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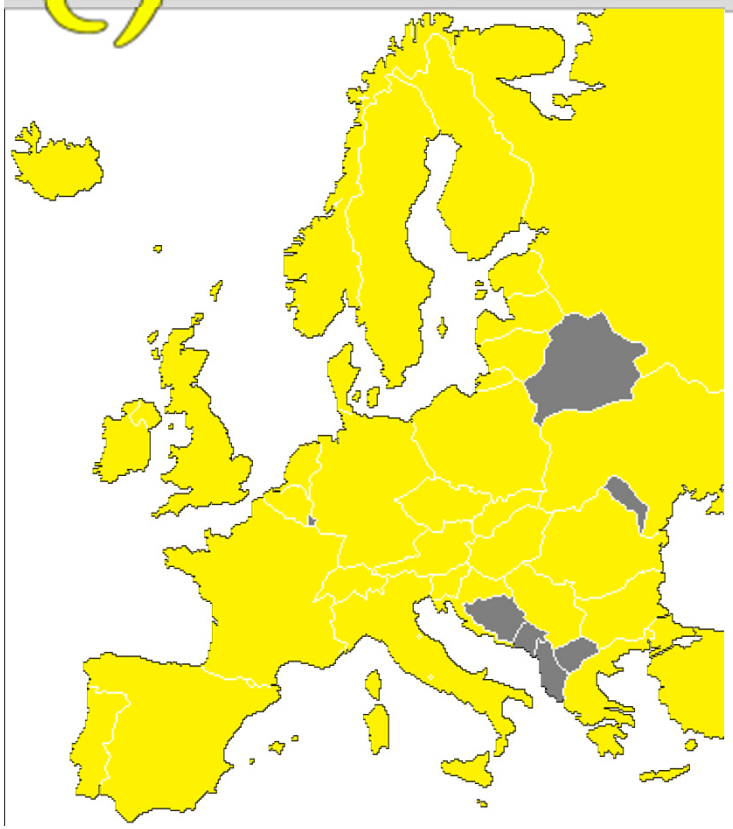
A Focus for Analytical Chemistry in Europe



- a network of organisations in Europe focusing on analytical quality
- Objective: establishing a system for the international traceability of chemical measurements and the promotion of good quality practices.
- How: providing
  - a forum for the discussion of common problems and for developing an informed and considered approach to both technical and policy issues.
  - a focus for analytical chemistry and quality related issues in Europe.
- Actions: Working Groups, Authoritative Guidance, Workshops

Talking to: analytical laboratories, accreditation bodies, regulatory authorities, laboratory customers and other users of measurement results.

www.eurachem.org / national representatives

See the Eurachem posters!!!

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News

Issue 35
Autumn/Winter 2017

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Words from the Chair....

Ladies and gentlemen,

With a great pleasure I keep track of the growing international recognition of Eurachem and its unflagging effort in the field of metrology in chemistry. You may not be aware that several of our guides were translated to non-European languages. For instance the Quantifying Uncertainty in Analytical Measurement Guide is

David Milde speech at the OPCW event.
Photo: Michalis Ioannou

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Treatment of an observed bias

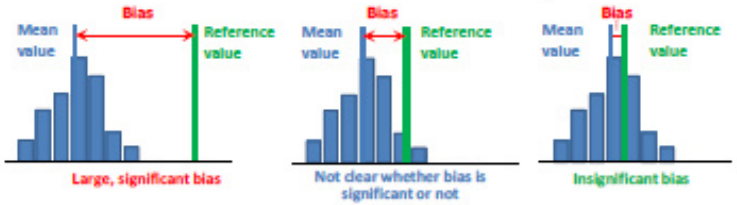
In this leaflet we discuss whether or not you should correct for an observed significant bias and the impact this may have on the measurement uncertainty (MU). How to apply the correction and how to increase the uncertainty to take account of an uncorrected bias is outside the scope of this leaflet.

Important issues for deciding on how to treat an observed significant bias are:

1. whether we understand the cause of the bias, and
2. whether its size can be reliably determined.

Further we must decide:

3. whether the bias is consistent for all test samples within the scope of the method and
4. whether any correction for bias should be multiplicative or additive, depending on whether the magnitude of the bias is constant or changes with the concentration level.



Should we correct, and should we increase the measurement uncertainty?

The ISO Guide to the expression of uncertainty in measurement, GUM [1], assumes that "the result of a measurement has been corrected for all **recognised significant** systematic effects" (GUM 3.2.4). This implies that when developing a measurement method all known sources of bias should be investigated and if possible, eliminated or their effect minimised. If this cannot be achieved, then, if appropriate, a correction should be applied and the measurement uncertainty revised.

