

Election Assistance Commission (EAC)
Interim Accreditation
Independent Test Authorities (ITA)

Assessment Report

CIBER

Conducted: Dec 06-08, 2006
Huntsville, AL

Assessor: Steven V. Freeman

Introduction

This accreditation assessment was a follow-up to an earlier assessment of CIBER Inc.'s ITA Practices office under the Election Assistance Commission (EAC) Interim Accreditation Program conducted in July 2006. The assessment used the NIST Handbook 150-2006, NVLAP Procedures (HB 150) and General Requirements and NIST Handbook 150-22- 2005 NVLAP Voting System Testing (HB 150-22) as the criteria for certification. The interim program is designed to accredit ITAs formerly authorized under the National Association of State Election Directors (NASD) accreditation program to continue voting system testing under an EAC accreditation until such time as the NVLAP/EAC joint accreditation has qualified one or more testing laboratories as Voting System Test Laboratory (VSTL).

The July assessment found that the CIBER ITA Practice program in non-compliance in four areas:

- a. There was no record of an internal audit or management review performed since the creation of the policy and procedures for ITA Practice. That was not serious in itself because there may be delays but queries about records from the last audit to the corporate office with related responsibilities did not indicate the results were available for corrective action at the ITA Practice level.
- b. The corporate quality manual requires the ITA Practice Director to maintain a log of Corrective Action Reports (CARs). The CARs are also required at other points to capture and track complaints, reports of non-compliance, and other problems which should receive management review and follow-up.
- c. QA Representatives were named last year to provide local people responsible for QA requirements in the absence of the remote QA manager. Their major role was to perform Process Conformance Audit at the end of each test campaign of the test and test report to ensure conformance to processes and procedures. No Process Conformance Audit has been done since the creation of the requirement.
- d. During review of requirements for standard testing methods, the ITA Practice Director stated that they could not use standard methods but either used the vendor's tests or created new tests for each system's test. The requirement for standard test methods is necessary to ensure that consistent and conforming testing is applied for each tested system. The standard test method provides a base for comparison against the vendor's tests and, when system variations require some adaptation, the changes needed are reported based on the pre-defined established test method.

In addition to these items, the July assessment went through issues and expected features needing development based on the application of the new ISO 17025 requirements as presented in the checklists prepared from the HB 150 and HB 150-22 criteria. CIBER ITA Practices and Wyle Labs had formed a Team Partnership for performing the testing but the policies and procedures needed further development to define each lab's responsibility with one lab (the 'VSTL' in HB 150 and HB 150-22 terms) taking the primary responsibility for managing and reporting the complete voting system test results. Additional requirements resulting from applying the ISO 17025 standards for more complete reporting were also reviewed and copies of the checklists were left.

CIBER was not granted an interim accreditation but was given a 120 day response period to submit corrections. Based on the documentation presented as a response, this follow-up assessment was conducted in Huntsville during the period of December 6-8 at the CIBER ITA Practice office in Huntsville.

Summary of Findings

A thorough internal audit was performed after the July assessment and a plan for correction developed [NC Item a] Within corporate CIBER, an Executive Management Steering Committee was created consisting of the President of CIBER Federal Civilian, VP Contracts Federal, and a Consulting Services Manager to perform high management oversight and ensure adequate resources would be available. Personnel have been brought in to assist in revising the program and to assist with responsibilities in the Quality Assurance (QA) and Project Management roles pending the staffing of additional staffing positions for ongoing support. [NC Item c].

The management documents were completely rewritten and updated, reducing the number of documents and confusion over what requirements were where. The new structure has two manuals plus associated forms.

- ITA Practice Operational Manual (POM) Quality Management program
- CIBER ITA Test Methods (TM). Technical test procedures

QA procedures and a test projects (simulated) were performed using the actual staff to make sure the procedures, tools, and resources such as the Corrective Action Report (CAR) input forms and logs were linked, active, and accessible (permissions granted) for ITA Practice personnel. The CAR contained entries resulting from the internal audit. [NC Item b.]

CIBER has entered a Team Partnering agreement with Wyle where Wyle will be performing the non-core hardware based test requirements under separate scope of accreditation programs. In this review, CIBER was reminded that, under the Interim scope, CIBER will be responsible for the overall program. CIBER still needs to develop procedures in what had formerly been a Hardware ITA exclusive area, recognizing their own out of scope status for some requirements requiring the use of other labs with the appropriate accreditation. The procedures shall include CIBER's responsibility in these cases to provide contractual specification of test operation and setup configuration information

CIBER ITA Practice currently has no test projects in house to test and validate these new procedures and can not complete minor corrections and adjustments until they do so.

Minor revisions and non-compliant items identified as needed include:

1. Updating record retention periods to support the EAC Voting System Testing and Certification Program Manual (EAC Certification Program).
2. Records showing when and for what methods test engineers are qualified.
3. Including reporting of non-core requirement testing in the Test Plan and Report
4. Validation of test methods for the core requirement test methods.
5. The TM specifies the application will be installed by the vendor and fails to provide verification that the software installed matches the Witnessed Build including the operating system and third party software.
6. The ITA needs to explicitly specify in contracts and reports which test methods that the ITA does not hold accreditation for and what accredited lab will be used for such tests.
7. Test methods and tools need to be validated and the validation documented.
8. In the Functional Requirements checklist, need to incorporate HAVA 301 requirements in with the Voting System Standard (VSS-2002) requirements.
9. Need to include Accuracy test details in TM. Some issues exist over whether automated testing using simulated voter inputs are acceptable for this test, especially in the environmental phase of the test.
10. Need to include Reliability test details in TM.
11. Need to calculate and report the Availability Index in TM.
12. Need to include volume tests
13. Need to include required security tests in TM and in Test Report.
14. Need to include Telecommunication tests (in System Integration testing)

(Other tests and requirements may need to be developed in the TM but were not reviewed in this assessment.)

Recommendation

CIBER has made substantive improvements in the documentation and implementation of the quality assurance policies and procedures. A similar level of improvement is provided in the CIBER Test Method procedures and the potential exists to develop and respond as additional requirements are recognized as needing to be included.

If CIBER is accredited, their initial test plans and some of the more critical tests such as accuracy, reliability, and security should be subject to test plan review and on-site observers until the TM has had a chance to be validated and samples of the test reports are available to verify the level of reporting is adequate. This should include clarification of the tasks to be performed by CIBER personnel and Wyle personnel.

(signed)

Steven V. Freeman

To: Election Assistance Commission
Attn: Brian Hancock

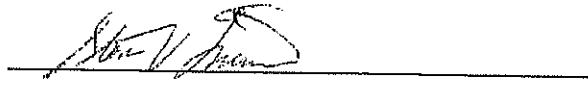
EAC Interim Accreditation Program On Site Assessment- CIBER

SIGNATURE SHEET

Lab Legal Name: CIBER, Inc

Address: CIBER ITA Practices
7501 South Memorial Parkway, Suite 107
Huntsville, AL 35802

Assessor: Steven V. Freeman



On-Site Assessment Dates: 6-8 Dec 2006

Prior Assessment Visit: 20 Jul 2006

This report was presented on-site at the conclusion of the visit and presents a summary of the findings.

Resolution of previous findings

The qualify management and technical documents describing the procedures for documenting and conduction of a test campaign had been completely revised prior to the assessment visit. Test methods (cases) have been developed and added in the form of the Test Methods document. In addition, personnel have been brought in to assist in revising the program and to assist with responsibilities in the Quality Assurance (QA) and Project Management roles. Within corporate CIBER, an Executive Management Steering Committee was created consisting of the President of CIBER Federal Civilian, VP Contracts Federal, and a Consulting Services Manager to perform high management oversight. Finally, QA records and logs were activated to store, track, and follow-up records of Corrective Action Reports (CAR) and audit findings.

