

# Quality Procedure

Calibrated Equipment

## Table of Contents

<b>1 CALIBRATED EQUIPMENT .....</b>	<b>3</b>
<b>1.1 INTRODUCTION &amp; PURPOSE.....</b>	<b>3</b>
1.1.1 Process Activity Map.....	3
1.1.2 References.....	3
1.1.3 Terms & Definitions .....	3
<b>1.2 APPLICATION &amp; SCOPE.....</b>	<b>4</b>
<b>1.3 RESPONSIBILITIES .....</b>	<b>4</b>
<b>1.4 CONTROLLING CALIBRATED EQUIPMENT .....</b>	<b>4</b>
1.4.1 General .....	4
1.4.2 Existing Devices.....	4
1.4.3 Calibration Frequency .....	5
1.4.4 Calibration Due Date .....	5
1.4.5 Calibration Label.....	5
1.4.6 Environment .....	5
1.4.7 Outsourced Calibration.....	5
1.4.8 New Devices.....	6
1.4.9 Maintenance.....	6
1.4.10 Non-conforming Equipment.....	6
<b>1.5 SOFTWARE .....</b>	<b>6</b>
1.5.1 Calibrating Software.....	6
1.5.2 Validation of Automated Equipment and Processes .....	7
<b>1.6 REVIEW .....</b>	<b>7</b>
<b>1.7 TRAINING.....</b>	<b>7</b>
<b>1.8 FORMS &amp; RECORDS.....</b>	<b>7</b>
<b>1.9 CALIBRATED EQUIPMENT PROCESS MAP.....</b>	<b>8</b>

4. Update device details on the controlled equipment log;
5. Verify device performance and calibrate;
6. Affix new calibration label;
7. Update the Controlled Equipment Log;
8. Issue device for use.

### 1.4.3 Calibration Frequency

Calibration frequency is determined by comparing the performance of the measuring equipment to:

1. Equipment purpose;
2. Manufacturer's specifications;
3. Degree of usage;
4. Equipment type;
5. Stability/reliability;
6. Update the Calibration Log.

### 1.4.4 Calibration Due Date

After the calibration frequency has been established; the specific calibration due date is established and documented.

1. Attach the calibration label to the equipment;
2. Update the Calibration Log;
3. Ensure equipment is re-calibrated by the due date.

### 1.4.5 Calibration Label

Upon completion of calibration, satisfactory equipment is tagged with a calibration label indicating:

1. Calibration date;
2. Due date of the next inspection;
3. Initials of the person performing the calibration.

For inspection and test equipment too small to affix a sticker, an alternative method of labelling will be used:

1. String tag on equipment;
2. Label affixed to container;
3. Notation on calibration log.

### 1.4.6 Environment

As appropriate, environmental controls are established and maintained to ensure that monitoring and measuring instruments are calibrated and used in an environment that will not adversely affect the accuracy required. Consideration is given to the effects of temperature, humidity, vibration, and cleanliness when purchasing, using, calibrating, and storing instruments.

### 1.4.7 Outsourced Calibration

A commercial laboratory accredited to ISO 17025:2005 is used for calibration when calibration cannot be accomplished in-house.

1. The calibration facility must comply with internationally recognized calibration standards;
2. The calibration facility will be evaluated by the [Quality Manager](#);
3. Calibration certificates will be required.

### 1.4.8 New Devices

These steps are to be followed to control the registering and calibration verification new devices:

1. Assign device identification/asset number;
2. Add the device details to the [Controlled Equipment Log](#);
3. Determine calibration frequency;
4. Determine next calibration date;
5. Verify device performance and calibrate;
6. Affix **Calibration Label**;
7. Add the device details to the [Calibration Log](#);
8. Issue device for use.

Certification includes the accuracy after calibration, standards used, and environmental conditions under which the equipment was calibrated. The certification must be signed and dated. If confirmed that inspection and test equipment is out of calibration, the [Quality Manager](#) is required to:

1. Remove suspect device from service;
2. Investigate the validity of measurements for which the equipment was previously used;
3. Assess the acceptance status of all affected products;
4. Select appropriate corrective actions to mitigate the subsequent non-conforming product;
5. Immediately inform the customer if the product has been shipped;
6. Re-calibrate any inspection or test equipment that appears to give inaccurate readings.

### 1.4.9 Maintenance

The user usually determines if specific measuring equipment requires maintenance by reviewing the equipment's operation and maintenance manuals supplied by the manufacturer. A commercial laboratory accredited to ISO 17025:2005 is used for repair and maintenance when it cannot be accomplished in-house.

### 1.4.10 Non-conforming Equipment

If confirmed that inspection and test equipment is out of calibration, the [Quality Manager](#) is required to:

1. Remove suspect device from service;
2. Investigate the validity of measurements for which the equipment was previously used;
3. Assess the acceptance status of all affected products;
4. Select appropriate corrective actions to mitigate the subsequent non-conforming product;
5. Immediately inform the customer if the product has been shipped;
6. Re-calibrate any inspection or test equipment that appears to give inaccurate readings.

## 1.5 Software

### 1.5.1 Calibrating Software

Test software developed in house or purchased from commercial suppliers is validated before it is used for product verification.