

MicroVote General Corporation Quality Assurance Audit

September 8-9, 2014 Indianapolis, Indiana

Conducted by: United States Election Assistance Commission
Testing and Certification Division
1335 East-West Highway
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Silver Spring, MD

Executive Summary

MicroVote General Corporation (MicroVote) is an EAC registered voting system manufacturer based in the Indianapolis, Indiana metropolitan area and has been registered with the U.S. Election Assistance Commission (EAC) since 2007. On September 8-9, 2014, the Election Assistance Commission conducted a quality assurance audit of MicroVote in order to collect sufficient data to assess the manufacturer's quality systems and their compliance with the quality assurance requirements of the EAC certification program and the 2005 Voluntary Voting System Guidelines.

The quality assurance audit found that while MicroVote had very recently developed and incorporated a quality assurance manual into their company processes, the manual needs to be strengthened, fully implemented with the backing and support of senior management and backed up with internal procedures that would allow independent auditors to determine if MicroVote is actually meeting their stated quality goals.

This report provides six specific recommendations for MicroVote in order for the company to improve overall quality management and quality assurance and to bring their current process more in line with the intention of the requirements of VVSG Section 8. These recommendations are detailed in the Audit Recommendations Section of this report.

Introduction

On September 8-9, 2014, the Election Assistance Commission conducted a quality assurance audit of MicroVote at the company headquarters in Indianapolis, Indiana. Participating in the audit for EAC were Brian Hancock, Director, Testing and Certification, Jessica Myers, Program Specialist, Mark Skall, Technical Reviewer and Tom Caddy, Technical Reviewer.

The quality assurance audit was performed pursuant to Section 2.3.1.4 and Section 8 of the EAC Testing and Certification Program Manual as well as Section 8 of the 2005 Voluntary Voting System Guidelines (VVSG).

This report, along with the attached appendices, documents the audit findings, conclusions and recommendations and will be forwarded to MicroVote and included as an attachment to the MicroVote EMS 4.1 Test Report in order to assist the manufacturer with meeting the requirements of VVSG Section 8 and improving their overall operations and quality control.

Purpose

The EAC conducted the audit because of ongoing questions about the quality assurance practices of the manufacturer based on concerns noted by NTS Laboratories and previous EAC experience on MicroVote test campaigns.

Scope

This audit was conducted in order to collect sufficient data to assess the manufacturer's quality systems, their compliance with the quality assurance requirements of Section 8 and the configuration management requirements of Section 9, Volume 1 of the 2005 Voluntary Voting System Guidelines (VVSG), and to compare MicroVote quality practices to IT industry standard QA practices.

To accomplish the audit objectives noted above, the EAC:

- Met with MicroVote management and senior staff as well as the management and staff of Carson Manufacturing (Carson).
- Listened to briefings and participated in discussions regarding MicroVote management and quality systems.
- Reviewed documentation related to the MicroVote QA system.
- Use EAC Quality Audit Checklist (Appendix A) to determine compliance.

Why Conduct a Quality Audit?

Quality assurance is often defined as a process-centered approach to ensuring that a company or organization is providing the best possible products or services to its customers. Quality assurance focuses on enhancing and improving the process that is used to create the product, rather than focusing on the product itself. Among the parts of the process that are considered in QA are planning, design, development, production and service.

Quality assurance demands a degree of detail in order to be fully implemented at every step. Planning, for example, could include determining specific levels of quality or measurable results that the organization wants to achieve. Checking could involve testing and other objective measurements to determine whether the goals were met, rather than mere subjective evaluation of quality. Acting could mean a total revision in the manufacturing process to correct a technical or cosmetic flaw or very small changes to improve efficiency or accuracy.

Quality assurance verifies that any product, regardless whether it is new or modified, is produced and offered with the best possible materials, in the most comprehensive way and with the highest standards. Quality assurance provides the mechanism to exceed customer expectations in a measurable and accountable process.