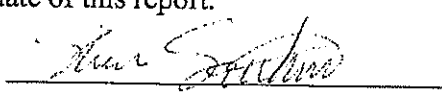
Latest Internal Audit: 15 November 2006, Terry L. Debell,

Latest Management Review: ^{5 Dec 06} ~~(Pending)~~ Manger, Internal Audit & Compliance
Executive Management Steering Committee

Acknowledgement of Receipt

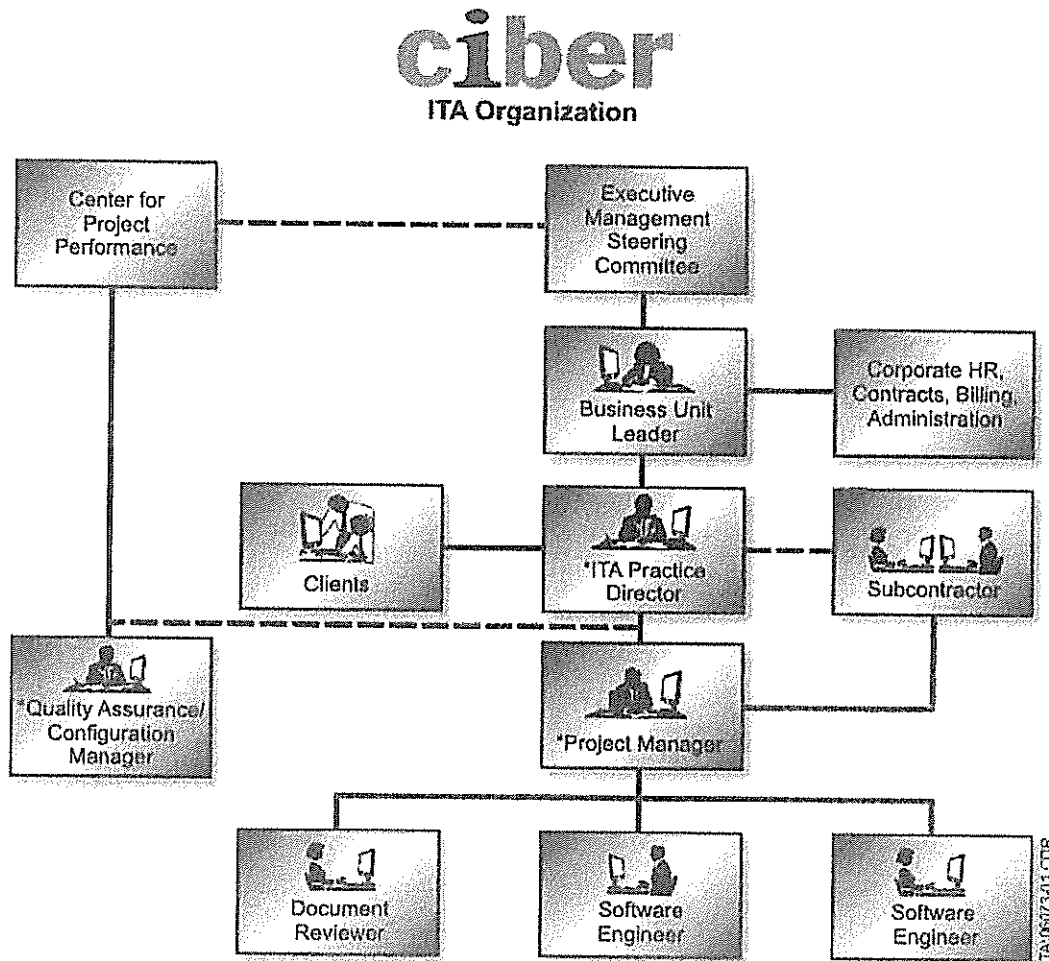
The assessor has discussed the contents of this report with members of the laboratory management who agree to respond in writing to EAC regarding resolution or correction of any nonconformities noted within 30 days of the date of this report.

Signature of Authorized Representatives or designee



Printed Name: Shawn Southworth

ITA Practices Organization:



Key Personnel:

1. Executive Management Steering Committee:
 - a. Wally Birdseye, President CIBER Federal
 - b. Paul Rainville, Director of Delivery, Federal Civilian Branch
 - c. Terry Debell, Center for Project Performance
 2. Center for Project Performance: Terry Debell, Manager, Internal Audit & Compliance
 3. Business Unit Leader: Robert MacFarlane, Federal Civilian Branch
 4. ITA Practice Director: #Shawn Southworth
 5. Project Manager: *#Kelly Rohacek
 6. QA Configuration Manager: *Amber Willburn
- Test Engineers:
7. Document Reviewer: Diane Grey

8. Senior Software Engineer: *Victor (Vic) Daily
9. Software Engineer: Jack Cobb

Primary Contacts.

*New Personnel (Resumes attached):

1. Amber Willburn, Proposal Manager, has been working with Shawn Southworth, the ITA Practices Director, and other resident staff to revise the documentation and develop the processes for the quality management of the certification testing. She serves as the acting QA Manager but is expected to be replaced by a permanent position for a full-time resident QA Manager. Amber has been mentored within the QA operations by Terry Debell, Manager, Internal Audit & Compliance
2. Kelly Rohacek, Project Manager, has been added to the staff to assist in the project management of the test campaigns/projects. In this position she will be the Technical Lead Contact. She is mentored by John Manning, Consulting Services Manager.
3. Victor (Vic) P. Daily, Senior Software Engineer, has been added to the Test Engineers/Software Engineers.

ON-SITE ASSESSMENT NARRATIVE SUMMARY

CHANGES TO CURRENT OR REQUESTED SCOPE OF ACCREDITATION

EAC Interim Independent Test Authority (ITA)

ACCREDITATION STANDARD

NIST Handbook 150,
NIST Handbook 150-22,

As a documented accreditation standard to be used by the new Voting System Test Laboratory Accreditation Program, these handbooks apply the requirements of ISO/IEC 17025. The EAC accreditation Program will require accreditation under the NIST National Volunteer Laboratory Accreditation Program (NVLAP) on completion of the full accreditation program for new labs and prior labs who complete the upgrade. This assessment was to update the accreditation of prior ITA labs as an interim program to ensure availability of testing labs during the transition from the NASED accreditation which was terminated in July 2006 until the VSTL accreditation program had established

OVERALL SUMMARY

The management documents were completely rewritten and updated, reducing the number of documents and confusion over what requirements were where. The new structure has two manuals plus associated forms.

- ITA Practice Operational Manual (POM) Quality Management program
- CIBER ITA Test Methods (TM) Technical test procedures

These manuals and associated forms and record files are stored on the CIBER sharepoint service supporting controlled access for CIBER offices across the country. The ITA Practice files and document/records are located under the ITA Portal and provide version and access control to maintain separation of test campaign documentation between authorized users while giving all the project team access to the resource they need.

As part of this effort, QA procedures and a test projects (simulated) were performed using the actual staff to make sure the procedures, tools, and resources such as the Corrective Action Report (CAR) input forms and logs were linked, active, and accessible (permissions granted) for ITA Practice personnel.