Let's assume we have available a standardised method or a fully developed in-house method, with a clear description of the measurand, where any known bias has been minimised during method development (e.g. the effect of interferences has been minimised or a correction is included in the method). The next step, as a part of the validation, is to reliably determine any additional bias for the concentration interval and different matrices specified within the scope of the method. On the next page we present a roadmap outlining how to handle any additional significant bias.

Note that the observed bias in a laboratory could be due to laboratory as well as method bias. For empirical methods where the measurand is operationally defined by the method, the method bias is by definition zero, however, the laboratory bias still needs to be considered.

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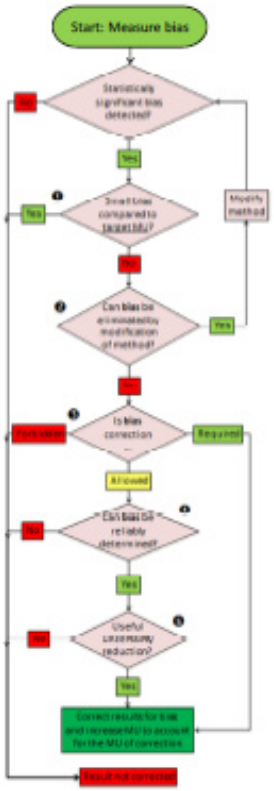

(1) There is no point in trying to eliminate or correct a small bias, since both elimination and correction need resources.

(2) If bias is not negligible then the best approach, if possible, is to try to eliminate it by modifying the method.

(3) If bias is not negligible, but eliminating it is either impossible or impractical, then we can consider correcting for bias. There are three possibilities:

1. Correction may be required (e. g. by regulations).
2. Correction may be forbidden, in which case no correction should be made.
3. Correction may be allowed. Then we should look at two more criteria to determine whether correction is justified.

(4) If bias can be reliably determined and a correction method can be applied that is relevant for all test samples within the scope of the method we may decide to correct for bias. However, if the cause of bias is not known then correcting for bias cannot be generally recommended. If bias cannot be reliably determined then we should not correct for it. If we correct the result on the basis of an unreliable bias estimate then we may even increase the uncertainty of the results.

(5) Correcting for bias is meaningful only if a useful reduction of measurement uncertainty (MU) is achieved. Correcting for the bias is only meaningful if the MU of the correction is smaller than the component of the MU arising from not applying the correction.

(6) If a significant bias is not corrected, it is difficult to give clear guidance on what action to take. For the case of recovery correction, IUPAC [2] lists some possibilities if no correction is applied:

1. No action;
2. Report recovery separately, including the uncertainty of both the result and the recovery
3. Take the bias into account in the uncertainty estimate of the results

These principles can be applied to other forms of bias. Further options have also been reviewed in the literature: See, for example, reference [3]

[1] JCGM 100:2008, Evaluation of measurement data – Guide to the expression of uncertainty in measurement, http://www.bipm.org/en/publications/guides/gum.html
[2] Harmonised guidelines for the use of recovery information in analytical measurement, Pure & Appl. Chem., Vol. 71, No. 2, pp. 337–348, 1999.
[3] B. Magnusson, S. L. R. Ellison Anal Bioanal Chem 2008, 390, 201–213.

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A new ISO/IEC 17025 for laboratories

Something is changing in the life of laboratories!

A significant revision has led to the publication of ISO/IEC 17025:2017. A three-year transition period is provided for all parties to fully implement the new version but some effort will be required to ensure a smooth transition. This applies to laboratories and national accreditation bodies. The latter will be supported by regional and international accreditation organisations which need to ensure a harmonised procedure for the implementation of the Standard, the assessment of laboratories and the peer review of the accreditation bodies. The structure of the Standard has changed extensively to be in line with the format of the new ISO/IEC 17000 series but the requirements for laboratories remain broadly similar.

What is changing?

- The structure (see Fig. 1)
- Sampling addressed as a standalone activity
- The use of a decision rule
- Risks and opportunities
- The management system
- Reference to new standards
- The Annexes

Figure 1: Comparison of 2005 and 2017 versions of ISO/IEC 17025

New definition of "laboratory"

A laboratory is defined as a body performing one or more of the following activities: testing; calibration; and sampling, associated with subsequent calibration or testing. The "subsequent calibration or testing" are not necessarily carried out in the same entity. This means that sampling as a standalone activity can be accredited against the Standard.

