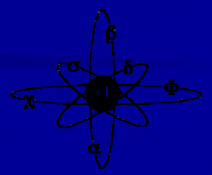
The Perspective of the Independent Consultant

Wiley PT Symposium

AOAC, Anaheim

17 September, 2007

Dan Tholen, MS

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Traverse City
MICHIGAN
Detroit
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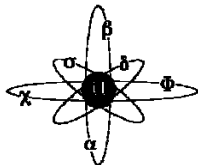
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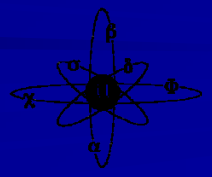
Traverse City and PT

- “Home” of PT, where CAP Surveys began in late 1960’s, until 1990 (40000+ medical labs)
- Key originators: Brad Copeland MD, Larry Skendzel MD, Jack Youden, Frank Stulen
- Also the birthplace of numeric control of machines (1948) - John Parsons and Stulen
- Current home of API
  - Medical PT, 15000 labs
  - Food PT

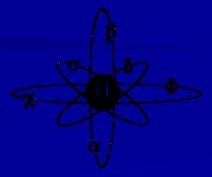


What's the perspective of the Independent Consultant?

- Somewhat clouded by jetlag

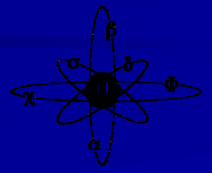
2005-2007 Travel

- Argentina
- Australia
- Austria
- Brazil
- Canada
- China
- Denmark
- Dubai
- France
- Great Britain
- Honduras
- Hong Kong
- Japan
- Malaysia
- Mexico
- New Zealand
- Norway
- Romania
- Slovenia
- South Africa
- Spain
- Sweden
- Switzerland
- Syria
- Taiwan
- Thailand
- Zimbabwe