CIBER has entered a Team Partnering agreement with Wyle where Wyle will be performing the non-core hardware based test requirements under separate scope of accreditation programs. In this review, CIBER was reminded that, under the Interim scope, CIBER will be responsible for the overall program

CIBER ITA Practice currently has no test projects in house to test and validate these new procedures and can not complete minor corrections and adjustments until they do so. The large rewrite has resulted in new nonconformist observations listed in the following sections which CIBER is expected to respond to within 30 days

4.1 ORGANIZATION

In response to the previous assessment, CIBER has responded by providing resources to support:

- a. QA Configuration Manager. Ms Willburn has been attached to provide support in QA and QA Management documentation until a full-time QA manager can be approved and hired.
- b. Kelly Rohacel has been assigned as Project Manager to steer the test campaign projects and the completion of tasks and products with review.
- c. The President of CIBER Federal formed an Executive Management Steering Committee (EMSC) and to provide high level management attention and overview through the corporate CIBER audit and other QA reporting paths and to ensure that the process improvement activities received the attention and resources needed.
- d. Key management positions were tasked to provide mentoring support to the new key personnel and for follow up attention.

All this may be an initial flush of action and response but the activities included the activation, test, and use communication paths to establish use and practice. In the next assessment review, the organization support indicated in the Organization chart should be checked for continuation of support.

No non-conformities were identified.

4.2 MANAGEMENT SYSTEM

The management documentation was changed from four or more major documents to two major documents supported by forms and some independent procedures.

ITA Practice Operations Manual provides a more streamlined management procedures document.

CIBER ITA Test Methods captures the technical test procedures, documentation and reporting,

Upward management processes and reporting are defined through corporate CIBER procedures to maintain communications channels and ensure follow up review of issues and problems.

The CIBER Sharepoint Internet service hosts the ITA Portal that is the control point for documents, reports, tracking logs, and resources. Access through sharepoint allows individual access control to define and limit access to specific resources and maintain separation of information/procedures with version control showing active versions and control access to only the active versions as needed.

comment for developing
4.2.7 (HDB150) requirement to maintain integrity during planned change is a new accreditation requirement that needs some basic attention to initial setup.

4.3 DOCUMENT CONTROL

The CIBER Sharepoint Internet service hosts the ITA Portal that is the control point for documents, reports, tracking logs, and resources. Access through sharepoint allows individual access control to define and limit access to specific resources and maintain version separation of information/procedures with seamless version control showing active versions and control access to only the current versions as needed.

The ITA Portal home hosts a calendar that the QA manager keeps posted to show upcoming QA events and required reporting. As a comment, the definition of the periodic cycle for these events was not as well defined with a tendency to point to the next event rather than show how these events were to be scheduled but this expected to resolved before the next review.

No non-conformities were identified

4.4 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

A "test method" (TM 2) for Negotiating supports the policies for the review of requests, tenders, and contracts. The basic process showed no issues or problems. Specific items that needed to be identified in a negotiation such as the areas where the CIBER ITA Practice was not qualified under the scope of accreditation (HDBK 150-22, 5.4.6) were identified in the later sections where encountered.

No non-conforming items were noted.

4.5 SUBCONTRACTING OF TESTS AND CALIBRATIONS

CIBER has an exclusive Team Partnering agreement with Wyle Labs based on Wyle's current EAC Interim accreditation.

The relationship of the lead lab under the NVLAP 150/150-22 procedures and EAC preliminary guidance needs some clarification in the instructions to recognize the accredited voting system test lab's increased responsibility under the core requirements as compared with past practice of software/hardware lab. The current procedures for subcontracting recognize the need for the subcontracted tests to be with a lab accredited for the appropriate scope of testing but CIBER is just recognizing that their scope of responsibility for the testing has shifted and they need to be more responsible in the direction and performance of tests formally conducted by the 'hardware' labs. With Wyle's experience and current accreditation, this extended responsibility is blurred as Wyle is in a position to provide more of the service and management than would expected otherwise.

CIBER will need to pay attention to develop practices in what had formerly been a Hardware ITA exclusive area. Some later non conformance will be in specific areas where CIBER needs to include more details on the full range of test requirements, recognizing their own out of scope status requiring the use of other labs with the appropriate accreditation and CIBERs responsibility in these cases to provide contractual specification of test operation and setup configuration information

4.6 PURCHASING SERVICES AND SUPPLIES

Not applicable

4.7 SERVICE TO THE CUSTOMER

CIBER has a strong customer service orientation. Although not noted in the checklist, it may be worth noting the emphasis on working with previously prepared and validated test methods to provide standard conforming tests rather than acceding too quickly to requests to modify tests at request to vendors. The increased role of providing monitoring and direction by EAC as a regulatory body will also support more consistent reporting of the conformance of tested systems.

No non-conforming items were noted.

4.8 COMPLAINTS

CIBER has a Customer Complaint/feedback Survey system which is independently under the control of upper management and is routinely used as part of the management review cycle. This process has been actively in use for other units of CIBER but no complaints have been submitted against the ITA Practice activity and survey reports have been favorable. The program is restricted to customer complaints and other sources of complaints are not routinely submitted.

No non-conforming items were noted.

4.9 CONTROL OF NONCONFORMING TESTING AND/OR CALIBRATION WORK

Calibration work does not apply at this time

Basic policy and procedures follows recommended practices based on the NIST Handbook standards (ISO 17025) but there is no evidence that the process work since there have been no non-conforming reports submitted. Test case on this and other processes were made to ensure that the form linkage and operation worked and would post a report. In the assessment it was noted that the only source of non-conforming reports was from internal audit reports. CIBER is to consider changes to recognize EAC or related stakeholder reports of non-conformance, possible through official EAC process communication or otherwise provide a path (see comments on Complaints) for recognizing such inputs from legitimate stakeholders.

No formal non-conformance issues were identified.

4.10 IMPROVEMENT

An active program and policy statements recognizing and supporting on-going improvement was noted in the management procedures.

No non-conformance issues were noted.

4.11 CORRECTIVE ACTION

Prior visit observation that the corporate CIBER required CARs log was not active and showed no reports. has been corrected. Test cases were added to validate the operation and use. No action had been taken on the management review and monitoring because the annual management review that would review and take follow up action had not occurred yet but is expected within the next week. *Review completed today 5/2*

No non-conformance items have been identified

4.12 PREVENTIVE ACTION

Processing of review of management indicators, including the review of audit forwarded Corrective Action Requests (CARs), was not observed due to lack of activity. Two Audit directed CARs (ACARS) have been placed into the log to suggest improvements to the CARs upload operation but have not yet processed by the annual management review (see above)

No non-conformance items have been identified.

4.13 CONTROL OF RECORDS

The sharepoint ITA Portal supports the storage, maintenance and control of records as well as documents. Under this the records are identified, ownership is established and versioning is automatically performed. All management and test records are uploaded to the appropriate sharepoint directory with the exception of HR sensitive records which are processed, along other networks to preserve confidentiality. Hardcopy manual records are stored in QA/CM secure filing cabinets and logged in a directory log in a directory within the ITA Portal. Test campaign records are stored in Project Workbooks with different directories for each vendor to maintain separation and protection of records.

Current record retention is the life of the project + 3 years. CIBER is to review the new EAC Certification Program Manual and consider adopting the matching retention for election records. No disposal procedures are specified and are to be developed. Check with next assessment review.

Backup copies are saved daily and maintained in another location by corporate policy. The policy includes the periodic test of backup recovery.

The records for each test were not checked for the identity of personnel responsible as there are no Project Workbooks active (pending accreditation). However, procedures/test methods do require such records.

No non-conforming issues were identified

4.14 INTERNAL AUDITS

The last internal audit was completed 15 Nov in response to the previous assessment report by Terry Debell from the CIBER Center for Project Improvements. Improvements have been initiated out of that audit and it is to be reviewed in the next management review (pending) by the Executive Management Steering Committee (see organization information).

