# Laboratory validation of new equipment

### **1. Installation, Safety & Documentation**

* Ensure the incubators are installed according to the **manufacturer’s instructions**, including electrical safety checks and PAT testing.
* Label each incubator with a **unique asset number** and enter into the **equipment register**.
* Record commissioning details and **responsible personnel** in the **QMS**.

### **2. Comprehensive Validation and Calibration**

* **Manufacturer Protocols:** Follow installation, operation, and maintenance instructions provided by the manufacturer.
* **Temperature Accuracy:** Verify that each incubator maintains its setpoint (30 °C or 37 °C) within **±2 °C** over multiple test cycles.
* **Independent Monitoring:** Place a **calibrated digital data logger** (accuracy at least ±0.5 °C) inside each incubator, with probes immersed in a **buffering medium** (e.g. glycol) near specimens, away from walls and vents.
* **Calibration Records:** Document initial and periodic calibration (every 1–2 years).
* **Stability Testing:** Run test incubations at different shelf positions to confirm **uniformity of temperature**.
* **Alarms/Safety:** Check high–low alarms and backup systems.

### **3. Validation for Intended Use**

* Perform **parallel incubation** of control organisms in the new and existing validated incubators to demonstrate equivalent growth performance.
* Include organisms relevant to each temperature (e.g. bacterial pathogens at 37 °C; yeasts and moulds at 30 °C).

### **4. Specimen Processing and Contamination Control**

* **Risk Assessment:** Identify any specimens that may contain **Hazard Group 3 organisms or dimorphic fungi** and ensure they are handled at the correct containment level.
* **Biosafety Protocols:** Manipulations of hazardous organisms (e.g. *Mycobacterium*, *Brucella*, dimorphic fungi) must be performed in a **microbiological safety cabinet** under **CL3 conditions**.
* **Prevent Cross-Contamination:**
  + Ensure workflows proceed from **‘dirty’ to ‘clean’** areas.
  + Consider using **uninoculated control plates** or sterile tins between specimens to reduce cross-contamination, especially with fungal cultures.
  + Establish a schedule for **regular cleaning and disinfection** of incubator interiors, particularly humidified units.
* **Humidity Management:** Provide appropriate humidification where prolonged incubation is required (e.g. for certain mycoses, *Bartonella* species) to prevent agar desiccation.

### **5. Routine Monitoring & Staff Training**

* Set up **daily/weekly temperature checks** (min–max thermometer or automated logger).
* Train staff on the correct use, cleaning, and documentation of the incubators.
* Incorporate into existing **SOPs** and **preventive maintenance schedules**.