

# International Standards for Proficiency Testing Providers

Michael A Noble MD FRCPC

Chair, Clinical Microbiology Proficiency Testing Program

Department of Pathology and Laboratory Medicine

University of British Columbia Canada



# About this Presentation

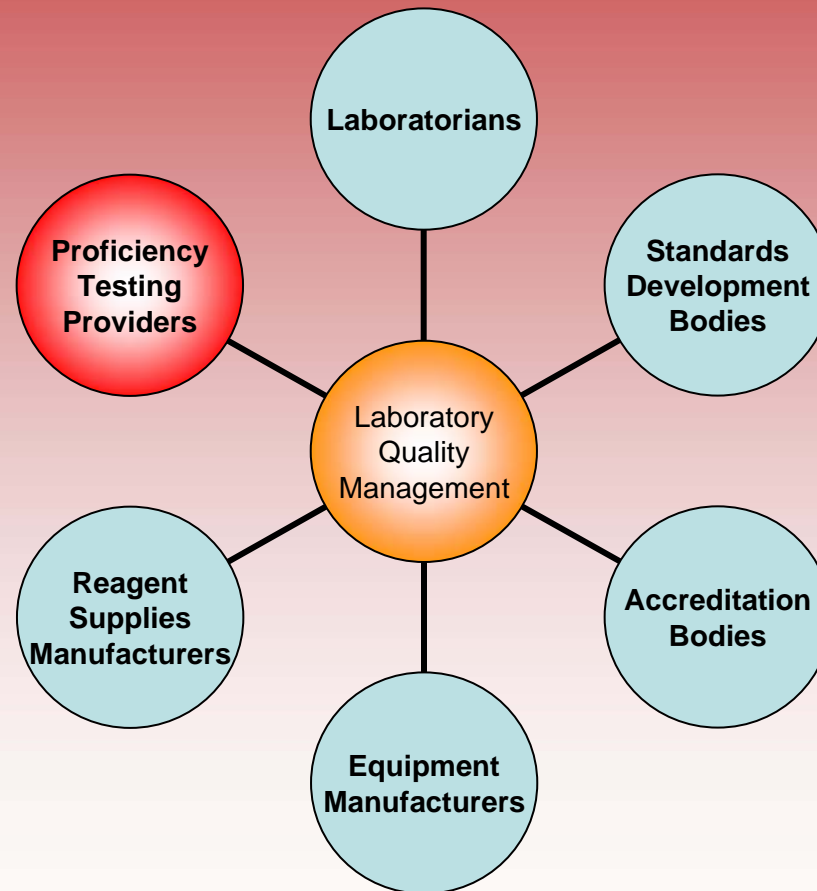
- This presentation was given at a workshop (June 2009 – Leuven Belgium) of the EuGeneTest, the EU-funded network of excellence for European genetics testing laboratories and PT providers.
- The topic was to look at standards for quality and competence for proficiency testing providers.
- The subject was the new creation of an ISO standard 17043, and where it would fit as a measure that EuGeneTest providers could consider.



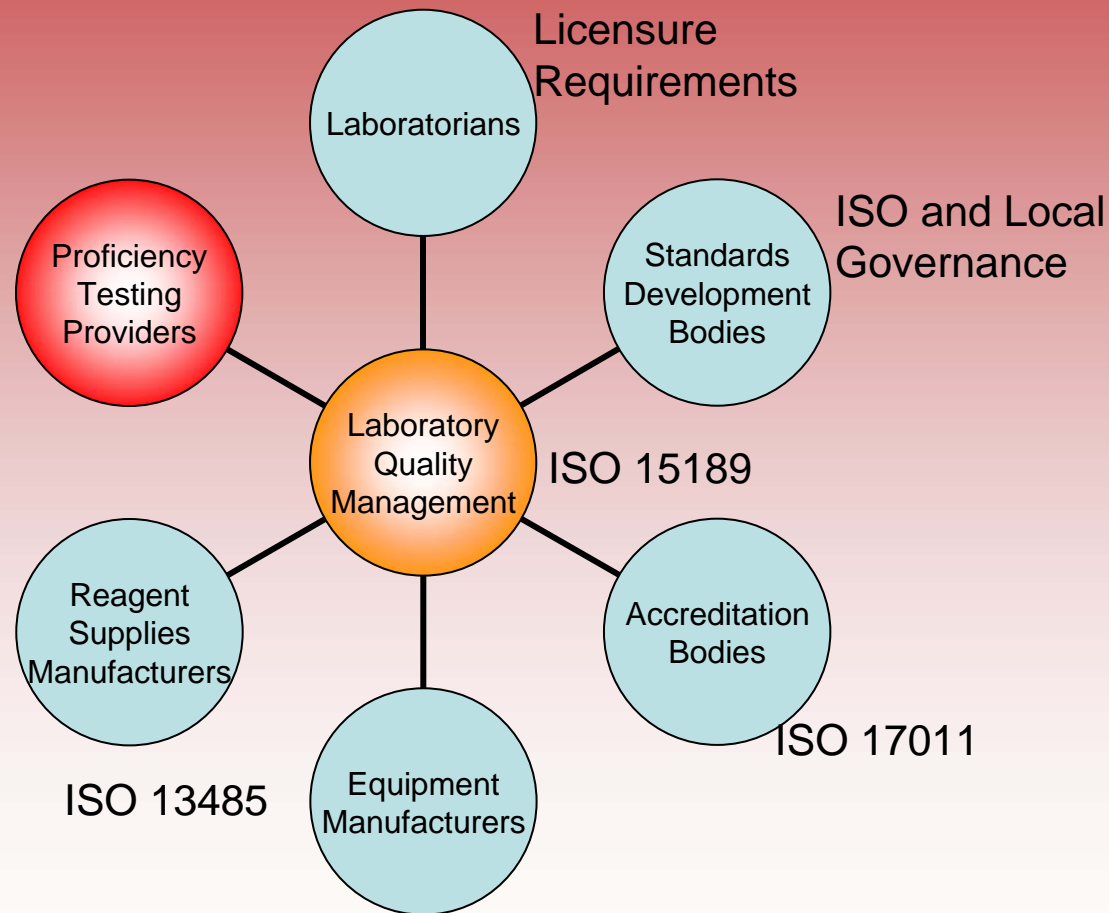
# Proficiency Testing is Laboratory Quality