No non-conforming issues identified

4.15 MANAGEMENT REVIEWS

clear of
Non-conforming item. *Management Review performed & in (S/A)*
No management reviews had been made yet. However, the prior assessment report and internal audit have started major performance improvement actions including the management review requested by next week. A copy of the management review report was made available and I confirmed that the items in 4.15.1 were all included. (Copied from the HDBK 150 checklist).

This item is pending evidence to show that it is functioning but seems to be more a matter of timing at this time.

5.1 GENERAL

The technical test procedures have been completely rewritten into the CIBER ITA Test Methods. The organization of the document is oriented to the description used in the HDBK 150-22 Technical Supplement (Section 6.0) showing the test/review areas from the Voting System Standards (VSS) 2002 core responsibilities.

5.2 PERSONNEL

Resumes, position description, and training records were reviewed for the new personnel:
Amber Willburn QA Manager (temp)
Kelly Rohcek Test Project Manager
Vic Daily Software Engineer (Tech Engineer)

Amber was brought in primarily as a technical writer to assist in preparing the QA management documentation and resources. She has little prior experience of the position but here work on developing the program under the Mentorship of Terry Debell has prepared to some degree.

Kelly Rohcek is highly qualified as a technical Project Manager but lacks voting system experience

Vic Daily has extensive technical testing background but lacks voting experience.

Position descriptions were adequate and gave relevant information. The training records, while showing an active training program were inconsistent with different names for scope of training for the same activity. No standardized training plan appears to exist beyond corporate policy of Security and 30 day training.

Non-conforming. No clear designator that a test engineer is qualified or for what methods.

5.3 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

Current space small and crowded, especially with new staffing. Cyphers locks on front and back door. Site can "accommodate" four vendors by placing them into the offices which also contain people and storage. This is a temporary situation with a move schedule to place them closer to their Team Partner Wyle Labs.

For the Accuracy and Reliability Environmental Operating test, environmental conditions are a critical condition of the test but this level of facilities is to be gained through the services of a sub-contractor/Team partner. Other tests can require more space but these may be conducted at the Hardware Team Partner facility where the environmental controls are more appropriate to their scope of accreditation.

Testing at a vendor site may involve more significant conditions. Procedures for remote operation require the CIBER test team are defined but consist mainly of taking control of security conditions to ensure reduced risk of interference with testing.

5.4 TEST ~~AND CALIBRATION~~ METHODS AND METHOD VALIDATION

The Test Method document lists different sets of test activities required for all voting system testing. In reviewing the coverage of these sets, test methods were not listed for a number of test objectives, primarily those which have formerly been the responsibility of the "hardware ITA" such as the Transportation and Storage, EMC, accessibility. Most of these have their own test accreditation process are not part of the core requirements for the test lab.

Non-conform. The TM does not provide for the inclusion of the non-core test requirements in the test plan or test report. Although not a core requirement, the lab needs to include it in the test planning and report for direction and integration with the voting system test report as a single document supporting a system certification.

Non-Conform, the test method for the core requirements lack validation and reports for the validation of the tests. They appear to be too general for validation in some cases.

(See section 6 for more specific listing of missing test methods)

Non-Conform, The TM specifies the application will be installed by the vendor and fails to provide verification that the software installed matches the Witnessed Build including the operating system and third party software.

Non-conform. The test lab needs to explicitly identify tests that it does not hold accreditation *7/6/5*

5.5 EQUIPMENT

TM provides for test equipment (support, not the equipment to be tested and certified); to be checked in and inventoried but does not include provisions for maintenance, setup and validation that is operating correctly and for the intended purpose, handling of damaged equipment, or disposal for either CIBER owned or rented equipment or that provided by the vendor for testing such as certified pieces needed to complete test objectives.

In the latter case, readiness testing, care, validation, and setup verification are equally important as for the Equipment under test but needs the care extended beyond the actual test campaign. This area should be relatively minor unless specialized equipment is involved.

This section was not completely reviewed due to time limits and little applicability

5.6 MEASUREMENT TRACEABILITY

Not applicable at this time

5.7 SAMPLING

Not applicable

5.8 HANDLING OF TEST AND CALIBRATION ITEMS

(Handling and care of the actual Equipment Under Test (EUT))

(not reviewed in detail due to time but it has parallel issues to 5.5 and the test equipment)N

5.9 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

Not reviewed due to time.

5.10 REPORTING THE RESULTS

Non-conform. Work by other accredited labs needs to be identified (test plan and contract also) and validated that the lab is qualified. The results need to be validated that they are appropriate for the report. If the work is outside of the scope of accreditation for the contracting lab, this condition needs to be explicitly stated (ref 5.4.6 in the HDBK 150-22)

HDBK 150/150-22 requires specification of processing for reports for other purposes. Note that this involves branding issues where claiming the authority as an accredited lab may not be appropriate. Recognized alternate reports are for state certification and internal to the vendor.

**6.0 TECHNICAL SUPPLEMENT
Voting System Test Campaign
Procedures and Methods**

The review included an overview of required test requirement categories and where they are to be reported in the Certification test report. The following items were found missing or requiring further work:

TDP Review:

1. k. TM 4. Test plan should include the tests that are not in the core responsibilities but are still required for the certification of the system. The test plan is to be complete for all requirements. Where the test requirements are outside of the core tests, the plan should identify the accredited lab to be used, what materials and directions need to be given to the lab, what support is to be provided, how the lab's report will be validated (correct configuration for the certification, appropriate operations for a voting system) and how the report is to be included in the final report

Source Code Review

2 d. Need to validate Using Exam Diff Pro and provide validation report.

Physical Configuration Audit

- 3 b. Accessibility CIBER provides test cases to Wyle
- 3 c. Construction to be included in planning and reports but identifies as out of the scope of accreditation for CIBER and performed by accredited lab (Wyle);
- 3 e. Hardware transportation and storage tests needed to be included but identifies as out of the scope of accreditation for CIBER and performed by accredited lab (Wyle);
- 3 f. EMC and electrical test suit. identifies as out of the scope of accreditation for CIBER and performed by accredited lab (Wyle);
- 3. i. Include tests above in report.

Functional Configuration Audit

- 4 e. Verify HAVA functional requirements
In the Functional Requirements Checklist v.1.1 need to update for HAVA 301 requirements that are not in current VSS 2002 list.

System Integration Tests

- 5. a. Accuracy
- 5 b. Reliability
Also need Ai to be calculated and reported
- 5 c. Volume tests (could not find in review but may be there)
- 5 d. Security tests, need to perform and add to report layout
- 5. f. Telecommunication tests per VSS 2002/HAVA

ATTACHMENTS

1. Resumes for New Personnel

Ms. Willburn is a Proposal Manager with over five years of writing experience. She has played a key role in furnishing proposal and business development expertise in support of defining/refining company proposal development processes and procedures. Provided writing and editing for technical documentation and business development tasks as needed, including design and direction for graphics. In addition, she has defined and prepared documentation schedules, outlines, writing assignments, themes, and discriminators. Provided other as-requested technical writing and document review support to various company business units. Developed and designed marketing collateral for federal clients and inter-office fact sheets on current CIBER technologies. Lastly, Ms. Willburn has exceptional communication and interpersonal skills which allow her to work effectively with all levels of management and personnel.

