ETA-HIQA01

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AUDIT OF THE QUALITY ASSURANCE PROGRAM FOR THE CONTROL AND USE OF MEASURING AND TEST EQUIPMENT

Prepared by

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Appendices

1.0 Audit Objectives

The objective of an audit is to verify the adequacy of the operational characteristics of this facility's quality assurance practices, specifically as they relate to the control of metrology.

2.0 Audit Purpose

The purpose of the audit is to ensure that the Quality Assurance Program requirements which address the control of metrology, or Measuring and Test Equipment (M&TE), used at facilities which may be subcontracted to Electric Transportation Applications. This includes control measures for all aspects of the calibration and use processes, repair and rework of defective instrumentation. The Audit Plan shall include, but not be limited to, one or more aspects of the following:

- Control of the facility's metrology calibration processes
- Control of the facility's metrology calibration standards
- Control of the facility's metrology procedures
- Control of the facility's metrology records, including retention requirements
- Control and reporting of defective metrology
- Rework/repair of defective metrology
- Rework/repair of metrology which fails in service

3.0 Audit Requirements

The Quality Assurance (QA) Plan being audited shall have been developed in accordance with the requirements of The National Bureau of Standards Handbook (NBS/HB)-145, or another similar document. The QA Plan is required to contain controls for those items specified as necessary by the NBS/HB-145. For those items required by the NBS/HB but not specifically contained in the QA Plan, then the NBS requirements for alternatives must have been followed.

4.0 Audit Personnel

Personnel who conduct the audit shall either be trained or have experience in this type of activity. Training may be formal, such as through post-secondary or post-graduate studies, or through an approved or generally accepted Industry or Corporate Training Program. Experience should have been gained through actual auditing of QA Activities or Plans at other facilities or companies, which may include those controlled by Federal or State Governments. Individuals should be capable of being certified as an auditor to the requirements of the QA standard used as the basis for the QA Plan being audited.

Personnel who are assigned as members of the audit team shall have the experience, training or educational background, as identified in Section 8.7, necessary for them to participate as audit team members.

5.0 Audit Documentation

The documentation used and generated during the Audit Process should be retained as a permanent part of the audit package. Copies of the completed audit, including all checklists and reports, noted deficiencies and any corrective action activity reports, shall be made available to all members of the audit team, as well as to the management of the facility being audited. The audited facility shall maintain the results of the Audit in accordance with the external auditing requirements of their QA Plan, if so stipulated. If not otherwise stipulated, the results of the audit shall be maintained until the date of completion of all activities addressed by the governing contract.

All documents shall be signed by the person completing the document and the Audit Team Leader. The names of the audit team members shall be listed in the document. The final Audit Package will be signed by all members of the Audit Team, and signed by the Manager of the facility or group being audited, or a designated representative. These final signatures shall be attached following completion of the exit meeting process, and will signify that all signers have been made aware of the audit findings, and have received a copy of the final report. Signatures of additional facility personnel, as required by NBS/HB-145 or the facility's QA plan or audit program, shall be affixed as appropriate.

6.0 Audit Process

The audit shall utilize checklists and interviews to obtain data. Procedures and controls specified by NBS/HB-145 and others as may be specified by the Facility's QA plan are subject to review. Only data which is relevant to the particular process under review will be collected. Every attempt will be made to keep the identify of interviewees confidential, as individual reproach is not the intent of this effort. Audit findings which in the opinion of the audit team are considered or judged to be unsafe, or could be reasonably expected to jeopardize the safety of the interviewee, other individuals or equipment, or which in turn could jeopardize the safety of subsequent individuals, shall be reported to a senior member of the Subcontractor’s organization.

7.0 Audit Protocol

Audit activities shall take place at the sub-contractor’s facilities, unless otherwise agreed to in advance. Activities are limited to those activities identified in this Plan. Activities not under the scope of this Plan should not be audited, but may be otherwise noted or reported. All ETA personnel involved in the audit at the subcontractor’s facility are

required to follow the confidentiality guidelines and the security and safety requirements of that subcontractor.

