



U.S. Election Assistance Commission Voting System Test Laboratory Policy and Procedures Compliance Management Assessment Report

iBeta Quality Assurance (iBeta) Denver, Colorado

EAC Lab Code: 0702

Dates: 5/14/2009 – 5/15/2009

Report Date: July 28, 2009

Assessment Objectives:

The objective of this assessment was to fulfill the requirements of Section 4.5.1 of the U.S. Election Assistance Commission (EAC) *Voting System Test Laboratory Program Manual (Manual)*. This section of the Manual requires the EAC to conduct on site policy and procedures practices review to verify that the laboratories policies, procedures and practices meet the requirements of the EAC laboratory accreditation program and international standards. This report is issued in compliance with Section 4.8 of the Manual requiring the EAC to issue written reports after performing any on site laboratory reviews. The purpose of the report is to provide the lab with the EAC's findings regarding their operations so that items of noncompliance may be identified and rectified, so that exceptional practices may be identified and encouraged, and so that EAC recommendations may be provided in an effort to improve the laboratory's program.

Scope of Assessment:

The assessment encompassed a review of all relevant management policies and procedures including:

- The laboratory management system.
- Document control, change and retention.
- Control of nonconforming testing.
- Corrective action.
- Control of lab records.
- Personnel policies and procedures.
- Test Methods and Validation
- Procedures for handling test items.
- Procedures for assuring the quality of test results.

To carry out this scope of work, the EAC assessment team reviewed all relevant documentation and records and conducted interviews with selected staff and management of the laboratory.

Assessment Team:

The EAC assessment team consisted of Brian Hancock, Director of Certification, Laiza Otero, Deputy Director of Certification, Tom Caddy, EAC Technical Reviewer and Mark Skall, EAC technical Reviewer.

Assessment Criteria:

Substantive criteria used as a basis for this assessment are contained in the following:

- ISO 17025:2005- General Requirements for the competence of testing and calibration laboratories.
- United States Election Assistance Commission (EAC) Voting System Test Laboratory Program Manual.
- EAC VSTL Policy, Procedures and Practices Audit Checklist.
- EAC Notice of Clarification 07-002 – VSTL work with manufacturers outside voting system certification engagements.
- EAC Notice of Clarification 07-005- VSTL responsibilities in the management and oversight of third party testing.
- EAC Notice of Clarification 08-001- Validity of prior non-core hardware, environmental and EMC testing.
- EAC Notice of Clarification 08-003- EAC conformance testing requirements.

Assessment Findings:

During the assessment, each element audited was evaluated as either a nonconformity, an element eliciting a comment, or as acceptable. Nonconformities noted during EAC audits require a critical finding conclusion under Section 4.8.3.1 of the EAC Test Laboratory Program Manual. Items receiving comment can fall into either a required finding as defined in Section 4.8.3.2, or a recommended finding as defined in Section 4.8.3.3.

The EAC assessment of iBeta Quality Assurance (iBeta) found no instances of nonconformities critical to the laboratories capability to test voting systems.

The EAC assessment found 14 items for which we recommend that the lab practices be improved to continue to meet EAC and ISO 17025 program requirements. The 14 recommendations are as follows:

- 1. Checklist item 1.3(g): Provide adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures, purpose of each test, and with the assessment of the test results.** - EAC assessors noted that interviews conducted with staff as well as document review led to the conclusion that each of the two current laboratory leads/department heads has their own unique approaches to managing staff and leading test engagements. EAC recommends that the lab develop methods to ensue and document that work products are uniform and consistent across testing engagements.

- 2. Checklist item 2.4(b): (Management System) All personnel concerned with testing activities within the laboratory familiarize themselves with the quality**

documentation and implement the policies and procedures in their work - EAC assessors found that the current process used by the lab to familiarize employees with the quality management system is weak. The test given to employees is trivial and does not necessarily verify that an employee read the Quality Manual let alone understands and can use the principals contained in the manual. The EAC recommends that iBeta develop a more rigorous and thorough method for educating and testing employees on the requirements of the labs quality manual.

