ISO/IEC 17025:2005
ISO Guide 34:2000

Nuclear Spectroscopy User Forum
NPL – 23rd May 2006
Jeff Ruddle
ISO/IEC 17025:2005 - Background

• Why?
  – to align with ISO 9001:2000

• …but…
  – major revision req’d therefore decided to make them ‘compatible’

• …so…
  – Stds no longer linked, lab can’t make ISO 9000 claims
ISO/IEC 17025:2005 – Main Changes

• Meeting ISO 17025 requirements doesn’t mean meeting ISO 9001 requirements.
• Requirement for continual improvement and focus on customer satisfaction
• ‘clients’ ➔ ‘customers’
• ‘QMS’ ➔ ‘MS’
ISO/IEC 17025:2005 – Main Changes

- Requirement for effective communication.
- Effectiveness of training actions needs to be evaluated.
- QC data shall be analysed and CA taken to prevent incorrect results being reported.
- Annex A cross references updated.
ISO/IEC 17025:2005 – New/Amended Clauses

• 1.4/1.6 ISO 9001 linkage (amended)
• 4.1.5 k) Relevance of Activities (new)
• 4.1.6 Appropriate Communication (new)
• 4.2.2 e) Continual improvement (amended)
ISO/IEC 17025:2005 – New/Amended Clauses

- 4.2.3 Develop and Improve Management System (new)
- 4.2.4 Importance of Customer and Regulatory Requirements (new)
- 4.2.7 Integrity during change (new)
- 4.7.2 Customer Feedback (new)
ISO/IEC 17025:2005 – New/Amended Clauses

- 4.10 Improvement (new)
- 4.15 Management Review (amended)
- 5.2.2 effectiveness of training (amended)
- 5.9.2 QC data review (new)
- Annex A

• Published 15/05/05
  – ILAC 2 year transition

• Assessment via annual visits

• Findings Raised
  – New certificates and schedules issued on clearance

• All organisations to be accredited to 17025:2005 by end of May 2007
ISO/IEC 17025:2005 – Summary

• No essential changes to Technical Requirements
• Greater Emphasis on Improvement
• Most Changes are Minor
• TPS 53 – Details on ISO 9000
• Organisations Being Assessed Against New Version
• Schedules and Certificates Define Date of Standard.
Proficiency Testing Providers

ISO Guide 34:2000
Reference Material Producers
PT Providers - Why assess?

- Valuable tool for Labs and AB’s
  - Must be Reliable
- Labs need confidence in the PT Provider’s competence.
- Accreditation allows for an independent assessment of competence.
- PT providers requested accreditation.
- ISO/IEC 17025 requires that suppliers of critical services are evaluated.
PT Providers – Pilot
Background

• Original Pilot 1996/97.
• Project re-started 2000/01.
• 9 Pilot organisations from a range of disciplines.
PT Providers - First Steps

- Set up Steering Group
- Determine Assessment Approach
- Train Staff – UKAS and external assessors
- Update UKAS processes to accommodate PT assessment
PT Providers - Steering Group

- PT Providers
- Accredited Laboratories
- Laboratory Customers
- UKAS staff and Assessors
- Statistician
PT Providers Assessment Criteria

- Combination of Assessment Standards
- ILAC G13:2000
- ISO/IEC 17025:1999
  - Now ISO/IEC 17025:2005
PT Providers - Identify and Train Staff

• UKAS - Two Assessment Managers, One Accreditation Manager
• Four external Technical Assessors with ISO17025 experience
• One Statistician
• Internal Training Course
PT Providers - Outcomes of pilot

• Areas of Non-compliance
• Guidance Document - PT1
• Technical Policy – TPS 47
• Feedback from Providers and Labs
• Accredited PT Providers
PT Providers - Non-compliances raised against “G13” Clauses
PT Providers - Guidance
Document PT1

• Developed as an output of the pilot
• Amplification of ILAC G13 requirements
• Issued June 2005
• Available on www.ukas.com
PT Providers - Accreditation Organisations

- 8 organisations received accreditation in 2002 following the completion of the pilot
- Subsequently 1 organisation has received accreditation
- Currently 9 applicants from a range of disciplines
PT Providers - Feedback

• Positive feedback received from pilot organisations
• Laboratories have noted an improvement in the service provided
• Technical Assessors have noted better clarity in reporting and increased awareness in lab staff
RM Producers - Why assess?

• Valuable tool for Labs and AB’s
  – Must be Accurate, Stable and Homogeneous
• Labs need confidence in the RM Producers competence.
• Accreditation allows for an independent assessment of competence.
• International drive for RMP Accreditation.
• ISO/IEC 17025 requires that suppliers of critical services are evaluated.
RM Producers – Pilot
Background

• ILAC General Assembly Resolution 8.12 “..against harmonized criteria based on ISO Guide 34 and ISO/IEC 17025 in combination”.

• UKAS Development Project, Part Funded by DTI.
  – Provision an Accreditation Scheme for RM Producers.

• 5 Participant Organisations.
RM Producers - First Steps

- Formation of Steering Committee
- Develop Assessment Approach
- Identify Staff – UKAS and external assessors
- Existing processes used for assessment.
RM Producers - Steering Group

- RM Producers
- Accredited Laboratories
- UKAS Staff
- Independents
- UKRMWG
- ISO REMCO
RM Producers - Assessment Process

• Management System
  – Guide 34 in combination with 17025

• Homogeneity, Stability and Characterisation
  – 17025 (Calibration for single lab, testing for multi-lab)
RM Producers - Assessment Process

• Collaborators
  – ISO 17025 or demonstration of competence

• Certificates
  – ISO Guide 31

• Statistics
  – Principles of ISO Guide 35
RM Producers - Assessment Teams

• Existing Assessment Managers
• Existing Technical Assessors
• Specific Reference Material Resource
  – Dr Steven Westwood & Jeff Ruddle
• Statistical Technical Experts
RM Producers – Pilot Programme Current Status

- Accreditation Mark
- Schedules – ILAC G12 Appendix C and ISO Guide 34 Annex A a.2
- Awareness Amongst Technical Assessors
  - Assessor training days
  - Assessor newsletter
RM Producers - Assessment Findings

Pilot Programme - Spread of Findings

ISO Guide 34 Principle Clauses
RM Producers Assessment
Findings

• “Zero” Clauses
  – 4.4 “Contract Review”
  – 4.9 “Corrective Action”
  – 4.10 “Preventative Action”
  – 5.5 “Environment”
  – 5.6 “Handling and Storage”
  – 5.8 “Material Preparation”
RM Producers Assessment
Findings

• “High” Clauses
  – 4.1 “Quality System”
  – 5.3 “Production Planning”
  – 5.9 “Homogeneity and Stability”
  – 5.15 “Property values and Uncertainties”
  – 5.16 “Certificates”
RM Producers Future Plans

- Launch Event – Summer 2006
- UKAS Update Articles
- Technical Policy Statement – Use and Selection of Reference Materials
- “RM” Document for Producers
- International Harmonisation
## Nuclear Spectroscopy RM and PT Providers

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