EDUCATION, CERTIFICATIONS & TRAINING

BA, English, University of Colorado at Colorado Springs, 2004

Certificate in Professional and Technical Writing, University of Colorado at Colorado Springs, 2004

TECHNICAL EXPERIENCE

Software/Tools: Word, PowerPoint, Outlook, Internet Explorer, Project

PROFESSIONAL EXPERIENCE

CIBER, Inc.,
Proposal Manager

7/04 – Present

- Furnished proposal and business development expertise in support of defining/refining company proposal development processes and procedures.
- Provided writing and editing for technical documentation and business development tasks as needed, including design and direction for graphics.
- Defined and prepared documentation schedules, outlines, writing assignments, themes, and discriminators.
- Provided other as-requested technical writing and document review support to various company business units.
- Developed and designed marketing collateral for federal clients and inter-office fact sheets on current CIBER technologies.

Project Excel Writing Center
Writing Tutor, Newsletter Editor

2002 – 2004

- Worked with students on technical documents and taught grammar and document design.
- Edited student papers over online forum.
- Instituted first Excel Center newsletter and acted as editor.
- Designed layout and graphics for newsletter.
- Assigned writing responsibilities to contributors.

Asylum Youth Project
Director

Summer 2002

- Implemented youth center for a small rural town.
- Designed all marketing material and developed Procedures and Policies manual for volunteers.
- Provided monthly progress, cost reports, and a large season-end report to Board of Directives.

Scribe
Reporter

2001 – 2002

- For a small newspaper, contributed numerous articles, including front page news. Responsibilities included locating newsworthy stories, interviewing eye witnesses, and writing and editing articles.

A Senior Project Manager professional with expertise in Banking, Information Technology (IT), Manufacturing, Supply Chain, and Defense and Aerospace programs. Seventeen years of proven management expertise with a strong business sense for converting business needs into development solutions.

TECHNICAL EXPERIENCE

Languages:

Software/Tools: MS Project 98/2000/2003 ; Niku/Clarity, Primavera/Team Play, Lawson/Account 4, Planview/5.3 and 7.2, time tracking, project portfolio, and reporting; WBS Chart Pro, Microsoft suite; Lotus Notes office suite; Mercury Test Tool, Aristotle, Sharepoint, Clear Quest, RUP, PVCS.

Systems: Windows, AS400.

Databases: Oracle.

Residential Unit 20 Projects

PROFESSIONAL EXPERIENCE

SANMINA SCI, (Huntsville, AL)
Program Manager /IPT Lead

12/05 – 10/06

Managed "build to print" programs in the Defense and Aerospace division of Sanmina – SCI. Completed 1440 hours in project initiation, planning, execution, and control by;

- High level performance in the Program Managers role for a 37M program of In Flight Entertainment (IFE) products for an Avionics customer – France and US, managing two of the five products
- Promoted to Program Manager with in three months by learning the manufacturing industry, its standards and processes as an ITP Lead.
- Lead New Product Implementation (NPI) team's in preparation for new electronic product induction. Planned, executed and controlled "build to print" schedules at the manufacturing, supply chain- material planning, and change controls levels of the program.

NATIONAL CITY BANK, (Cleveland, OH)
Senior Project Manager

7/04 – 11/05

Managed the installation of large integrated projects for loan origination in the Lending Portfolio of National City's IS organization. Completed 1920 hours in project initiation, planning, execution, control and closure by applying;

- The application and management of iterative development using Fusion /Agile methodology and coordinating it with the life cycle of waterfall methodology.
- Managed a 4.5M National Home Equity broker on line origination system development project.
- Coordinated and lead the project through initiation, project approval and the first two releases of five and then successfully transitioned future releases with the sustaining Project Manager.
- Managed the implementation of a 2.5M Loan Express system for a best in class initiative.
- Managed a 1.3 M project for the new business venture of on-line loan applications with Lending Tree. Participated on the board of reviews as a subject matter expert for the new project office rewrites of processes and new methodologies for project management.

ROBERT HALF CONSULTING, (Cleveland, OH)

6/03 -- 7/04

Senior Project Manager

Managed strategic initiatives and the installation of integrated systems Completed 2040 hours in RFP processes, project initiation, and full project life cycle management for the clients of Key Bank and National City by;

- Successfully and quickly creating the schedule and demonstration of the Request for Proposal (RFP) process and defined process attributes.
- Coordinating demonstrations and sandbox sessions for product understanding.
- Created financial proposals that included vendor package and labor costs.
- Learned and applied the new roll out of Rational Unified Process Methodologies and tools with an in-flight project team.
- Successfully managed an infrastructure project through the redesigning of an external and internal network solution.
- Performed and planned validations and test strategies with the RUP methodologies using Clear Quest, Test Manager and Rational Rose tools.

HANDLEMAN COMPANY, (Troy, MI)

4/01 -- 4/03

Senior Project Manager

Managed teams in project activities with staff ranging up to 30 team members Completed 2,800 hours in Project Management practices by;

- Successfully installing major projects such as a new multi-million dollar sorter, new business system implementation into Canada, Oracle 3.06/11i upgrade, Discreet Order system and the ERP Oracle solution.
- Lead international projects in England, Canada, Mexico, Puerto Rico, and the Virgin Islands working with diverse cultures and business practices to achieve corporate goals.
- Introduced new processes of Project Management PMI and Software development guidelines (SDLC) as a member of the SEPG committee, ensuring adherence to methodology standards.
- Managed teams in requirement gathering, development, validation and testing, implementation and deployment.
- Awarded the "Caught in the Act of Excellence". Awarded twice for strategic project installations
- Demonstrated practices in estimating, budget, and financial tracking of projects.
- Certified/participation in quality concepts, tracking and application of the project life cycle.

MICHIGAN NATIONAL BANK, (Lansing, MI)

7/99 -- 3/01

Project Office Manager

KELLY ROHACEK
Project Manager



Incorporated and lead the induction of a Project Office into the IT division of Michigan National operations center. Completed 1850 hours in Project Management practices managing a staff of five that supported the project office time tracking and project portfolio business by;

- Training and managing compliance of the CMM and Methodology rollout in IT
- Supporting the strategic vision of system development through holding an active position on the board of project initiatives
- Lead the introduction and training of Risk Management rollout in IT
- Implemented processes for Quality Assurance teams using the Mercury Automated tool for validation and test scripting. (customized process for Michigan)
- Presented a project management concept to students of the University of Namibia, Africa.
- Lead the planning effort and implemented the business plan model for management of IT System Solutions division
- Achieved CMM level three award by implementing business practice improvements in the project office and through out the IT divisions
- Implemented the Quality Management and assurance models to the development staff through training and process presentations
- Performed the instruction and implementation of the time tracking tool - Primavera Team Play, retiring the Niku / ABT workbench product from production

NATIONAL CITY / FIRST OF AMERICA, (Kalamazoo, MI)

6/89 – 6/99

Project Manager II 1996-1999

Managed 12 programmers of the Special Projects Force and completed 4120 hours in Project Management practices by;

- Successfully managing multiple projects related to the year 2000 preparations.
- Lead the conversation of Desk Top applications for Lotus/Ami Pro to Microsoft Word/Excel office suites
- Performed /planned validations in unit, system, integration, production readiness, and end user testing
- Lead the consolidation efforts of the Project Office of First of America and National City

Business Analyst 1989-1996

- Successfully implemented small project work and gained project leadership responsibilities by completing 3250 hours of Project Management practice by;
- Coordinating all project work for the Hogan systems by priority and business needs
- Leading requirements gathering and feasibility studies in the initiation and requirements phase of the project life cycle
- Performing/executing test plans and validations in unit, system, integration, production readiness, and end user testing for Hogan system
- Using and applying Project Management practices as a junior project manager and moving into a senior project manager's role.