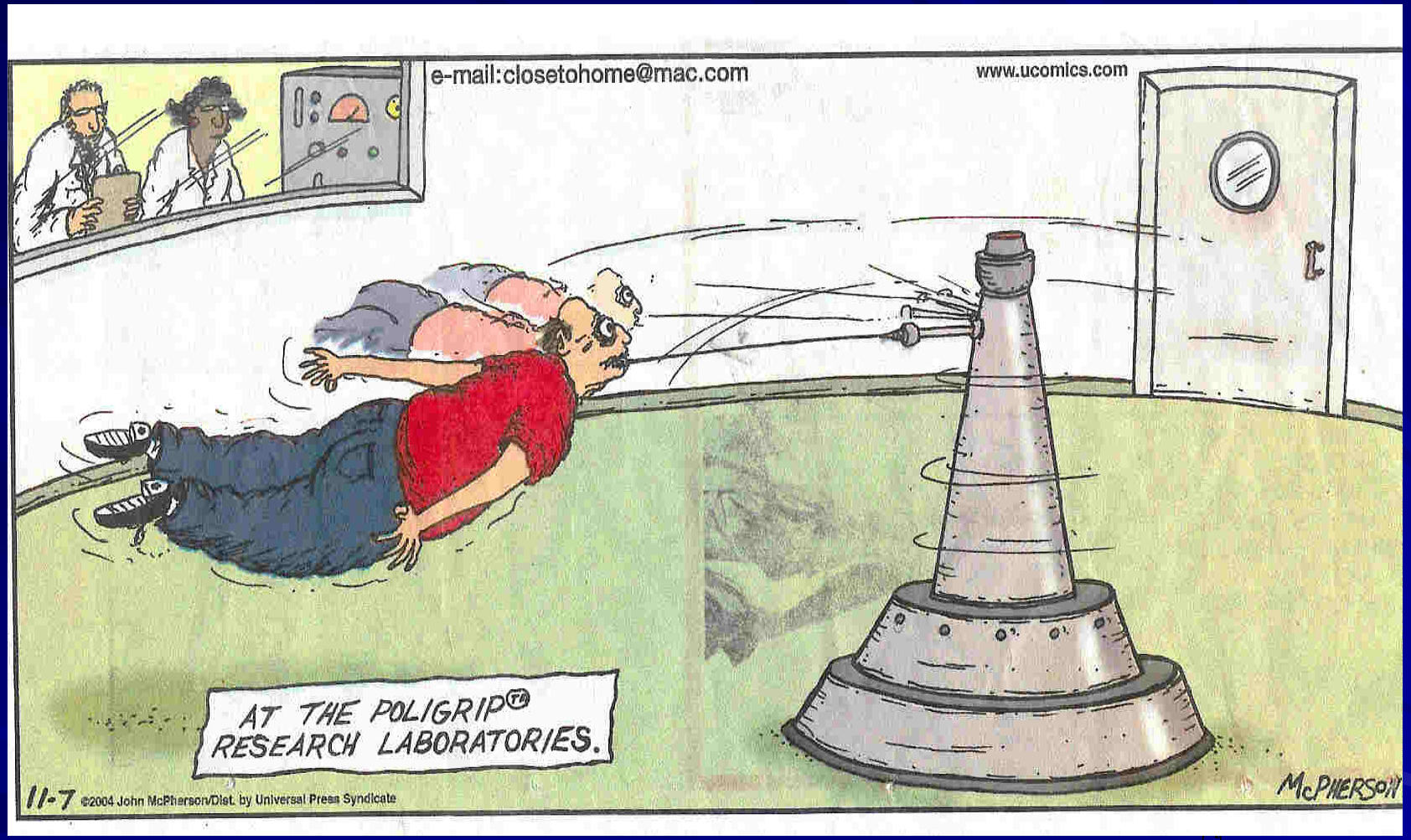


PT Fields of Testing/Calibration

- Environmental - Water
  - Water, Soil, Tissue
  - Sampling
- Medical - Chemistry
  - Chemistry, Hematology
  - Anatomic, Microbiology
- Calibration
  - Electrical, Dimensional
  - Hardness, Temperature
  - Mass, Volume, Acoustic
- Automotive emissions
- Food
  - Chemistry, Microbiology
- Construction materials
- Mechanical properties
  Toy safety
- Petroleum
- Telephone radiation
- Sensory evaluation
- …etcetera




FEAR-O-SENSOR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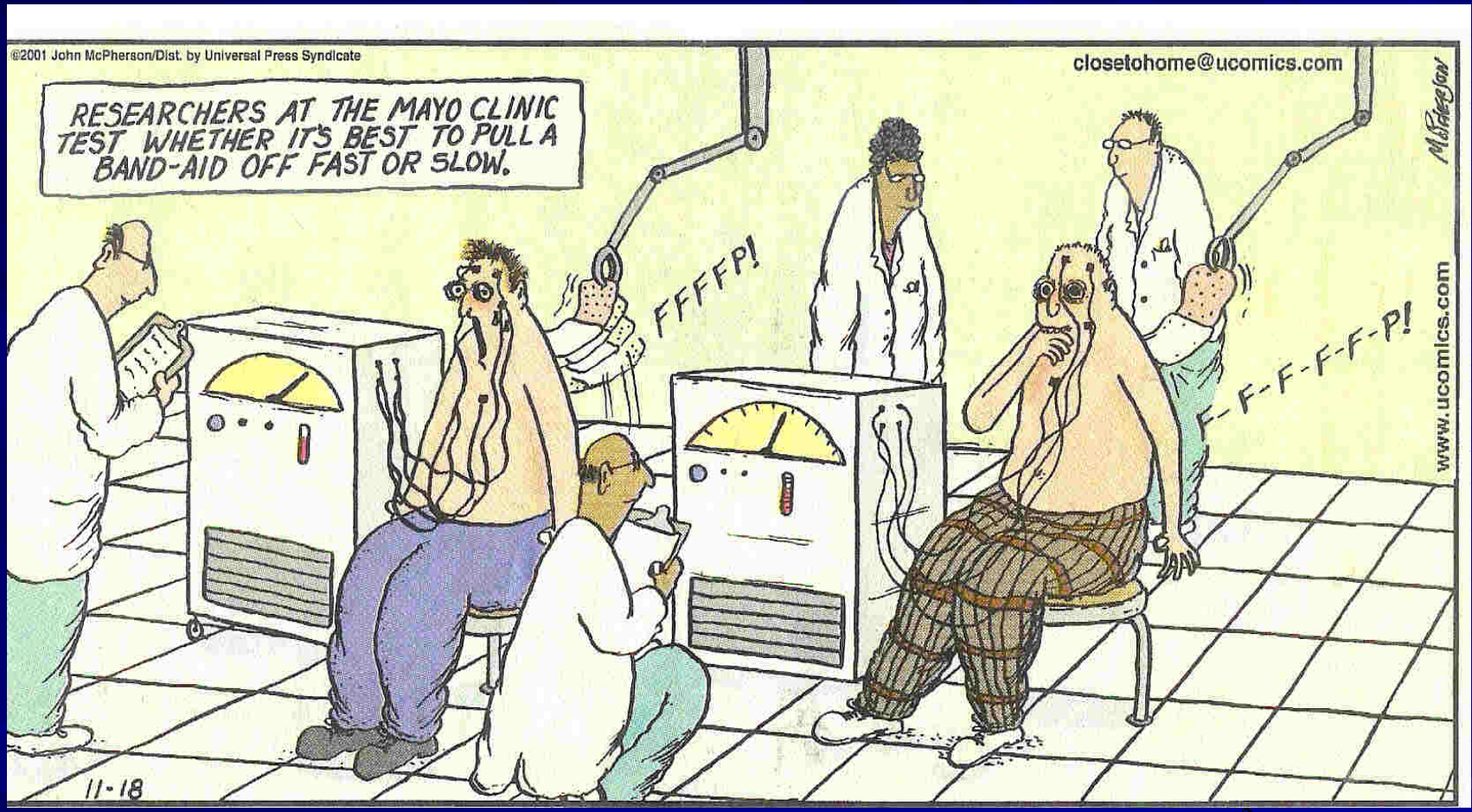
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Perspective of the Independent Consultant

