

GE - Aviation, Services Supplier Quality Specification

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Title: QUALITY SYSTEM STANDARD FOR CALIBRATION SOURCES

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I. PURPOSE

To establish the quality requirements for suppliers of calibration services to GE - Aviation, Services.

II. DEFINITIONS

- A. **Calibration** - Comparison of Measurement and Test Equipment (M&TE) with a measurement system or standard of known and greater accuracy to detect and report any variation from required accuracy and/or performance and accuracy specifications, the adjustment required to meet such specifications as necessary. The term "calibration" includes inspection of tools and fixtures used for acceptance purposes.
- B. **Accuracy** - - Is the closeness with which an M&TE reading approaches the true value of the variable being measured.
- C. **Purchaser** - The procuring activity of GE - Aviation, Services that issued the procurement document invoking this document.
- D. **Resolution** - The degree to which a measurement can be determined.
- E. **Supplier** - Sources other than GE - Aviation, Services who supply material, parts or services for GE - Aviation, Services Facilities and Controlled Affiliates.
- F. **Measurement Equipment** - Measuring instrument, standard and single purpose gages, software, measurement standard, reference material or auxiliary apparatus, or a combination thereof, necessary to realize a measurement process.

III. SCOPE

This standard is in addition to or in conjunction with any other requirements that may be referenced in the purchase order. This standard specifies requirements for a quality management system where an organization

needs to demonstrate its ability to consistently provide calibration services that meets customer requirements.

IV. PROCEDURE REQUIREMENTS

A. GENERAL

1. This standard applies to all suppliers of calibration services.
2. This standard shall apply to all purchase orders in which it is specifically referenced.
3. The Purchaser reserves the right to revise this standard. Such revisions shall be binding upon the Seller's acceptance of them after notification through a Purchase Order or a supplement thereto.

B. ORGANIZATION AND MANAGEMENT

1. The supplier shall operate in such a way that its permanent, temporary, and mobile facilities meet the requirements of this document.
2. The supplier shall:
 - a. Specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work-affecting quality of calibrations.
 - b. Have a technical designee who has overall responsibility for the technical operations.
 - c. Have a quality designee who has responsibility for the quality system and its implementation.
 - d. Designate alternates in case of absence of the technical or quality designee.
 - e. Have documented policy and procedures to ensure the protection of customer's confidential information and proprietary rights.
 - f. Have documented policy and procedures concerning the submittal of deviations from customer, (e.g. GE - Aviation, Services) requirements including supporting justification for the customer, and requirements for customer approval.

C. QUALITY SYSTEM DOCUMENTATION

1. The supplier shall establish and maintain a quality system appropriate to the type, range, and volume of calibration activities it undertakes. The elements of this system shall be documented. The quality documentation (quality system documentation, calibration manual, etc.) shall be maintained current under the responsibility of the quality designee.
2. The quality documentation shall state the supplier's policies and operational procedures established in order to meet the requirements of this document. The quality documentation shall contain:
 - a. Procedures for control and maintenance of documentation.
 - b. The supplier's procedures for achieving traceability of measurements.
 - c. The supplier's scope of calibrations.
 - d. Reference to the calibration procedures used.

- e. Procedures for handling calibration items.
- f. Reference to the reference standards used.
- g. Reference to procedures for calibration of equipment used.
- h. Significant out-of-tolerance (SOT) condition defined.
- i. SOT condition and supporting data are reported to the customer for evaluation and appropriate action.
- j. Procedures to be followed for feedback and corrective action whenever measurement discrepancies are detected, or departures from documented policies and procedures occur.
- k. How to handle departures from documented policies and procedures or from standard specifications.
 1. Procedures for audit and review.

D. PERSONNEL

Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained and available.

E. ACCOMMODATION AND ENVIRONMENT

1. Supplier facilities, calibration area, energy sources, lighting, temperature, humidity, and ventilation shall be such as to facilitate performances of calibration.
2. The supplier shall effectively monitor, control and record environmental conditions as appropriate.
3. Adequate measures shall be taken to ensure good housekeeping in the supplier.

F. MEASUREMENT AND TEST EQUIPMENT (M&TE)

Each item of M&TE shall be labeled, marked or otherwise identified to indicate its calibration status.

G. MEASUREMENT TRACEABILITY AND CALIBRATION

1. The supplier shall have an established program for the calibration of its measuring and test equipment to ensure the recall or removal from service of any standard or equipment which has exceeded its calibration interval or is otherwise judged to be unreliable, (e.g. broken seals).
2. Where traceability to international, national, or intrinsic standards of measurement is not available, traceability requirements may be satisfied by mutual consent standards which are clearly specified, documented and mutually agreed upon by all parties concerned.

H. CALIBRATION METHOD

1. The supplier shall have documented instructions for calibration. All instructions, standards, manuals, and reference data relevant to the work of the supplier shall be maintained up-to-date and be readily available to the staff.
2. Calibration procedures shall contain the required range and tolerance or uncertainty of each item or

unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description for the measurement standards.