- 3. Checklist item 2.5: (Management System) Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness. -** EAC assessors noted that many of the written policies are quite old and have not been updated since first released in 2006. Testing over the last two years for the EAC Certification Program are likely to have surfaced improvements that the EAC recommends be incorporated into the quality documentation. It was also noted that findings surfaced in the 2007 internal management review have not yet resulted in changes to the documents or processes.
- 4. Checklist item 3.2(b): (Document Approval and Issue) A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and be readily available to preclude the use of invalid and/or obsolete documents. -** The EAC assessors were not able to view a consolidated list of document revision status. It is likely that SharePoint can print a report with specified the specific content noted for this section. If not, the EAC recommends that the lab develop and maintain such a list or equivalent document control procedure.
- 5. Checklist item 3.3(d) (Procedures Adopted shall ensure that) ...obsolete documents retained for either legal or knowledge preservation purposes are suitably marked. -** EAC assessors noted that obsolete documents are currently marked by notation only in the document file name. The document itself does not appear to contain any date stamp or identification that is obsolete. The EAC recommends that in the future, suitable marks are contained on the document itself.
- 6. Checklist item 3.5.2(b): (Document Changes) Amendments shall be clearly marked, initialed and dated. A revised document shall be formally reissued as soon as practicable. -** EAC assessors note that the current process used by iBeta for document changes only describes the modifications at a high level in the change log, but does not delineate specific changes and updates in the body of the document. The EAC recommends that iBeta institute a more detailed process for identifying document changes.
- 7. Checklist item 5.3: (Monitoring Corrective Actions) The laboratory shall monitor the results to ensure that the corrective actions taken have been**

effective. - EAC assessors found no evidence that validated the effectiveness of corrective actions. Typically this is a focus of annual audits (per NVLAP 150 and 150-22) but iBeta does not include this aspect in their annual audit. Note: the 2008 audit was not completed at the time of the assessment and the findings of the 2007 audit did not appear to result in modifications to their system of monitoring results of corrective actions. The EAC recommends that iBeta complete the 2008 internal audit and develop written procedures to monitor the results of corrective actions.

- 8. Checklist item 7.4: (Personnel) The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel.** - Although a training log is maintained for each employee, EAC assessors found no evidence of the existence of formal personnel training plans or goals. Discussions with iBeta seem to indicate training needs are a part of employee annual review but no evidence was available to confirm that fact. Management explained that the more substantial part of employee training is conducted as on-the-job training, and that all testing was conducted by two people at all times. The EAC recommends that iBeta work with their employees to develop long-term strategies for the development of educational and training goals, and the implementation of those goals.
- 9. Checklist item 7.5: (Personnel) The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel.** - No evidence was observed by or presented to EAC assessors of a laboratory-wide policy to identify training needs of employees. See the EAC recommendation above in Section 7.4.
- 10. Checklist item 7.10(Personnel) 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.** - EAC assessors were unable to find evidence of documentation of levels of competency established for technical personnel of the laboratory. While past training, certifications and education are contained in resumes contained in personnel files, assessors were not able to determine where iBeta generated records of additional training might exist. The EAC recommends that iBeta develop and maintain such record on a regular basis.
- 11. Checklist item 8.1(c): (Test Methods and Method Validation- General) 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.** - EAC assessors found that iBeta documents are not updated real time as they are used by testers, but instead appear to be updated on something like an annual basis. This practice may enable testers to accidentally use obsolete documents or unapproved documents for a period of time up to several months. The EAC recommends that iBeta develop procedures for keeping all relevant

documents updated and available to all personnel on an as needed basis.

- 12. 8.4 b) (Non-standard Methods) The method developed shall have been validated appropriately before use.**
- 13. 8.5.1 a) (Validation of Methods) The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.**
- (b) The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.**

(Response to items 12– 13 above) EAC assessors found that general practices and procedures appear to need improvement in the consistency of test method validation. The process currently used for test validation appears to rely on as-run testing, instead of pre-test validation. iBeta does perform peer review, which is a very useful action, but does not constitute formal validation. The EAC recommends that iBeta develop additional test method validation procedures which may or may not include the current peer review practice. The EAC further recommends that iBeta develop written procedures regarding its peer review methodology.

- 14. Checklist item 9.7: (Handling of Test Items) When there is doubt as to the suitability of an item for test, or when an item does not conform to the description provided, or the test required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.** - EAC assessors note that this process does not appear to be followed on a consistent basis. The EAC recommends that iBeta develop a consistent written process and accompanying documentation for the handling of test items. In addition, the EAC recommends that all testers be trained on these procedures.

Assessment Conclusions:

The May 14-15, 2009 EAC audit assessment of iBeta found no nonconformities in the labs policies and procedures determined to be critical to the VSTLs technical capability to test voting systems. In addition, the audit assessment found no items that would require the laboratory to initiate immediate corrective action or to formally resolve a noncritical noncompliance. The EAC will, however, expect iBeta to address the recommendations noted in this report. The EAC will also share this information with the National Voluntary Laboratory Accreditation Program (NVLAP) for review during the next regularly scheduled NVLAP audit of iBeta. In addition, the EAC encourages iBeta to keep the EAC informed of any and all progress related to the 14 recommendations, in preparation for the next regularly scheduled EAC assessment in 2011. The EAC will also independently

follow up with iBeta to determine the extent to which the 14 recommendations noted in this assessment report will be implemented by the laboratory.