

# ETA-HIQP01

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## QUALITY PROGRAM

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## 1.0 Objective

The objective of this procedure is to develop and maintain a program that provides guidance for the quality requirements and aspects of work performed during the conduct of contracts between Electric Transportation and outside agencies, including HICEV America.

## 2.0 Scope

This program applies to all activities conducted by Electric Transportation Applications in support of performance testing of electric vehicles performed pursuant to the requirements of HICEV America. This program may also apply to other activities, if it is specifically invoked by the documents controlling those other activities.

## 3.0 Documentation

Documentation addressed by this procedure shall be consistent, easy to understand, easy to read, and readily reproducible. Documents shall contain enough information to "stand alone;" that is, be self-contained to the extent that all individuals expected to review it could be reasonably expected to reach a common conclusion, without the need to review additional documentation. Storage and retention of records during and following testing activities shall be completed as described in Procedure ETA-HIAC01, "Control, Close-out and Storage of Documentation."

## 4.0 Prerequisites

- 4.1 Personnel conducting work under this program, or in accordance with the procedures associated with the HICEV America shall be aware and trained/certified as to its contents.
- 4.2 All procedures controlling work or program related activities shall be subject to the requirements of this program.
- 4.3 All personnel within the cognizance of this program shall be responsible for its implementation.
- 4.4 All personnel within the cognizance of this program shall be responsible for the quality of their work activities and products. These products may be tangible or otherwise.
- 4.5 All personnel are responsible for identifying conditions adverse to quality and if possible correcting those conditions.
- 4.6 Conditions adverse to quality will be reported to management, regardless of whether they were corrected.

## 5.0 Exclusions

- 5.1 This Program does not apply to activities outside of those specifically addressed by the programs and procedures developed and associated with HICEV America being administered by Electric Transportation Applications.
- 5.2 Should this program be applied to other activities administered by Electric Transportation Applications, it shall be invoked by those activities, without the necessity to revise this document.
- 5.3 Specific exclusions from this program should be made within the document requiring the exclusion.

## 6.0 Quality Assurance Criteria

### 6.1 Program

This document functions as the written Quality Assurance Plan. It will describe, as necessary, the functional responsibilities, levels of authority (as appropriate) and interface requirements for individuals managing, assessing or performing work. The program has or directs the establishment of specific attributes. These may be included in other approved procedures or programs under the control of Electric Transportation Applications. The program should include the following attributes:

- 6.1.1 A formal Quality Assurance Plan (QAP). This document is that Plan.
- 6.1.2 Management retention and responsibility for an effective QAP. Each individual is responsible for the quality of their work.
- 6.1.3 The promotion of effective achievement of the performance objectives.
- 6.1.4 The QAP is binding on all personnel completing work under any ETA series procedures relative to the HICEV America Program.
- 6.1.5 The quality of processes are ensured to an extent consistent with their risk.
- 6.1.6 A description of or reference to the organizational structure, functional responsibilities, levels of authority and interfaces.
- 6.1.7 A common vocabulary along with key terminology. Personnel indoctrination should include appropriate definitions.
- 6.1.8 Work assigned or contracted outside of the organizations should be identified, along with any required management controls, such as responsibilities and lines of communication.
- 6.1.9 Readiness reviews should be completed for all projects prior to initiation.

6.1.10 Responsibility and authority for the stoppage of unsafe or unsatisfactory work should be assigned and clearly denoted for each task or project.

## **6.2 Personnel Training and Qualification**

6.2.1 Personnel performing work should be capable of performing their assigned tasks. Qualification requirements should be established for specific job categories. Training includes both education in principles and enhancement of skills and practices.

6.2.2 Training should emphasize correct performance of work and provide an understanding of the fundamentals of quality, safety and the importance of “doing work right the first time.”

6.2.3 Training plans should address and stimulate professional development.

6.2.4 Personnel performing work that requires special skills or abilities should be qualified prior to performing work. Qualification should require demonstrated proficiency of each candidate.

6.2.5 The following job categories will have the noted minimum requirements

6.2.5.1 The Program Manager shall have a minimum of a BS Degree in Engineering or Technology, and four (4) years of electric vehicle experience and/or four (4) years of Program Management experience. A master’s degree may be considered as fulfilling the requirements for one of those years of experience.

6.2.5.2 The Test Director shall have a minimum of a BS Degree in Engineering or Technology, and four (4) years of electric vehicle experience and/or four (4) years of Project Management experience. A master’s degree may be considered as fulfilling the requirements for one of those years of experience.

6.2.5.3 The Test Manager shall have a minimum of a BS Degree in Engineering or Technology, two (2) years of Program/Project Management experience and two (2) years of test experience in a professional commercial industrial or government setting. A Master’s degree may be considered as fulfilling the requirements for one of those years of experience.

6.2.5.4 The Test Engineer should have a BS Degree in Engineering or Technology and two (2) years of test experience in a professional commercial industrial or government setting.

6.2.6 Certification of personnel shall be completed in accordance with the requirements of the specific test procedure or program.