3. The supplier shall ensure that:
 - a. The collective uncertainty of the applicable reference standard does not exceed 25% of the acceptable tolerance test accuracy ratio for each characteristic being calibrated.
 - b. Deviations from the required minimum 4:1 test accuracy ratio are documented and approved by GE - Aviation, Services.
4. Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration data, the supplier shall ensure that:
 - a. The requirements of this instruction are complied with.
 - b. Computer software is documented and adequate for use.
 - c. Computer software is validated for use and subject to software library control.
 - d. Procedures are established and implemented for protecting the integrity of the data; such procedures shall include, but are not limited to, integrity of data entry or capture, data storage, data transmission and data processing.
 - e. It establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and unauthorized amendment of, computer records.

I. HANDLING OF CALIBRATION ITEMS

1. The supplier shall have a documented system for uniquely identifying the items to be calibrated, to ensure that there can be no confusion regarding the identity of such items at any time. The system shall include all personally owned M&TE used for calibration, if such M&TE is used for calibration.
2. Upon receipt of the calibration item, any abnormalities or departures from standard condition as prescribed in the relevant calibration method shall be recorded.
3. The supplier's calibration system shall provide instructions for the use of tamper-resistant seals and for the disposition of equipment with damaged or broken seals.

J. RECORDS

1. The supplier shall established a documented procedure for the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of calibration records.
2. Records shall be maintained of all M&TE calibrations performed. The records shall include:
 - a. The name of the M&TE.
 - b. The manufacturer's name, type identification, and serial number or other unique identification.
 - c. Where applicable, dates and results of calibration and date or criteria when the calibration and/or expires.

- d. History of any damage, malfunction, modification or servicing.
 - e. Measured value observed for each parameter found to be out of tolerance during calibration.
 - f. Personnel involved in performing the calibration.
 - g. Standards used to perform the calibration and the calibration expiry date of the standards.
 - h. Special marking (e.g. Typeface, asterisk, highlight, etc.) to distinguish out of tolerance calibration occurrences.
3. The supplier shall maintain the calibration records for the period specified in the quality manual.

K. CERTIFICATES AND REPORTS

1. Each certificate or report shall include at least the following information:
 - a. A title (e.g. Calibration Report" or Calibration Certificate").
 - b. Name and address of supplier, and location where the calibration was carried out if different from the address of the supplier.
 - c. Unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages.
 - d. Name and address of customer, where appropriate.
 - e. Description and unambiguous identification of the items calibrated.
 - f. Characterization and condition of the calibration item, where appropriate.
 - g. Date calibration performed.
 - h. Identification of the calibration procedure used, or unambiguous description of any nonstandard method used.
 - i. Any deviation from, additions to, or exclusions from the calibration method, and any other information relevant to a specific calibration, such as environmental conditions.
 - j. Measurements, examinations and derived results, supported by tables, graphs, sketches, and photographs, as appropriate, and any failures identified.
 - k. A signature and title or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue.
 - l. Special limitations of use.
 - m. Traceability statement.
 - n. A statement of the estimated uncertainty of the calibration test results.
 - o. Where the certificate or report contains results of calibrations performed by subcontractors, these results shall be clearly identified.

2. Amendments to a calibration report or calibration certificate after issue shall be made only in the form of a further document. Such amendments shall meet all the relevant requirements of IV.K.1 of this instruction.

L. SUBCONTRACTING OF CALIBRATION

1. Where a supplier subcontracts any part of the calibration, this work shall be placed with a subcontractor complying with the requirements of this document. The supplier shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of the competence as the supplier with respect of the work being subcontracted
2. The supplier shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a list of their approved subcontractors. This shall include the timing of investigations.

M. COMPLAINTS

Where a complaint, corrective action request, or any other circumstance, raises a concern regarding the supplier's compliance with the supplier's policies or procedures, or with the requirements of this instruction or otherwise concerning the quality of the supplier's calibrations, the supplier shall ensure that complaints in those areas of activity and responsibility involved are promptly resolved.

N. INTERNAL AUDIT AND SURVEILLANCE

1. The supplier shall carry out or arrange to be carried out, periodic quality auditing of the calibration, system in order to ensure its continuing effective implementation and compliance with the requirements of this document. This shall include the timing of internal audits.
2. The supplier shall assure the timely resolution of deficiencies found during internal audits.
3. Based on the results of internal audits, assessments and any other relevant factors, such as customer feedback, the supplier shall review and modify the system as necessary.
4. The supplier shall establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with the requirements of this instruction.

O. INTERVALS OF CALIBRATION

1. The supplier have a documented process to establish calibration intervals. The documentation shall contain guidelines for establishing and adjusting the calibration intervals.
2. The recall system shall document the guidelines for the temporary extension of the calibration due date, if applicable.

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