



RM's and PT's from accredited producers/providers – what does it mean?

LGC 6th Environmental Laboratory Quality Day – 17th Nov 2011

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Outline

- Requirements for Accreditation
- Reference Materials
- Proficiency Testing



ISO17025 Requirements

Clause 5.9 states:

The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of results. The monitoring shall be planned and reviewed and may include.....

.....regular use of **CRMs and/or IQC**

.....participation in **ILCs or PT** programmes....



ISO17025

Clause 5.6.2.2.2

Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, **certified reference materials**, agreed methods and/or consensus standards, are required as for calibration (ref 5.6.2.1.2)

Clause 5.6.2.1.2

.....the use of **certified reference materials** provided by a **competent supplier** to give a reliable characterisation of the material.....



ISO17025

Clause 4.6.1

The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations.

Clause 4.6.4

The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration.....



ISO 17011:2004

- **Standard by which accreditation bodies (e.g. UKAS) are required to operate**
 - This requires the AB to ensure accredited laboratories participate in PT or other comparison programmes where available and appropriate.



Reference Materials



So you need to use a (C)RM?

- **WHY?**
 - Method validation
 - Calibration
 - Estimation of measurement uncertainty
 - Training
 - Internal quality control
 - External quality assurance (proficiency testing)
 - To keep my accreditation body happy??!!



How do you choose a (C)RM?

- **First you have to find one!**
 - Matrix reference materials
 - Pure materials
 - CRMs
 - Calibration standards
 - QC Materials
- **Determine suitability of the material**
 - For the technical application (matrix, range etc)
 - Confidence and reliability (production of the material assigned values and associated uncertainties)



Suitability of the material

- **Traceability** – used for calibration? How has the property value(s) been assigned?
- **Homogeneity** – what is the potential for heterogeneity within the material, how ‘homogenous’ does it have to be?
- **Stability** – Inherent stability of matrix and property of interest? How long does the reference material need to be stable? Has stability been checked?



Reference Materials

- **Accreditation can be sought to meet the requirements of**
 - ISO Guide 34:2009 (General requirements for the competence of reference material producers)
 - ISO/IEC 17025 (Calibration)
 - ISO/IEC 17025 (Testing)
 - Occasionally also see RM's certified to ISO9001



Determining the Competence of RMP's

- **ISO Guide 34**
 - competent to produce RM's which are traceable, homogenous and stable. Fit-for-purpose.
- **ISO/IEC 17025 (Calibration)**
 - assigned values of RM are competently generated. May need to establish homogeneity and stability.
- **ISO/IEC 17025 (Testing)**
 - may demonstrate suitability of RM but information is usually required on traceability, homogeneity and stability.
- **Certification to ISO 9001**
 - does not demonstrate competence of production or suitability of RM in any way. Further information is always required.



Proficiency Testing / Inter-Laboratory Comparison



Proficiency Testing - Uses

- **Evaluation of laboratory performance**
 - specific tests or measurements
 - monitoring laboratories' continuing performance
- **Identification of problems in laboratories**
 - inadequate test or measurement procedures
 - effectiveness of staff training and supervision
 - calibration of equipment
 - interlaboratory differences



Proficiency Testing - Uses

- Additional confidence to laboratory customers / regulators / accreditation bodies
- Learning points for laboratories based on the outcomes of schemes / comparisons
- Establishing the effectiveness and comparability of test or measurement methods
- Validation of uncertainty
- Facilitate improvements



Proficiency Testing - Types

- Qualitative and quantitative
- Data transformation
- Single item testing (round robin)
- One-off exercises
- Continuous schemes
- Sampling



Practical Considerations

- Need to look at all QA/QC measures
- Economic impact of participation
- Resource required to review the data
- Effective handling of the outcome including review and corrective actions
- Appropriateness of the scheme
- Possibility to rotate participation



Accreditation Body Expectations

- Demonstration of competence
- Want to see that you perform well?
- Well planned participation
- Want to see that you address deficiencies
- Want you to treat the PT test item as a normal sample



PT – The Ultimate QA Tool

- **Focus on the assessment of the effectiveness of corrective actions as well as the results**
- **Look at the trends**
- **Encourage use of PT in method development and validation**
- **Select PT providers who are:**
 - Competent (accredited or otherwise assessed)
 - Consider educational aspects
 - Offer well designed PT Programmes



Proficiency Testing

- Accreditation can be sought to meet the requirements of ISO/IEC 17043:2010 (Conformity assessment — General requirements for proficiency testing)
- Accreditation has been available since 2002
- Currently 9 organisations hold accreditation in the UK, with approximately 50 across Europe.



Well Designed PT

- Use of test method information to assist in interpretation of results
- Use of >1 sample per round
- Design of rounds to test the capability of lab (range of concentration, matrix types and so on)
- Excess samples available for retest and/or use as an in house reference material



Well Designed PT

- Prompt release of reports
- Provide assistance/information to allow lab to interpret results
- Provide an estimate of MU on assigned/ reference value
- Encourage labs to report MU and consider in the data evaluation



Well Designed PT

- Provide appropriate samples to cover the whole analytical process
- Provision of workshops, user groups
- Liaison with key stakeholders (e.g labs, end users, regulators, ABs etc)



Summary

- Plan your participation
- Participate
- Review participation
- Maximise benefits for you
- Choose a competent provider
- Consider other QA tools



Resources

- **Online RMP Databases**

- <http://www.rminfo.nite.go.jp/rminfo/en/index.do>
- <http://www.comar.bam.de>

- **Online PT Database**

- <http://www.eptis.bam.de>

- **Technical Guidance - Reference Materials;**

- UKAS TPS 57: UKAS policy on the selection and use of reference materials
- EA document EA-04/14 Selection and Use of Reference Materials
- ILAC G9:2008 Guidelines for the use and selection of reference materials

- **Technical Guidance – Proficiency Testing;**

- UKAS TPS 47 - UKAS Policy on Participation in Proficiency Testing Schemes
- ILAC G22:2004 Use of Proficiency Testing as a Tool for Accreditation in Testing
- EA document EA-04/18 Guidance on the level and frequency of proficiency testing participation



Questions ?



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