

## Existing Devices

- Remove device from use before calibration due date
- Determine whether calibration is to be done in-house or by an external supplier
- Verify need for maintenance and undertake maintenance where required
- Update device details on the controlled equipment log
- Verify device performance and calibrate
- Affix new calibration label
- Update the calibration log
- Issue device for use

## New Devices

- Assign device identification/asset number
- Add device details to the controlled equipment log
- Determine calibration frequency
- Determine next calibration date
- Verify device performance and calibrate
- Affix calibration label
- Add device details to the calibration log
- Issue device for use

## Calibration Frequency

Determine calibration frequency by comparing the performance of similar equipment by:

- Equipment purpose
- Manufacturer's specifications
- Degree of usage
- Equipment type
- Stability/reliability

## Calibration Due Date

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

- Attach the calibration label to the equipment
- Update the calibration log
- Ensure equipment is re-calibrated by the due date

## Calibration Label

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

- Calibration date
- Due date of the next inspection
- 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:

- String tag on equipment
- Label affixed to container
- Notation on calibration log

## Outsourced Calibration

A commercial laboratory will be used for calibration and repair that cannot be accomplished in-house.

- The calibration facility must comply with a nationally or internationally recognized calibration standards
- The calibration facility will be evaluated by Quality Management Representative
- Calibration certificates will be required

## Software

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

- Standard software purchased from commercial sources is ordered with validation certificates
- Software developed in-house is validated and approved in accordance with customer requirements
- Software is re-validated at prescribed intervals or whenever a change from the original release is introduced

## Non-conforming Equipment

If it is confirmed that inspection and test equipment is out of calibration, the Quality Management Representative is required to:

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

## Records

Each instrument is traceable through its own calibration record which contains:

- Identification number
- Manufacturer and model
- Frequency of calibration
- Reference standards used
- Validation certificates and calibration findings
- Details of actions be taken in case of unsatisfactory results

## Calibration Process Map