The decision rule

A decision rule describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. It is the laboratory's responsibility to document the decision rule, including the statistical basis, and to communicate it to and agree it with the customer. Further information is available in ISO/IEC Guide 98-4 [1] and a guide published by Eurachem/CITAC [2].

Risks and opportunities

It is the laboratory's choice how to address risks. This requires deliberate consideration of what is important for the individual laboratory. The process involves identifying, evaluating and defining measures to control risks and enhance opportunities for the laboratory to achieve its purpose and objectives.

The Standard requires the laboratory to plan and implement actions to address risks and opportunities. This is reflected not only in a number of subclauses – i.e. on impartiality, statements of conformity, management of nonconforming work, and management reviews – but in its philosophy as a whole. No reference is made to "preventive actions" – risk-based provisions as well as clauses relating to improvement cover the need.

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The management system

Figure 2: Management system options
Annex B gives more detailed information

There are two management system options (see Fig. 2).
Option A: Compliance with the provisions of clauses 4-7 and 8.2-8.9.
Option B: Laboratories implementing a management system in accordance with ISO 9001 need to comply with clauses 4-7 of ISO/IEC 17025.

Some other significant changes

- Clause on improvement now includes feedback from the customer.
- Emphasis on impartiality – defined as "presence of objectivity" – and confidentiality.
- Liability is covered in more detail; some of its aspects are addressed under confidentiality.
- Metrological traceability is addressed in more detail (reflecting the provisions of ILAC P10 [3]) with reference to relevant international agreements. Annex A provides further details.
- Specific requirements for reporting sampling activities.
- Requirement to take into account uncertainty from sampling.
- More detailed requirements on expression of opinions and interpretations.
- Additional tools are listed to ensure the validity of results. More strict requirements are set with regard to participation in proficiency testing.
- More detailed requirements for control of data and information management, taking into account new technology.
- Management review shall reflect the various changes, including risks and opportunities.
- A quality manual, as such, is not required.
- Additional requirements are set for externally provided products and services; according to a Note, the latter can include, among others calibration, sampling and testing services (i.e. subcontracting).
- "Laboratory management" is used instead of "top management". The terms "technical manager" and "quality manager" are not used; relevant responsibilities are to be assigned to competent personnel.

How can laboratories proceed smoothly?

- Obtain a copy of the new standard and have a clear understanding of its philosophy and provisions.
- Make a cross-reference table illustrating the link between existing processes and procedures and the relevant clause in the new standard.
- Examine existing procedures in light of the risk-based approach to evaluate whether they are still relevant for your laboratory.
- Identify any clauses that seem to require new procedures (gap analysis plus risk assessment).
- Communicate with the national accreditation body.
- Plan internal audit and management review to check the appropriateness of the revised system.

Useful information on the new standard...

Can be found in the Eurachem News article at bit.ly/ECNWS17025, the Eurolab "cookbooks" at bit.ly/ELCookbook, the ISO videos at bit.ly/17025VID1 and bit.ly/17025VID2, and the ISO brochure at bit.ly/ISOBROCHURE.

References

[1] ISO/IEC Guide 98-4:2012, Uncertainty of measurement – Part 4: Role of measurement uncertainty in conformity assessment (available as JCGM 106 from www.bipm.org)
[2] S L R Ellison and A Williams (Eds). Eurachem/CITAC guide: Use of uncertainty information in compliance assessment. First Edition (2007) (available from www.eurachem.org)
[3] ILAC P10:01/2013 ILAC Policy on Traceability of measurement results (available from www.ilac.org)

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Setting Target Measurement Uncertainty

Measurement results are only fit for purpose if the measurement uncertainty (MU) is reliable and has a magnitude small enough for the intended use. The target MU is the maximum admissible uncertainty defined for a specific measurement goal.

In compliance assessment, the MU should be small enough to enable identification of deviations from compliance relevant to the interests to be protected (such as public health or industrial productivity). Too large an uncertainty would not provide the required protection, while an uncertainty that is too small could mean the use of unnecessary expensive measurements.

The Eurachem/CITAC guide on 'Setting and Using Target Uncertainty in Chemical Measurement' suggests how to set upper boundaries for the uncertainty based on the intended use of the result [1].

The impact of the MU on decisions is illustrated in a fictional scenario.

Mr. Reis is a farmer planning to sell oranges to a juice producer. The juice producer checks oranges for thiabendazole pesticide residues and Brix level (degrees Brix provides a measure of orange juice sweetness). The producer only accepts oranges with thiabendazole residues below 1 mg kg^{-1} and a Brix level above 55 °Bx, paying more if the Brix level is above 65 °Bx.