All findings of the Audit shall be maintained confidential until the report has been completed, reviewed and signed by all members of the Audit team, or their designated representative. The final report should be maintained as previously stipulated. It may be maintained for longer periods, as directed by the facility's requirements for records retention.

8.0 Audit Activities

8.1 Quality Assessment

The term that describes those activities and procedures utilized to monitor the effectiveness of the quality control program and to evaluate the quality of the data output. Such an assessment can be from either an internal or external approach. Because this assessment is intended to quantify the reviewed activities as satisfactory or unsatisfactory only as they relate to the HICEV America Performance Test Program, it will be implemented using an external approach. This Plan could be utilized in either manner, however. Appendices C through G shall be used to document the results of the assessment

8.2 Quality Assurance Program Document

The various aspects of the QA practices should be developed and described in a QA program document. This document should describe the maintenance procedures for facilities and equipment, the control charts to be maintained and the records of "out-of-control" that should be kept. [As used here, out-of-control means that the records in question have been removed from controlled status, either by time frame or supercession.] This program is only as effective as it is systematically implemented. This means that the QA Program shall have been formally established, and that it documents the policy and procedures to be followed.

8.3 Documentation

All data shall be technically sound and supportable by evidence of unquestionable reliability. Requirements for specific activities and personnel qualification are set forth in Section 8.4, 8.5, 8.6 and 8.7. At a minimum, records shall be both adequate and accurate, and should contain the following items:

8.3.1 What measurements are being performed;

8.3.2 Name of the individual(s) performing the measurement;

8.3.3 What time the measurements are made:

8.3.4 How measurements are made:

8.3.4.1 The kinds of equipment being used;

8.3.4.2 Calibrated or not calibrated and any supporting data

8.3.4.3 Methodology for measurement

8.3.5 The data obtained

8.3.6 Calculations used to collect or quantify the data

8.3.7 Quality assurance support

8.3.8 Reports

8.4 Laboratory Administration

The following administrative practices have been identified as necessary for providing proper management of a metrology laboratory and to facilitate good measurement. These items may be duplicates of those listed previously.

8.4.1 Maintenance of Standards and Instruments

8.4.2 Maintenance of a proper laboratory environment, including:

8.4.2.1 Laboratory temperature;

8.4.2.2 Laboratory humidity;

8.4.2.3 Laboratory air flow/currents;

8.4.2.4 Vibrations;

8.4.2.5 Restricted access;

8.4.2.6 Cleanliness.

8.4.3 Filing Systems, including the following separate categories:

8.4.3.1 Reference Materials;

8.4.3.2 Annual data sheets and reports;

8.4.3.3 Reference standards, reports of calibrations and tests;

8.4.3.4 Reports of Calibrations and Tests;

8.4.3.5 Correspondence.

8.4.4 Numbering Systems for Tests, including:

8.4.4.1 Calibration tests and tests, with the year, sequence number;

8.4.4.2 State name (abbreviation or initials);

8.4.4.2 Master record of all test numbers, items, dates, submitters;

8.4.5 Training programs and records, including:

8.4.5.1 Records of a continuous educational program;

8.4.5.2 Participation in NBS training Programs (required)

8.5 Laboratory Records

8.5.1 All data should be recorded in notebooks or on data sheets specifically designed for the purpose.

8.5.2 All entries shall be dark and clear enough for photocopy.

8.5.3 Erasures (including the use of whiteout or any similar substance) are not permitted in notebooks or data sheets. If an error is made, it shall be crossed out with a single line, and the correct data recorded. The initials of the person who made the change, along with the date of the change shall be recorded in the margin at the point of error.

8.5.4 Clear identification of what was tested, how the measurements were made and by whom are prime requirements. Any deviations from standard practices shall be documented.

8.5.5 The identity of the sample or item tested must be unquestionable. This may require a chain-of-custody, providing evidence of positive and unbroken custodial action for the sample or test item. There should be no gaps of custody, unless such gaps can be identified as having been due to locked storage or shipping container.

