1. GENERAL

A. This guide was developed as a tool for evaluating a calibration facility whose foremost function is the calibration/repair of precision equipment. It appears here for general use and may be adopted entirely or in part at your own discretion.

B. This guide was produced and is controlled by the Air Carrier Section within the C.A.S.E. organization. Any change requests must be submitted through the Standards and Procedures Committee.

CAUTION: This guide is meant for non-FAR 145 certificated facilities. It is not meant to replace or augment in any way the calibration portion of the 1-A Standard.

2. QUALITY SYSTEM/MANUAL

A. The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration activities it undertakes. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual or other appropriate document and communicated to, and implemented by all laboratory personnel concerned. The document shall be maintained current under the responsibility of the quality manager. [Z540]

B. The quality system shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements. [Z540]

C. The document shall include, but not limited to, a detailed description of the following elements:

- Quality Organization
- Internal Audits
- Corrective/Preventive Actions
- Technical Data/Procedure Control
- Training/Personnel
- Measuring and Test Equipment (Std.)
- Work Processing
- Facilities environment operations
- Records
- Certificates and Reports
- Shipping
- Scrapped Parts
- Shelf Life Control
- Safety/Security/Fire Protection
3. QUALITY ORGANIZATION

A. The laboratory shall have managerial staff with the authority and resources needed to discharge their duties. The laboratory shall specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations. The document shall including an organizational chart showing the relationship of the quality department to the rest of the organization. [Z540]

B. The laboratory shall be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times. [Z540]

C. Personnel and back-up that are responsible for quality systems must be identified by title.

4. INTERNAL AUDITS

A. Audits shall be performed at appropriate intervals to verify the effectiveness of the quality program. Audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. All audits, findings, and any corrective actions that arise from them shall be documented. [Z540]

5. CORRECTIVE/PREVENTIVE ACTIONS

A. The laboratory shall have a documented corrective/preventive action system that requires corrective/preventive action whenever evidence arises that the quality system is not functioning properly. Corrective action shall: [Z540]
   1. Be appropriate and prompt
   2. Correct the discrepancies reported
   3. Correct the root cause of the problem evidenced by the discrepancy
   4. Implement follow-up action to eliminate reoccurrence.
   5. Immediately notify, in writing, any client whose work may have been affected.

6. TECHNICAL DATA/PROCEDURE CONTROL

A. Technical data/procedures applicable to the laboratory shall be maintained in a manner that ensures such data is current and accessible as appropriate. Technical data/procedures shall include: [Z540]
   1. Calibration and verification procedures used
   2. Procedures for calibration, verification and maintenance of equipment used
   3. Procedures for achieving traceability of measurements
   4. Policy for establishing and changing calibration intervals
   5. Policy concerning the technique to be used for determining measurement uncertainty and calibration/verification adequacy.
B. Technical data/procedures shall be stored in a manner protecting them from dirt and damage. Hand entries in, or hand corrections to, technical data are not acceptable. If an electronic viewing device is required for viewing, it must be maintained in good working order, protected from damage and available to persons using the data.

7. TRAINING/PERSONNEL

A. The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions. This includes up-dating personnel training consistent with employee assignments and development. [Z540]

B. Training records, classroom and on-the-job (OJT), shall be documented and the records maintained for a minimum of two years after the employee leaves the company.

C. Training records shall include:
   1. A description of the training
   2. Date and number of hours of instruction
   3. Name of student and instructor with signatures of both
   4. Name of the organization conducting the training if performed by an outside agency.

8. MEASURING AND TEST EQUIPMENT CALIBRATION (STDS)

A. The laboratory shall have an established program for measuring and test equipment used to verify conformance to applicable specifications, be calibrated periodically to ensure that measuring and test equipment are traceable to national, international, or intrinsic standards of measurements where available. [Z540]

B. Where computer/automated equipment is used for measurement, processing, manipulation, recording, reporting, storage or retrieval of calibration data, the laboratory shall ensure that the software is documented and adequate for use. [Z540]

C. The laboratory shall have procedures to prevent measuring and test equipment, which are past due calibration, from being used and ensure their recall or removal from service.

