

Standard Operating Procedure

Title: Calibration Policies for Laboratory Instruments

instruments not requiring calibration are labelled accordingly. The calibration programme for each piece of equipment is also outlined in the Equipment Log.

- 4.3. When out of calibration, the QA Manager and the Laboratory Manager are notified and a label stating its status will be attached to the equipment or instrumentation.
 - 4.4. Equipment that is out of calibration may not be used for testing. Refer to Section 6.
5. Security
- 5.1. A security password is used to safeguard, where applicable, software calibration settings.
 - 5.2. The Laboratory instrument and equipment calibration is a delegated job controlled through the work rotation programme.
 - 5.3. The Engineering Services calibration programme is controlled through the Plant Maintenance Module system (see SOP LAB-025).
 - 5.4. The standards used for calibration are traceable to national/international standards where appropriate and are subjected to the defined storage and in use controls.
 - 5.5. Records of all calibration activities are retained, either electronically or manually in Logbooks, by either the Engineering Services Department Calibration staffs or the Laboratory.
 - 5.6. Refer to the Laboratory Equipment Log folders on the storage of the calibration and service records.
6. Failed Calibration
- 6.1. The following action is to be taken when a calibration fails on equipment or instrumentation and product has been passed in the previous period prior to the failure.
 - 6.2. A service call is placed and the instrument or equipment is repaired and calibrated by the service technician.
 - 6.3. The instrument is re-calibrated by a Technician according to requirements. The instrument may need to be re-validated by the manufacturer of the instrument (see SOP VAL-025).
 - 6.4. A decision on the planned action is taken in consultation with the Analyst, QA and Laboratory Manager.
 - 6.5. An out of specification investigation is undertaken using SOPs D.9.16. and QMS-035 where the appropriate action to investigate the effect of the un-calibrated instrument or equipment on the product is decided by the QA Manager.
 - 6.6. If an instrument is out of calibration at the time of performing the testing, a further system is in place to assure the results by using validated methods, equipment and instruments, tight release limits, and by evaluating finished goods, stability and trials in the same testing runs an out of calibration instrument is highlighted at the point of testing.