Mr. Daily is a Senior Software Engineer with over 12 years experience specializing in certification, support and deployment of technical software applications. Self-motivated team member possessing excellent interpersonal and communication skills. Familiar with ISO 9000 and CMM methodology.

EDUCATION, CERTIFICATIONS & TRAINING

B.S. in Industrial Operations, Auburn University, Auburn, Alabama, March 1984

Microsoft Certified Professional - 2000

TECHNICAL EXPERIENCE

Languages:

Software/Tools:

Systems:

Databases:

PROFESSIONAL EXPERIENCE

Intergraph Corporation, Huntsville, Alabama

1994 – Present

Senior Software Engineer, 1997 – Present

Responsible for software certification and validation of Intergraph's SmartPlant 3D application software. Develop and execute formal test plans which correspond to detailed software specifications. Document findings during testing and submit detailed program change requests and trouble reports to software developers. Retest software before deployment to verify conformance to customer's expectations.

Provide support and direct interface with customers to coordinate on-site deployment of complete operating system and application software.

Senior Software Engineer, 1994 – 1997

System implementation specialist of the U.S. Army's Digital Storage and Retrieval Data System (DSREDS) and Joint Engineering Data Management System (JEDMICS). Responsible for configuring UNIX, Windows NT and IBM PC (DOS / Windows) hardware to various software platforms. Edited vector and digital data utilizing Intergraph application software conforming to MIL-STD-1840B file standards. Provided technical support to MICOM user base in addition to eight additional Army installations.

Sverdrup Technology, Huntsville, Alabama

1989 - 1993

Mechanical Designer

Utilized Intergraph's Engineering Modeling Software (I/EMS) to support NASA's Marshall Space Flight Center Science & Engineering Directorate. Design tasks ranged from intricate man-rated flight hardware to large structural steel components. Duties included performing conceptual design, three dimensional modeling, two dimensional detailing, interference checking, extracting mass properties, stress analysis, trade studies, producibility and procurement for all design tasks. All final drawings conformed to standards, DOD-D-1000B, DOD-STD-100C, MSFC-STD-555B and ANSI Y14.5M.

VICTOR P. DAILY
Senior Software Engineer

ciber

Recipient of two Extra Miler Awards in 1990 and 1992 for exceptional job performance.

NIST HANDBOOK 150 CHECKLIST (Adapted for EAC Interim Accreditation)

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.

EAC Interim Accreditation This checklist is adapted for use in the EAC Interim Accreditation

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: CIBER, Inc _____

Format Note: Legal name is all caps for CIBER

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.

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.

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.

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

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

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);
- OK b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;
- OK c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
- OK d) ^{POM 4.1, CIBER's Code of Business Conduct as Evidence} have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;
- OK e) ^{define} 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;
- f) ^{Comprehensive Procedures - Federal Crime Branch, (Location or champion)} specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations; ^{POM 4.2 (clear job description)}
- 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; ^{POM 5.2.1 Training Responsibilities}
- 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;
 Name of person: ^{See 11B 950-22 5.2} _____
 Area of responsibility: _____
 Repeat as necessary: _____
- OK i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions

are made on laboratory policy or resources;

Name of person: Amber Wilton (see 150-22 Checklist Item)
Job description

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

Name(s): Pam Kelly

Name(s): ~~Pam~~ Lead Test Engineer (in org chart lists a Software Engineer)

Name(s): Pam ← ~~Pam~~ Fed Gov staffing as needed.

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.

As part of annual review

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

— ♦ 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.

As part of the steering committee responsibility to communicate to others as well as set up agreed communication paths

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. Pam

C 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. Pam & Test Methods Document

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

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. Pam Training; as far as possible to ensure int information is present books. ITR from Personal creation Pam, JM and off (between shared point on network)

Date of most recent quality manual: 11.20.2006

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

CIBER's commitment to quality (etc)

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

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

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

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

commented
 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.

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

OK 4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements. *Steering Committee, done letter & supporting documents (EMSC) Executive Management Steering Committee Policy statement in IIR Portal*

4.2.5

OK a) The quality manual shall include or make reference to the supporting procedures including technical procedures. *POM 1.3, Ciber IT & Test*

OK b) It shall outline the structure of the documentation used in the management system. *POM 1.2 document overview Methods, the various system Software Structure (ITM)*

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. *POM 4 Organization and 4.2. Roles and Responsibilities*

◆ 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. *see to above comment*

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. *POM 4.3. Document Control (ITM) Policy on share-point*

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. *certificates, anything except source code which is kept separate for proprietary control reasons.*

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. *Issue (authorized access)*

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. *Regulation of all ITR documents and reference materials*

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; *Share printers*

OK b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements; *Part 4*

OK c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; *Part 12.4 Management Review G.I. CIBER ITR Part 4 (Process Control) Control*

OK d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked. *Part 6.1 also general documents have legal that are not obsolete (Annual or calendar) obsolete*

4.3.2.3 Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include: *Part 6.1 provide for archiving or sharepoint. Obsolete documents are moved to ITR (not for work)*

OK a) the date of issue and/or revision identification, *Part 6.3 Document Standards*

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. *Part 12.4 Management Review Part 6.3 Document Standards*

OK 4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments. *Part 12.4 Management Review Part 6.3 Document Standards*

Track changes (MS Word) record of change log in front of log. change notification (CIBER Corporation)

4.3.3.3

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

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

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

POM 6. GILCIBER ITA Point Control

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:

OK a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2); *POM 7. Reviews of Requests, Tenders, and Contracts TM 2 Negotiation*

OK b) the laboratory has the capability and resources to meet the requirements; *POM 7. in Request Tenders TM 2 Negotiation 2.1.1. Test Test Methods*

OK c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2). *POM 7 TM 2 Negotiation*

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. *TM 2.1.1. Test Methods*

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. *POM 7 TM 2 Negotiation*

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. *POM 7*

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. *Project Book examined*

OK 4.4.3 The review shall also cover any work that is subcontracted by the laboratory. *POM 8 SOW will identify subcontractors (single)*

OK 4.4.4 The customer shall be informed of any deviation from the contract. *POM 7 TM 2*

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. *POM 7 TM 2*

4.5 Subcontracting of tests and calibrations

C 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. *POM 8, 2-Subcontracted Services*

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. *Sec 5.0-2.2 checklist 5.5/1.3 Agency reference*

C 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. *TM 2 Negotiating POM 8*

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. *Sec 5.4.6 for related topic Approved Subcontractors and/or Training Partners*

4.6 Purchasing services and supplies

7/4 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.

4.6.2

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

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

4.7 Service to the customer

- OK 4.7.1 The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

NOTE 1 *POM 18 Review & Review Letters, TM 1 Supp*
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;
POM 18 Service to customer - on Solicit Customer Feedback.
- b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

POM 18
NOTE 2 Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.

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

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

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. *Customer Complaint Log. Item 30 in book*
- 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). *Customer Complaint Log. Form 18. / p's record*
No records of evidence *Procedure/Policy in Customer Complaint Policy.* *BUL* *Assure User Letter*

4.9 Control of nonconforming testing and/or calibration work

- ok 4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:
 - ok a) *Per 14.2 Control of Non Conformance* the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;
 - ok b) *Handled from the HOPK* an evaluation of the significance of the nonconforming work is made;
 - ok c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;
 - ok d) where necessary, the customer is notified and work is recalled;
 - ok e) the responsibility for authorizing the resumption of work is defined.

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

- 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. *Per 14.2 describe from 19 process improvement. Slight rewording needed to delete reference to only "an" test result*

4.10 Improvement

◆ 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.

Per 19 continuous improvement & management review
Need to worded for reference in Audit, Analysis, corrective actions

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.