8.6 Calibration/Test Report Preparation

Test reports are the viable output of the laboratory/facility. They should be prepared with the utmost care to ensure they accurately convey all of the pertinent information of the testing activity. A properly prepared test report can be considered a "stand-alone" document, one which contains or refers to all of the information necessary to justify the data therein. It may contain fill-in blanks, or may contain a detailed narrative, or both. Appendices A and B contain recommended formats for these processes. Regardless of the final form, the following information shall be included:

8.6.1 Client;

8.6.2 Purpose of the test (or reference to a "motherhood" document);

8.6.3 Description of the test/calibration item, including:

8.6.3.1 Manufacturer's Name;

8.6.3.2 Manufacturer's Model Number;

8.6.3.3 Manufacturer's Serial Number;

8.6.3.4 Laboratory Number;

8.6.4 Test Method, including how the test was done, or explicit reference to another document, or narrative descriptions of the test activity.

8.6.5 Test Results

8.6.6 Limits of uncertainty

8.6.7 Traceability/In-Tolerance, including;

8.6.7.1 Reference standards used;

8.6.7.2 Traceability to national standards;

8.6.7.3 Whether or not the instrumentation used was/was not in tolerance at the time of calibration.

8.6.8 References

8.6.9 Signatures

8.6.9.1 The laboratory director or designated alternate shall sign all laboratory test reports

8.6.9.2 Other signers may be required, at the direction of the Laboratory Director.

8.6.10 Conclusions of the test, especially when the test is of more than routine significance. This is especially true when the conclusions drawn can result in limitations on the results, whether necessary or desirable.

8.6.11 Each Test Report shall:

8.6.11.1 Be given a unique characteristic identification number according to the system developed by the Laboratory.

8.6.11.2 Be filed according to the Test Report Number.

8.6.11.3 Copies of the test reports shall be retained for a minimum of five years, until superseded by a subsequent report, or until deemed by the laboratory director as having no future value.

8.7 Personnel

A competent staff is an absolute necessity for quality measurements. Each member shall have an educational background, supplemented with specific training and experience, sufficient for the duties to be performed. Each person shall be aware of and understand the responsibilities of their position (which can be accommodated by suitable position descriptions and indoctrination) and must have the personal desire to perform them at a high level of competence. Further, these individuals are critical factors in the operational aspects of quality assurance. They must perform technical operations intelligently and skillfully, and in the full spirit of quality assurance requirements. To this end, the following should be verified:

8.7.1 Educational background of each individual;

8.7.2 Supplemental training of each individual;

8.7.3 A position description for each individual;

8.7.4 An indoctrination record for each individual.

9.0 Glossary

9.1 Accuracy - Closeness to the true or accepted (or nominal) value. See inaccuracy.

9.2 Calibration - comparison of a measurement standard or instrument with another standard or instrument to detect, correlate, report or eliminate by adjustment any inaccuracy of the compared.

9.3 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.

9.4 Inaccuracy - deviation from the true or accepted (or nominal) value. Inaccuracy may result from both imprecision and bias (or systematic error) in the measurement process.

9.5 Measurement Assurance Program - A quality assurance program for a measurement process that quantifies the total uncertainty of the measurements (both random and systematic components of error) with respect to national or other designated standards.

9.6 Measurement Process - A sequence of operations who's purpose is to assign a number(s) that represent how much of a certainty property a given substance or object has.

9.7 Precision - The degree of mutual agreement of independent measurements of a single quantity yielded by repeated applications of a process under specific

conditions. It is the quantitatively stated by a precision measure such as a standard deviation, for example.

9.8 Quality Assessment - The procedures and activities utilized to verify that a quality control system is operating within acceptable limits, and to evaluate the quality of the product/measurement produced.

9.9 Quality Control - The procedures and activities developed and implemented to produce products/measurements of desired quality.

9.10 Random Errors - Errors that vary in a non-reproducible way (fortuitously) around the limiting mean. For a large set of measurements, the errors are distributed evenly above and below the average. Also, small errors occur more frequently than large ones. These errors can be treated statistically by use of the laws of probability.

9.11 Shall - Items which require adherence without deviation. Shall statements identify binding requirements. A go, no-go criterion.

