I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for identification, calibration, and maintenance of measuring and test equipment.

II APPLICATION

This procedure applies to measuring and test equipment, to comparative reference hardware (such as templates), and to test software used for verification of product conformance and for controlling of production processes.

This procedure directly concerns the Quality Control department, and is indirectly relevant to Production and Production Engineering.

III PROCEDURE

1. Measurement Identification and Selection of Equipment

1.1 Identification of measurements to be made and the tolerance of the measured characteristics are documented in Control Plans and in product drawings and specifications.

1.2 Gauges, instruments, and other measuring and testing equipment are selected on the basis of their capability to provide the necessary accuracy and precision. Performance of a measurement system, and thereby its acceptability, are determined by conducting a formal measurement system study (refer to Procedure QOP-11-02 Measurement System Evaluation). The QC Engineer is responsible for conducting measurement system studies and selecting appropriate measuring and test equipment.
2. Calibration

2.1 QC is responsible for maintenance, calibration, and control of all inspection, measuring, and test equipment, including equipment belonging to employees or on loan. Equipment is calibrated in accordance with written instructions, unless calibration is simple and obvious. When applicable, calibration instructions specify for each type of equipment the acceptable limits of temperature, pressure, humidity, and other environmental conditions that may affect calibration.

2.2 When gauges, instruments, or other equipment are returned for calibration or checking, their condition and actual readings are recorded prior to calibration or adjustment. Equipment that is sent out for calibration is required to be likewise checked and recorded prior to calibration.

2.3 Calibration of measuring and test equipment is carried out using calibration instruments or standards certified to have a known relationship to a nationally recognized standard. This relationship is identified on the calibration record. Equipment that is sent out for calibration is required to be returned with certification that is likewise traceable to a national standard. Calibration records and certificates are maintained by the QC department.

2.4 Calibrated equipment is labeled with a sticker indicating the due date for next calibration. If it is not possible to attach a sticker, the equipment is painted with a green dot in a conspicuous location to indicate that it is exempted from carrying a sticker. Such equipment is traceable to its calibration record through its serial number or other unique marking. Equipment with a past-due calibration date or without a calibration sticker (or a green dot) are not used and are immediately returned to QC.

2.5 QC maintains a list of all active measuring and test equipment, whether or not the equipment is owned by the company. The list identifies every piece of equipment by its name, type, size, serial number, location, calibration frequency, last calibration date, and next calibration due date. The list is updated at least once a month.

3. Product-Specific Comparative Reference Hardware

3.1 Jigs, fixtures, templates, patterns, and samples used in production and inspection are uniquely identified with the part number and engineering revision level to which they pertain. When a new engineering level is released, QC verifies whether the changes affect the hardware, and either upgrades the revision identification or withdraws the equipment.

3.2 The comparative reference hardware is entered on the list of active measuring and test equipment (see Subsection 2.5), and is periodically checked for accuracy. Records of the accuracy checks are maintained.
4. **Test Software**

4.1 Test software used for product verification and/or monitoring of process performance is validated and certified. Standard software, purchased from commercial sources, is ordered with validation certificates whenever possible. Software developed in-house is tested and approved prior to release. Its documentation comprises testing specification approved by the QC Engineer and testing records demonstrating its correct functioning.

4.2 Software that has been used for product verification for at least one year prior to implementation of this procedure, and that has consistently given satisfactory and correct performance, may be approved by the QC Engineer without validation testing.

4.3 Every new revision of software is validated, approved, and identified with a release number. Software is also re-validated whenever there is a change of any conditions for which the software was initially validated.

5. **Storage and Maintenance**

5.1 Measuring and test equipment is stored in a secured storage area adjacent to the QC offices. The equipment is maintained, stored, and handled in such a way as to preserve its accuracy and fitness for use. Equipment that is out of calibration or is otherwise not fit for use is withdrawn from the inspection and production areas, and is segregated.

6. **Nonconforming Equipment**

6.1 When a piece of measuring or test equipment is found to be out of calibration or appears to give inaccurate readings, the piece is checked. If it is confirmed that the equipment is indeed out of calibration and the readings are outside of required accuracy, QC investigates and assesses the validity of measurements for which the equipment was previously used. Identification of such equipment and the impact of its use on acceptance of products are reported in a nonconformance report, in accordance with Procedure QOP-13-01 Control of Nonconforming Product. If suspect material has been shipped, the customer is notified.

7. **Equipment Exempted From Calibration**

7.1 Inspection and test equipment may be exempted from the calibration requirement when used in situations where accuracy of measurement is not important, or where the measurement does not have any relation to product verification or process control. Such equipment is labeled with stickers warning that it is not calibrated. Production and inspection personnel are made aware of the limitations in using uncalibrated equipment.

IV ASSOCIATED DOCUMENTS
- Measurement System Evaluation — Oper. Proc. QOP-11-02
- Control of Nonconforming Product — Oper. Proc. QOP-13-01