Implementation of ISO 17043

EURACHEM 2011 – Istanbul, Turkey

October 4, 2011

Jane Gun-Munro, FCSMLS, MBA, CQMgr

Director, External Quality Assessment

Quality Management Program—Laboratory Services

Why accreditation for QMP–LS?

Mandatory Program for Ontario labs

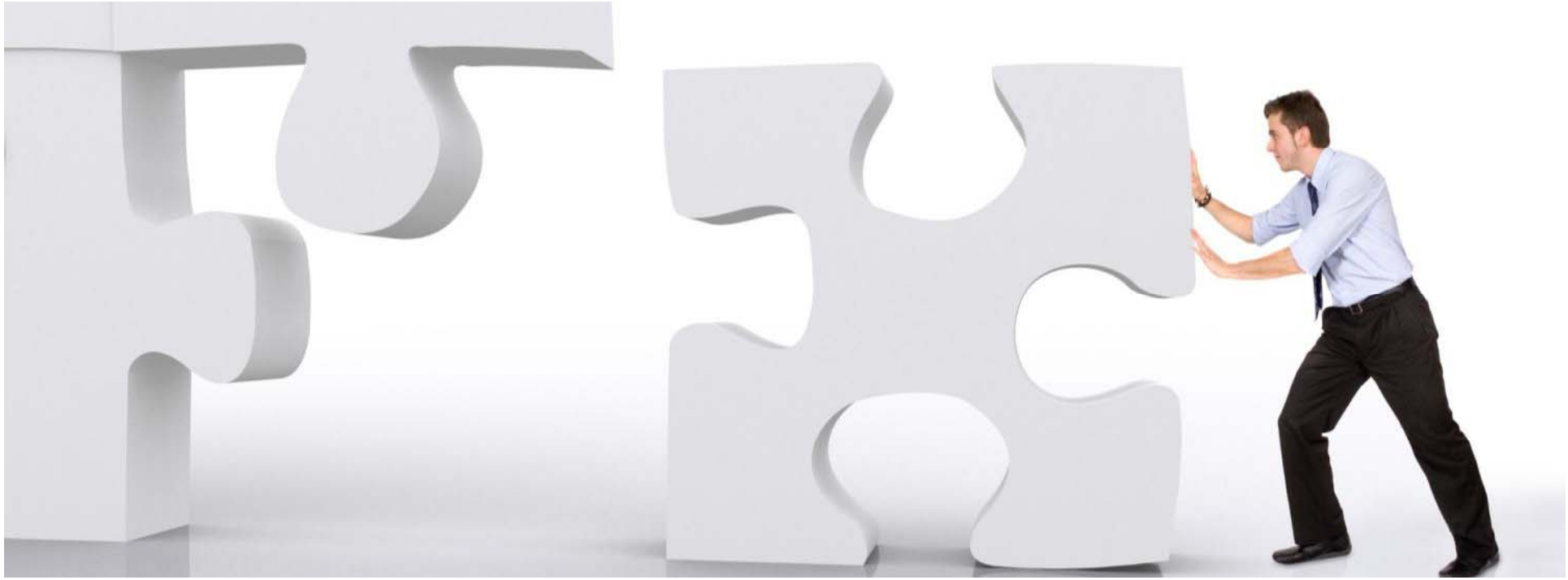
- 46 PT schemes (chemistry, cytogenetics, hematology, microbiology, pathology)
- Office-based provider with >20 sub-contractors of PT items

PT Schemes dependent upon volunteers

- 11 committees of 60-70 experts
- Lacked standardization, control, consistency

2000-03: QMP-LS developed accreditation program based on ISO 15189

- Requires labs to have QMS
- Requires labs PT schemes based on ISO 43-1



Initial GAP analysis

ISO 43-1 & ILAC Guide 13

- Management Requirements
- Technical Requirements
- Focus on quantitative schemes
  - Statistical Analysis

QMP–LS 2003-4

- No quality management system
- Less than 20% compliance
- Possible only for 16 of 46 schemes
- Needed statistics expert