# Proficiency Testing is a Quality Partner



# All Quality Partners have Recognition Requirements



# Expectations of Quality Partners

Work within the Quality partnerships.

Quality partners should meet their  
Recognition Requirements.

Provide their product or service  
as required, on time, and on budget.



# History of Proficiency Testing Provider Standards

THERE IS NO INTERNATIONAL  
ORGANIZATION, COALITION, COOPERATION  
DEVELOPED BY AND FOR  
PROFICIENCY TESTING PROVIDERS



# EQALM

*may be an exception*



European Committee for External  
Quality Assurance Programmes  
in Laboratory Medicine

EQALM

Evolving into an international  
community

EUROPE  
CANADA  
ARGENTINA  
JAPAN





# ILAC

*an assisting organization for PT providers*

Created guidelines (Guides 13 and 43)  
for Accreditations Bodies to consider  
when selecting an PT provider to work with their programs.

Created the  
Proficiency Testing Consultation Group.

Worked with ISO to develop  
Quality Requirements for PT Providers  
ISO 17043



# EQALM SURVEY on PT Accreditation 2006

## Medical EQA providers

- ILAC G13 + ISO Guide 43: 7
- Accredited according to ISO 17020/ISO Guide 43: 4
- Accredited according to ISO 17025/ISO Guide 43: 4
- Accredited according to ISO 17025/ ISO 17020/ISO Guide 43: 4
- ILAC G-13: 1
- Certified ISO 9000: 9
- CPA accredited: 2

TOTAL  
31 Programs



# CMPT and ISO9001



***Innovation  
Education  
Quality Assessment  
Continual Improvement***

*We at **CMPT** are  
a university based,  
peer directed program,  
and strive to provide Innovative  
External Quality Assessment  
committed to education and  
continual improvement  
for the benefit of healthcare,  
our participants and our program.*



# ISO 17043



## DRAFT INTERNATIONAL STANDARD ISO/IEC 17043

CASCO                      Secretariat: ISO/ICS  
Voting begins on            Voting terminates on  
2008-11-13                    2009-04-13

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION  
INTERNATIONAL ELECTROTECHNICAL COMMISSION • МЕЖДУНАРОДНАЯ ЭЛЕКТРОТЕХНИЧЕСКАЯ КОММИССИЯ • COMMISSION ELECTROTECHNIQUE INTERNATIONALE

### Conformity assessment — General requirements for proficiency testing

*Évaluation de la conformité — Exigences générales pour les essais d'aptitude*

ICS 03.120.20

#### ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard. Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

In accordance with the provisions of Council Resolution 16/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 16/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au secrétariat central de l'ISO au stade de publication.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

© International Organization for Standardization, 2008



Initiated in June 2007.

Currently just passed a successful DIS vote.

