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REASON FOR UPDATE:4.2.2 'Review' added as a gauge status4.2.4 Updated to include marking status as 'review' during escalation

ASSOCIATED DOCUMENTS: QPD88, OPI16, OPI252, OPI303, F632

1. <u>PURPOSE</u>

1.1 To provide a procedure for calibration of onsite measuring and testing equipment.

2. <u>SCOPE</u>

- **2.1** This document applies to all measuring and testing equipment associated with product and material realisation.
- **2.2** Measurement equipment not deemed critical to final inspection and testing are identified as 'reference only' or 'indicator only' and not subject to calibration requirements.
- **2.3** Specialist measuring devices or equipment such as the K2A Compound Mixer, Micro-Vu machines, Basler machine, CMM and other Laboratory and Product Testing equipment are calibrated by a third party supplier, managed by the Engineering and Product Testing departments.

Measuring devices or equipment, as listed in Appendix A, are calibrated externally by a approved third-party supplier.

Measuring devices or equipment, as listed in Appendix B, is are calibrated internally to referenced procedures using master equipment linking back to Appendix A.

Certificates for specialist machines or devices are made available to Quality.

3. **RESPONSIBILITY**

- **3.1** The Quality Manager is responsible for updating and communicating the details within this procedure.
- **3.2** Equipment affixed with 'JWCQE' will be maintained by the Quality Department. Equipment affixed with 'JWCLE' will be maintained by the Laboratory Department.
- **3.3** It is the responsibility of the individuals using measuring equipment to check calibration details to ensure the device is within calibration and to ensure that all detail contained on the label is fully legible and in good condition.
- **3.4** The use of personally owned equipment is not permitted.
- **3.5** It is the responsibility of the individuals using measuring equipment to safeguard the equipment from damage or deterioration through appropriate handling and storage.
- **3.6** If items are outside of calibration, they must not be used and must be handed into the Quality or Laboratory Department with immediate effect. Equipment that is not able to be physically moved must be appended with a quarantine label identifying it's out of calibration status. Further use of equipment that has lapsed calibration may render the user liable for disciplinary action.

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- **3.7** The Quality Department will remove any alteration tools from equipment to safeguard them from adjustments that may invalidate the calibration status and subsequent measurement results.
- **3.8** Sub-contracting of calibration beyond the approved provider is not permitted without prior written approval.

4. <u>PROCEDURE</u>

4.1 General

- **4.1.1** Measurement and testing equipment is to be calibrated with traceability to national or international standards as per defined criteria in appendix A.
- **4.1.2** Temporary calibrations are permissible at the discretion of the Quality Manager, but should only be considered under extreme circumstances.

4.2 Identification and Traceability

- **4.2.1** A gauge list shall be maintained in the ERP system listing all measuring and testing equipment associated with each area of the MBU, with the exception of the Product Test Team and Maintenance Engineering who control some equipment externally to the ERP system. A separate log is kept for those items concerned.
- **4.2.2** Within the gauge list, equipment will be controlled by the use of the following gauge status' as relevant

GAUGE STATUS	DESCRIPTION
Active	Active and in use
Inactive	Withdrawn from use and quarantined
Lost	Device has been lost
Off Site	Sent off site for calibration
Pending	Awaiting calibration certificate
Scrapped	Scrapped
Review	Review in progress

- **4.2.3** Specific details relating to the equipment shall be recorded, including:
 - I. Location of equipment, identifying responsible person where applicable.
 - II. Serial no. or other unique identity of the individual item.
 - III. Instrument type, measurement range and unit of measure.
 - IV. Next calibration due date and number of days till due.
- **4.2.4** Calibrated equipment will be identified by a calibration label specifying as a minimum, the equipment's unique ID reference, calibration date and next calibration due date.

4.3 Equipment Recall

- **4.3.1** The gauge list is formatted to highlight gauges due for calibration within 30 days. The list will be interrogated on a weekly basis (as a minimum) and a notice issued to departmental managers to recall any identified equipment.
- **4.3.2** Departmental supervisors shall collect the equipment identified and hand into the relevant department who will arrange for the re-calibration. If any items are

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reported as missing, this must immediately be reported to the relevant department and annotated as 'Lost' in the gauge list. Missing items shall be replaced from departmental budget. Loss of equipment as company property may result in disciplinary action against the recorded holder.