QMP–LS QMS
ISO 9001:2000
Management Responsibility
Resource Management
Service Realization
Measurement & Assessment
Customer Requirements & Satisfaction

Policy Framework

Customer Requirements & Satisfaction

Management Responsibility
- Quality policy
- Organization
- Document management

Resource Management
- Equipment
- Facility/safety
- Fiscal resources
- Human resources
- Information

Service Realization
- External quality assessment
- Accreditation

Measurement & Assessment
- Service & satisfaction
- Process assessment & improvement

ISO 9001:2000

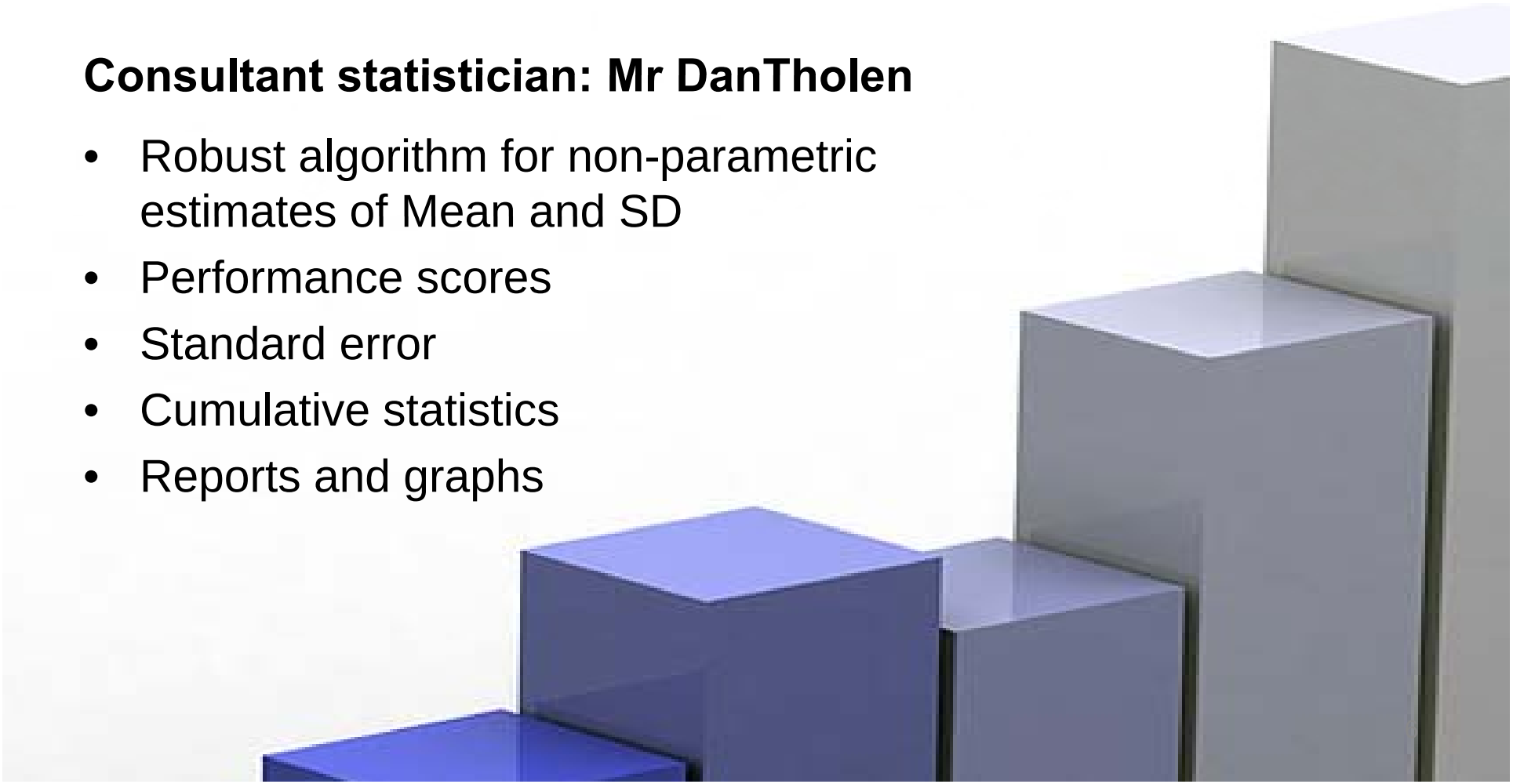
QMP–LS QMS

Back to statistics...