FDIS vote likely in September 2009

# So Let's Compare...

**ISO IEC**

**DRAFT INTERNATIONAL STANDARD ISO/IEC 17043**

Secretariat: ISO/IEC  
Voting terminates on  
2008-04-15

CASCO  
Voting begins on  
2008-11-15

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • ORGANISATION INTERNATIONALE DE NORMALISATION  
INTERNATIONAL ELECTROTECHNICAL COMMISSION • COMMISSION ELECTROTECHNIQUE INTERNATIONALE

**Conformity assessment — General requirements for proficiency testing**

Évaluation de la conformité — Exigences générales pour les essais d'aptitude

ICS 03.120.20

**ISO/CEN PARALLEL ENQUIRY**

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. In accordance with the ISO-led mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European standard. Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

In accordance with the provisions of Council Resolution 16/1989 this document is circulated in the English language only.  
Conformément aux dispositions de la Résolution du Conseil 16/1989, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the competent secretariat (ISO Central Secretariat work of editing and text composition will be under publication stage).  
Pour accélérer la distribution, le présent document est distribué tel qu'il est reçu du secrétariat central de l'ISO au stade de composition de texte.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND SHOULD NOT BE REFERENCED OR QUOTED IN ANY STANDARD OR TECHNICAL DOCUMENT. IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, INTERNATIONAL AND/OR NATIONAL REGULATIONS, NATIONAL STANDARDS BODIES SHOULD TAKE INTO ACCOUNT ANY AND ALL INTERNATIONAL STANDARDS REFERENCED HEREIN. REVISIONS TO THIS DRAFT ARE INVITED TO SUBMIT WITH THEIR COMMENTS, NOTIFICATION OF WHICH IS TO BE MADE TO THE SECRETARIAT OF THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, 2008

**ISO IEC**

**GUIDE 43-1**

**Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes**

Second edition 1997





ILAC  
Guide  
13

ILAC  
Guide  
43



ISO  
Guide  
43-1



# ISO Guide 43-1:1997

## General

- Measurement comparison schemes
- Interlaboratory testing schemes
- Split-sample testing schemes
- Qualitative schemes
- Known-value schemes
- Partial-process schemes

## Organization and design

- Framework
- Staff
- Data-processing equipment
- Statistical design
- Test item preparation
- Test item management
- Choice of method/procedure
- Evolution of proficiency testing schemes

## Operation and reporting

- Coordination and documentation
- Instructions
- Packaging and transportation
- Data analysis and records
- Scheme reports
- Evaluation of performance
- Communication with participants

## Confidentiality/ethical considerations

- Confidentiality of records
- Collusion and falsification of results

## Annexes

- A Examples of statistical methods for treatment of proficiency test data
- B Quality management of proficiency testing schemes



# ISO 17043: 2010(?)

## Technical Requirements

- Personnel
- Equipment, Accommodation, and Environment
- Design
- Preparation of Materials
- Choice of Methods
- Operation of Program
- Data Analysis
- Reports
- Communications
- Confidentiality

## Management Requirements

- Organization
- Management System
- Document Control
- Review of Requests, Tenders, Contracts
- Subcontracting Services
- Purchasing services and supplies
- Service to the customer
- Complaints
- Control of nonconforming activities
- Improvement
- Corrective Actions





# ISO 17043: 2010(?)

## Technical Requirements

- Personnel
- Equipment, Accommodation, and Environment
- Design
- Preparation of Materials
- Choice of Methods
- Operation of Program
- Data Analysis
- Reports
- Communications
- Confidentiality

## Management Requirements

- Organization
- Management System
- Document Control
- Review of Requests, Tenders, Contracts
- Subcontracting Services
- Purchasing services and supplies
- Service to the customer
- Complaints
- Control of nonconforming activities
- Improvement
- Corrective Actions



# Staff

## Guide 43-1

The staff involved in providing the scheme should have, or collaborate closely with those holding adequate qualifications and experience in the design, implementation and reporting of interlaboratory comparisons. They should include appropriate technical, statistical and administrative skills.

the operation of particular interlaboratory comparisons will also require the guidance of persons with detailed technical knowledge and experience of the test methods and procedures involved. To this end the coordinator may need to enlist one or more appropriate persons drawn from, for example, professional bodies, a contract laboratory (if any), scheme participants or end users of the data, to act as an advisory group.



# Technical Requirements

## Personnel 17043:2010?

- Personnel

- Management shall define qualifications
- Management shall provide and monitor education and training as required.
- Management shall monitor competency.

- Personnel shall be authorized to perform the following tasks:

- Selecting materials
- Planning challenges
- Performing sampling
- Operating equipment
- Conducting measurements
- Preparing, handling, and distributing items
- Conducting statistical analysis.
- Evaluating performance
- Creating and distributing reports
- Providing opinion and interpretation



# Technical Requirements

## Personnel 17043:2010?

- Personnel

- Management shall define qualifications
- Management shall provide and monitor education and training as required.
- Management shall monitor competency.