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.

*From 14.3 - Suggestion, Issue, Corrective Action
EMSC responsible for analysis of (CAR) and corrective action response*

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.

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.

From 14.3, Step 4.5 QMM 4.4.1, 6.4.1

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.

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

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

*From 14.3, step 6 QMM 4.4, 6.4.1
ditto.
ditto step 7 QMM workste*

4.11.4 Monitoring of corrective actions

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

*From 14.3 QMM workste / Revised current
connections to log (etc)
(example, not need to be checked 1 time
2 previously audit result improve*

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.

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

*From 14.3 within 10-day
EMSC audit annual.*

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. *Form 19 Process Improvement Prevention Action Process Form*
- 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.

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. *Form 19 Process Improvement Prevention Action 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.

Review and records of process improvement *Archives*
under CAPA log *ASAS*
not actively *Prevention action*

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. *Follows CIBER Record Management*

4.13.1.2 *Form 15, Record Collection, on a internet e-journal retention*
Note customer compliance log is not directly accessible to ITA
But in customer's ASAS customer's subdomain's saving time is used by ITA

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.

C b) Retention times of records shall be established. *Share point* *Form 15 Record Collection directed from 6 Document*
Hand copy stored in QA files some files with electronic log
Noted EAC has generating request

NOTE Records may be in any media, such as hard copy or electronic media. *IT/IS systems & signs*

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

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. *Form 15, 6 Project* *EMSC retains access limits on compliance and records management process (CIBER) some internal* *TAM 13.1 Archiving activities architect*

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. *Form 15, 6*
- 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. *close of case, in 4 yrs. (see comment on earlier calibration) Form 13.1 Step 2 observation, data, and calculations in observations Log*
- C c) The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results. *Form 15/6 recorded in electronic hard copy archive check*

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.

4.13.2.3 *The other IIA Observation Log, to all points and handwritten at time of observation. TM 2.1.2*

C 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. *TM 13, pom 6 13.1 Step 13 does greatly interfere*

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

4.14 Internal audits *TM 13.1 Step 3 changes tracking / observation 6 form log*

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.

Form 12 Reim, 13 Status Reporting

Dates of most recent internal audit: *stand copy Nov 15, 2006*

Note to assessor: Attach a copy of the full internal audit schedule. *File of activities 11.2 extract table*

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

NOTE The cycle for internal auditing should normally be completed in one year. *From 12 Reviews, performed by Terry Deibel, responsible for ITP-Certification and reported by KMSC for independent*

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. *From 14.3 Suggestion Issues, Correction Action*

4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. *ITP Post-ITP Audit (Close point) report & indicators that ACAS should be used*

4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken. *From 14.3 ACAS show correction addressed as limited for follow up action through Post-Review for 12-15-06 since the previous working environment review recommended*

4.15 Management reviews

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. *Submitted copy on Nov 12/04*

Date(s) of most recent management review: *(a) quarterly, not yet performed*
forward copy to be completed

What is the review schedule? *Quarterly Quality Management Review*

The review shall take account of: *(Report submission and assessment and checked to see if following items were covered activities)*

- a) the suitability of policies and procedures;
- b) reports from managerial and supervisory personnel;
- c) the outcome of recent internal audits;
- d) corrective and preventive actions;
- e) assessments by external bodies;
- f) the results of interlaboratory comparisons or proficiency tests;
- g) changes in the volume and type of the work;
- h) customer feedback;
- i) complaints;

- l j) recommendations for improvement;
- k 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

- x a) Findings from management reviews and the actions that arise from them shall be recorded. *To be forwarded.*
- x 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); *From 4.1.2 Policy & Responsibilities*
- iii) test and ~~calibration~~ *Test Plan* methods and method validation (5.4); *TM 2.1 Determining calibration*
- iv) equipment (5.5); *TM 3.1 Product submitted* *Determine & include any fixed*
- v) measurement traceability (5.6 and Annex B); *for testing*
- vi) sampling (5.7); *requirements for (N/A) requirements*
- vii) the handling of test and calibration items (5.8). *(exam - check list)*

NO 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.

NO
with 0.15.200
so not expect
to find
it
on 10/10/06

TM 3.1 Product submitted
Inventory Log
Test Instructions for
Item Control Plans

5.2 Personnel

5.2.1

- sk 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. *Personnel*
- sk b) *5.2.1 Training Responsibilities*
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. *5.2.1 includes language for personnel under training who are under supervised performance.*

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

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

- i) relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;
- ii) knowledge of the general requirements expressed in the legislation and standards; and
- iii) an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.

5.2.2

- sk a) The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. *in performance approved and (5.2.1) in assignment to tasks*
- sk b) The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. *Person 5.2.1*
- sk c) The training program shall be relevant to the present and anticipated tasks of the laboratory. *5.2.1 Training for IIA personnel includes: ... cover internal procedures & personnel requirements as well as state, Federal*
- sk d) The effectiveness of the training actions taken shall be evaluated. *Security in 5.2.1, Training responsibilities*

5.2.3

- sk a) The laboratory shall use personnel who are employed by, or under contract to, the laboratory. *Person 8 Subcontracted, management or sub-contracting customer*

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. *contract under subcontracting guidelines.*

5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations. *PM 4.2 Roles & Responsibilities, descriptive in Local Business Manual.*

NOTE Job descriptions can be defined in many ways. As a minimum, the following should be defined: *Review Kelly, Kim, Anne (G.D.)* *Special note: ITH Organization bucket is necessary for this assessment to review. Document to actually on local network branch office site.*

- i) the responsibilities with respect to performing tests and/or calibrations; *PM: Yes*
- ii) the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results; *PM: No*
- iii) the responsibilities for reporting opinions and interpretations; *PM: Yes*
- iv) the responsibilities with respect to method modification and validation of new methods; *PM: No*
- v) expertise and experience required; *PM: Yes*
- vi) qualifications and training programs; *PM: No*
- vii) managerial duties. *PM: No*

5.2.5

C 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. *Review of records and PM 5.2.1.*

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

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.

TM 3.1 17.1 on-site security include environmental housekeeping.

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 b)

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

5.3.2

Part TM 10.1 Crime Facility include Test Procedures Observability Test Report

NA 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.

NA comments required

OK b)

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

It occurs it would be reported as anomaly in test

NA 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.

NA 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.

OK 5.3.5

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

IT & Security

5.4 Test and calibration methods and method validation

5.4.1 General

C 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.

*1. Test plan
2. TM 3.1
3. TM 3.2
4. TM 3.3
5. TM 3.4*

NA 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.

see sample TM 9 functionality coverage report form Test Methods are provided as TM document

Not used, Not used

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).

Document Content includes instructions & test methods

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.

(See ISO-22, 5.14.5 example) 2.1.1. Determining Methods Step to Test Method Deviation Form

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

5.4.2 Selection of methods

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

*TDP
Semi-Cont.
PCA
System Integration*

The accuracy & Reliability Test is Standard based on VSE/VVSE but needs further development on details - procedures

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

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.

TM 2.1.1 Determine Test Method may need to address EAC on stakeholder in determining method. TM 2.1.1. Step 9

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

C 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.

TM 2.1.1. need to add decision point

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

TM 2.1.1. Step 2 see also ISO-22 checklist for 5.4.1 requirements

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.

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

TM 14. Major Change to CIBER (in Test Laboratory) or Quality System

5.4.4 Non-standard methods

X 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.