ISO 13528:2005. Statistical methods for use in proficiency testing by interlaboratory comparisons

Consultant statistician: Mr DanTholen

- Robust algorithm for non-parametric estimates of Mean and SD
- Performance scores
- Standard error
- Cumulative statistics
- Reports and graphs



ISO CASCO 17043 Working Group 28

Intent of ISO/IEC 17043:2010 single standard for PT/EQA providers

ISO 43 | ISO 17043 | ILAC G 13

For all types of lab-based PT schemes

Testing of conformity assessment activities

Applicable to current and evolving areas

QMS consistent with ISO 9001

Implications of one PT standard for different industry sectors

Agreement on Fitness for Purpose for the sector

PT Providers need to be **creative**

Assessors need to be **flexible**

- Calibration, testing, inspection, measurement
- Quantitative, qualitative, data interpretation
- Laboratory, organization, individual

ISO 17043 management system requirements

5.1 Organization	5.8 Complaints
5.2 Management system	5.9 Non-conforming activities
5.3 Document control	5.10 Improvements
5.4 Contract review	5.11 Corrective action
5.5 Subcontracting services	5.12 Preventive action
5.6 Purchasing services & supplies	5.13 Records
5.7 Service to customer	5.14 Management reviews

ISO 17043 challenges

5.5 Subcontracted services

- Prohibits subcontracting of planning evaluation or authorization of reports
- Assure competence of subcontractors
  - Complies with relevant parts of ISO 17043 and other appropriate standards (ISO17025, 15189)
- Notify participants of subcontracted services
- Provider accepts responsibility for subcontracted work
- Maintain register of all subcontractors and competence assessments

QMP–LS subcontractors

- Ontario medical labs (10)
  - **ISO 15189: 2007. Medical laboratories – Particular requirements for quality and competence**

- Commercial Labs (8)
  - **ISO 13485: 2003. Medical devices – Quality management systems – Requirements for regulatory purposes**

- Reference Laboratories (3)

Evidence of competence

- Confirmation of certification/accreditation
- Self-assessment against relevant clauses of ISO 17043 and ISO 15189
- Second party audit
- Retesting by laboratory accredited to ISO 15189
  - Homogeneity, stability, assigned value

ISO 17043 technical requirements

4.1 General
4.2 Personnel
4.3 Equipment, accommodation & environment
4.4 Design of PT schemes
4.5 Choice of method or procedure
4.6 Operation of PT Schemes
4.7 Data Analysis & Evaluation of PT Results
4.8 Reports
4.9 Communication
4.10 Confidentiality