9.12 Should - Items which require adherence if at all possible. Should statements identify preferred conditions.

9.13 Tolerance - The maximum allowable departure of a standard from its nominal value.

9.14 Traceability - The ability to relate an individual measurement result to national standards of measurement.

9.15 Uncertainty - Allowance assigned to a measured value to include two major components of error: bias and random error.

10.0 References

10.1 Handbook for The Quality Assurance of Metrological Instruments, National Bureau of Standards, Published November, 1986; Library of Congress Catalog Card Number 86-600583.

10.2 ETA-HIAC07, “Control of Measuring and Test Equipment”

10.3 ETA-HIQP01, “Quality Program”

APPENDIX A

Recommended Format for Routine Test Report

Test Report
Issued by
(Name of Testing Laboratory)
Laboratory Report Number _____

Test Item(s)/Lab No(s): _____
_____

Submitted by: _____
Date: _____
Purpose of Test: _____
_____
_____
_____

Test Results*:

As-Found	**After Adjustment**

Reference Information:

Test Method: _____
Traceability: _____
Data Reference: _____
Test Results Certified by (Name, Title, Date): _____
_____
_____
_____

***See Test Report, if appropriate**

APPENDIX B

Recommended Format for Certificate of Traceability

Company Name

Company
Address

CERTIFICATE OF TRACEABILITY

Name of Device:

Model: **Serial Number:**

Submitted By:

The calibration was performed on (date) _____. The ambient conditions were _____ °C and _____ % relative humidity. The item tested was/was not in tolerance at the time of calibration. Any out of tolerance data are attached.

Data:

The primary standards to which the above data are traceable are identified in this report. The calibration of these standards is traceable to the National Bureau of Standards. The cycling and certification of all standards of measurement at this facility meet the requirements of MIL-STD-45662.

Name of Standard	NBS Report	Date Calibrated	Date Due

Test Results Certified by (Name, Title, Date): _____

_____

_____

_____

APPENDIX C - Checklist #1

DOCUMENTATION

Sect.	Requirement	Acceptable Yes	Acceptable No	Initials/Date
8.3.1	What measurement is being performed	_____		_____/____
8.3.2	Who performed the measurement is noted	_____		_____/____
8.3.3	Time of measurement is recorded	_____		_____/____
8.3.4	How measurements are made	_____		_____/____
8.3.4.1	What kind of equipment is being used	_____		_____/____
8.3.4.2	Data supporting calibrated/not calibrated is noted	_____		_____/____
8.3.4.3	Methodology for measurement is noted	_____		_____/____
8.3.5	The data obtained is noted and relevant	_____		_____/____
8.3.6	Calculations used to collect or quantify the data	_____		_____/____
8.3.7	Quality assurance support is noted	_____		_____/____
8.3.8	Reports are issued and complete	_____		_____/____

Comments, Exceptions, Corrective Actions, Etc. _____

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Checklist Completed by (name, title, Company) _____

_____

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_____

Date Initiated_____ **Date Completed** _____

Reviewed By (Name, Title, Company)/Date _____

Approved by (Name, Title, Company)/Date _____

APPENDIX D - Checklist #2

ADMINISTRATION

Sect.	Requirement	Acceptable Yes	Acceptable No	Initials/Date
8.4.1	Standards and Instruments are maintained	_____		_____/____
8.4.2.1	Laboratory temperature is controlled (± 1° C)	_____		_____/____
8.4.2.2	Laboratory humidity is controlled (35-55%)	_____		_____/____
8.4.2.3	Laboratory air flows/currents are dampened	_____		_____/____
8.4.2.4	Facility is free of vibrations	_____		_____/____
8.4.2.5	Facility has restricted access	_____		_____/____
8.4.2.6	Facility is clean	_____		_____/____
8.4.3.1	Reference Materials Files exist	_____		_____/____
8.4.3.2	Annual data sheets and reports files exist	_____		_____/____
8.4.3.3	Reference standards files exist	_____		_____/____
8.4.3.4	Reports of Calibrations and Tests files exist	_____		_____/____
8.4.3.5	Correspondence files exist	_____		_____/____
8.4.4.1	Documents have a sequence number, with year	_____		_____/____
8.4.4.2	Sequence number uses State name (abbr./initials)	_____		_____/____
8.4.4.2	Master record exists with appropriate data	_____		_____/____
8.4.5.1	Continuous educational program records exist	_____		_____/____
8.4.5.2	NBS Training Program Participation is evidenced	_____		_____/____

