Quality Standards

Outline

- Quality standards
- Brief comparison
- ISO/IEC 17025 standard
- Management requirements
- Technical requirements

Quality standards

- ISO 9001:2000
  - used by organisations supplying products or services
  - Certification - BSi, Lloyds, SGS etc
- ISO/IEC 17025 :2005
  - requirements for the competence of calibration and testing laboratories
  - Accreditation - UKAS
- ISO 15189:2003
  - medical requirements for quality and competence
  - Accreditation - CPA
- Good Laboratory Practice Regulations 1999
  - non-clinical safety studies listed in sectoral Directives
  - Compliance - UK GLP MA

ISO/IEC 17025 vs ISO 9001

- Management requirements of ISO/IEC 17025:2005 mirror those in ISO 9001:2000
  - to comply with ISO/IEC 17025 the laboratory must operate a quality management system that meets the principles of ISO 9001
  - ISO/IEC 17025 covers technical competence requirements not covered by ISO 9001
- ISO/IEC 17025
  - first choice for measurement laboratories

Management system

- Quality Manual
- Quality Assurance
  - organisational structure underpinning reliable results
    - internal QA gives confidence to management
    - external QA gives confidence to the customer
- Quality Control
  - planned activities designed to verify the quality of the result

Quality *control* vs Quality *assurance*

Quality Control

- A planned system of activities to provide a quality product
  - what you do on a day to day basis

Quality Assurance

- A planned system of activities designed to ensure that the quality control system is effective
  - how you do it and prove that it has been done

Aiming to provide a product or service (analytical results) that will satisfy given requirements for quality (fit for purpose)

Quality control

It costs less to prevent a problem than it does to correct it!

- Run blanks
  - check for contamination or interferences
- Analyse check (QC) samples
- Use statistical quality control
  - plot QC results on control charts
  - check the method is working consistently
- Use reference materials/substances
  - calibration
- Level of QC depends on the consequence of being wrong

ISO/IEC 17025

Implications for Laboratories

Why ISO/IEC 17025?

- Basis for “competence”
- International standard
- Facilitates mutual recognition and multilateral agreements
- Enables greater comparability of operations and results

ISO/IEC 17025 Sections 4 & 5

- Much of the text is guidance
  - the standard is intended to stand alone
- Less specificity, greater flexibility
- More freedom, more responsibility

} compared to previous standards

- Essentially an expression of good practice

ISO/IEC 17025 Standard

- Clause 4
  - specifies the requirements for sound management
- Clause 5
  - specifies the requirements for technical competence for the types of test the laboratory undertakes
- Appendix A
  - cross references to ISO 9001:2000
- Appendix B
  - guidelines for specific fields

Clause 4 - Management (1)

- 4.1 Organization
  - legal responsibility of the laboratory
- 4.2 Management system
  - content of quality manual less rigidly defined than in previous standards
- 4.3 Document control
  - issue number, revisions marked etc
  - computer generated documentation permitted
- 4.13 Control of records

Clause 4 - Management (2)

- 4.4 Contract review
- 4.5 Subcontracting
- 4.6 Purchasing of services and supplies
- 4.7 Customer/laboratory relationship
- 4.8 Complaints
- 4.10 Improvement

- 4.14 & 4.15 Audit and review
  - customer feedback

Clause 4 - Management (3)

- 4.9, 4.11, 4.12 Formal procedure for nonconforming testing
  - cause analysis
  - corrective action
  - monitor and evaluate effectiveness
  - continuous improvement
  - preventive action

Clause 5 - Technical requirements

- 5.2 Personnel
- 5.3 Accommodation and environmental conditions
- 5.4 Method selection and validation
  - measurement uncertainty
- 5.5 Equipment
  - equipment qualification
- 5.6 Measurement traceability
- 5.7 Sampling
- 5.8 Handling of test and calibration items
- 5.9 Assuring the quality of test and calibration results
- 5.10 Reporting the result
  - opinions and interpretations

Validation (ISO/IEC 17025)

"*Confirmation* by examination and the provision of *objective evidence* that the particular requirements for a *specific intended use* are fulfilled"

- specific intended use = analytical requirement (c.f. contract review)
- objective evidence = experimental data → method performance parameters
- confirmation (from comparison of requirement with evidence)

ISO/IEC 17025 Test methods

- Fit for purpose
  - methods/procedures
  - all operations
- Preference for standard methods
  - normally most recent version
- Verification of method performance
- Customer has to agree deviations

Fitness for purpose

- Define the purpose - the problem/enquiry
  - qualitative, semi- quantitative, quantitative
  - constraints: time, cost, quality
  - criticality
- Define the performance criteria
- Experimental plan

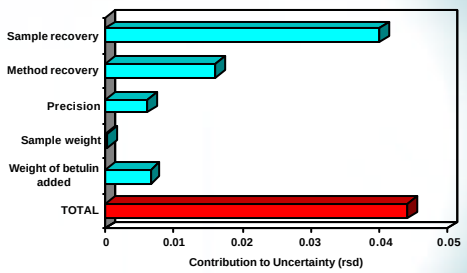
The practical process that determines the suitability of a method for providing useful analytical data

Measurement uncertainty

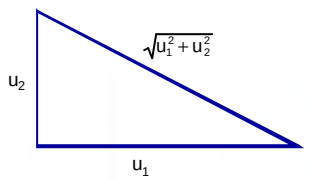
- ISO definition
  "A parameter, associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurand"

The number after the ±

Uncertainty components
Determination of cholesterol



Combining uncertainties



Measurement uncertainty in ISO/IEC 17025

- Calibration laboratories* "shall have and shall apply a procedure…"
- Testing laboratories "shall have and shall apply procedures…."
  - "at least attempt to identify all components and make a reasonable estimation"
  - "…. based on knowledge of performance and … validation data"

**Or test laboratories doing own calibrations*

Traceability

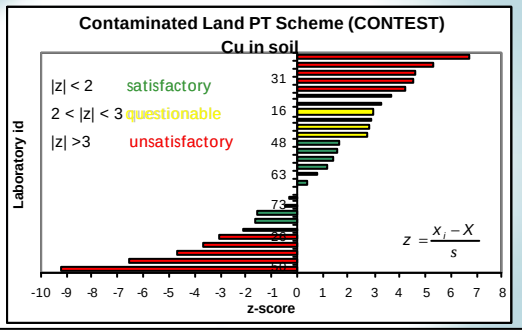
- "Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards through an unbroken chain of comparisons all having stated uncertainties" (VIM 1993)
- 'Stated references'
  - calibration standards
  - traceable reference materials for independent checks

Interlaboratory comparisons (PT schemes)

- Homogeneous samples distributed simultaneously
  - representative of routine test samples
- Results statistically analysed
  - performance of each laboratory evaluated
- Results reported to participants
- Technical advice available from scheme co-ordinator
- Confidentiality maintained

Independent assessment of laboratory performance

Proficiency testing



Summary

- Accreditation provides an independent assessment of a laboratory's quality procedures
- ISO/IEC 17025 is the most commonly used standard in analytical laboratories
- Consistent with good practice and VAM principles
- Main emphasis is
  - increased customer dialogue
  - continuous improvement
- User has freedom but extra responsibility (QA & QC)

Workshop 2
Choosing an analytical laboratory

- Apple grower wants some apples analysed to determine the levels of pesticide residues present
- Analysis is required to ensure residue levels do not exceed the current maximum residue levels defined in legislation
- Apple grower: What questions would you ask the laboratory to establish whether they are capable of carrying out the work?
- Laboratory: What questions would you ask the apple growers before agreeing to take on the work?

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