered in paragraph 4.13.2.2 of the iBeta Quality Policy and Paragraph 6.2.4 of the procedure "Test Planning, Execution, and Recording of Results"**

**4.13.2.3**

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

**Covered in paragraph 4.13.2.3 of the iBeta Quality Policy and Paragraph 6.2.4 of the procedure "Test Planning, Execution, and Recording of Results"**

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

**Covered in paragraph 4.13.2.3 of the iBeta Quality Policy and Paragraph 6.2.4 of the procedure "Test Planning, Execution, and Recording of Results"**

150-22 4.13.2 The laboratory shall maintain a functional record-keeping system that is used to track each product or system.

a. Records shall be easily accessible and contain complete information for each Qualification/National Certification test.

b. Required records of testing activities shall be traceable to requirements in the VSS-2002
NOTE: Technical reviewers of the Qualification/National Certification Test Reports have requested tha report include a standardized test requirement matrix against the VSS 2002/VVSG 2005 requirements sl which tests/reviews were performed, whether the results were accepteed, and, if based on reports from e tests or laboratories, the reference for the report of the test.

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.

d. Entries in laboratory notebooks shall be dated and signed or initialed

e. All records shall be maintained in accordance with laboratory policies and procedures and in a manner that ensures record integrity.

f. There shall be appropriate backups and archives

**Sharepoint is being used to track the documentation. The electronic records are backed up and stored off-site.**

**4.13.3** Laboratory records shall be maintained, released, or destroyed in accordance with the laboratory' policy on proprietary information and contractual agreements with customers.

**Handled by the Contracts procedure**

**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.

**Handled through Sharepoint. Records are kept for a minimum of three years.**

## 4.14 Internal audits

**4.14.1**

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

Dates of most recent internal audit: September of 2006 and November of 2006

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

**September of 2007 is the next scheduled internal audit. This is covered in Paragraph 4.14 of the iBeta Quality Policy. Also, the iBeta procedure is "Audit and Management Review"**

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

**This is covered in Paragraph 4.14 of the iBeta Quality Policy. Also, the iBeta procedure that covers this is "Audit and Management Review"**

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

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

**Action plans are generated to cover the deficiencies uncovered in the internal audits. Each item on the action plan has a completion date that it is to be resolved. Customer notification is covered under the Action Plans.**

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

**Covered under 4.14 of the Quality Policy and the resulting action plans.**

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

**The action plans cover this element.**

## 4.15 Management reviews

OK **4.15.1** In accordance with a predetermined schedule and procedure, the

laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

Date(s) of most recent management review: **14 September 2006**

What is the review schedule? **September 2007**

The review shall take account of:

**Covered in the iBeta Quality Policy (Paragraph 4.15) and the iBeta Procedure "Audit and Management Reviews." Thirteen Action plans were generated as a result of the Management Review. Reviewed one of the "Audit Findings and Action Plan of the Review of Action Plans Procedure."**

OK a) the suitability of policies and procedures;

OK b) reports from managerial and supervisory personnel;

OK c) the outcome of recent internal audits;

OK d) corrective and preventive actions;

OK e) assessments by external bodies;

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

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

OK h) customer feedback;

OK i) complaints;

OK♦ j) recommendations for improvement;

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

**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.

**Details on each of thirteen action plans indicated that some have closed out all**

**open actions and some are still being worked on.**

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

## 5 Technical requirements for accreditation

### 5.1 General

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

i) human factors (5.2);

ii) accommodation and environmental conditions (5.3);

iii) test and calibration methods and method validation (5.4);

iv) equipment (5.5);

v) measurement traceability (5.6 and Annex B);

vi) sampling (5.7);

vii) the handling of test and calibration items (5.8).

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

### 5.2 Personnel

**5.2.1**

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

**Covered in Paragraph 5.2.1 of the iBeta Quality Policy and in the iBeta Procedure "Personnel and Training"**

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

**Summer employees are given 2 days of intensive training, 3 days of self-study, then, one week of work with close supervision. After the first two weeks, the**

**individuals are evaluated and permitted to work without supervision, or more training is required or the person is terminated.**

**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;

**Technical degrees are preferred for the full-time employees checking software.**

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

**ok**

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

**Ok**

**150-22 5.2.1** The laboratory shall maintain a competent administrative and technical staff appropriate for testing voting systems to be recognized by the EAC under the HAVA. The laboratory shall maintain position descriptions, training records and resumes for responsible supervisory personnel and laboratory staff members who have an effect on the outcome of Qualification/National Certification tests.