### 6.3 Quality Improvement

- 6.3.1 Processes should be established and implemented with the objective of preventing problems and improving quality. These processes can include peer review, design review, probabilistic risk assessment, etc.
- 6.3.2 Information collected during various processes should be analyzed for trend identification.
- 6.3.3 All individuals covered by this policy should foster a no-fault attitude.
- 6.3.4 Non-conforming items and processes should be controlled to prevent their inadvertent use.

### 6.4 Documents and Records

#### 6.4.1 Documents

- 6.4.1.1 Processes should be established and implemented to control the preparation, review, approval, issuance, and revision of documents.
- 6.4.1.2 The scope of document control should be defined, and should include procedures, test results, procurement documents, audit reports, findings, vendor supplied data, etc.
- 6.4.1.3 The same organizations and levels that reviewed and approved the original document should review revisions to controlled documents.
- 6.4.1.4 Controlled documents should be distributed to and used by personnel performing the work.
- 6.4.1.5 Record copies should be marked as such, and maintained for a specified period of time.

#### 6.4.2 Records

- 6.4.2.1 A process should be established to ensure that sufficient records are specified, prepared, reviewed, approved and maintained to accurately reflect completed work.
- 6.4.2.2 A process should be established which specifies the minimum period for storage, as well as the requirements for storage.

## 6.5 Work Processes

### 6.5.1 Work

- 6.5.1.1 Personnel performing work are responsible for the quality of that work.
- 6.5.1.2 Review personnel are responsible for ensuring that personnel performing work are adequately trained and certified to complete the assigned work.
- 6.5.1.3 Work should be planned and accomplished in a controlled manner using approved standards and/or procedures.
- 6.5.1.4 Work-related instructions and procedures should be developed verified validated and approved by technically competent personnel.

### 6.5.2 Calibration and Maintenance of Monitoring and Data Collection Equipment

- 6.5.2.1 A process should be established or verified to be established which controls the calibration maintenance and use of measuring and test equipment used for monitoring and data collection.
- 6.5.2.2 This equipment should be suitable for the use intended, and should have calibration certifications and standards traceable to national standards, where possible.

## 6.6 Design

- 6.6.1 A process should be established for the design process which uses sound engineering/scientific principles and appropriate standards.
- 6.6.2 Changes to final design, whether prior to installation or use or not, should have the same restrictions and review processes that the original design was subjected to.
- 6.6.3 Verification processes should be consistent for all design levels, and should be accomplished by individuals technically competent in the field the design is in.
- 6.6.4 Testing to verify or validate the design or protocol should be accomplished prior to a production use of the design or protocol.

## 6.7 Procurement

- 6.7.1 A process should be established and implemented to ensure that purchased items and services meet the established requirements and perform as expected.
- 6.7.2 Prospective suppliers should be evaluated to ensure only qualified suppliers are selected.
- 6.7.3 Actual performance of items should be compared with original performance criteria.
- 6.7.4 The quality of purchased items and services should be verified at intervals consistent with the item's complexity, service conditions and risk.

## 6.8 Inspection and Acceptance Testing

### 6.8.1 Inspection

- 6.8.1.1 A process should be established and implemented to specify when and what type of inspections are required.
- 6.8.1.2 Inspections may be implemented by or for the organization performing the work to be inspected. Personnel shall not inspect their own work.
- 6.8.1.3 When acceptance criteria are not met, deficiencies should be resolved and re-inspection occur, as required.

### 6.8.2 Acceptance Testing

- 6.8.2.1 Testing processes should be established and implemented to demonstrate that items and processes will perform as intended.
- 6.8.2.2 Testing may be implemented by or for the organizations performing the work to be tested.
- 6.8.2.3 Item and process test requirements and acceptance criteria should be provided by or approved by the organization responsible for the activity.



- 6.8.2.4 Test procedures should be developed and include the following:
  - 6.8.2.4.1 Instructions and prerequisites to perform the test;
  - 6.8.2.4.2 Completeness and accuracy of data;
  - 6.8.2.4.3 Use of test equipment;
  - 6.8.2.4.4 Acceptance criteria (if applicable);
  - 6.8.2.4.5 Inspection points, as required;
  - 6.8.2.4.6 Test article configuration
- 6.8.2.5 Retesting of items or processes to determine that they meet acceptance criteria is required after deficiencies have been corrected.

### **6.8.3 Measuring and Test Equipment**

- 6.8.3.1 A process should be established and implemented or verified to be present which controls the calibration, maintenance, accountability and use of equipment used to control any process or data collection system.
- 6.8.3.2 The types of equipment to be used, such as instruments, tools, gages, reference and transfer standards, and non-destructive examination equipment, should be defined.
- 6.8.3.3 Measuring and test equipment (M&TE) should be calibrated at specified intervals, on the basis of the item's required accuracy intended use, frequency of use stability characteristics and other conditions affecting its performance.
- 6.8.3.4 M&TE should be labeled, tagged or otherwise controlled to indicate its calibration status and ensure its traceability to calibration test data.
- 6.8.3.5 M&TE should be calibrated against standards having an accuracy that will ensure that equipment being calibrated will be within required tolerances. If nationally recognized standards exist, calibration standards should be traceable to such standards.
- 6.8.3.6 M&TE found out-of-calibration or out-of-tolerance should not be used until it is successfully recalibrated. The acceptability of items inspected, tested or measured with an out-of-calibration device should be determined.

