SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
LABORATORY ACCREDITATION SCHEME OF MALAYSIA

SAMM POLICY 5 (SP5) – POLICY ON MEASUREMENT UNCERTAINTY REQUIREMENTS FOR SAMM TESTING LABORATORIES

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JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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1 Introduction

1.1 This document specifies the policy of the Department of Standards Malaysia (Standards Malaysia) with regard to measurement uncertainty requirements imposed on applicant and accredited testing laboratories under the *Skim Akreditasi Makmal Malaysia* (SAMM).

1.2 This policy document should be read in conjunction with other SAMM requirements.

2 Scope

This policy provides guidelines on the estimation and expansion of measurement uncertainty and applies to all applicants and accredited testing laboratories.

3 Definitions

For the purpose of the document, the following definitions shall apply:

3.1 **Calibration (VIM 3 clause 2.39)**
Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

NOTE 1 A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

NOTE 2 Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.

NOTE 3 Often, the first step alone in the above definition is perceived as being calibration.

3.2 **Metrological traceability (VIM 3 clause 2.41)**
Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

NOTE:
For this definition, a ‘reference’ can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

The ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals.

3.3 **Measurement uncertainty (VIM 3 clause 2.26)**
Non-negative parameter characterising the dispersion of the quantity values being attributed to a measurand, based on the information used

NOTE:
The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

3.4 **Measurand (VIM 3 clause 2.3)**
Quantity intended to be measured.

3.5 **Measurement (VIM 3 clause 2.1)**
Process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity.

4 Requirements of MS ISO/IEC 17025 and MS ISO 15189

4.1 MS ISO/IEC 17025, clause 7.6 states the following:

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

7.6.3 A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement

uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.

4.2 MS ISO/IEC 17025 clause 7.8.3.1 c) states the following:
[In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:]

c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:

— it is relevant to the validity or application of the test results;

— a customer's instruction so requires, or

— the measurement uncertainty affects conformity to a specification limit;

4.3 MS ISO 15189, clause 5.5.1.4 Measurement uncertainty of measured quantity values states the following:

The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.

NOTE 1: The relevant uncertainty components are those associated with the actual measurement process, commencing with the presentation of the sample to the measurement procedure and ending with the output of the measured value.

NOTE 2: Measurement uncertainties may be calculated using quantity values obtained by the measurement of quality control materials under intermediate precision conditions that include as many routine changes as reasonably possible in the standard operation of a measurement procedure, e.g. changes of reagent and calibrator batches, different operators, scheduled instrument maintenance.

NOTE 3: Examples of the practical utility of measurement uncertainty estimates might include confirmation that patients' values meet quality goals set by the

laboratory and meaningful comparison of a patient value with a previous value of the same type or with a clinical decision value.

The laboratory shall consider measurement uncertainty when interpreting measured quantity values. Upon request, the laboratory shall make its estimates of measurement uncertainty available to laboratory users.
Where examinations include a measurement step but do not report a measured quantity value, the laboratory should calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result.

5 Policy

5.1 General

It is the policy of SAMM that testing laboratories accredited by Standards Malaysia shall comply with the requirements of MS ISO/IEC 17025 or MS ISO 15189 in relation to the estimation and reporting of uncertainty of measurement in testing.

The complexity involved in estimation of uncertainty of measurement in the case of testing varies considerably from one test field to another and also within one field itself.

Clause 7.6.3 of MS ISO/IEC 17025 allows a less rigorous process than that which can be followed for calibration. Standards Malaysia requires the testing laboratory to make a reasonable estimate of the uncertainty.

NOTE: Uncertainty components/budgets are a combination of many factors that may include, but are not limited to:

- Reference standards;
- Reference materials;
- Test methods used;
- Equipment used;
- Environmental conditions;
- Properties and condition of item being tested;
- Calibration;
- Operator; and
- Known physical characteristics of components.

6 Tests for which uncertainty does not apply

The following types of test methods do not require estimate of the measurement uncertainty:

6.1 Qualitative tests. (Test results are not numerical such as pass/fail; positive/negative or other qualitative expressions).

6.2 In those cases where a well-recognised test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the clause by following the test methods and reporting instructions.

7 Tests for which uncertainty applies

Where a test produces numerical results (or the reported result is based on numerical result), those uncertainty of those numerical results shall be estimated. In cases where the nature of the test method precludes rigorous, metrologically and statistically valid estimation, of the measurement uncertainty, a laboratory shall make a reasonable attempt to estimate the uncertainties of those results. This applies whether the test methods are rational or empirical.

The following types of test methods need a reasonable estimate of the measurement uncertainty. The tests under this however, require varying degrees of rigor when estimating the measurement uncertainty.

7.1 Consensus tests methods or methods or published by regulatory bodies (examples: chemical, environmental, or microbiological test methods published by AOAC, ASTM, DOE) for which the major source of uncertainty of measurement is not stated in the method.

7.2 Test methods that need identification of the major components of uncertainty and a reasonable estimate of measurement uncertainty. (Such as laboratory-developed methods) [Laboratory-developed methods also require method validation]

7.3 Published methods (such as found in text books, journal and bulletins).

8 Evidence of compliance

8.1 Objective evidence of compliance, including the procedure for estimating measurement uncertainty, and the resulting documented uncertainty budgets and uncertainty values, where relevant, will be reviewed in accordance with the following schedule:

a) For applicant laboratories, compliance will be verified by the assessor during the laboratory's on-site assessment.

b) For accredited laboratories due for renewal, compliance will be verified by the assessor during laboratory’s on-site assessment. All necessary measurement uncertainties, including the uncertainty budgets shall be documented and made available.

9 Guidance on steps to be taken by laboratory

9.1 Estimating measurement uncertainty

The laboratory may adopt the following approach:

a) Specifying the measurand i.e. relationship between the measurand and the variables of the analytical procedure.

b) Describe the measurement/testing procedure. Flowchart with the description of all steps of analytical procedures.

c) Identify all uncertainty sources. The uncertainty of each variable in the uncertainty budget is identified by mean of a cause and effect diagram. Identify major uncertainty components (Laboratories may adopt methods provided in the EURACHEM / CITAC / CSLI / NPAAC Guide. Other methods will also be considered, if they present a valid approach to the estimation of measurement uncertainty).

d) Quantification and combination of uncertainties. The above identified uncertainties are quantified and combined to give the total uncertainty on the measurand.

9.2 Reporting expanded uncertainty

The result *x* should be stated together with the expanded uncertainty *U* calculated using coverage factor k=2. The following form is recommended:

"(Result): ($x \pm U$) *(units)"*

[where] the reported uncertainty is (an expanded uncertainty as defined in the International vocabulary of metrology - Basic and general concepts and associated terms (VIM), 3rd ed.) calculated using a coverage factor of 2, (which gives a level of confidence of approximately 95%). The coverage factor should be adjusted to show the value actually used.

Bibliography

1. MS ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories

2. MS ISO 15189, Medical laboratories - Requirements for quality and competence

3. EURACHEM/CITAC Guide CG 4:2012, Quantifying uncertainty in analytical measurement

4. JCGM 100:2008 Evaluation of measurement data - Guide to the expression of uncertainty in measurement (GUM)

5. JCGM 200:2012, International vocabulary of metrology - Basic and general concepts and associated terms (VIM), 3rd edition

6. ISO 5725 Accuracy of measurement methods and results package

7. Clinical and Laboratory Standard Institute (CLIS): Guideline describing the principles of estimating measurement uncertainty (C51-A)

8. The National Pathology Accreditation Advisory Council (NPAAC): Requirements for the estimation of measurement uncertainty (2007)