1.0 Purpose of Procedure

This document is intended to describe the system and instructions and to assign responsibilities for the calibration, identification, and maintenance of inspection, measuring, and test equipment.

2.0 Scope of Process

The scope of this procedure is to outline criteria as well as retention of records for calibrated equipment.

3.0 Process Owner(s)

3.1 Engineering

3.2 Quality Assurance

4.0 Procedure

4.1 Identification of Measurements and Equipment

All inspection, measuring, and test equipment must be capable of measuring to the required accuracy. All equipment used in product acceptance shall be tagged with the calibration status and calibration expiration date and shall be assigned and shall display a control number in the form of a 42-XXXX Product Resources part number. Equipment not calibrated should be identified as such (and shall still be assigned a control number). Equipment with a limited calibration should be prominently identified as such, along with the nature of the limitation.

4.2 Calibration Procedures

The manufacturer's calibration specifications and procedures (if any) for the individual piece of equipment shall be used in the calibration of company test equipment. If a manufacturer does not supply calibration procedures for a piece of test equipment and if the calibration is not simple and obvious, the Engineering or QA Department shall create procedures in accordance with the manufacturer's calibration specifications, or the outsourced calibration lab shall do the same.

When applicable, calibration instructions specify the acceptable limits of temperature, pressure, humidity, or other environmental conditions that might adversely affect calibration.

If a piece of equipment is critical and if the manufacturer’s calibration procedure does not include a point in the range of its critical use, Product Resources shall supplement the calibration procedure with the needed points to ensure confidence in the range of critical use. If this calibration is performed by an outside lab, QA shall communicate these instructions to the lab and shall ensure that the additional points are present in the calibration report/certificate upon the equipment’s return.

New instruments purchased with calibration certificates can be put to use immediately. For instruments not purchased with calibration certificates, calibration must be performed before the instrument can be used.

Equipment with a past-due calibration date or without a calibration sticker normally is not to be used and should immediately returned to QA. If the equipment is to be left

accessible but has gone beyond its calibration expiration date, the equipment must be marked as out of calibration and must not be used for product release.

The calibration interval shall be designated as Normal or Critical or Other. The Normal calibration interval is one year. Normal interval calibrations expire in a given month and year, not on a particular date. Instruments must be taken out of service for calibration following the last day of the calibration-due month and may be taken out of service earlier. The Critical calibration interval is six months and is reserved for situations in which the consequence of an out-of-calibration situation is more severe, for example, when the device is being used for product calibration. Critical calibrations expire on a particular date, and instruments must be taken out of service following that date and may be taken out of service earlier. The Other designator is used for all other intervals at the discretion of QA or based on customer requirements. The special interval will be designated in the database (see below). Most instruments have the Normal designation.

Note that QA may not assign a calibration interval that is longer than 12 months for any measuring equipment that is used for regulated product.

If it becomes absolutely necessary to use an instrument for product release beyond its calibration due date and with approval of this process reserved for QA's discretion, the instrument is checked against a similar instrument with equal or better accuracy that is within its calibration period. The results of this check are documented. All efforts shall be made to take such an instrument out of service at the soonest possible date.

4.3 Calibration Records

A database of all test equipment under calibration control shall be maintained by QA, and it shall be updated on all status changes to show the most current status of test equipment. In addition, calibration files shall be maintained and shall contain current calibration certificates/reports for all test equipment and all other calibration records described in this procedure.

The instrument calibration database is a module of Product Resources QMS software QT9, and it holds both the identities and statuses of all equipment and associated files, as described above.

The database identifies each piece of equipment by its Product Resources part number and description, manufacturer, model, serial number, location, calibration frequency, last calibration date, next calibration due date, calibration method, etc.

See procedure 43-1342 for a detailed explanation of this database and its use.

Calibration certificates/reports shall contain as-found data and as-returned data, substantiating as-found and as-returned status. Note that not all companies providing calibration services automatically include the data and that it must be specified to the supplier that all calibration reports for Product Resources shall include the data. Product Resources communicates this via the Supplier Guidelines Manual, 43-2248.

Calibration certificates and reports shall always contain the following, whether the calibration is performed by an outside lab or performed internally:

- A full identification of the equipment calibrated (manufacturer, model, serial number, Product Resources' control number)
- The party performing the calibration
- The date of the calibration

- The reference standards used in the calibration: their identification, type of traceability, and due date
- As-found data with an assessment of in tolerance or out of tolerance
- As-returned data with an assessment of in tolerance or out of tolerance
- Signature or initials of the party performing the calibration

QA, upon accepting back a calibrated instrument from an outside lab, shall review the calibration certificate/report for correctness and for the as-received and as-returned statuses. If received out of calibration, please see the "Out of Tolerance" and "Nonconforming Equipment" sections of this document. QA shall electronically sign and date the certificates/reports as evidence of this review. If returned out of calibration, QA shall deactivate the equipment and shall not put it back into use. If returned with a limited calibration, QA shall ensure that the limited calibration status is prominently identified with the limitation stated. Certs are then uploaded into the cal record of the item in QT9

4.4 Out of Tolerance

During calibration, if a piece of test equipment is found to be out of tolerance, the effect it had on the released product shall be determined by QA. QA may call upon Engineering for assistance in this determination. This assessment shall be documented in the calibration files. Corrective actions, which may include product recall, shall be implemented if deemed necessary by the results of the investigation, i.e., if a detrimental effect is determined.

If product has been impacted by an out-of-calibration situation, QA will work in conjunction with Manufacturing to determine the range of affected product. QA will then work in conjunction with Sales to notify the customer or will do so directly depending on the business relationship. A product recall will be organized as the product impact demands. This notification, or a pointer to it, is documented in the instrument's calibration file.

4.5 Storage and Maintenance

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 otherwise not fit for use is returned to QA.

4.6 Nonconforming Equipment

When a piece of inspection, measuring, or test equipment is suspected by its users to be out of calibration and appears to be giving inaccurate readings, the piece is checked against similar equipment with similar accuracy. If still suspected to be out of calibration, or if known to be out of calibration, the equipment is returned to QA, typically followed by a calibration, or otherwise deactivated and taken out of use if there is no criticality to as-found status and if a decision to not repair is made.

4.7 Equipment Exempted from Calibration

Inspection, measuring, and test equipment used in situations where the accuracy of measurements is not important – typically equipment not used for product release or equipment used in conjunction with other equipment that provides the measurement – are exempted from the calibration requirement. Such equipment is labeled with stickers warning that it is not calibrated.

4.8 Computer Software

Computer software may be used in an inspection, measuring, and test process. Software used for this purpose is given a Product Resources part number and is controlled by Document Control. Computer software is validated by Engineering before use. Computer software may have a periodic calibration requirement, and if so the computer software shall be present in the calibration database and treated like other equipment described in this procedure.

5.0 Control of Records

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.