**Uddrag fra minutes i ILAC AIC december 15th 2021:**

Danielle Dicker gave an update from the sMU taskforce and the discussions of the TFG on the revised version of the position paper to resolve some of the issues identified through the sMU survey.

Revised position statement addressing the two issues around MU arising from sampling & decision rules raised at ILAC AIC Mexico April 2019 is by the TFG as final version**. It shall be reminded that a position paper is neither a guide nor a policy and that there is no formal approval mechanism for it. The position paper is the result of discussions as held so far.**

Danielle commented that CABs and ABs still need more experience in this field.

The chair thanked the TFG for the work done with this challenging task.

**POSITION STATEMENT**

**ILAC AIC**

**ISO/IEC 17025:2017: Measurement uncertainty and decision rules associated with sampling**

**Version 02 XXXX 2020**

**Background:**

*"The fitness for purpose of measurement results can only be judged by having reliable estimates of their uncertainty; A proper understanding of uncertainty from sampling must therefore be embedded in the broader perspective of fitness for purpose; Accordingly, if the MU is underestimated, for example because the sampling is not taken into account, then incorrect decisions may be made that can have large financial, health and environmental consequences"* (Eurachem/CITAC Guide 2019).

An appropriate sampling plan for the collection of the items to be tested and the reliability of the measurement process, including the estimation of measurement uncertainty (MU), are key inputs for ensuring the confidence in measurement results.

Although it is acknowledged that sampling may contribute the largest source of uncertainty, it is often omitted from the process of MU estimation.

Previously, ISO/IEC 17025:2005 only required the MU associated with testing (the analytical portion) to be considered. The 2017 version of the Standard now requires that the MU contribution(s) of the sampling also be considered (*Clause 7.6.1* and *Clause 7.8*) if the laboratory is responsible for the sampling.

For many laboratories, determining the MU contributions of the sampling activity (sMU) may be a new concept. For Accreditation Bodies (ABs), assessing sMU may also be new.

This position paper has been developed by the ILAC AIC to address concerns raised with the practical application of *Clauses 7.6.1* & *7.8* as well as to provide some further guidance to ABs in relation to sMU and its impact on statements of conformity and associated decision rules.

This position paper will be reviewed and revised as necessary as further awareness and experience is gained.

**Purpose:**

This paper aims to address the implementation of the MU requirements in ISO/IEC 17025:2017 in relation to sampling, in order to ensure transparent and consistent application. Specifically, the paper addresses the situations when the contributions from sampling must be considered in evaluating MU and its impact on results reported and statements of conformity.

Although there are other areas of accreditation which may overlap (e.g. ISO 15189), this position paper focuses solely on ISO/IEC 17025 and is restricted to accredited activities only.

**Considerations:**

When assessing sampling, ABs should consider the aspects below.

A laboratory responsible for sampling may:

- perform the task itself;
- subcontract the task.

A laboratory not responsible for sampling will only test samples "as received".

When reporting results, it may seem a disadvantage for those laboratories responsible for sampling activities and who take into account the sMU in addition to the analytical MU (aMU) and this is not clearly stated in the report. In such cases, the final MU estimate may appear significantly larger compared with laboratories that only estimate and take into account the aMU which may compromise the comparability of test results between laboratories.

Where decision rules do not specify inclusion or exclusion of sMU, a larger MU may result in an increased or decreased number of non conforming results reported depending on the decision rule applied.

The implementation of *Clause 7.6.1* in the regulatory environment may give rise to some challenges, notably when the measurand is close to the specification / limit and whether sMU is considered. To compound this issue, established regulatory limits may not take into account sMU, or may be ambiguous as to whether sMU should be considered when reporting results.

**Position Statement:**

The contribution of sampling when evaluating MU must be considered when:

- the laboratory is responsible for the sampling activity(s) (i.e. where it has control or significant influence over the sampling process);
- the customer is responsible for sampling and has provided the sMU with the sample to the laboratory who subsequently performs the testing and reporting.

The laboratory does not need to evaluate sMU when:

- the laboratory is not responsible for sampling (i.e. the sample is "tested as received");
- the test method used is qualitative[1, 2] (i.e. where results of tests are not numerically derived);

  *Note 1: This should not however preclude the laboratory from developing an understanding of all the components that contribute significantly to the variability of results of such tests*

  *Note 2: For tests where a numerical value is reported as a qualitative result (e.g. assays with a 'cut off value' where the numerical value is reported as 'detected' or 'not detected') the contribution of sampling when evaluating MU must be considered*

- the laboratory uses a well-characterized method which includes the sampling plan and the sampling method and describes the uncertainty calculations, or a method that has overall MU established and validated.

Where a laboratory is responsible for the sampling as well as the testing activities, and where the measurement uncertainty is necessary to be included on the test report as per clause 7.8.3.1C, it can report the MU as:

- overall MU (sum of sMU and aMU); or
- separate components (aMU and sMU); or
- only the aMU, provided this is clearly indicated in the test report, has been agreed to by the customer, or is a legislative requirement.

When a laboratory makes a statement of conformity, the decision rule must be clearly defined, communicated to and agreed with the customer, unless inherent in the requested specification (*Clause 7.1.3)*.

Laboratories may exclude sMU from the decision rule provided that:

- the report describes the rule applied and whether sMU is included or excluded;
- there is no explicit regulatory requirement to include it; or
- none of the situations described in *Clause 7.8.3.1c* apply.

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**Reference**

Eurachem/CITAC (2019), *Measurement uncertainty arising from sampling - A guide to methods and approaches*