**The training for the voting systems is covered in the business vertical procedure for Voting "VSTL Training and Training Records." The records are stored in the VSTL Staff Log on the computer in a read-only format.**

**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.

**No goals are required from employees but additional education is encouraged from the employees.**

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

**In-house courses are offered to employees on an occasional basis.**

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

**Paragraph 5.2.2 of the iBeta Quality Policy covers Training. Training is difficult in some specialized areas; it is more business-oriented to hire people with specific skills. At the start of projects, a need analysis is done and some employees may receive additional training at that time.**

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

**Feedback is received from employees on in-house courses via e-mail. The courses**

**are evaluated based on that feedback.**

**150-22 5.2.2** The laboratory shall maintain a list of personnel designated to fulfill NVLAP requiremen including: An individual may be assigned or appointed to serve in more than one position; however, t extent possible, the laboratory director and the quality manager positions should be independently staf

**Laboratory Director: __Earl Wing – Vice-President_____**

**Technical Director: _____Jonathan Goodman_____**

**Authorized Representative: List names and titles**
**a. ____Carolyn Coggins – QA Director_____**

**Approved Signatories:**

**a. ____Carolyn Coggins_____**

**b. _____Gail Audette_____**

**c. _____**

**Team Leaders (reference Org chart): Carolyn Coggins and Gail Audette**

**Quality Manager: Gail Audette**

**Note**: A organization chart identifying positions and titles shall be provided as part of the VSTL application and updated when these positions are changed with the EAC.

**5.2.3**

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

**ok**

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**

**150-22 5.2.3 The laboratory shall notify both NVLAP and the EAC within 30 days of any change in key personnel. When key personnel are added to the staff, the notification of changes shall include a current resume for each new staff member.**

**The iBeta procedure entitled "Project Management-Voting" has paragraph 6.1.1 which states "advise NVLAP and EAC" of any changes to key personnel within 30 days of the change.**

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

**Paragraph 5.2.4 of the Quality Policy has general descriptions of QA Director, Project Manager, QA Senior Lead, QA Lead, Senior Tester, and Tester.**

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

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

**ok**

ii) the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;

**ok**

iii) the responsibilities for reporting opinions and interpretations;

**ok**

iv) the responsibilities with respect to method modification and development and validation of new methods;

**ok**

v) expertise and experience required;

**ok**

vi) qualifications and training programs;

**ok**

vii) managerial duties.

**Ok**

**150-22 5.2.4** Laboratories shall document the required qualifications for each staff position. The staff information may be kept in the official personnel folders or in separate, official folders that contain only the information that the NVLAP assessors need to review.

**Each voting procedure has requirements for qualifying personnel to work on that particular procedure. The qualifying personnel and their skills are listed in the VSTL Staff Log.**

**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.

**Reviewed one personnel file and found it included a diploma from college plus additonal training records.**

X c) This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

**The file that was reviewed had dates on the training record.**

**150-22 5.2.5** The laboratory shall have documented a detailed description of its training program for new and current staff members. Each new staff member shall be trained for assigned duties. The training program records shall be updated as individuals are assigned new responsibilities. Each staff member may receive training for assigned duties either through on-the-job training, formal classroom study, attendance at conferences, or another appropriate mechanism. Training materials that are maintained within the laboratory shall be kept up-to-date.

**For iBeta, the VSTL Training and Training Records Procedures covers this in Paragraphs 6.1.1. 6.1.2, and 6.3.1. VSTL training is documented in the VSTL Staff Log**

**X - 150-22 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.

**The competency review program is not documented fully in the Voting training procedure**.

**150-22 5.2.7** Individuals hired to perform testing activities are sometimes referred to as *contractors*. 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.).

