ILAC Guidance on contribution to measurement uncertainty arising from sampling and testing

Erik Oehlenschlaeger, DANAK,
ILAC AIC chair

What has happened in the ILAC AIC

- ILAC AIC is the accreditation committee in ILAC that works with technical issues related to ISO/(IEC) 17025, 15189, 22870, 17034, 17043 and 20387.
- Query on measurement uncertainty associated with sampling (sMU) raised at the AIC meeting in Mexico April 2019.
- The AIC decided to have a position paper developed to be presented at the AIC meeting in Frankfurt October 2019.
- The AIC discussed the position paper and some additional questions at the meeting of the AIC in Frankfurt 24 October 2019.
- This paper will be circulated for comments in the AIC because there was not a clear consensus.
- The paper will be discussed further in a workshop on implementation ISO/IEC 17025:2017 scheduled for the AIC meeting in Beijing March 2020.

Extracts from ISO/IEC 17025:2017

- 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.

Comment:

Taking into account that sampling may well be "the largest contribution to the overall uncertainty budget" 7.6.1 *could be read* as a criteria to always include sMU.

Extracts from ISO/IEC 17025:2017

- 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.

Comment:

7.6.2 and 7.6.3 are specific to calibration and testing.

So one could read this as the criteria for sMU evaluation is much more strict than criteria for MU in testing (aMU). The conditional criteria in 7.6.3 could be read as not being valid for sMU (although sampling is under the testing MRA).

Extracts from ISO/IEC 17025:2017

- **7.8.5** Reporting sampling - specific requirements. Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:

  …

- f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

Extracts from ISO/IEC 17025:2017

- **3.7** Decision Rule = Rule that describes how MU is accounted for when stating conformity with a specified requirement
- **7.8.6** Reporting statements of conformity
- **7.8.6.1** When a statement of conformity to a specification or standard is provided, the laboratory must agree with the customer the decision rule to apply, taking into account the risk e.g. the false acceptance or rejection of results and the statistical assumptions made
- **7.8.6.2** The statement of conformity must include the decision rule applied (unless inherent in the requested specification or standard)

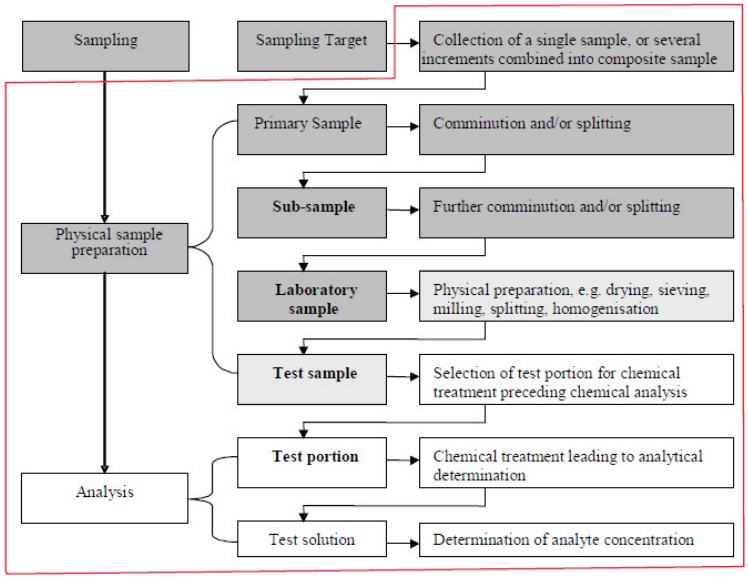
Comment: Some decision rules (legislation) explicitly excludes sMU to be taken into account.

Eurachem guide MU sampling (2019)

Extract from Foreword:

If the objective of the measurement is to estimate the value of the analyte concentration in a sampling target, then the uncertainty associated with the sampling process must inevitably contribute to the uncertainty associated with the reported result. It has become increasingly apparent that sampling is often the more important contribution to uncertainty and requires equally careful management and control. The uncertainty arising from the sampling process should therefore be evaluated. While existing guidance identifies sampling as a possible contribution to the uncertainty in a result, procedures for estimating the resulting uncertainty are not well developed and further, specific, guidance is required.