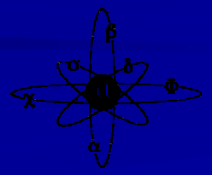
- PT is experiencing explosive growth internationally
- This demonstrates the success of the ILAC Mutual Recognition Agreement

Caveat

- I can’t speak for other consultants
- Independent consultants can work on different parts of PT, such as design, sample manufacture, data analysis, accreditation assessments, or assisting labs with error resolution.

But in very general terms….

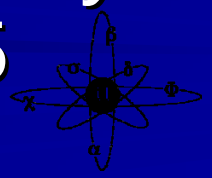
- Its good for consultants!
- There are few people who have experience with interlaboratory comparisons, and most of them work for a PT provider or accreditation body, and do not consult.
- Accreditation bodies and laboratories have limited resources available for PT.



My Background in PT - CAP

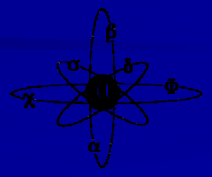
- 1981-1995, College of American Pathologists (CAP) – world's largest PT provider, all areas of medical testing

  (My first guidance in statistics for ILC – AOAC's Manual by Youden and Steiner)
- Data ReCAP 1970-1980 (published, 1982)
- ISO Guide 43 revision, 1995-1997
- Gaining perspective of "self-unemployed" independent consultant since 1995



First Global Perspective - Europe

- 1997-2001 attend EEE-PT as guest (EEE=Eurachem, Eurolab, EA)
- 2 meetings/year, discuss all areas of PT, all EEE countries
- See that all technical issues, except calibration, are similar to medical issues



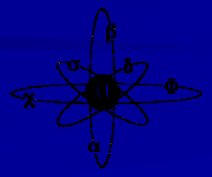
EEE-PT Issues

EEE –PT has resolved many difficult issues, and has ongoing discussions of others:

- Availability of PT
- Priority for new schemes
- Funding (by Accreditor? By lab?)
- Cross-border rules
- Accreditation of Provider
- Educational aspects
- Trade-off between PT frequency and assessment interval
- EPTIS

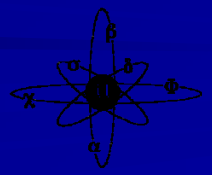
My Current Activities (PT-related)

- Assessor, A2LA accreditation of PT (ILAC G13)
- ILAC Liaison to ISO TC69 for Application of statistical methods (ISO 13528)
- Convener of ISO CASCO WG28 (ISO 17043)
- Training in PT requirements, statistical methods
- “Expert Consultant” (employee) for US CDC Division of Laboratory Systems (CLIA PT and Global HIV/AIDS Program for EQA)
- Consultant to several PT providers



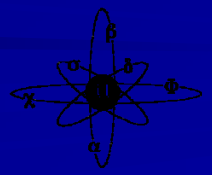
Growth in demand for PT is motivated by global trade

- How to trust results from labs in a different country?
- Need a reliable system of 3rd party attestation of competence
- Need to trust the recognition system
- Set up a system that is difficult but achievable; also transparent and verifiable by any stakeholder.