**The Voting Business procedure VSTL Training and Training Records covers this issue; no distinction is made between full time or part-time employees for training.**

**150-22 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.

**Section 4 of the VSTL procedures covers this issue for each person working on the Procedure. The VSTL staff page summarizes the capabilities of the individuals**.

**150-22 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.

**The VSTCA Project Management Procedure covers this in Paragraph 6.2.2.**

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

## 5.3 Accommodation and environmental conditions

**5.3.1**

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

**Accommodations are typical office environment.**

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.

**ok**

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

**ok**

**5.3.2**

OK a) The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.

**Normal office environment**

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

**ok**

OK **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.

**Separate areas are maintained for security (separation of business activities).**

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

**Tight security in the office areas; locked doors, special biometric entry requirements, camera monitoring and motion/infrared detection are part of the overall security.**

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

**Good housekeeping.**

**150-22 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.

**The iBeta PCA Configuration Template has specific instructions on testing outside the lab.The procedure on Test Case Preparation and Execution also covers this topic in Paragraph 6.2.2**

**150-22 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.

**The iBeta PCA Configuration Template has specific instructions on testing outside the lab. The procedure on Test Case Preparation and Execution also covers this topic in Paragraph 6.2.2. In addition, the Trusted Build Procedure covers this in section 6.1.4 with a digital signature element.**

## 5.4 Test and calibration methods and method validation

### 5.4.1 General

X 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.

**Covered in Paragraph 5.4.1 of the iBeta Quality Manual**

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

**The lab uses Personal Computers for their work on validating and checking software. In preparing items for testing, the Operational Status check on voting systems prior to environmental testing and after environmental testing. Functional testing is done , including using their manuals to set up the system, before formal testing is begun.**

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

**Personal computers and associated software is used.**

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

**Handled with a selection of test methods in paragaph 6.1.1. of the iBeta procedure on "Test Planning, Execution and Recording of Results."**

**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

X 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.

**Covered in Paragraph 5.4.2 in the iBeta Quality Manual**

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

**ok**

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

**5.4.2 of the Quality Manual**

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

**5.4.2 of the Quality Manual**

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

**5.4.2 of the Quality Manual**

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

**5.4.2 of the Quality Manual**

### 5.4.3 Laboratory-developed methods

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

**5.4.3 in the Quality Policy. In the Voting Project Management Procedure, checking with the EAC for technical interpretations is covered in section 6.2.5.**

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

**The business vertical procedure for voting covers the test plans for voting.**

### 5.4.4 Non-standard methods

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

**Covered in 5.4.4 of the iBeta Quality Policy**

OK 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.

**5.4.5.2**

X 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.

**Covered in 5.4.5.2 of the Quality Policy. Some minor references but there is no apparent description of validation techniques. In the format used, this may be difficult as it needs to be done on a test case basis in each test campaign.**
Note: iBeta uses the term "proof of concept" for "validation"
**The testing procedures are very complete in coverage but lack the form appropriate for identifying as methods. For example, the security requirements require a specific test which should be in a methods type format to support transparency of the testing . Accessibility, Accuracy and/or Reliability, and others also need to be explict methods.**

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

**Covered in 5.4.5.2 of the Quality Policy. No evidence was found of the results.**

**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.

N/A **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.

### 5.4.6 Estimation of uncertainty of measurement

N/A **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.

N/A **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).

OK **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

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

**Covered in Paragraph 5.4.7.1 in the Quality Policy. The Procedure on "Test Planning, Execution and Recording of Results" is appropriate.**

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

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

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

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

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

## 5.5 Equipment

**5.5.1**

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

**The personal computers are used to run the software which is used to check and validate software for voting.**

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

**The purchase process covers rental of equipment which is seldom done.**

**150-22 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.

**Covered in VSTCA Test Plan Template, PCA configuration instruction and test, and the Environmental Test Case.**

**5.5.2**

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

**Paragraph 5.5.2 of the iBeta Quality Policy covers this.**

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

**N/A**

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

**Covered in Paragraph 5.5.2 of the Quality Policy. The procedure that covers this is the iBeta "Equipment Procuring, Handling, and Validation" Procedure.**