- **4.3.3** The Quality team will ensure that the loan equipment is calibrated. Traceability of loan equipment will be maintained via the main Gauge List and the completion of F632 Quality Loan Equipment Log which includes sign off.
- **4.3.4** Equipment where calibration has lapsed without successful recall shall have its system status marked as 'review' and be escalated to the departmental manager with the Quality Manager and relevant exec level manager included. The item shall be immediately withdrawn from the department (where location is known) and quarantined until a time when it can next be re-calibrated. If the equipment is not portable, a label should be affixed in a prominent place indicating the equipment is "NOT IN CALIBRATION, DO NOT USE".

4.4 Introduction of New Equipment

- **4.4.1** All new equipment shall be delivered to the Quality or Laboratory Department to ensure that it has been accompanied by a calibration certificate traceable to national or international measurement standards. Any item arriving not meeting calibration requirements will be retained by the Quality or Laboratory Department until calibration can be arranged with the external provider.
- **4.4.2** New equipment will be entered onto the Gauge List (in line with clause 4.2.1) prior to release into the relevant department for use.

4.5 Equipment found damaged or unfit for intended purpose

- **4.5.1** Any equipment that may have been damaged to the point that it would invalidate the calibration status and subsequent measurement results shall be handed into the Quality or Laboratory Department with immediate effect.
- **4.5.2** Any equipment found to be outside of the acceptance criteria during re-calibration shall be immediately withdrawn from use and quarantined.
- **4.5.3** The Quality Department must review any equipment found damaged or outside of the acceptance criteria to determine risk where used. In the event that product is deemed at risk, product recall may be instigated as per QPD88.

4.6 Acceptance of calibration equipment and associated certificates

- **4.6.1** Calibration certificates are reviewed to ensure that they contain accurate information relating to the equipment's:
 - identification
 - date and expiry of calibration
 - results of calibration (ensuring they are fit for purpose in accordance with acceptance criteria).
- **4.6.2** QPD06 section 25 controls the valid list of approval authorities able to approve and accept incoming calibration certificates from external providers
- **4.6.3** Acceptance of equipment and certificate is evidenced by the equipment being made 'active' within the gauge list.

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Appendix A (below)

Instrument Type	<u>Frequency</u>	Method	Acceptance Criteria	<u>Conditions</u>
Vernier	12 Monthly	External provider procedure	B 7505:2016 Table 5	Ambient room temperature
Micrometer	12 Monthly	External provider procedure	+/-0.02mm	Ambient room temperature
Рі Таре	12 Monthly	External provider procedure & Visual check for any kinks or tears	10% of diameter tolerance allowance based on JW 200 009 iss 6 table 3	Ambient room temperature
Depth Gauge	12 Monthly	External provider procedure	+/-0.04mm	Ambient room temperature
Portable Shop Floor Weighing Scales	12 Monthly	External provider procedure	+/-1% of measurement range	Ambient room temperature
Thickness Gauge	12 Monthly	External provider procedure	+ B 7505:2016 Table 5	Ambient room temperature
Lux Light Meter	12 Monthly	External provider procedure	As per Calibration supplier results certificate	Ambient room temperature
Slip Gauges	5 Yearly	External provider procedure	EN ISO3650:1999 – Grade 1	UKAS Lab Controlled
Diameter Cones	5 Yearly	External provider procedure	As per Calibration supplier results certificate	Ambient room temperature
Temperature Verifier	12 Monthly	External provider procedure	As per Calibration supplier results certificate	UKAS Lab Controlled
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Appendix B (below)

Instrument Type	Frequency	Method	Acceptance Criteria	Conditions
TFN (Digital Thermometer)	12 Monthly	OPI252 & SOP0342	OPI252 & SOP0342	Ambient room temperature
Annealing and post-bake factory ovens	3 Monthly	OPI16	OPI16	Ambient room temperature
Laboratory Ovens	3 Monthly	OP1303	OPI303	Ambient room temperature
Squirrel Data Logger	12 Monthly	SOP0342	SOP0342	Ambient room temperature
Pressure Transducers	12 Monthly	QPD117	±1% of full scale	Ambient room temperature
Temperature RTDs	12 Monthly	QPD113	±1°C deviation	Ambient room temperature
Speed Potentiometers	12 Monthly	QPD121	±1% of full scale	Ambient room temperature
Torque Transducers	12 Monthly	QPD133	±1% of full scale	Ambient room temperature
Surface Roughness Tester	12 Monthly	QPD115	±5% of reference specimen	Ambient room temperature
Carbolite Gero Oven	12 Monthly	QPD132	±10°C deviation	Ambient room temperature
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