



ISO/IEC 17025:2005
ISO/IEC Guide 43-1:1997
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

ISO/IEC 17025:2005 – Implementation



- 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.



ISO/IEC Guide 43-1:1997 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
- ISO/IEC Guide 43-1:1997
- ILAC G13:2000
- ISO/IEC 17025:1999
 - Now ISO/IEC 17025:2005

PT Providers - Identify and Train Staff



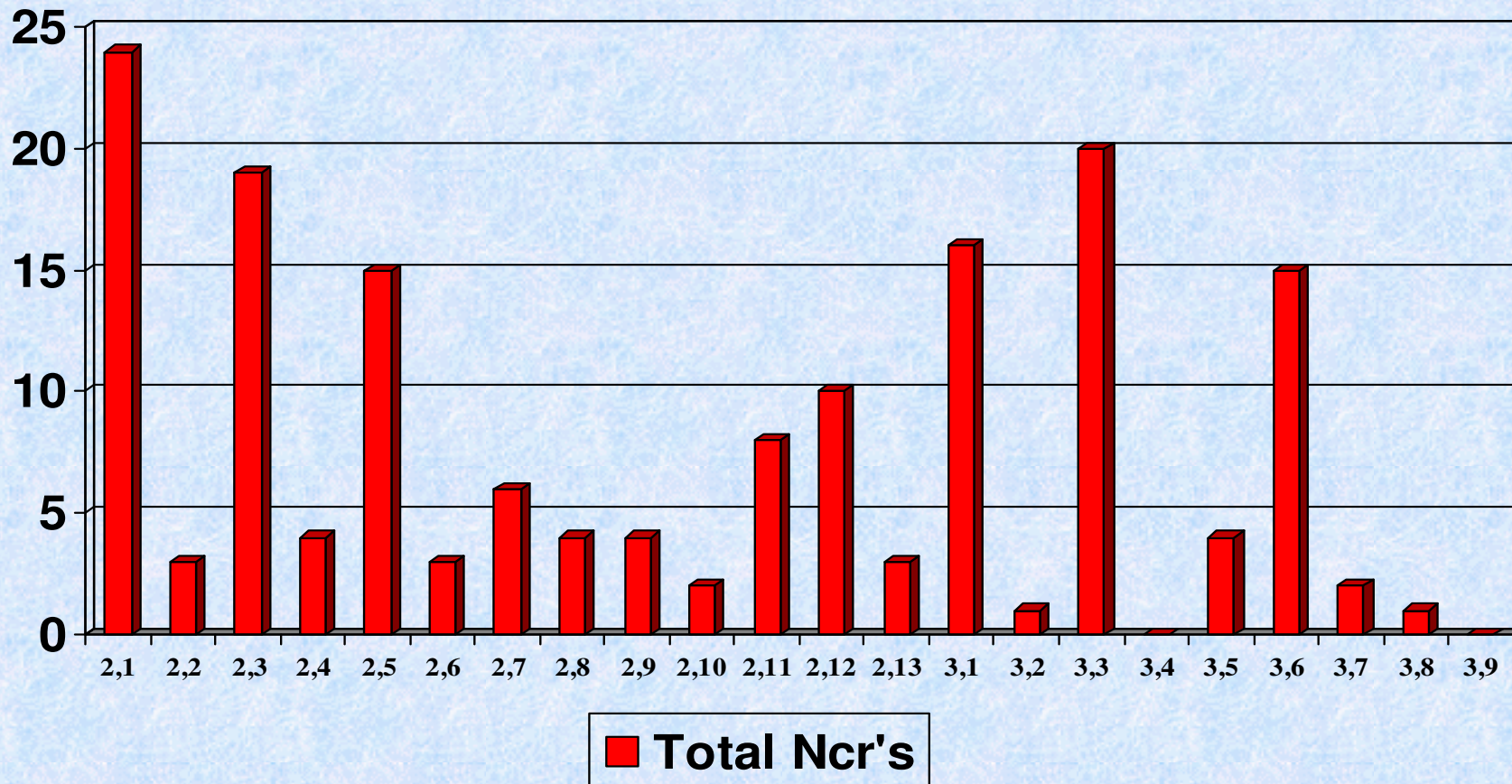
- UKAS - Two Assessment Managers, One Accreditation Manager
- Four external Technical Assessors with ISO17025 experience
- One Statistician
- Internal Training Course