ISO 9000 is a family of standards published by ISO, the International Organization for Standardization, related to quality management systems and designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to the product. ISO 9001 is a global quality management standard dealing with the requirements that organizations wishing to meet the standard must fulfill. As of 2011, more than a million organizations worldwide were certified to the ISO 9001 standard. While not a panacea for every quality related problem an organization may face, the principles of ISO 9001 have been the guiding force in organizational quality since the early 1990's.

ISO 9001 defines quality as something that can be determined by comparing a set of inherent characteristics with a set of requirements. If those inherent characteristics meet all requirements, high or excellent quality is achieved. If those characteristics do not meet all requirements, a low or poor level of quality is achieved. Quality assurance (QA) is defined as a set of activities intended to establish confidence that quality requirements will be met. QA is one part of quality management. A quality management system (QMS) is a set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved.

Finally, a *quality manual* documents an organization's quality management system (QMS). It can be a paper manual or an electronic manual. According to ISO 9001 section 4.2.2, a quality manual should:

- Define the scope of your QMS.
 - Explain reductions in the scope of your QMS.

- Justify all exclusions (reductions in scope).
- Describe how your QMS processes interact.
- Document your quality procedures or refer to them.

While not requiring ISO 9001 certification from voting system manufacturers, the 2005 VVSG recognizes the importance of quality assurance in voting systems with the specific requirements related to quality contained in Section 8.

VVSG Section 8.1 defines the scope of QA.

"Quality assurance provides continuous confirmation that a voting system conforms with the Guidelines and to the requirements of state and local jurisdictions. Quality assurance is a vendor function that is initiated prior to system development and continues throughout the maintenance life cycle of the voting system. (Emphasis added) Quality assurance focuses on building quality into a voting system and reducing dependence on system tests at the end of the life cycle to detect deficiencies, thus helping ensure the system:

- Meets stated requirements and objectives
- Adheres to established standards and conventions
- Functions consistently with related components and meets dependencies for use within the jurisdiction
- Reflects all changes approved during its initial development, internal testing, national certification, and, if applicable, state certification processes."

VVSG Section 8.2 defines the general requirements for quality assurance:

"The voting system vendor is responsible for designing and implementing a quality assurance program to ensure that the design, workmanship, and performance requirements are achieved in all delivered systems and components. At a minimum, this program shall:

- a. Include procedures for specifying, procuring, inspecting, accepting, and controlling parts and raw materials of the requisite quality
- b. Require the documentation of the hardware and software development process
- c. Identify and enforce all requirements for:
 - i. In-process inspection and testing that the manufacturer deems necessary to ensure proper fabrication and assembly of hardware
 - ii. Installation and operation of software and firmware
- d. Include plans and procedures for post-production environmental screening and acceptance testing
- e. Include a procedure for maintaining all data and records required to document and verify the quality inspections and tests."

Because determinations of quality can often be subjective, the EAC uses the Quality Audit Checklist to focus auditors and to provide a general basis for determining if the

manufacturer meets the quality requirements of the VVSG and the general principles of quality outlined in ISO 9001.

Current MicroVote Quality Assurance Processes

The formal QA process at MicroVote is essentially a new development triggered by the EAC Quality Audit notification and some issues related to testing the MicroVote QA/CM process as required by in the VVSG for the current MicroVote test campaign. This statement is reflective of the fact that the MicroVote Quality Assurance Manual (Version 1.0 & 1.1) are dated September 1st and 2nd, 2014. In addition, the MicroVote Training Manual (Version 1.0) is dated August 25, 2014, and the one and only staff training session related to the new quality manual and process was held on September 2, 2014 from 10:00am until approximately 12:40pm.

MicroVote is a small company with approximately 15 full time equivalent employees, including the Chief Executive Officer and President. Additional temporary staff is hired prior to each election and may or may not receive updated voting system/election training from MicroVote. Source code change control is managed via a Microsoft Team Foundation Server. Commercial Off-the-Shelf (COTS) component and end-of-life (EOL) components as well as supplies and vendors are managed by the MicroVote Chief Operating Officer. Internal testing is conducted under the QA department who develop their own test cases. It was unclear how validation of these test cases was performed by MicroVote. Hardware EMC testing has just recently (3-4 months) been contracted out to Technicolor Laboratory Service, located in the Indianapolis area.