ISO 17043 Technical Requirements

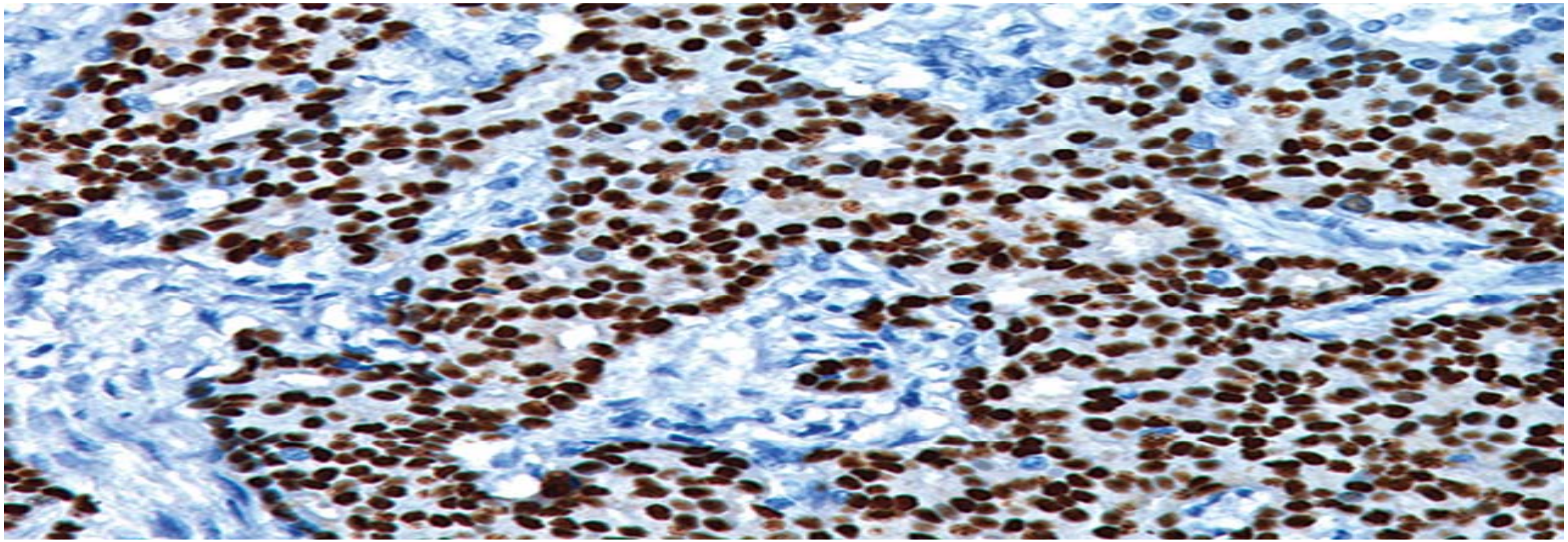
Our Guiding Principle

- Should ensure fitness for purpose

as appropriate for each PT scheme

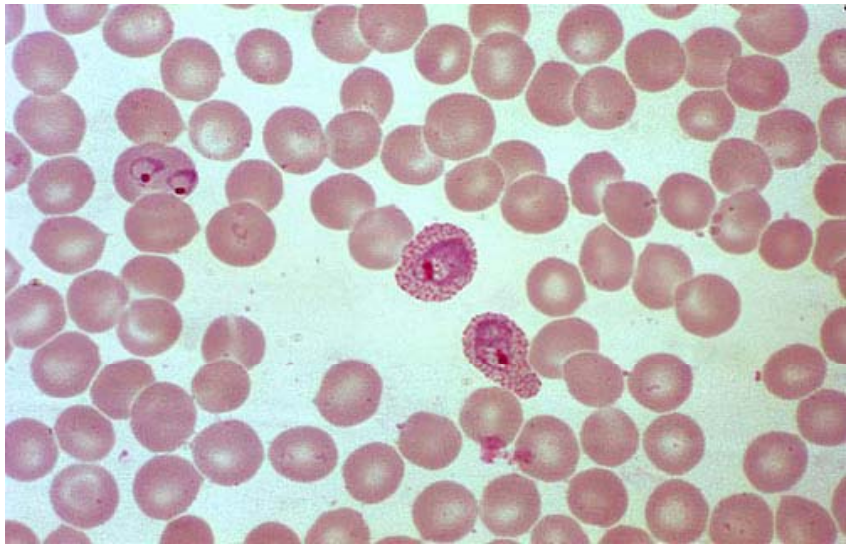
4.4.3 Homogeneity and stability

- Ensure PT items comparable for all participants
- If not feasible, demonstrate procedures are sufficient
- Use ISO 13528:2005 statistical methods where applicable
- Document what you do



Homogeneity and stability challenges

- Insufficient patient material (up to 13 samples per PT item)
- High cost of testing (up to 26 tests per PT item)
- Multiple analytes per PT item (up to 15)
- Analysis of qualitative test results
- Inherent inhomogeneity of tissue or bacterial cultures



