

Standard Operating Procedure

Title: Validation of Laboratory Instruments

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Document Owner

Laboratory/Validation Manager

Affected Parties

All Technical service and Laboratory staffs involved in validation of laboratory instruments.

Purpose

To describe Validation practices for Laboratory instrument/equipment to be validated or calibrated and the confirmatory documentation required showing that the instrument/equipment is capable and operating effectively for its intended purpose.

Scope

Depending on the complexity of the instrument/equipment, Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) can be performed by the qualified equipment Service Technician in the presence of the Laboratory staff with reference to the Instrument/equipment manual.

Definition

GLP	Good Laboratory Practice
DR	Deviation Report

Related Documents

LAB-005	Calibration Policies for Laboratories
VAL-005	Validation-Concept and Procedure
QMS-035	Deviation Report System

EHS Statement

Follow safety recommendations and requirements from the supplier's manual during Installation and Validation.

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accessories received to the checklist as purchased. Confirm that the equipment is complete and in good condition. Notify the supplier/manufacture immediately of any problems found.

3.2. Setting up considerations

3.2.1. Laboratory equipment/instrumentation can be sensitive to certain environmental factors. By observing the following factors during installation, the Operator can minimise the effects of these influences where appropriate:

- Location near output of air conditioner causing excessive drafts;
- Direct sunlight and other high temperature locations, i.e. near an oven or furnace;
- Vibrations through the Laboratory bench.

For further considerations always consult the instrument manual and the Equipment Service Technician/Engineer for any further requirements.

3.2.2. Some electrical precautions should be observed, (refer to the instrument manual for any special requirements for each particular instrument and consult the Equipment Service Technician):

- Avoid using an extension cord where possible.
- Don't place the unit in the same circuit with large electrical motors.
- Plug all line cords into a surge protector.

3.2.3. Observance of two basic Housekeeping rules.

- To allow a unit to cool properly, keep the vents on the back clean.
- Minimise the unit's exposure to dust and provide sufficient bench space for the instrument and the computer, printer and keyboard.

3.2.4. Allow enough space nearby for sample handling.

3.3. Attachment of modules

3.3.1. Certain laboratory equipment/instruments are designed to provide full flexibility and modules can be attached.

3.3.2. Section 1 to 3 should also be considered when installing modules.

3.4. Hardware and Software orientation

3.4.1. Installation of the software may be carried out by the supplier at point of purchase or on-site installation.

4. Method Validation Documentation

4.1. Validation Tests performed In-house

4.1.1. The Validation documentation follows a similar format to the validation requirements of **SOP VAL-005**, including Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). The extent of documentation required is dependent on the function of the particular instrument being validated. For simple instruments the Validation document can combine IQ/OQ/PQ into the one document and for more complicated equipment separate documents will be required. For particular applications only the OQ or PQ tests need to be performed.

4.1.2. **SOP VAL-005** will be used as a guide when developing the validation documentation:

4.2. Validation Tests provided/performed by Instrument Supplier

For validation packages provided by the instrument supplier the package must be assessed for suitability to in-house requirements. If found to be unsuitable a new document using the appropriate in-house format of IQ/OQ/PQ must be used by transferring the relevant useful validation protocols from the supplier's documentation.