A unique and potentially problematic scenario exists because MicroVote owns the Intellectual Property (IP) rights to their software, while the IP rights to the hardware that runs the voting system is owned by Bill Carson, Technical Support Specialist of Carson Manufacturing Company, Inc. (Carson). Carson is the sole manufacturing facility for the MicroVote system and, like MicroVote, is located in the Indianapolis metropolitan area. This relationship led the EAC audit team to also review the Carson quality process at their facilities on September 9, 2014. Because no voting system products were being manufactured by Carson at the time of the EAC visit, EAC audit team concentrated on a review of the Carson quality program.

The EAC audit team met with Carson staff, reviewed documentation related to the quality system and toured the manufacturing area of the facility. The Carson Quality Manual reviewed by EAC was Revision C, dated November 1st, 2011. No updates or revisions have been incorporated since that time. No separate quality unit or department exists at Carson. Currently no quality manager has been designated, and currently, all quality functions default to the company Chief Executive Officer (Barbara Ferguson, President and CEO).

Carson in general appears to have a very minimal quality program.

Audit Results

This section details the results of the quality audit by highlighting findings noted by the audit team in their quality audit checklist. The EAC quality audit checklist contains five major sections covering:

- Organizational Quality Management System
- Product Design and Development
- Pre-Production Design and Development Testing
- Identify and Control Nonconforming Products
- Labeling

1. Organizational Quality Management System

EAC auditors conclude that MicroVote has not operated under any corporate quality policy prior to the EAC audit, since the initial version of their quality manual was dated just days before the EAC audit team arrived in Indianapolis. MicroVote has no separate division of quality responsibilities but instead splits QA duties between the Director of Software Development, who is also Director of QA, and the Director of Customer Service, who is also the QA Manager. Since no separate QA unit exists at MicroVote, the EAC was told that QA is reviewed by the division directors who ultimately report to the Chief Executive Officer or Chief Operating Officer. This bifurcation of responsibility can lead to questions related to who has the ultimate authority over QA decisions as well as providing the potential for issues to slip through gaps between the two individuals if responsibilities are not clearly and expressly defined. The MicroVote Quality Manual does not include a process for the review of production records and no records or documentation was provided to the EAC.

The MicroVote individuals currently responsible for QA duties have no claimed or documented training in QA processes (Either ISO 9001 or otherwise), and because the QA Manual and associated processes are new, no formal internal audits have been conducted and only one short and minimal training session was claimed and documented for MicroVote staff to be informed of the existence of the Quality Manual.

2. Product Design and Development

The MicroVote Quality Manual does not contain a design review policy statement. This would obviously preclude any systematic internal review or audit of design concepts as well as any systematic method to determine if design objectives are being achieved. Because

formal design reviews are not a part of the MicroVote process, record keeping for this function is not applicable at this time. General review of product functionality is a joint effort between the Director of Software Development and the Director of Customer Service. Lack of a design review policy may be partially related to the fact that the MicroVote product has remained essentially unchanged at least since its initial certification efforts as part of the NASED program in 2006. Any design review done is therefore ad hoc in nature. MicroVote noted that they may develop a formal product design and review policy if the EAC recommends such an activity.

- 3. Pre-Production Design and Development Testing Some internal design and developmental as well as general functional testing is done on the MicroVote software by the Director of Software Development. This individual develops his own test cases and it was unclear how these test cases were validated, or even if the test cases were validated. Because of this limited process, no ongoing formal test cases appear to exist which brings into question the repeatability of such test cases.
- 4. Identifying and Controlling Nonconforming Products Section 12.0 and 13.0 of the MicroVote Quality Assurance Manual outline general requirements for the Control of Nonconforming Articles and Corrective Actions. Unfortunately it appears that MicroVote has no accompanying procedures to enable the company to consistently incorporate these requirements into product development, product testing or product delivery.