**150-22 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.

**Covered in the PCA Configuration Template and the VSTCA Certification Test Report (Tables 4 - 7).**

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

**Covered by Paragraph 5.5.3 of the Quality Policy.**

**150-22 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.

**QMS Test Planning, Execution, and Recording of Results is used as well as the environmental test case.**

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

**Paragraph 5.5.4 of the Quality Policy covers this.**

**150-22 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.

**See the PCA Configuration – Instruction TAB.**

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

**IBeta uses a Red Beam Asset Tracking system to keep track of their testing hardware and software.**

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

**ok**

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

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

OK d) the current location, where appropriate;

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

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

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

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

**Pictures are taken of most equipment that is received from customers and stored digitally.**

**150-22 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.

**VSTCA Test Report Template plus the test cases cover this issue. The system test configuration table for each test allows the test to be reproduced**.

N/A **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**

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

**Equipment can be marked in the computer so that it is not used for testing.**

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

**iBeta "Equipment Procuring, Handling, and Validation" Procedure**

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

**There is a bar code on every piece of equipment that can be read by the Red Beam Asset Tracking system.**

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

**Paragraph 6.2 of iBeta "Equipment Procuring, Handling, and Validation" Procedure handles this issue.**

N/A **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.

N/A **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.

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

**Paragraph 5.5.12 of the Quality Policy covers this. The IT Handbook also covers this topic. The IT Handbook is called the "Technology Policies and Procedures Handbook" and each employee signs a statement saying they have read and understand the policy. This statement is kept in the employees personnel file.**

## 5.6 Measurement traceability

### 5.6.1 General

N/A 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.

N/A 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**

N/A a) For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**5.6.2.2 Testing**

N/A **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.

N/A **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**

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

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

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

**5.6.3.2 Reference materials**

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

**5.6.3.3 Intermediate checks**

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

#### 5.6.3.4 Transport and storage

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

**150-22 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 VSTCA Test Planning, the VSTCA test report procedure, and the FCA test document cover this .**

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

## 5.7 Sampling

### 5.7.1

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

**Covered in the test plan (section 6.2.1 )in the procedure "Test Planning, Execution, and Reporting of Results"**

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

**Covered in the test plan (section 6.2.1 )in the procedure "Test Planning, Execution, and Reporting of Results"**

**150-22 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.

**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.

OK **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.

**Paragraph 5.7.2 of the Quality Policy. Also, Paragraph 6.2.4 in the procedure "Test Planning, Execution, and Reporting of Results"**

**150-22 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).

**Covered in the FCA Test Document Review Procedure**

OK **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.

**Covered in the test plan and test case preparation (section 6.2.1 )in the procedure "Test Planning, Execution, and Reporting of Results"**

**150-22 5.7.3** Sampling shall be part of the test record.

**Covered in the VSTCA Test Plan Template.**

## 5.8 Handling of test and calibration items

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

**Paragraph 5.8.1 of the Quality Policy covers this. The iBeta procedure on "Equipment Procuring, Handling and Validation" is appropriate**

**5.8.2**

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

**The iBeta procedure on "Equipment Procuring, Handling and Validation" is appropriate**

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

**The iBeta procedure on "Equipment Procuring, Handling and Validation" is appropriate**

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

**The iBeta procedure on "Equipment Procuring, Handling and Validation" is appropriate**

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

**The iBeta procedure on "Equipment Procuring, Handling and Validation" is appropriate**

**5.8.3**

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

**The iBeta procedure on "Equipment Procuring, Handling and Validation" is appropriate**

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

**The iBeta procedure on "Equipment Procuring, Handling and Validation" is appropriate**

**5.8.4**

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

**The iBeta procedure on "Equipment Procuring, Handling and Validation" is appropriate.The facilities are adequate for storing test items and are very secure.**

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

**The iBeta procedure on "Equipment Procuring, Handling and Validation" is appropriate**

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

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

**Very secure conditions exist in the lab area.**

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

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

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

## 5.9 Assuring the quality of test and calibration results

**5.9.1**

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

**Paragraph 5.9.1 of the Quality Policy is pertinent.**

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

**Paragraph 5.9.1 of the Quality Policy is pertinent.**

OK 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;

OK 3) replicate tests or calibrations using the same or different methods;

