ISO 17025 Mapping?

Dr Phil Gilvin Public Health England, UK



# 5.4.2 Selection of methods

The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published In international, regional or national standards shall preferably be used.



# 5.4.2 Selection of methods

When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international. regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.

### 5.4.5 Method Validation

5.4.5.2 The laboratory shall validate nonstandard methods, laboratory-designed/developed methods, standard methods used outside their intended scope . . . The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

### **5.4.5 Method Validation**

The range and accuracy of the values 5.4.5.3 obtainable from validated methods (e.g. the uncertainty of the results, detection limit, sensitivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or crosssensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.



## 5.6 Measurement Traceability

#### 5.6.1 General

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.



# 5.6 Measurement Traceability

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.

## 5.6.3.1 Reference standards

The laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.



Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules. The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:



a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

- b) participation in interlaboratory comparison or proficiency-testing programmes;
- c) replicate tests or calibrations using the same or different methods;
- d) retesting or recalibration of retained items;
- e) correlation of results for different characteristics of an item.