

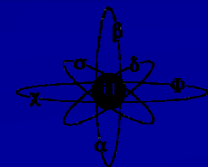
Revision of ISO 13528: Statistical Methods for PT by Interlaboratory Comparison

Eurachem PT Conference

4 October, 2011

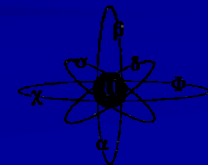
Daniel Tholen, M.S.

American Proficiency Institute (API)



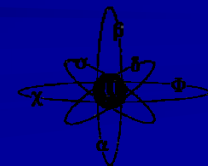
Revision of ISO 13528

- ISO TC69
- Ballot CD1
- Major revisions agreed by TC69/WG9
- Proposed changes not accepted
- Next steps



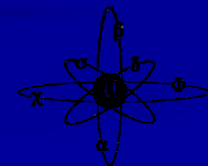
ISO TC69: Application of Statistical Methods

- TC69 is a “Horizontal Committee” in ISO – all other TCs are obliged to follow TC69 Standards, if applicable
- TC69 Standards must therefore be broadly applicable – no language for specific use
 - 23 Participating member countries
 - 29 Observing members
 - 11 Organizations in liaison, including ILAC
- Secretariat is AFNOR (France)



ISO TC69/SC6

- ISO 13528 developed by TC69 Subcommittee 6 on *Measurement methods and results*
 - Secretariat is JISC (Japan)
- TC69/SC6 Working Group 9 on Statistical methods for PT by ILC
 - Convener, D. Tholen



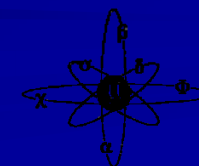
ISO 13528:2005

- Project proposed in 1997 and published in 2005, but writing was completed in 2003
- Written as a requirements document
- Written as statistically optimal methods for evaluating bias and repeatability
- Widely adopted (in part) by ILAC member countries
- ISO 13528:2005 reaffirmed in 2009
- ILAC work proposal to revise ISO 13528 was approved in 2010



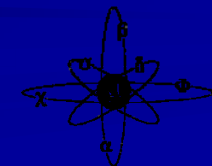
Revision of ISO 13528

- ISO TC69/SC6 met in 2010 and agreed to form WG9.
 - Agreed to make a “minor revision” of the document to correct errors and areas of confusion and to consider changes suggested by IUPAC Harmonized Protocol (2006).
- CD1 ballot in March, 2011
 - 14 “Yes” (advance as DIS), 4 “No”
 - Many comments received (72 pages)



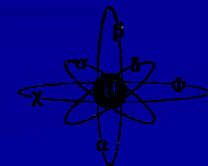
Revision of ISO 13528

- ISO TC69/SC6/WG6 met in July, 2011 and reviewed the comments received.
 - No major disagreements
 - Agreed to re-ballot as CD due to the large number of comments and the significant changes agreed by WG.
- Next draft is in preparation
- To be balloted as CD2 in time to discuss at next TC69 Plenary, June, 2012.
- Publication no earlier than 2013.



Changes to ISO 13528

- Nothing is certain.
- Several changes have been agreed by SC6/WG9, and were not challenged in comments to ballot CD1.
- Several changes suggested by comments, and agreed by SC6/WG9 in 2011 could be changed later



Probable Changes to ISO 13528

- Change language to be more as guidance and less as requirements
- Add guidance for qualitative and ordinal results
- Rearrange sections to reflect progression of activities in ISO/IEC 17043
 - Design
 - Review participant results
 - Produce summary statistics and scores
- Put all examples in an informative annex



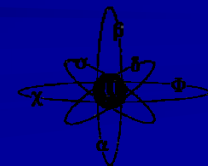
Probable Changes to ISO 13528

- Remove requirements that could lead to PT results that are different than what a laboratory would report to a customer
 - Number of replicates
 - Number of significant digits
 - Reporting results below lab's LoQ or LoD
- Better consideration for calibration PT
- Enhanced discussion of En and Zeta
 - Consider both the numerator (accuracy) and denominator (uncertainty), not just $< \text{ or } > 1.0$



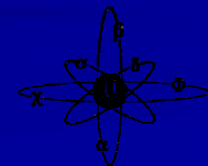
Probable Changes to ISO 13528

- Enhanced discussion of use of reference values and mean from expert labs as assigned values
 - Align this section with ISO Guide 35
- Add discussion on the correlation between participant result and assigned value
 - Allow use of z' when the assigned value is the consensus mean



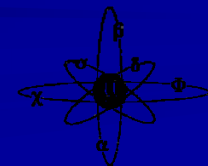
Probable Changes to ISO 13528

- Add 2 more robust estimates for mean
 - Median and Hampel Qn
- Add 3 more robust estimates for SD
 - nIQR, MAD, Hampel Qn
- Add guidance on outlier removal
- Enhanced discussion of composite scores and “expert” scoring.



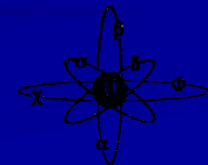
Proposed changes that will not occur (probably)

- Will NOT align (fully) with ISO Guide 35
 - PT has different purpose than CRM
- Will NOT change multiplier for uncertainty of robust mean (from 1.25 to 1.05 or less)
 - Considered to be a reasonable precaution for datasets with unknown levels of contamination



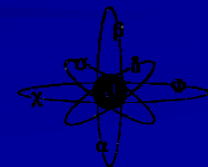
Next Steps

- Convener to prepare next draft
- Ballot as CD2 (to advance as DIS)
- Review ballot results and comments (6/12)
- Revise again.....
 - Ballot again as CD? Ballot as DIS?
- Consider CD/DIS comments in 2013
- Ballot as DIS or FDIS
- Publish in 2013? ... 2014? ...



ILAC PTCG WG6

- Within ILAC PT Consultative Group
 - For ILAC members who cannot access TC69 through their National Standards Body
- Will receive drafts at same time as SC6/WG9, opportunity for informal comment
- Opportunity to submit formal ILAC comments on balloted CD, DIS, FDIS
 - ILAC cannot vote, but can comment
- See me to join PTCG WG6



The End

Thank you!

