Advanced instrumentation technique **BP8111TT**

ICH and WHO Guideline for validation and calibration of equipment

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NATIONAL BOARD OF ACCREDITATION

Validation and Calibration

- **Validation:** Action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results.
- **Calibration:** The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (for example, weight, temperature and pH), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard.

WHO Guideline

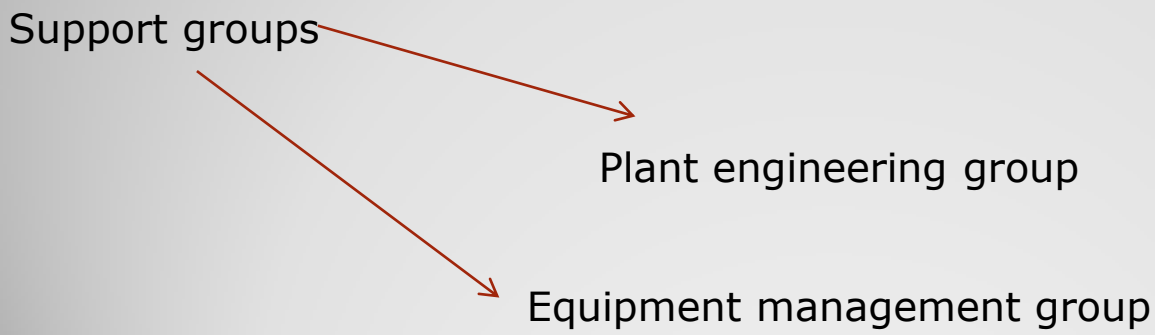
- Equipment validation/qualification (EQ) include:
  - Design qualification (DQ)
  - Installation qualification (IQ)
  - Operational qualification (OQ)
  - Performance qualification (PQ)

DESIGN QUALIFICATION

- *"Design qualification (DQ) defines the functional and operational specifications of the instrument and details for the conscious decisions in the selection of the supplier".*
- It include:
  - Description of the analysis problem
  - Description of the intended use of the equipment
  - Description of the intended environment
  - Preliminary selection of the functional and performance specifications (technical, environmental, safety)

INSTALLATION QUALIFICATION

- *"Installation qualification establishes that the instrument is received as designed and specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation and use of the instrument."*



OPERATIONAL QUALIFICATION

- *"Operational qualification (OQ) is the process of demonstrating that an instrument will function according to its operational specification in the selected environment ."*
- It include:
  1. Application S.O.P's
  2. Utilization List
  3. Process Description
  4. Test Instrument Utilized To Conduct Test
  5. Test Instrument Calibration
  6. Critical Parameters
  7. Test Function (List)
  8. Test Function Summaries

PERFORMANCE QUALIFICATION

- *"Performance Qualification (PQ) is the process of demonstrating that an instrument consistently performs according to a specification appropriate for its routine use ".*

ICH GUIDELINE

- **ICH Q2** defines typical analytical validation characteristics, to which tests to apply them and examples on the "how to".

- It include:
  1. **SPECIFICITY** is the ability to assess unequivocally the analytes in the presence of components which may be expected to be present.

  2. **DETECTION LIMIT** of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value.

3. **ACCURACY** of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found. This is sometimes termed trueness.

E.g.
Theoretical value =37

Practical value A= 35, 35.5,34.5
ACURATE

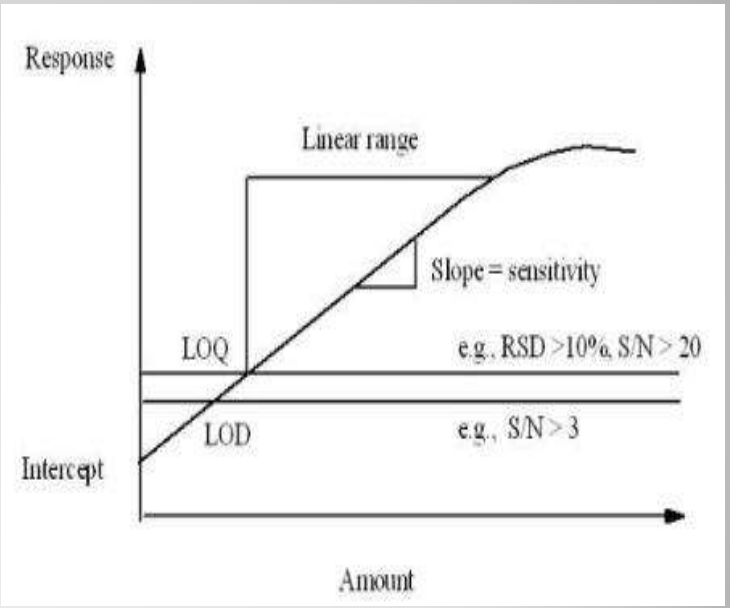
4. **PRECISION** expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision may be considered at three levels: repeatability, intermediate precision and reproducibility.

Practical value B=34, 38,40
PRECISE

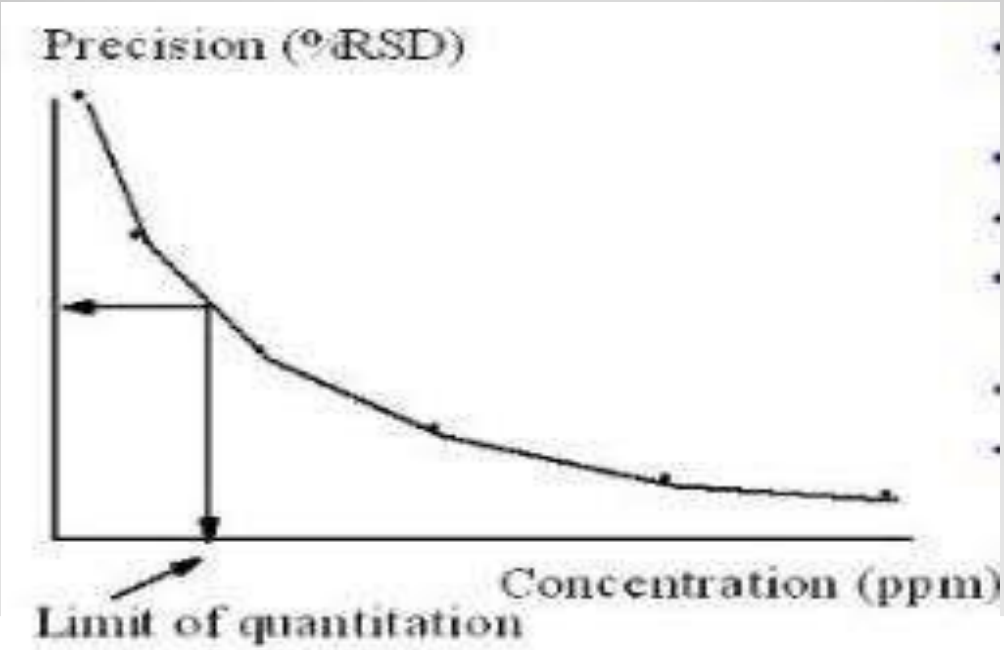
5. **LINEARITY** of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample.

6. **ROBUSTNESS** is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage.
   1- Change in pH of mobile phase.
   2- Change of column
   3- A little bit change of temperature

7. **RANGE** of an analytical procedure is the interval between the upper and lower concentration (amounts) of analyte in the sample (including these concentrations) for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy and linearity.



8. **QUANTITATION LIMIT** of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy. The quantitation limit is a parameter of quantitative assays for low levels of compounds in sample matrices, and is used particularly for the determination of impurities and/or degradation products.



THANK YOU