Comments, Exceptions, Corrective Actions, Etc. _____
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Checklist Completed by (name, title, Company) _____
_____
_____
_____

Date Initiated_____ **Date Completed** _____

Reviewed By (Name, Title, Company)/Date _____
Approved by (Name, Title, Company)/Date _____

APPENDIX E - Checklist #3

LABORATORY RECORDS

Sect.	Requirement	Acceptable Yes	Acceptable No	Initials/Date
8.5.1	Data recorded in notebooks or data sheets	_____		_____/____
8.5.1.1	Documents specifically designed for this purpose	_____		_____/____
8.5.2	Entries are dark and clear enough for photocopy	_____		_____/____
8.5.3	No erasures or whiteouts are present	_____		_____/____
8.5.3.1	All changes are lined out, initialed and dated	_____		_____/____
8.5.4	Deviations from standard practices are noted	_____		_____/____
8.5.5	Sample or item tested identity known	_____		_____/____
8.5.5.1	Was a chain-of-custody used	_____		_____/____
8.5.5.2	Was locked storage or a shipping container used	_____		_____/____

Comments, Exceptions, Corrective Actions, Etc. _____
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Checklist Completed by (name, title, Company) _____
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Date Initiated_____ **Date Completed** _____

Reviewed By (Name, Title, Company)/Date _____
Approved by (Name, Title, Company)/Date _____

APPENDIX F - Checklist #4

CALIBRATION & TEST REPORTS

Sect.	Requirement	Acceptable Yes	Acceptable No	Initials/Date
8.6.1	Client is clearly identified	_____		_____/____
8.6.2	Purpose of the test is described	_____		_____/____
8.6.3.1	Tested item's manufacturer's name	_____		_____/____
8.6.3.2	Tested item's manufacturer's model number	_____		_____/____
8.6.3.3	Tested item's serial number	_____		_____/____
8.6.3.4	Testing laboratory's number	_____		_____/____
8.6.4	Test method(s) identified	_____		_____/____
8.6.5	Test results are included and complete	_____		_____/____
8.6.6	Limits of uncertainty are stated	_____		_____/____
8.6.7.1	Reference standards used are appropriate	_____		_____/____
8.6.7.2	Traceability of reference to national standards	_____		_____/____
8.6.7.3	Test instrument in/not in tolerance at time of test	_____		_____/____
8.6.8	References listed, as applicable	_____		_____/____
8.6.9	Required signatures affixed	_____		_____/____
8.6.10	Test conclusions are included and complete	_____		_____/____
8.6.11.1	Report has a unique identification number	_____		_____/____
8.6.11.2	Test Reports are filed according to Appendix D	_____		_____/____

Comments, Exceptions, Corrective Actions, Etc. _____

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Checklist Completed by (name, title, Company) _____

_____

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Date Initiated_____ **Date Completed** _____

Reviewed By (Name, Title, Company)/Date _____

Approved by (Name, Title, Company)/Date _____

APPENDIX G - Checklist #5

TRAINING RECORDS

Sect.	Requirement	Acceptable Yes	Acceptable No	Initials/Date
8.7.1	Individuals have appropriate education	_____		_____/____
8.7.2	Individuals have supplemental training	_____		_____/____
8.7.3	Position descriptions exist	_____		_____/____
8.7.4	Indoctrination records exist	_____		_____/____
8.4.5.1	Continuous educational program records exist	_____		_____/____
8.4.5.2	NBS Training Program Participation is evidenced	_____		_____/____

Comments, Exceptions, Corrective Actions, Etc. _____
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Checklist Completed by (name, title, Company) _____
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Date Initiated_____ **Date Completed** _____

Reviewed By (Name, Title, Company)/Date _____
Approved by (Name, Title, Company)/Date _____

APPENDIX H

BLANK COMMENT SHEET

Additional Comments for Appendix ____