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

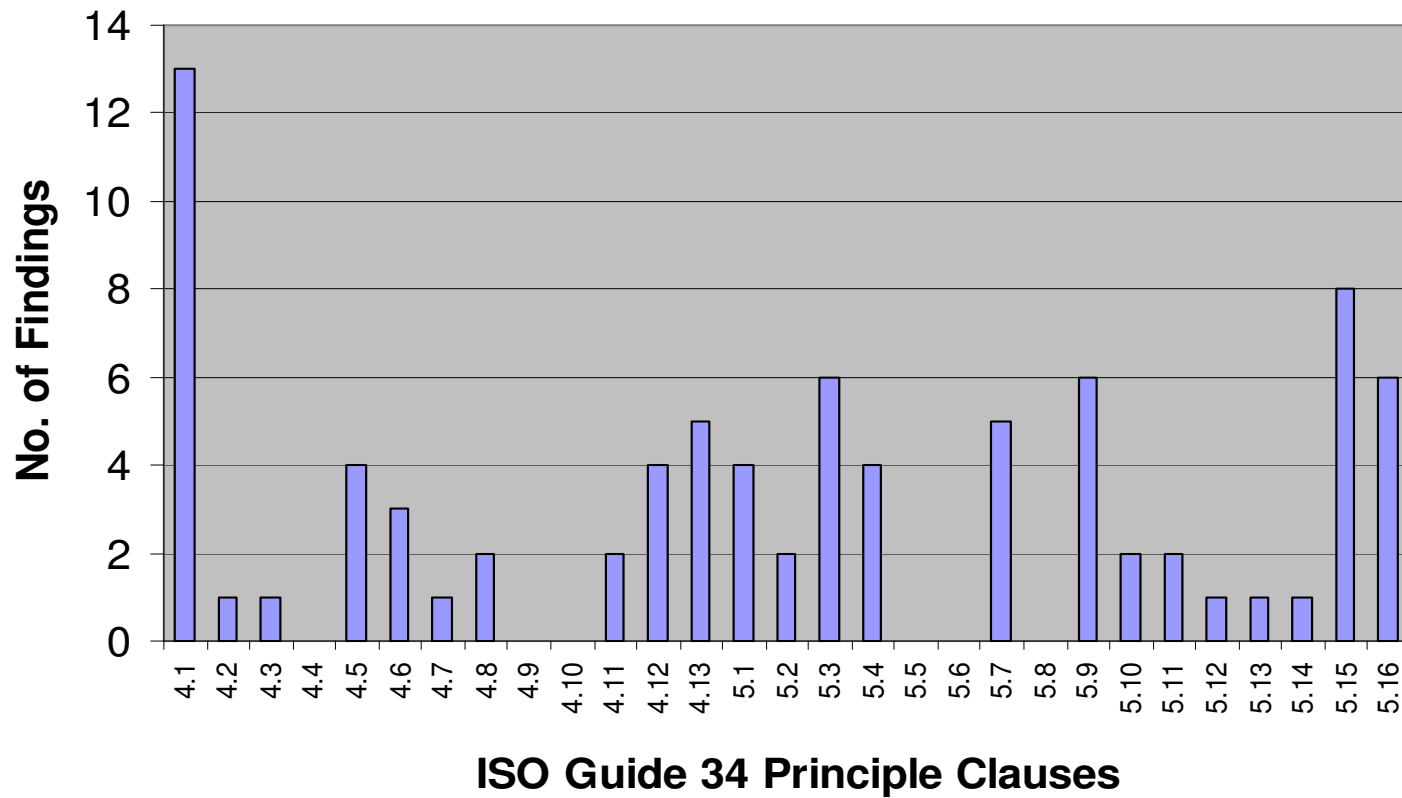


- Accreditation Mark
- Schedules – ILAC G12 Appendix C and ISO Guide 34 Annex A a.2
- Awareness Amongst Technical Assessors
 - Assessor training days
 - Assessor newsletter

RM Producers - Assessment Findings



Pilot Programme - Spread of Findings



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



Organisation	PT	RM	Web
Analytics Inter-lab Cross Checks	Y	Y	www.analyticsinc.com
ERA	Y	Y	www.eraqc.com
IAEA	Y	Y	www.iaea.org
IRMM	Y	Y	www.irmm.jrc.be
New Brunswick Laboratory	Y	Y	www.nbl.doe.gov
NIST	Y	Y	http://physics.nist.gov
NPL	Y	Y	www.npl.co.uk
Oak Ridge National Laboratory	Y		www.ornl.gov
Procorad	Y		www.procorad.org
USE DoE	Y		www.inel.gov