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

SysTest Labs, Denver, Colorado   EAC Lab Code: 0701

Dates: 5/12/2009 – 5/13/2009

Report Date: June 18, 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:
   o   The laboratory management system.
   o   Document control, change and retention.
   o   Control of nonconforming testing.
   o   Corrective action.
   o   Control of lab records.
   o   Personnel policies and procedures.
   o   Test Methods and Validation
   o   Procedures for handling test items.
   o   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 an acceptable element. 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 SysTest labs found no instances of nonconformities critical to the labs capability to test voting systems.

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

1. **Checklist item 3.3(c): The procedure(s) adopted shall ensure that: invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use**- Currently, access to obsolete laboratory documents is not currently limited, potentially enabling staff to use out of date documents. The EAC recommends SysTest introduce a process to prevent unintended use of obsolete documents.
2. **Checklist item 3.3(d): The procedure(s) adopted shall ensure that: obsolete documents retained for either legal or knowledge preservation purposes are**

3. **Checklist item 3.4(a): Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include: the date of issue and/or revision identification-** Current laboratory conflict of interest form has no date or other revision markings. The EAC recommends that SysTest insert the current revision date on this document.
4. **Checklist item 3.**5.2 **(Document Changes) Where practicable, the altered or new text shall be identified in the document or the appropriate attachments-** New text of revised documents is generally unmarked, but change notes are made in a configuration tracking log indicating the primary purpose of the change. The EAC recommends that SysTest implement the use of track changes or some other systematic method of identifying new and changed text in laboratory documents.
5. **Checklist item 8.5.1(a): Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. 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. -** SysTest SLP#29 currently indicates that the EAC approves validated test methods. The EAC recommends that these multiple incorrect references should be removed.

Assessment Conclusions:
The May 12-13, 2009 EAC audit assessment of SysTest Labs found no nonconformities in the labs policies and procedures and, in addition found no items that would require the laboratory to initiate corrective action or to formally resolve and noncritical noncompliance. The EAC will follow up with SysTest to determine the extent to which the five recommendations noted in this assessment report will be implemented by the laboratory.

In addition, the EAC finds that the policy and procedures currently in place at SysTest Labs show a dramatic, significant effort representing a company-wide commitment to the EAC laboratory Accreditation Program and ongoing quality improvement.