Eurachem guide MU sampling (2019)



Extracts from ISO/IEC 17025:2017

- **7.8.2.1** Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

....

l) a statement to the effect that the results relate only to the items tested, … or sampled;

Questions to the ILAC AIC

Answer from AIC in red

1. Is 7.6.3 applicable to sampling? YES.
2. Is there a difference between non accredited sampling provided by the accredited laboratory that does the testing (i.e. where the laboratory is responsible for the sampling) and non accredited sampling performed by another part (including the customer by itself)

   No consensus and need to be discussed further.
3. Can an accredited laboratory report test results including sMU for the target of the sampling (ref 7.8.2.1 l)? Or is that an opinion and interpretation?

   More consensus. Clearly one need to be cautious about what the customer requested. Not all customers realize the complexity of this question.

Questions to the AIC

4. If evaluation of sMU almost requires some kind of research activity will that then allow labs to abstain from evaluating sMU? YES by 7.6.3.
5. If the customer and/or regulators specify that sMU shall not be taken into account does the lab then need to evaluate sMU? Some said yes here
6. If a regulatory rule is ambiguous as to whether the sMU needs to be taken into account does the lab need to evaluate and report the sMU? No consensus

Questions to the AIC

7. Implementation of requirements - Are there certain areas that should be excluded from this requirement? (e.g. Forensic science - Proper consideration of MU is imperative when testing a sample against legal/compositional limits. *This task can be quite challenging when the entity measured in the investigated sample is so close to the limit that its uncertainty critically affects decision making. If a laboratory that is responsible for sampling must consider the additional uncertainty arising from sampling activities, this may leave measurements open to being challenged in legal defence).* No consensus – or no time to reach consensus.

The AIC supported that sMU and analytical Measurement Uncertainty (aMU) should be reported separately and not combined – although that is against the principles of both GUM and VIM.

What was heard around…

- There are not (enough/mature) valid methods to determine sMU.
- How to estimate sMU if you do not know which tests will be performed at a later stage. In many cases sMU will be hugely dependent on parameters in the matrix sampled.
- If the U_{anal} is 4 % and the U_{samp} is -50/+150 % does that then mean that the expandes uncertainty U is -50,2/+150,1 %
- Why do accredited sampling if that makes your uncertainties becoming bigger?
- sMU is not consistent and when uncertainties are not reported customarily then they are not challenged.
- ILAC Laboratory Committee: "Uncertainty in sampling; lack of rules for implementation; not enough guidance"

Next steps

- ILAC AIC collect comments to position paper and make further analyses ending with discussion Beijing end March 2020.
- Need for guidance to be determined. However the area of sampling is known to be huge, wide and complex as a former position paper from 2010 revealed.
- Need for clarification with ISO CASCO by their "maintenance groups" including 5 persons is a possibility. Questions need to be formulated as something that may be responded to by yes/no.

What also happened in the ILAC AIC

ILAC G17:2000 Measurement Uncertainty (MU) for testing

- Has been of hold for many years awaiting ISO/IEC 17025 revision.
- Passed a 60 day ILAC AIC circulation spring 2019.
- Will address testing based on ISO/IEC 17025.
- The purpose will specify that the guidance is valid also for other areas of conformity assessment where testing is performed and medical examination.
- Will NOT encourage customary reporting of MU.
- Will instead address and provide examples on interpretation of ISO/IEC 17025:2017 clause 7.8.3.1 c)

G17 draft March 2019

ISO/IEC 17025:2017 requires laboratories to:

7.8.3.1 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.*

G17 draft March 2019

"ISO/IEC 17025:2017 is however open to judging when it is necessary to report uncertainties. It is on the other hand clear that never reporting uncertainty of measurement is not in compliance with the requirements in the standard."

"In the following examples it will be necessary to report measurement uncertainty in order to comply with 7.8.3.1 c):"

- Environmental tests to a regulatory limit; and
- Product tests to a specification

Where measurement results are "close" to the limit. E.g. waste water treatment plants and noise emission from cars.