Homogeneity and stability solutions

- Perform testing according to ISO 13528:2005 when possible
- Use representative or indicator analytes
- If insufficient material, reduce number tested to 5 or 3
- For qualitative tests, use qualitative results
  - ***Sometimes simple presence of target is sufficient***

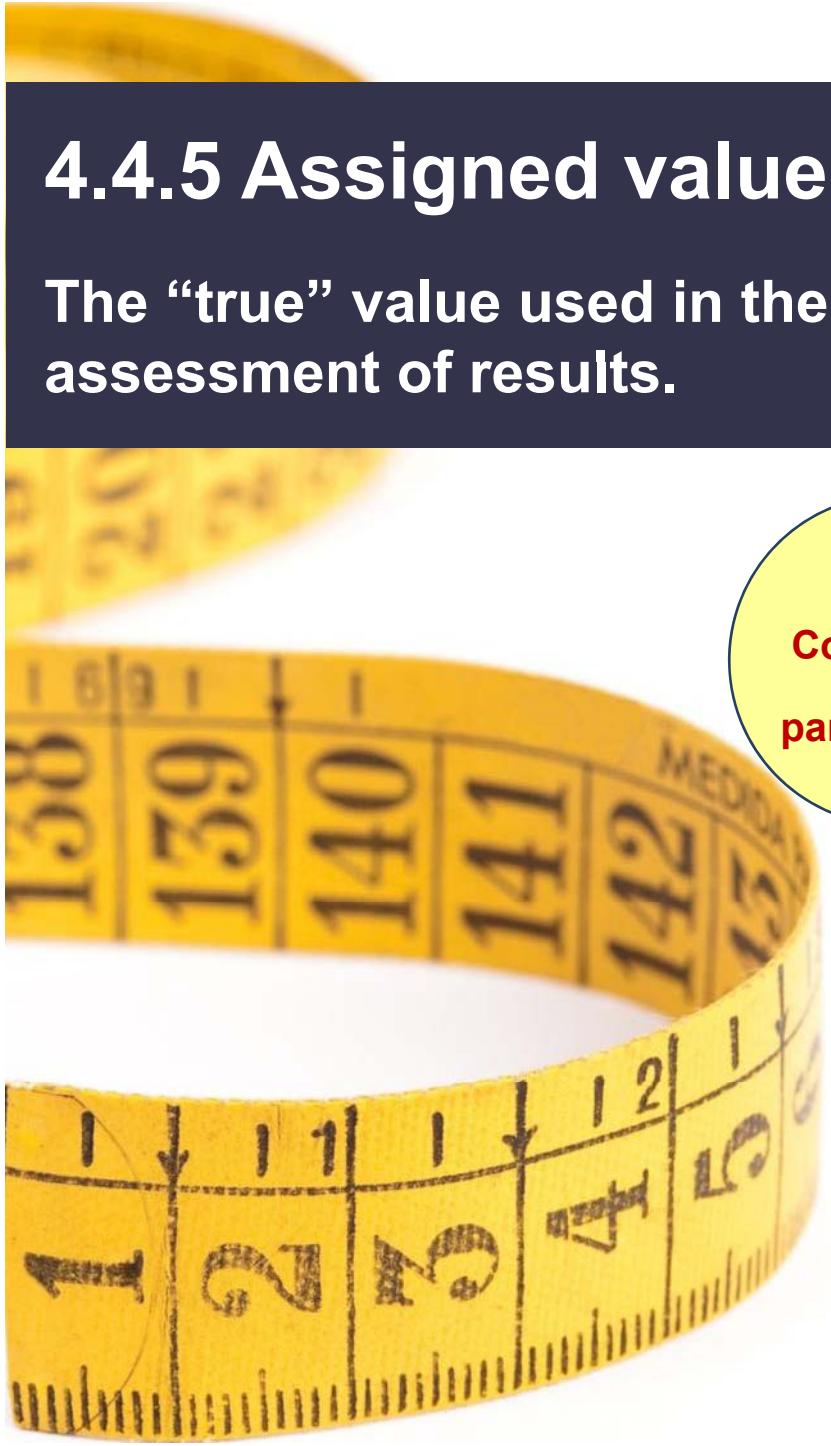
Confirm results by post-PT test review of uncertainty of assigned value