## 6.9 Management Assessment

- 6.9.1 Planned and periodic management assessments should be completed as a way to improve quality.
- 6.9.2 Results of management assessments should be documented. Recommendations resulting from the assessments should be promptly acted upon, and the results of those actions noted as appropriate.
- 6.9.3 This process should involve all levels of management.

## 6.10 Independent Assessment

- 6.10.1 A process of planned periodic independent assessments should be established as required, and should focus on improving items and processes by emphasizing achievement of quality.
- 6.10.2 Personnel performing independent assessments should act in a management advisory function, with responsibilities including monitoring of work performance, potential problems, problem precursors and opportunities for improvement.
- 6.10.3 Personnel performing independent assessments should be technically knowledgeable and focus on improving the quality of the processes being evaluated.
- 6.10.4 Personnel performing independent assessments should not have direct responsibilities in the area they are assessing.
- 6.10.5 These assessments should be conducted using criteria that describe acceptable work performance and promote improvement.
- 6.10.6 The management having responsibility in the area assessed should resolve assessment results. Follow-up review of the deficient areas should be initiated as necessary.
- 6.10.7 Responses to assessments should include the following, as applicable:
  - 6.10.7.1 Action to correct the deficiency;
  - 6.10.7.2 Cause identification;
  - 6.10.7.3 Actions taken to prevent recurrence;
  - 6.10.7.4 Lessons learned;
  - 6.10.7.5 Actions to be taken for improvement.

## 7.0 Glossary

- 7.1 Assessment/Verification - The act of reviewing, inspecting, testing checking, conducting surveillance's, auditing or otherwise determining and documenting whether items, processes or services meet specified processes.
- 7.2 Effective Date - The date, after which a procedure has been reviewed and approved, that the procedure can be utilized in the field for official testing
- 7.3 Item - An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, documented concepts or data.
- 7.4 Process - A series of actions that achieves an end result.
- 7.5 Program Manager - As used in this procedure, the individual within Electric Transportation Applications responsible for oversight of HICEV America. [Subcontract organizations may have similarly titled individuals, but they are not addressed by this procedure.]
- 7.6 Quality - The degree to which an item meets or exceeds the user's requirements and expectations.
- 7.7 Quality Assurance - Actions that provide confidence that quality is achieved.
- 7.8 Quality Assurance Program - The overall program established by an organization to implement the requirements of this procedure. The Program assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work.
- 7.9 Service - The performance of work, such as design, fabrication, inspection, nondestructive examination, repair or installation.
- 7.10 Test Director - The individual within Electric Transportation Applications responsible for all testing activities associated with the HICEV America Performance Test Program.
- 7.11 Test Engineer - The individual(s) assigned responsibility for the conduct of any given test. [Each contractor/subcontractor should have at least one individual filling this position. If so, they shall be responsible for adhering to the requirements of this procedure.]
- 7.12 Test Manager - The individual within Electric Transportation Applications responsible for the implementation of the test program for any given vehicle(s) being evaluated to the requirements of HICEV America. [Subcontract organizations may have similarly titled individuals, but they are not addressed by this procedure.]

- 7.13 HICEV America – Hydrogen Internal Combustion Engine Vehicle America Performance Test Program, the DOE sponsored test program for independently assessing the performance of vehicles submitted for testing.
- 7.14 Work - The process of performing a defined task or activity. Research and development, operations, maintenance and repair, administration, software development and use, inspection, data collection and analysis are examples of work.

## 8.0 References

- 8.1 Department of Defense (DOE) Order 5700.6C, “Quality Assurance,” dated 8-21-91
- 8.2 International Standard for Standardization (ISO) 9000, “Quality Management and Quality Assurance Standards-Guidelines for Selection and Use.”
- 8.3 EPA Guidance Document QAMS 005, “Interim Guidelines and Specifications for Preparing QA Project Plans.”
- 8.4 American Society of Mechanical Engineers (ASME)/NQA-1, “Quality Assurance Program Requirements for Nuclear Facilities.”
- 8.5 American Nuclear Society (ANS) 3.1, “Requirements for the Selection and Training of Personnel for Nuclear Power Plants.”
- 8.6 ETA-HIAC01, “Control, Close-out and Storage of Documentation.”
- 8.7 ETA-HIAC02, “Control of Test Conduct.”
- 8.8 ETA-HIAC03, “Preparation and Issuance of Reports.”
- 8.9 ETA-HIAC04, “Review of Test Results.”
- 8.10 ETA-HIAC05, “Training and Certification Requirements for Personnel Utilizing ETA Procedures.”
- 8.11 ETA-HIAC07, “Control of Measuring and Test Equipment.”
- 8.12 ETA-HIQA01, “Audit of the Quality Assurance Program for the Control and Use of Measuring and Test Equipment.”