Section 13.0 notes that "In the case of significant [Emphasis added] conditions adverse to quality, the root cause of the condition shall be determined and action planned to correct and preclude repetition." As with the rest of this document, no detailed process for implementing a root cause analysis was defined leaving open questions of the consistency and quality of root cause analysis. In addition, MicroVote should clearly define terms used in this section such as "significant" in order to be clear on what level of system anomaly would initiate root cause analysis.

Customers are notified of non-conforming products either via email, telephone or by mail through the United States Postal Service.

5. Labeling

The EAC auditors were unable to find detailed policies and procedure related to product labeling and the EAC Mark of Certification although Section 9.0 of the Quality Manual states that: "Labeling shall be verified during customer acceptance testing." This is surprising given that the EAC has provided the basis for such procedures in EAC Notice of Clarification (NOC) 2008-002 EAC Mark of Certification available on the EAC web site.

Audit Recommendations

In consideration of the findings outlined in this audit report, the EAC recommends MicroVote take the following six (6) steps to improve overall quality management and quality assurance and to bring their current process more in line with the intention of the requirements of VVSG Section 8:

- 1. While formal ISO 9001 certification is not recommended at this time, the EAC does recommend that MicroVote develop a formalized organizational quality management system based on the principles of ISO 9001. Quality management is defined as all activities carried out by the organization to direct, control and coordinate quality. The activities should at a minimum include formulating a quality policy, and setting quality objectives. This recommendation can best be met by one or more MicroVote staff members receiving formal training in ISO 9001 concepts via one of the numerous commercial ISO training organizations.
- 2. Augment and fully implement the new organizational quality manual. The quality manual documents an organization's quality management system (QMS) and should:
 - Define the scope of the QMS.
 - Justify all exclusions (reductions in scope).
 - Describe how your QMS processes interact.
 - Document your quality procedures.
- 3. Conduct regularly scheduled internal quality audits in order to monitor and measure your QMS, document any nonconforming procedures or products and perform corrective action to improve the nonconforming process or product.
- 4. Develop a systematic process for the review of new product design and design changes to already developed products. This process should include specific measurements to determine if design objectives are being met as well as a system of maintaining records of all design reviews.
- 5. Develop and implement detailed root cause analysis procedures to satisfy the requirements of Section 13.0 of the MicroVote Quality Manual.
- Undergo another EAC quality assurance audit within one year of the date of this report to allow the EAC to assess MicroVote progress in meeting the recommendations of this audit.

Although the above recommendations are purely voluntary, the EAC strongly suggests that MicroVote implement the recommendations for the following reasons:

- ISO 9001 is the standard best practice specification for QMS in use worldwide. ISO 9001 has a track record of saving money, streamlining operations and reducing waste, and increasing customer satisfaction.
- As the EAC moves towards improving and truncating the certification process through the use of Manufacturer Declaration of Conformity (DoC), it is likely that ISO 9001 certification will eventually become a requirement for all EAC registered manufacturers in order to provide some additional assurance to the DoC and ultimately, to MicroVote customers.

The EAC requests that an initial written response to this report be submitted within 45 days of the receipt date of this document.



Date: 9/8/14 – 9/9/14 Appenix A

Reviewer:

Question	QA Reference	Evidence (Note any additional evidence or comments may be included in a supplementary notebook).	Yes, No, or NA
1	Organizational Quality Management System		
1.1	Does this organization operate under a corporate quality policy?		
1.2	Does a Quality Assurance unit (department) exist as a separate organizational entity?		
13	Does the Quality Assurance unit alone have both the authority and responsibility to approve or reject all designs, parts, components, and finished products?		
1.4	Does the QA department routinely review production records to ensure that procedures were followed and properly documented?		
1.5	Does the organization have a documented Quality Assurance program? (Quality Manual)		

Question	QA Reference	Evidence (Note any additional evidence or comments may be included in a supplementary notebook).	Yes, No, or NA
1.6	 Does the Quality Manual contain (at minimum) A quality policy statement, including objectives and commitments by executive management? The reporting relationship between management, technical operations, production, support and the quality system? The organizations general scope of product inspection and testing? Appropriate and clear reference to inspection verification and test procedures to be used? Reference to any procedures for inspection, calibration and maintenance of test equipment? Procedures for handling nonconforming materials and products? 		
1.7	Does the Quality Manual provide means for finished products to be traced back to the production and quality control records at the manufacturing facilities?		

