

HN ISO 17043 – The New Standard for Proficiency Testing

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HN The Predecessors of ISO 17043

- ISO Guide 43-1:1997 and Guide 43-2:1997
 - Same generation as ISO Guide 25 for laboratories
 - First generation of guidance for accreditation bodies on proficiency testing
- ILAC G-13:2000
 - Based on ISO Guide 43-1 and ISO 17025:2000
 - ISO 17025:2000 compatibility not good
- ILAC G-13:2007
 - Based on ISO Guide 43-1 and ISO 17025:2005
 - Considered primarily an update of the noncontroversial management system requirements to be similar to those in ISO 17025:2005

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HN Structure

- Management system requirements mirror ISO 17025:2005 very closely
- Structure follows ISO PAS 17005: Conformity assessment - Use of management systems - Principles and requirements
 - Technical requirements before management requirements
 - Opposite of ISO 17025
 - Intended to show that the technical requirements are the primary requirements and that the management system requirements are there to support the technical system

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• Expect same arrangement in next edition of ISO 17025

HN Proficiency Testing Tasks

- Planning and designing proficiency tests
 - Artifacts, measurands, instructions, reference laboratory measurements, test pattern, metrics, etc.
- Operation of proficiency tests
 - Participant instructions, storage, handling, shipping and receiving of artifacts
- Data analysis and evaluation of results
 - Determining assigned values, identifying outliers, applying performance metrics
- Issuing reports

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HN Proficiency Testing Activities

- Proficiency testing is fundamentally a set of administrative and logistical processes on top of some metrological expertise and a competent reference laboratory
 - Reference laboratory not always needed
 - Consensus values
 - Facilities to manufacture test artifact are sometimes needed in addition
 - Usually not necessary in calibration and dimensional inspection

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HN What is a Proficiency Testing Provider?

- Most (all) of the proficiency testing activities can in principle be subcontracted
- Significant discussion in the working group of which activities shall not be allowed to be subcontracted
 - A proficiency testing provider should not be “one person with a phone”
 - ISO 17043 does not allow subcontracting of:
 - Planning of proficiency tests
 - Evaluation of performance
 - Authorization of final report

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HN Homogeneity and Stability

- ISO 17043 put more emphasis and definition onto homogeneity and stability
 - “Criteria for suitable homogeneity and stability shall be established and shall be based on the effect that inhomogeneity and instability will have on the evaluation of the participants' performance”.
 - Requires that they be tested as applicable

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HN Homogeneity

- Homogeneity ensures that each participant receives identical artifacts in split-sample testing
 - Brew a batch of material and distribute samples
 - Uniformity of hardness blocks
- In “calibration testing” homogeneity can be interpreted to mean well-defined measurands
 - Example:
 - Ring gages with good cylindricity
 - Or identified measurement orientation and location

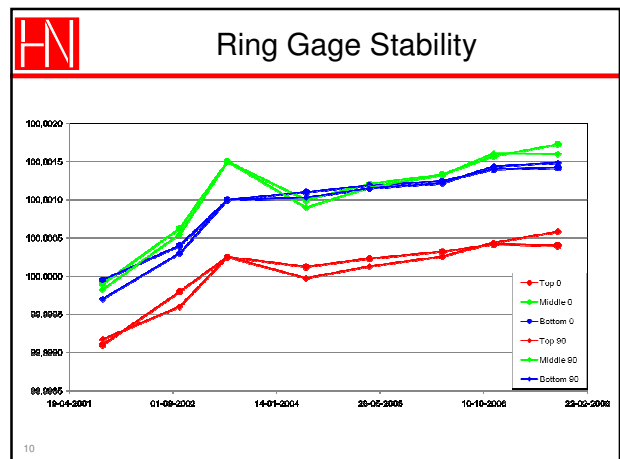


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HN Stability

- Proficiency test items shall be demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the proficiency testing
- Very difficult to prove in advance
- Must be verified when closing a testing round

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HN Traceability

- Required for assigned values for calibration
 - Uncertainty is per definition required for traceability
- Calibration laboratories are in the business of providing traceability
 - Makes sense that the values they are judged against shall also be traceable
 - Weighted average results can also be traceable
 - If the results that are averaged are traceable
- Most controversial requirement in the standard

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HN E_n-Values Background & Assumptions

- Assumptions:
 - Uncertainty stated at 95% coverage level
 - Errors follow normal distributions
 - Reference values are correct within their stated uncertainties
 - Participant values and reference values are independent
- 5% of E_n-values outside +/-1 should be expected based on these assumptions
 - Excessive failures can be due to:
 - Atypical measurement result for the process
 - Underestimated uncertainty

HN When Are These Assumptions Not True?

- When the resolution is the dominating uncertainty component
 - Calibration of hand gages
 - The uncertainty does not follow a normal distribution
- When the reference laboratory is the traceability source for the participant
- When the reference laboratory quotes conservative (or optimistic) uncertainty values

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HN How Bad Is It?

- Accreditation bodies generally require accredited laboratories to report unsatisfactory results
 - $E_n < -1$ or $E_n > 1$
 - With corrective action
 - Did you make a blunder?
 - Measurement not representative of your process
 - Are you just too optimistic?
 - Uncertainty not appropriate for your process

HN Figuring out Your Minimum Uncertainty

$$U_{\min} = \sqrt{\text{Error}^2 - U_{\text{Ref}}^2}$$

- This uncertainty would yield $E_n = 1$
 - Compare to your quoted uncertainty
 - Isolated cases (5% of the time) of 20%-30% difference OK
 - Uncertainty quoted at 95% coverage
 - Consider revising your uncertainty claim
 - Consistent 20%-30% difference or isolated larger difference without assignable cause
 - Revisit your uncertainty analysis

HN How Good Are Your Uncertainty Estimates?

- Long term average absolute E_n -values should be about 0.4
- BFAs:
 - Reference laboratories quote realistic uncertainty
 - Reference laboratories' errors follow a normal distribution
 - Your errors follow a normal distribution
 - Your measurements and the reference laboratory's measurements are independent

HN Conclusions

- ISO 17043 adds new requirements to proficiency testing providers
 - Homogeneity and stability
 - Traceability in the field of calibration
- Should improve the value of the testing
- Other changes, e.g. in subcontracting has little or no impact on participants
- No change in performance evaluation
 - Participants should make their own evaluations to get the full benefits of the testing

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