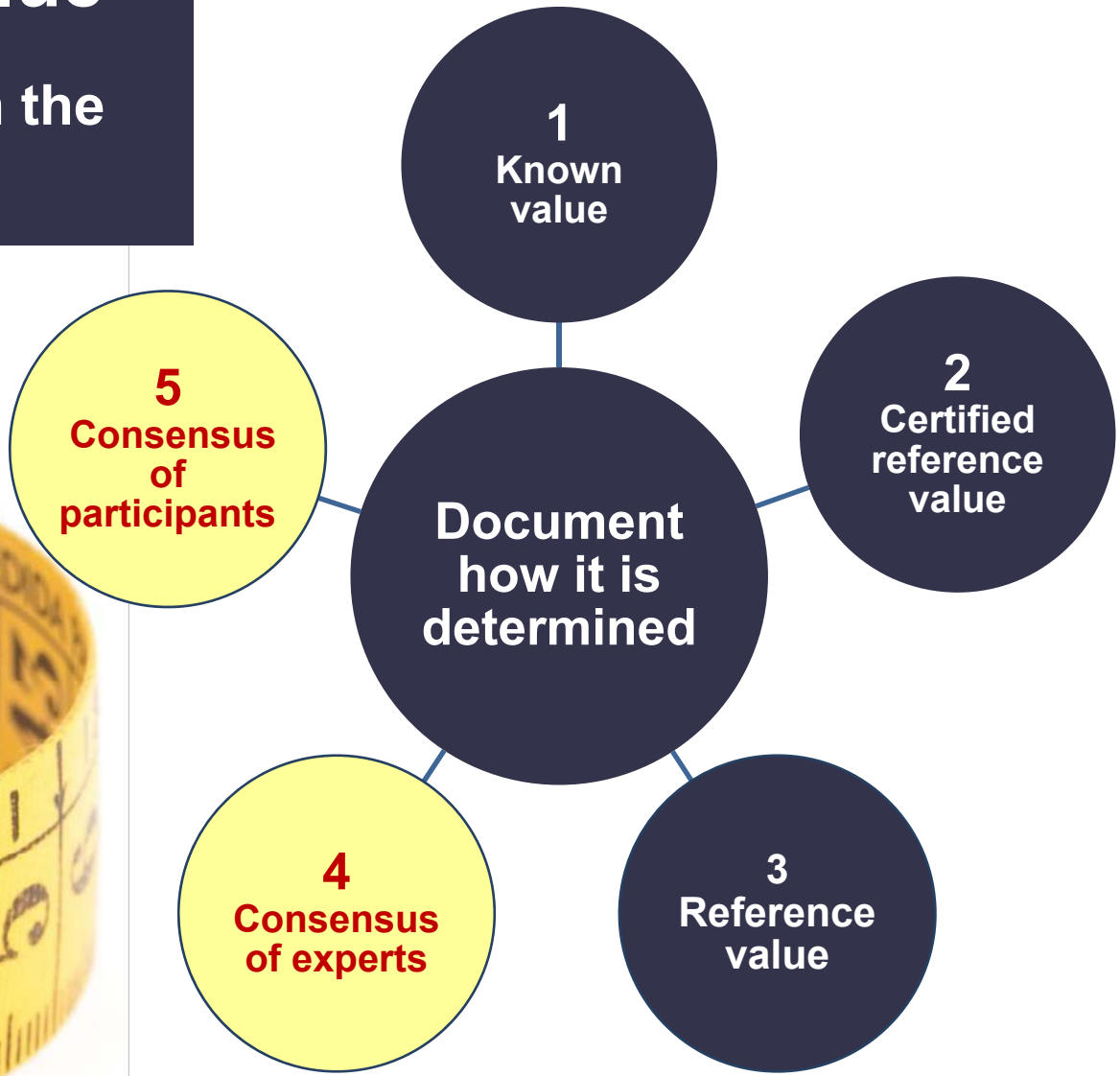
Evaluation of 3 years data

- 949 homogeneity events
  - 0.2% homogeneity failure
  - 4.0% stability failure
- Post PT review of Assigned Value Uncertainty
  - 0.4% samples: performance NOT evaluated

4.4.5 Assigned value

The “true” value used in the assessment of results.