D. Current documentation of calibration status shall be maintained.

9. WORK PROCESSING

A. The laboratory shall have a documented procedure for: [Z540]
   1. Uniquely identifying items to be calibrated to ensure no confusion regarding identity.
2. Recording any abnormalities from standard condition. Where there is any
doubt as to the item’s suitability for calibration, the laboratory shall consult the
customer for further instruction before proceeding. The laboratory shall
establish whether the item has received all necessary preparation, or whether
the customer requires preparation to be undertaken.
3. Avoiding deterioration or damage to the calibration item during storage,
handling, preparation, and calibration. Where items have to be stored or
conditioned under specific environmental conditions, these conditions shall be
maintained, monitored and recorded where necessary.

4. Containing the required range and tolerance or uncertainty of each item or unit
parameter being calibrated or verified. In addition, the procedures shall
contain the description of the measurement standards and equipment needed
for performing the measurement of the calibration or verification that are
capable of meeting the description for the measurement standards.
5. Ensuring that the calibration uncertainties are sufficiently small so that the
adequacy of the measurement is not affected. Well defined and documented
measurement assurance techniques or uncertainty analyses may be used to
verify the adequacy of a measurement process. If such techniques or analyses
are not used, then the collective uncertainty of the measurement standards shall
not exceed 25% of the acceptable tolerance for each characteristic of the
measuring and test equipment being calibrated or verified.

10. RECORDS

A. The laboratory shall maintain a record system to suit its particular circumstances
and comply with any applicable regulations. The records for each calibration shall
contain sufficient information to permit the repetition of the calibration. The
records shall include the identity of personnel involved in preparation and
calibration.

B. All records, certificates and reports shall be safely stored and held secure and in
confidence to the customer for the period specified in the quality manual.

11. FACILITIES ENVIRONMENT OPERATIONS

A. The laboratory facilities shall be such as to facilitate proper performance of
calibrations/verifications. The environment in which these activities are undertaken
shall be specified and not invalidate the results or adversely affect the required
uncertainty of measurement. [Z540]

B. The laboratory shall effectively monitor, control and record environmental
conditions as appropriate. Examples include: biological sterility, dust particle,
electromagnetic interference, humidity, line voltage, temperature, barometric
pressure, and sound and vibration levels as appropriate to the calibrations
concerned. [Z540]
C. The laboratory must prohibit smoking, eating, and drinking or storing food and drink in any area where parts or customer units are stored or worked that could adversely affected the calibrations.

12. CERTIFICATES AND REPORTS

A. When a certificate or report is issued, the results of the calibration, or series of calibrations carried out by the laboratory shall be accurate, clear, unambiguous and objective, in accordance with any instructions in the calibration methods. The results shall be reported in a calibration report or certificate and shall include the following information:
   1. Title - “Calibration Report” or “Calibration Certificate”
   2. Name and address of laboratory, including the calibration site, if different from the address of the laboratory
   3. A Unique identification on the certificate or report (such as serial number), and the total number of pages
   4. Customer’s name and address
   5. Description and unambiguous identification of the item calibrated
   6. Characterization and condition of the calibration
   7. Calibration date
   8. Identification of the calibration procedure used or unambiguous description of any non-standard method used
   9. Reference to sampling procedure
   10. Any deviation or exclusion from the calibration method, and any other information relevant to a specific calibration (i.e. environmental conditions)
   11. Measurements, examinations and derived results, supported by tables, graphs, sketches, and photographs, as appropriate, and any failures identified.
   12. A statement of the estimated uncertainty of the calibration result
   13. The date of issue, and the person’s signature and title, or an equivalent identification, who accepted responsibility for the certificate or report content
   14. A statement to the effect that the results relate only to the items calibrated, where relevant
   15. A statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory
   16. Special limitations of use
   17. Traceability statement

13. SHIPPING

A. Tool/test equipment shall be returned to the customer in an appropriate shipping container or one required by the customer.

B. Serial number (S/N) and part number (P/N) or model number, including dash numbers or letters, on the certificate/report for the tool/test equipment shall coincide with the numbers on that equipment.
14. SCRAPPED PARTS

A. The laboratory shall have a documented procedure to assure that any out-of-tolerance tool/test equipment is returned to the customer.

15. SHELF LIFE CONTROL

A. The laboratory shall document and maintain a program to assure the identification and proper handling of shelf life limited items.

16. SAFETY/SECURITY/FIRE PROTECTION

A. The housing and facilities shall provide adequate security and protection from fire.

B. Security systems shall be reviewed periodically by vendor management or by a qualified outside firm to assure that the system is still adequate.

C. Appropriate devices shall be maintained in good condition and shall be used.

D. Operations shall be conducted in a safe manner and in a safe environment that will avoid personnel injury and damage to customer property.