ILAC requirements

- Accreditation practices (ISO 17011)
- Accreditation requirements (ISO 17025)
- MOU with the World Trade Organization (WTO), to resolve the requirement in the Technical Barriers to Trade agreement that members must recognize testing and accreditation that is done in the country of origin
- Underpinned by PT (ISO Guide 43)
  - Requirements for PT providers in ILAC G13
  - Requirements for Laboratories in ILAC P9



ILAC Co-operations

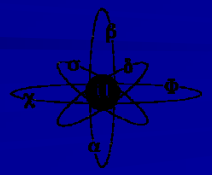
- Mutual Recognition Arrangement between 58 accreditation bodies in 46 economies.
- MOU with international organizations:
  - **WTO**
  - **UNIDO**
  - **ISO**
  - **IEC**
  - **CIPM**
  - **IAF**
  - **WADA**

Accreditation Essential for Trade, Public Health, Legal Issues

- Any country wishing to have their exported goods accepted should quickly develop systems for metrology, accreditation, standards (WTO, UNIDO)
- PT is essential for verifying competence, demonstrating harmony between countries

Role of Standards

- International expansion of PT not possible without consensus standards:
  - ISO/IEC Guide 43, 1st edition 1984
  - IUPAC Harmonized Protocol 1993
  - ISO/IEC Guide 43, 2nd edition 1997
  - ISO/IEC Guide 43 Part 2, 1st Edition 1997
  - ISO 13528 (Statistical methods) 2005
  - ISO/IEC 17011 (Accreditation practices) 2005
  - IUPAC Harmonized Protocol (rev) 2006
  - ISO/IEC 17043 ?? (2009?)

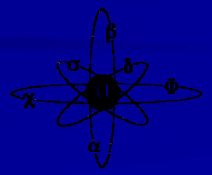


Role of Professional Groups

- Other Key Groups
  - AOAC/FDA: development of ILCs for method verification
  - IUPAC: development and promulgation of standards for PT
  - ILAC: requirements for PT in accreditation, work item proposals to ISO CASCO for 2nd edition of Guide 43-1, 43-2, and 17043, development of requirements document G13.

Role of Michael Thompson

- Author the Harmonized Protocols
- Clarity of thinking, writing
- Development of innovative statistical methods: robust analysis, homogeneity testing, “bump-hunting”
- Passionate advocacy of best practices, especially “Fitness for Purpose” criteria



Quotes from 2006 IUPAC Harmonized Protocol

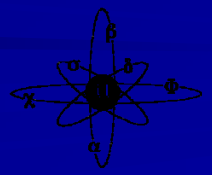
- 3.5.3 "*Scoring in some proficiency testing schemes is not based on the idea of fitness-for-purpose, which greatly diminishes the value of scoring*"
- … "*In such conditions, it would be better for the proficiency testing provider to provide no scoring at all …*"

Quotes from 2006 IUPAC Harmonized Protocol

- 3.6 "*This protocol does not recommend the reporting of participants' uncertainty of measurement with the result*."

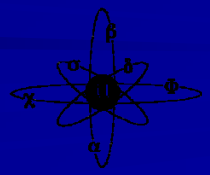
Quotes from 2006 IUPAC Harmonized Protocol

- 3.9 "*Classification of laboratories is not the goal of proficiency testing, and it is best avoided by providers as it is more likely to cause confusion than illumination*"
- 3.9 "*Ranking laboratories on their absolute z-score obtained in a round of a scheme…, is even more invidious than classification*."



What I have learned

- When PT is offered for the first time, experts rarely anticipate the level of interlaboratory disagreement. They learn from the experience.
- Lessons learned in one area of testing usually apply in other areas – we share the same problems, we need to share experiences.
- PT providers share a passion for laboratory improvement – every day they see the benefits of PT for correcting errors and increasing understanding of methods.
- PT improves measurements



Benefits of PT

- Allows mutual recognition of laboratories
- Facilitates trade
- Reduces waste
- Improves public health

This consultant's modest hopes for what PT (and accreditation) can do

Make life better for everyone everywhere

Thank you, Mike Thompson!

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