Challenges with consensus values

- Small group size
- Method reliability
- Material matrix or homogeneity
- Expert reliability

Uncertainty of consensus values

ISO 13528:2005 - guidelines for limiting uncertainty of the assigned value

– *Compare with standard deviation for proficiency*

– *If variability too great, do not evaluate, accommodate in evaluation or inform participants*

– Do not evaluate performance if variability is too great or pre-determined consensus not met for qualitative values

4.6.3 Packaging, labelling and distribution of PT items

4.6.3.2 The PT provider shall:

- specify relevant environmental conditions for the transport of PT items.
- monitor the pertinent environmental conditions of the PT item during transport
- assess the impact of environmental influences on the PT items

Challenges of packaging and distribution

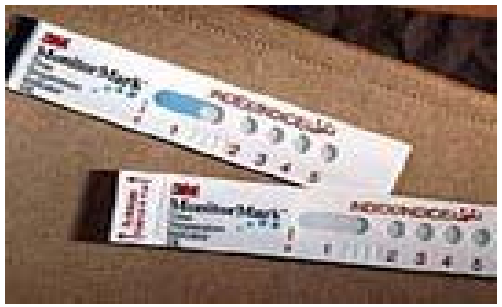
- Majority of PT items consist of biological material that is heat- and time-sensitive
- Acceptable Range 2-10ºC
- Extreme temperatures ranging from –30ºC in winter to +30ºC in summer
- Ontario is 1 million square km and courier may take up to 48 hrs

Packaging solutions

Package according to season, lab location and delivery time

- Styrofoam containers
  - 24 hr: 1 inch thickness
  - 48 hr: 2 inch thickness

- Ice Pack
  - Frozen +/- room temperature
    - Room temperature packs act as heat sink - absorb cold



- Temperature monitors
  - Included in selected participant packages for recording and reporting temperature

4.7 Performance evaluation

- Evaluation shall not be subcontracted
- **Document and use valid methods for appropriate evaluation**
- Advisory group shall provide expert commentary on performance
- Consider impact of method variation

4.7 Performance evaluation and data analysis

CHALLENGES

Error Assignment

- Expert panel assigned after each round
- Limited documented criteria
- Subjective, inconsistent