C b) *Need development, etc. so calibration may be needed*
The method developed shall have been validated appropriately before use.

see 5.4.5.2
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: *media development of media for external*

- 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

- C a) The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.
- X b) *TM 2.1.2 Validation, Sec 5.4.4. 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.

does not include documentation & reporting on the validation

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.

NA **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.

At current time, robotic system do not appear to recognize the type of debris.

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

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

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

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

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

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

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

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

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

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

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

5.4.7 Control of data

5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a

systematic manner. *Not found*

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:

- NA a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
- OK b) ~~Not found~~ *Penetration Security* 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; *Pen 17 Security*
- ? 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).

TM 11 Ensuring Quality of Test Data

Woke! use of Ref to 170251 & NBS 150 received

5.5 Equipment

5.5.1

- NA a) The laboratory shall be furnished with ~~all items~~ of sampling, measurement and test equipment ~~required for the correct performance of the tests and/or calibrations~~ (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data).
- b) In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this handbook are met.

Remote operation, special equipment, calibration

5.5.2

- a) Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.
- b) Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.
- c) Before being placed into service, equipment (including that used for sampling) shall be ~~calibrated or checked~~ to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).

TM 3.1.3 Handbook, Test Instruments

Issue: Procedure Item Control Procedure

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

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

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

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

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

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

5.5.7

- a) Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. *What happens if a BUT is discovered to be damaged?*
- 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). *not found*

Reg. Item Control/Trace

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

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

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

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

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

Note: 5.5x is generally not applicable in terms of equipment requiring calibration but test equipment (software) used in simulation or control may require documentation, calibration (NIST) and subsequent actions.

5.6 Measurement traceability

5.6.1 General

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

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

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

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

5.6.2 Specific requirements

5.6.2.1 Calibration

5.6.2.1.1

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

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

- ___ b) When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.
- ___ c) The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).

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

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

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

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

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

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

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

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

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

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

5.6.2.2 Testing

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

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

Test

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

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

- ___ a) The laboratory shall have a program and procedure for the calibration of its reference standards.
- ___ b) Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.
- ___ c) Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

5.6.3.2 Reference materials

___ Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far

as is technically and economically practicable.

5.6.3.3 Intermediate checks

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

5.6.3.4 Transport and storage

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

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

5.7 Sampling

5.7.1

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

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

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

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

5.7.2 Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

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

based upon.

5.8 Handling of test ~~and calibration items~~

C 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.

*TM 3. Product submitted Inventory Log Fish Process Form
Data Conting*

5.8.2
___ a) The laboratory shall have a system for identifying test ~~and/or calibration~~ items. *TM 3 data*

___ b) The identification shall be retained throughout the life of the item in the laboratory. *TM 3 data*

___ 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. *TM 3 data*

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

5.8.3 *TM 3 data*

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

___ b) When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion. *TM 3 data*

5.8.4 *TM 3 data*

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

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

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

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

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

- ___ a) The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.
- ___ b) The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.
- ___ c) This monitoring shall be planned and reviewed and may include, but not be limited to, the following:
 - ___ 1) regular use of certified reference materials and/or internal quality control using secondary reference materials;
 - ___ 2) participation in interlaboratory comparison or proficiency-testing programs;
 - ___ 3) replicate tests or calibrations using the same or different methods;
 - ___ 4) retesting or recalibration of retained items;
 - ___ 5) correlation of results for different characteristics of an item.

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

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

5.10 Reporting the results

5.10.1 General

TM 12 Fuel Report Preparation NETA

- ___ 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.

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. *to be applied to the file*

ok c) *100-22* In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.

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

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

5.10.2 Test reports and calibration certificates

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

ok a) a title (e.g., "Test Report" or "Calibration Certificate"); *App B mg*

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; *NCTR sample*

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; *CIBER part 3 EQ 2006 01 V.1*

ok d) the name and address of the customer;

ok e) identification of the method used; *with Doc*

ok f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated; *All NCTR*

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; *A system identification* *Handbook Cost Eff Documents*

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;

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

pk 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:

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

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

NA 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;

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

pl e) additional information which may be required by specific methods, customers or groups of customers.

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

 a) the date of sampling;

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

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

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

- ___ e) details of any environmental conditions during sampling that may affect the interpretation of the test results;
- ___ f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.4 Calibration certificates

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

- ___ a) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;
- ___ b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;
- ___ c) evidence that the measurements are traceable (see Note 2 in 5.6.2.1 .1).

5.10.4.2

- ___ a) The calibration certificate shall relate only to quantities and the results of functional tests.
- ___ b) If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.
- ___ c) When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.
- ___ d) When statements of compliance are made, the uncertainty of measurement shall be taken into account.

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

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

5.10.5 Opinions and interpretations

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. *PER 5-14*

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

- c a) When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. *NOTE 3, 2 will add explicit statement under 5.4.6 ISO 22 checks*
- etc b) The subcontractor shall report the results in writing or electronically. *NOTE 3, 2*
- N/A c) When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

5.10.7 Electronic transmission of results

OK In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this handbook shall be met (see also 5.4.7). *Per 17 Sec 1*

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 based on ISO A2 B format*

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

- etc 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: *TM 12.1*

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

- etc b) Such amendments shall meet all the requirements of this handbook. *TM 12.2*

- ____ 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.

- ___ a) An applicant laboratory that has not yet achieved accreditation may make reference to its applicant status. If the NVLAP Lab Code is used, it shall be accompanied by a statement accurately reflecting the laboratory's status. An applicant laboratory shall not use the NVLAP term, logo or symbol in a manner that implies accreditation.
- ___ b) The laboratory shall have a policy and procedure for controlling the use of the term *NVLAP* and the NVLAP symbol.
- ___ c) The term and/or symbol shall not be used in a manner that brings NVLAP into disrepute or misrepresents a laboratory's scope of accreditation or accredited status.
- ___ d) When the term *NVLAP* is used to reference a laboratory's accredited status, it shall be accompanied by the NVLAP Lab Code.
- ___ e) When the NVLAP symbol used to reference a laboratory's accredited status, it shall be comprised of the NVLAP logo and the NVLAP Lab Code in an approved caption. The caption shall appear below and in close proximity to the logo. The following captions have been approved by NVLAP:
 - "For the scope of accreditation under NVLAP Lab Code 000000-0"
 - "NVLAP Lab Code 000000-0".

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

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

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

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

h)

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

i)

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

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

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

- _____ 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

Item No. C or X	Comments and/or Nonconformities
4.1.15.j	C
4.2.1k	C
4.2.7	C
4.3.22	C
4.8.1	C
4.11.4	C
4.13.12	C
4.13.21	C

QPM will be handled by someone in Q/A community with documents based on Corporate QM/9000/9001. Documents use the "POM & Test method". Test Method is a parent document for related test procedure documents. Needs development in terms of being a conscious process but current controls of status of procedures are separate of the concept. The review is to be periodic but Plan Q/A Activities 11.2 Plan Q/A Activities "event is documented and stored in the ITA Project book..." and placed on a calendar. There is no calendar showing a planned schedule for documents but the calendar process fulfills the part. Q/A does all scheduling for reviews.

No examples / records in current Log. Check on next visit. Also shows example of log for another CIBER submit which starts with entry. The compliance log not accessible to ITA director "Custom: Compliance Log" title is used for the submission forms as well as the Log itself. The log items is retained for 1 year before cleared.

CAF Log, examples reviewed but this needs review on subsequent visits.

ETC new guidelines (Certification procedures) is specifying life cycle 4.3413. CIBER to look ETC Procedures in his adopted and adjust CIBER retention policy accordingly.

Review on subsequent assessment visit. No testing has been performed under this accreditation so records responsibility continue. See Test Method Form checklist of list.

(continued on back)

