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Interpretation of ISO/IEC 17025 Requirements for Measurement Uncertainty and Traceability

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New Requirements of ISO/IEC 17025

- **Based on current interpretation of 'good measurement practice'**
- **Extensive consultation leading to common interpretation and new Guides**
- **Accreditation bodies progressively implementing new requirements**
- **Target implementation date of Dec 2002**

International 'Guides' and ILAC MRA will help ensure 'level playing field'

The Distinction Between Calibration and Testing Labs

- More rigorous approach required for calibration labs
- Accreditation bodies apply additional ‘custom and practice’ requirements eg MU must be GUM compliant
- Calibration mode not much applied to chemical measurements and needs to be better developed

ISO/IEC 17025 MU Requirements

- **An uncertainty evaluation is required for all measurements**
- **Labs shall at least attempt to:**
  - **identify all significant components**
  - **make a reasonable estimation of U**
  - **ensure that reported results do not give a false impression of U.**

International MU Interpretation / Policy Documents

- ISO Guide to Uncertainty in Measurement, 1995
- E/C Guide to Quantifying Uncertainty in Analytical Measurement, 2001
- ILAC G17 (2002), Introducing the Concept of Uncertainty of Measurement in Association with the Application of the Standard ISO/IEC 17025
- APLAC Policy, Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing, Draft 3, 2002

International MU Policy

- The ISO GUM and Eurachem / CITAC strategies are recommended but not compulsory
- Strategies based on reproducibility need to also consider other significant effects
- The degree of rigour required depends on the end use of the measurement - it must facilitate reliable decisions

International MU Policy - contd

- The evaluation of uncertainties associated with qualitative tests is not required
- Any limitations associated with traceability and MU claims need to be reported with results
- It is expected that reporting MU will become the norm with time

Different Approaches to Estimating MU

Identification of significant effects, followed by:

1. **Mathematical combination of components**
2. **Evaluation based on method validation, PT and QC precision data**
3. **Evaluation based on professional judgement / literature data - e.g. Horwitz**

All approaches can be GUM complient -?

ISO/IEC 17025 Traceability Requirements

- Equipment shall be calibrated before use
- Lab shall have a program and procedure for calibration of measurement standards, including RMs
- Calibrations and measurements must be traceable to SI, where feasible
- Where above is not possible / or not relevant , traceability to other appropriate measurement standards is required, such as CRMs

Traceability Requirements - contd

- Traceability achieved by linking measurements to relevant standards
- Measurement standards, including CRMs, need to be provided by a competent supplier
- Accredited calibration labs are considered competent
- The degree of rigour required depends on the contribution of the calibration uncertainty to the total uncertainty

International Traceability Interpretation / Policy

- ILAC guides - G2, G9, P10 - Refer to traceability to CRMs and RMs and recognize:
  - There are difficulties with chemical measurements
  - However, chemistry is not in principle different
  - There is some confusion concerning traceability to SI, CRMs, methods
- Literature papers - Have helped develop the concepts and strategies
- Draft E/C Traceability Guide - Provides a description of a technically rigorous yet simple and achievable strategy

A Strategy for Establishing Traceability

- Define the measurand
- Decide types of references and units
- Establish the measurement equation
- Establish the traceability of each quantity in the measurement equation
- Consider the traceability of any other quantities that significantly affect the measurement
- Report the traceability

Example 1- Cd in soil

- **Measurand** Total Cd in soil, measured in mg/kg
- **Equation** $C = I \cdot \frac{dC}{dI} \cdot \frac{V}{m \cdot R}$ mg/kg
- **Traceability**
  - $I \cdot \frac{dC}{dI}$ is traceable to SI through PS - CRM
  - R is traceable to SI through matrix CRM or ...
  - m and V are traceable to SI through calibrated standards
  - Sample drying temperature is also important

If the model is valid then C is also traceable to SI

Traceability of RMs

- **Traceability of CRMs / RMs established by supplier:**
  - **Through primary (or reference) methods to SI**
  - **Through consensus values to RM/SI?**
- **Traceability of standard solutions prepared from commercial chemicals established by user**
  - **Through mass, volume and purity to SI**

For physical measurements, traceability of standards assured by accreditation of cal labs.

We need an equivalent system for chemical standards

What National Metrology Institutes Are Doing to Help

- Developing primary methods, CRMs etc.
- Demonstrating the equivalence of national standards
- Providing links for traceable and ‘fit for purpose’ RMs
- Organizing metrologically based PT
- Providing training and advisory services

Helping testing and calibration labs establish their traceability

Conclusions

- Good progress has been made in interpreting and implementing the MU requirements
- The draft Eurachem/CITAC guide on traceability provides a technically rigorous, yet simple strategy, that should be adopted by ILAC
- There is still work required to assure the quality of chemical standards
- There is still work to be done to train and gain the commitment of accreditation staff/assessors

ILAC Traceability Guides

- **ILAC Guides on Traceability - G2 (1994), P10 (2002)**
- **ILAC Guide on RMs - G9 (1996), G12 (2000)**

Assessing the Quality of RMs

- Accreditation to ISO34/ILAC Guide
- Evidence of conformance with ISO REMCO Guides
- Evidence of traceability to NMI or reference lab measurement values
- Other third party verification of RM
- Track record of producer