Question	QA Reference	Evidence (Note any additional evidence or comments may be included in a supplementary notebook).	Yes, No, or NA
1.8	Is the Quality Manual reviewed and/or revised at planned intervals?		
1.9	Has the organization implemented and maintained document and data control procedures for the Quality Manual/Quality System?		
1.10	Are the procedures followed? (Examine records to ensure consistent record-keeping and documentation.)		
1.11	Are QA supervisory personnel qualified by way of training and experience?		
1.12	Is a copy of the Quality Manual readily available to all employees?		
1.13	Is training provided in Quality Assurance and quality improvement?		
1.14	If "yes" to above, when provided?		
1.15	Does a formal auditing function exist in the Quality Assurance department?		
2	Product Design and Development		

Question	QA Reference	Evidence (Note any additional evidence or comments may be included in a supplementary notebook).	Yes, No, or NA
2.1	Do reviews occur at planned stages throughout the design process?		
2.2	Are reviews carried out in a systematic way involving representatives of all organizational functions concerned with the product development?		
2.3	When designs change from the original concept, are revised inputs and outputs reviewed and approved by the appropriate authorized individuals?		
2.4	Does the output demonstrate the suitability and conformance to specifications of the designed product?		
2.5	How is it determined if design objectives are being achieved?		
2.6	Are adequate records of design reviews maintained?		
3	Pre-Production Design and Development Testing		

Question	QA Reference	Evidence (Note any additional evidence or comments may be included in a supplementary notebook).	Yes, No, or NA
3.1	Is design and development testing done to validate that the product complies with the organizations own performance requirements and the requirements of customers and regulators (Federal and State certification authorities)?		
3.2	Are test methods traceable to pertinent system functional requirements and applicable Federal or State certification requirements?		
3.3	Are test records/reports maintained and do they confirm that appropriate testing has been carried out?		

Question	QA Reference	Evidence (Note any additional evidence or comments may be included in a supplementary notebook).	Yes, No, or NA
3.4	Do test records/reports include all information necessary for the reliable interpretation of test results? This information should include at minimum: Descriptive title Description and clear identification of the product being tested. Date of test. Identification of the test method used. Clear and unambiguous description of the results of the test (Pass/Fail). Signature and title of individual accepting responsibility for the content of the record/report.		
3.5	Do the records for each test contain sufficient information to permit repetition?		

Question	QA Reference	Evidence (Note any additional evidence or comments may be included in a supplementary notebook).	Yes, No, or NA
3.6	If test records/reports are performed and compiled by a contractor, that contractor must be audited by the manufacturer to ensure that the contractor is qualified to perform the testing contracted for (Including having appropriate accreditation) and meets the manufacturer's quality requirements.		
3.7	Manufacturer shall maintain and retain all records of contracted tests.		
4	Identify and Control of Nonconforming Products		
4.1	Does the organization define procedures used to identify, evaluate, and address any nonconforming product detected by inspection, customer report/complaint or Federal or State certification authority determination?		
4.2	Are corrective actions in place to explore the root cause of the nonconformance and provide a plan for eliminating the root cause?		
4.3	Is Information related to occurrences of nonconforming work recorded and maintained?		

Question	QA Reference	Evidence (Note any additional evidence or comments may be included in a supplementary notebook).	Yes, No, or NA
4.4	How are customers notified of nonconforming products and product upgrades resulting from root cause analysis and product redesign?		
5	Labeling		
5.1	What are the organizational policies on labeling (both marks of certification and other required labels such as URL)?		
5.2	How and when is correct labeling verified?		