SOLUTIONS

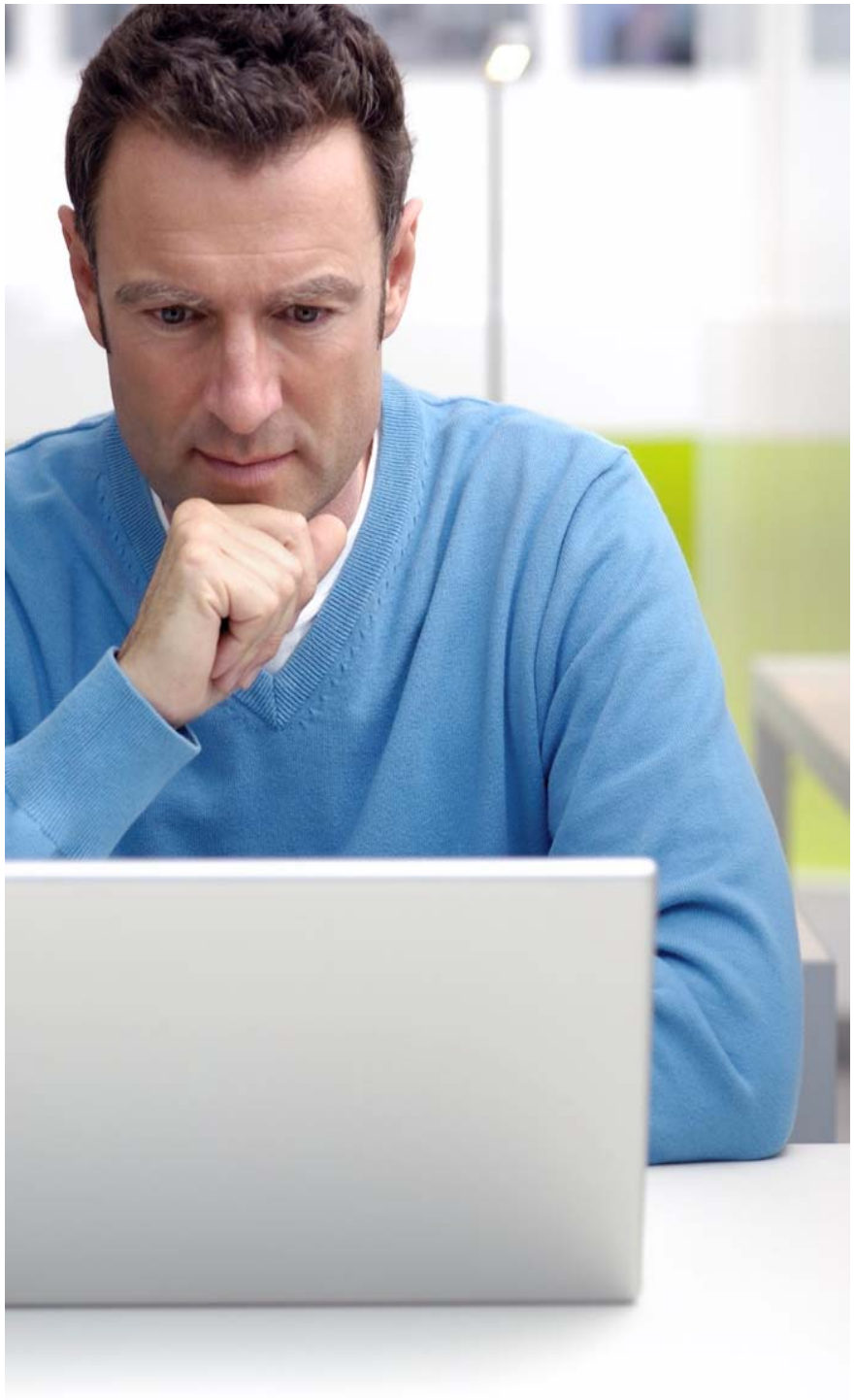
Performance Scores

- ISO 13528:2005
- Expert panel predefined criteria
- Objective, consistent

Benefits and challenges

- Control
- Customer Focus
- Effective, efficient processes
- Involved, competent staff
- **Confidence** in product
- Continual improvement
- **Peace of Mind**

- Top management commitment
- Staff involvement
- Training
- Maintaining documents
- Resources



Implementation Tips?

- Seek Mentor/Support
- Network, attend meetings
  - Eurachem, EQALM
- Use available resources
  - ISO 17043:2010
  - ISO 13528:2005
  - IUPAC Protocol
  - Accrediting Body guidance

Continuing Issues?

- **Subcontractor qualifications**
  - Quality of product more important than producer
- **Homogeneity and Stability**
  - Various ways to confirm uniformity of product
- **Qualitative schemes**
  - Limited guidance

ISO 17043 accreditation is worthwhile

- **ISO 17043 is comprehensive, progressive and inclusive standard**
- PT Providers and assessors must consider **fitness for purpose** for each PT scheme
- **Extreme Makeover for QMP-LS**
- If **we can** do it **anyone can** do it!

Teşekkür ederim!
Thank you!

Thanks and acknowledgements to QMP–LS Consultant Technologists:

Christine Fleming, Microbiology
Anne Raby, Hematology
Julia Stemp, Chemistry
Astrid Petersons, Transfusion Medicine
Lynn Yawney, Cytology, Genetics
Andrea Park, Pathology
and
Neela Khatri, Senior Systems Analyst
Maritess Koerner, Communications

QMP-LS
ONTARIO MEDICAL ASSOCIATION