

Standard Operating Procedure

Title: Validation of Laboratory Instruments

any part that is missing, broken or damaged. Compare and check off the parts and 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