**When an error is found, the same method is used to assure repeatability of the error. This is covered in Procedure "Test Planning, Execution, and Recording of Results" paragraph 6.2.4.**

___ 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.

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

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| **Paragraph 5.9.2 of the Quality Policy is appropriate. Metrics are used on defect tracking. This is found in "Action Plans" procedure; paragraph 6.2**<br><br>**150-22 5.9.2**<br>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.<br><br>The Quality Control Requirements are covered in Table 7 of each iBeta Procedure and each Voting Procedure. For example, the "Trusted Build Procedure" has a reference to "Vendor Discrepancies" and "Staff Conducting Tasks Must be Qualified.This is covered in general in iBeta Procedure "Creating or Modifying a Procedure." |

## 5.10 Reporting the results

### 5.10.1 General

OK a) The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

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| Paragraph 5.10.1 of the iBeta Quality Policy is appropriate. No current actual reports<br>Confirmed in Report Template, Report carries a version number but not unique number except the certification number which not issued until the report is approved<br>Create unique number for report independent of the certification number<br>These reports involve multiple methods and will need to have this addressed in contract, test plan, and report |
| |

OK 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.

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

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

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

### 5.10.2 Test reports and calibration certificates

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

OK a) a title (e.g., "Test Report" or "Calibration Certificate");

OK b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;

OK 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;

OK d) the name and address of the customer;

OK e) identification of the method used;

OK f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;

OK 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;

OK 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;

OK i) the test or calibration results with, where appropriate, the units of measurement;

OK j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;

OK 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:

X a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;

**Not Specified**

OK b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

N/A c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;

OK d) where appropriate and needed, opinions and interpretations (see 5.10.5);

OK 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:

N/A a) the date of sampling;

N/A b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);

N/A c) the location of sampling, including any diagrams, sketches or photographs;

N/A d) a reference to the sampling plan and procedures used;

N/A e) details of any environmental conditions during sampling that may affect the interpretation of the test results;

N/A f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

**5.10.4 Calibration certificates**

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

N/A a) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;

N/A b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

N/A c) evidence that the measurements are traceable (see Note 2 in 5.6.2.1.1).

**5.10.4.2**

N/A a) The calibration certificate shall relate only to quantities and the results of functional tests.

N/A b) If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

N/A c) When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

N/A d) When statements of compliance are made, the uncertainty of measurement shall be taken into account.

N/A **5.10.4.3** When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

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

**5.10.5 Opinions and interpretations**

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

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

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

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

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

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

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

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

**Add: New requirement from EAC Cert Manual that all certification records, including some email and fax, shall be transmitted by secure carrier, or, if electronic, encrypted and digital signature.**

### 5.10.7 Electronic transmission of results

C 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).

**Add: New requirement from EAC Cert Manual that all certification records, including some email and fax, shall be transmitted by secure carrier, or, if electronic, encrypted and digital signature.**

### 5.10.8 Format of reports and certificates

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

**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

X 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.

**Need additional details including a sample report.**

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

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| OK | 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. |

# Annex A (normative)

## Referencing NVLAP accreditation

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

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

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

X **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.

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

X **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.

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

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

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

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

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

X 1) The logo shall stand by itself and shall not be combined with any other logo, symbol, or graphic.

X 2) The aspect ratio (width to height) shall be 2.25 to 1.

X 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.

X 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.

X **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)**

X 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.

X 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.

X 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)**

X 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.

X 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.

| | | | |
|---|---|---|---|
| | X | 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. |
| | X | 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. |
| X | **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. |
| X | **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. |
| X | **l)** | | Laboratories shall not use the terms *certified* or *registered* when referencing their NVLAP accreditation or conformance to ISO/IEC 17025 requirements. The correct term is *accredited*. |