Mr. Reis contracted Laboratory C to analyse his oranges before shipping them to the producer knowing that the customer also checks the oranges in its laboratory.

Mr. Reis was very happy with the results provided by Laboratory C although the pesticide residue analyses were expensive.

The producer accepted the oranges but decided to pay less than expected.

After asking the juice producer, the detailed results of both laboratories were compared. This showed that although the results were metrologically compatible they supported different decisions on the oranges' price.

Laboratory C:
Thiabendazole: (0.592±0.019) mg kg^{-1} (k = 2; 95 %)
Brix: (70±25) °Bx (k = 2; 95 %)
(k is the coverage factor for stated confidence level)

Juice producer's Laboratory:
Thiabendazole: (0.51±0.20) mg kg^{-1} (k = 2; 95 %)
Brix: (61.2±1.1) °Bx (k = 2; 95 %)
(k is the coverage factor for stated confidence level)

The measurement of thiabendazole residues performed by Laboratory C is associated with an extremely low uncertainty making measurements more expensive than necessary. However, the uncertainty associated with the determination of the Brix level is too large, making compliance decisions too uncertain.

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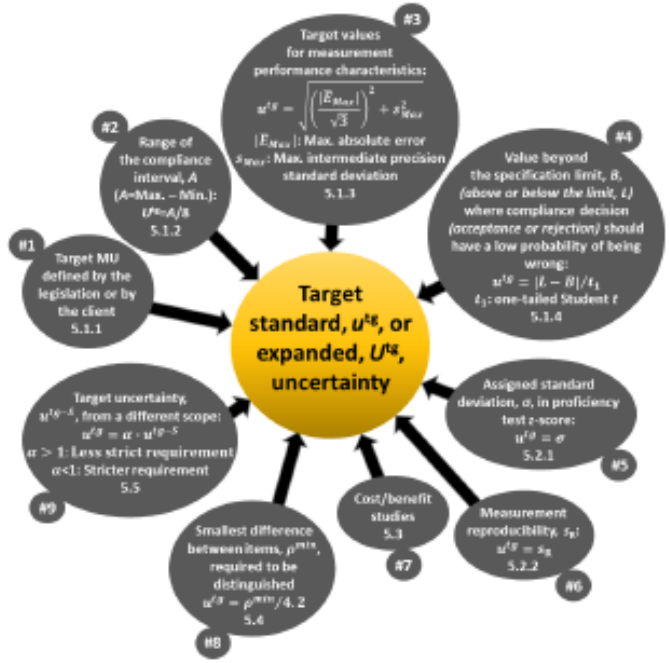
Measurement results are only fit for the intended use if the measurement uncertainty (MU) is smaller than a maximum acceptable value (i.e. the target MU).

Even if the customer or the regulator does not define the target MU, the laboratory should define it to decide if the measurement is fit for the intended use. The Eurachem/CITAC guide [1] suggests the use of different indicators of the measurement quality requirement to define the target MU. Information used to define the target MU is presented from the most likely to become harmonised to the ones supported with less adequate data. The following figure presents this hierarchy of adequacy with numbers from #1 to #9.



Approaches to defining the target MU described in the Eurachem/CITAC Guide, where u^{tg} and U^{tg} represent the target standard and expanded uncertainties, respectively. (the numbers in the bottom of the circles identify the sections of the Guide)

Reference

[1] R. Bettencourt da Silva, A. Williams (Eds.) Eurachem/CITAC Guide: Setting and Using Target Uncertainty in Chemical Measurement, (2015). ISBN 978-989-98723-7-0.
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First English edition 2018

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Topic of the scientific workshop:
“Validation of targeted and non-targeted methods of analysis”

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Pancyprian Union of Chemists
Division of Quality Assurance
Eurachem Cyprus Committee
email: qualityassurancepuc@gmail.com

Laboratory Accreditation

A TWO-DAY TRAINING COURSE - CRITICAL ISSUES OF THE ACCREDITATION STANDARDS - ISO/IEC 17025:2017 AND ISO 15189:2012

21st -22nd February 2019 ***Cleopatra Hotel, Nicosia, Cyprus***

https://eurachem.org/index.php/events/calendar/icalrepeat.detail/2019/02/21/21/-/laboratory-accreditation-2-day-training-event

the REAL nature of this event

Theory is good,
practice is better!

Please:

- Interrupt to ask questions!
- Talk to each other!
  Especially if your competences and experiences are different!
- Make mistakes!
  It is the best way…
  to avoid them later!!

Get's your own hands in the "pasta"!