# Annex B (normative)

## Implementation of traceability policy in accredited laboratories

### B.1 Policy overview

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

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

### B.2 General

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

___ 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

___ **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,

___ 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.

## 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* |
|---|---|---|
| 1-G | X | 4.1.6 - Not addressed in the "iBeta Quality Policy" |
| 2-G | X | 4.2.2 e) - No words in the quality policy statement nor the employee handbook to address this at the top level |
| 3-G | X | 4.2.3 - Not addressed in the "ibeta Quality Policy" |
| 4-G | X | 4.2.5 a) - Business vertical procedures need to be added to 2.3 of the Quality Policy which is referenced in 4.2.5 of the Quality Policy |
| 5-G | X | 4.5.1 -Clause 6.1.2 of the iBeta procedure "Subcontracting" states the term "independent subcontractor or contractor" where subcontractor is not consistent with 17025/150. The term "contractor" is defined in the iBeta procedure "Subcontracting" and is appropriate for clause 6.1.2 but "subcontractor" is defined as an "accredited lab' and is not appropriate for clause 6.1.2. |
| 6-G | X | 4.6.4 b) - No evidence of an approved vendor list was available |
| 7-G | C | .4.7.1 - The procedure called "Review of Contracts" covers this issue as well as Paragraph 4.7.1 in the Quality Policy. The 2005 version of ISO/IEC 17025 changed the word "client" to "customer " and this is consistent with NIST Handbook 150 (2006 version) where the term customer is defined but client is not defined. |
| | | |
| 9-G | X | 5.2.5 c) – 150-22 – 5.2.6 - The competency review program is not documented fully in the Voting Training Procedure |
| 10-G | X | 5.4.1 a) Some minor references but there is no apparent description of validation techniques. In the format used, this may be difficult as it needs to be done on a test case basis in each test campaign.<br>Note: iBeta uses the term "proof of concept" for "validation"<br>The testing procedures are very complete in coverage but lack the form appropriate for identifying as methods. For example, the security requirements require a specific test which should be in a methods type format to support transparency of the testing . Accessibility, Accuracy and/or Reliability, and others also need to be explicit methods.<br>Within the test cases, a section exists for prerequisite conditions relevant for the test case. It is expected that this will contain relevant information. The QP includes the copied statement but could not find evidence that it is being done or understood. |
| 11-G | X | 5.4.2 a) , The system uses combinations of test cases and templates, not methods. The lab recognizes and has developed test procedures for non-standard methods but need additional work on establishing a program for validating the "method" procedures they use. Some records are included for specific test cases. |

| | | |
|---|---|---|
| 12-G | X | 5.4.5 - Some minor references but there is no apparent description of validation techniques. In the format used, this may be difficult as it needs to be done on a test case basis in each test campaign.<br>Note: iBeta uses the term "proof of concept" for "validation"<br>The testing procedures are very complete in coverage but lack the form appropriate for identifying as methods. For example, the security requirements require a specific test which should be in a methods type format to support transparency of the testing . Accessibility, Accuracy and/or Reliability, and others also need to be explict methods. |
| 13-G | C | 5.4.3 - The development is based on each test campaign in the form of the Template process (Proof of Concept) and as stated in Test Planning, Execution, and Recording of Results, is used more as a selection technique than as a process needed for all but nationally validated test methods. Even in these cases, a validation is expected to verify the ability to perform the test method. |
| 14-G | X | 5.4.5 - Some minor references but there is no apparent description of validation techniques. In the Format used, this may be difficult as it needs to be done on a test case basis in each test campaign |
| 15-G | X | Annex A – No words in the policy or procedure that are apparent to cover the NVLAP logo issue |
| 16-G | C | 5.10.2 c) -Confirmed in Report Template, Report carries a version number but not unique number except the certification number which not issued until the report is approved Create unique number for report independent of the certification number |
| 17-G | C | 5.10.2 e) - These reports involve multiple methods<br>And will need to have this addressed in contract, test plan, and report |
| 18-G | C | 5.10.2 f) - need to add condition of equipment to the test equipment directory |
| 19-G | X | 5.10.3.1a – Not Specified |
| 20-G | C | 5.10.6 c) - Add: New requirement from EAC Cert Manual that all certification records, including some email and fax, shall be transmitted by secure carrier, or, if electronic, encrypted and digital signature. |
| 21-G | C | 5.10.7 - Add: New requirement from EAC Cert Manual that all certification records, including some email and fax, shall be transmitted by secure carrier, or, if electronic, encrypted and digital signature. |
| 22-G | X | 5.10.9 – There is a need to identify a unique test report number for amendments. |