- Personnel shall be authorized to perform the following tasks:

- Selecting materials
- Planning challenges
- Performing sampling
- Operating equipment
- Conducting measurements
- Preparing, handling, and distributing items
- Conducting statistical analysis.
- Evaluating performance
- Creating and distributing reports
- Providing opinion and interpretation



# Advisory Committee

## Guide 43-1

5.2.3 The functions of this advisory group may include:

the development and review of procedures for the planning, execution, analysis, reporting and effectiveness of the proficiency testing scheme;

the identification and evaluation of inter-laboratory comparisons organized by other bodies;

the evaluation of proficiency test results regarding the performance of participating laboratories;

providing advice to any body assessing the technical competence of participating laboratories,

providing advice to participants apparently experiencing problems; and resolving any disputes between the coordinator and participants.



# Advisory Committee duties

17043

planning requirements;

identification and resolution of any difficulties expected in the preparation and maintenance of homogeneous proficiency test items or in the provision of a stable assigned value for a proficiency test item;

preparation of detailed instructions for participants;

comments on any technical difficulties or other remarks raised by participants in previous proficiency testing rounds;

provision of advice in evaluating the performance of participants;

comments on the results and performance of participants as a whole and, where appropriate, groups of participants or individual participants;

provision of advice for participants (within limits of confidentiality), either individually or within the report;

responding to feedback from participants; and planning or participating in technical meetings with participants.



# Advisory Committee duties

17043

planning requirements;

identification and resolution of any difficulties expected in the preparation and maintenance of homogeneous proficiency test items or in the provision of a stable assigned value for a proficiency test item;

preparation of detailed instructions for participants;

comments on any technical difficulties or other remarks raised by participants in previous proficiency testing rounds;

provision of advice in evaluating the performance of participants;

comments on the results and performance of participants as a whole and, where appropriate, groups of participants or individual participants;

provision of advice for participants (within limits of confidentiality), either individually or within the report;

responding to feedback from participants; and planning or participating in technical meetings with participants.



# Instructions

## Guide 43-1

Detailed instructions covering all aspects of the scheme which should be adhered to by the participating laboratories should be provided. These may be provided, for example, as an integral part of a scheme protocol.

Instructions may include details concerning factors which could influence the testing of the supplied test items or materials. Such factors may include operators, the nature of items or materials, equipment status, selection of test procedure and timing of testing.

Specific instructions on the recording and reporting of test or calibration results may also be supplied (e.g. units, number of significant figures, reporting basis, result deadlines, etc.).

Participants should be advised to treat proficiency test items as if they were performing routine tests (unless there are some special requirements in the design of the proficiency test which may require departure from this principle).





# Detailed documented instructions

17043.

## Instructions to participants shall include:

- a) factors which could influence the testing or calibration
- b) procedure for preparing test items
- c) instructions on handling the proficiency test items, including safety
- d) specific environmental conditions for tests and/or calibrations
- e) instructions on the manner of recording and reporting results
- f) the necessity to treat proficiency test items in the same manner as the majority of routinely tested samples
- g) the latest date for the provider to receive results
- h) instructions on return of the proficiency test items.



# Detailed documented instructions

17043.

## Instructions to participants shall include:

- a) factors which could influence the testing or calibration
- b) procedure for preparing test items
- c) instructions on handling the proficiency test items, including safety
- d) specific environmental conditions for tests and/or calibrations
- e) instructions on the manner of recording and reporting results
- f) the necessity to treat proficiency test items in the same manner as the majority of routinely tested samples
- g) the latest date for the provider to receive results
- h) instructions on return of the proficiency test items.



# Instructions for participants

## 4.6.1.1

The proficiency testing provider shall give participants sufficient prior notice before sending proficiency test items, providing the date upon which the proficiency test items are likely to arrive or to be dispatched, **unless the design of the proficiency testing scheme makes it inappropriate to do so.**



# Evaluation of performance

4.7.2.1

The PT/EQA provider shall use valid methods of evaluation which **meet the purpose of the PT/EQA scheme.**

The methods shall be documented and include a description of the basis for the evaluation.

The evaluation of performance shall not be subcontracted.



# Commentary on Performance

## 4.7.2.2

Where appropriate for the purpose of the PT/EQA scheme, the provider shall provide expert commentary on the performance of participants *with regard to* the following:

- a) overall performance
- b) variation within and between participants
- c) comparisons with previous PT/EQA rounds, similar or published precision data;
- d) variation between methods or procedures;



# Commentary on Performance

continued

- e) possible sources of error and suggestions for improving performance;
- f) advice and educational feedback to participants
- g) situations where factors make evaluation of results impossible;
- g) any other suggestions, recommendations or general comments; and
- h) conclusions.



# PT and Uncertainty

*Some areas need discussion*

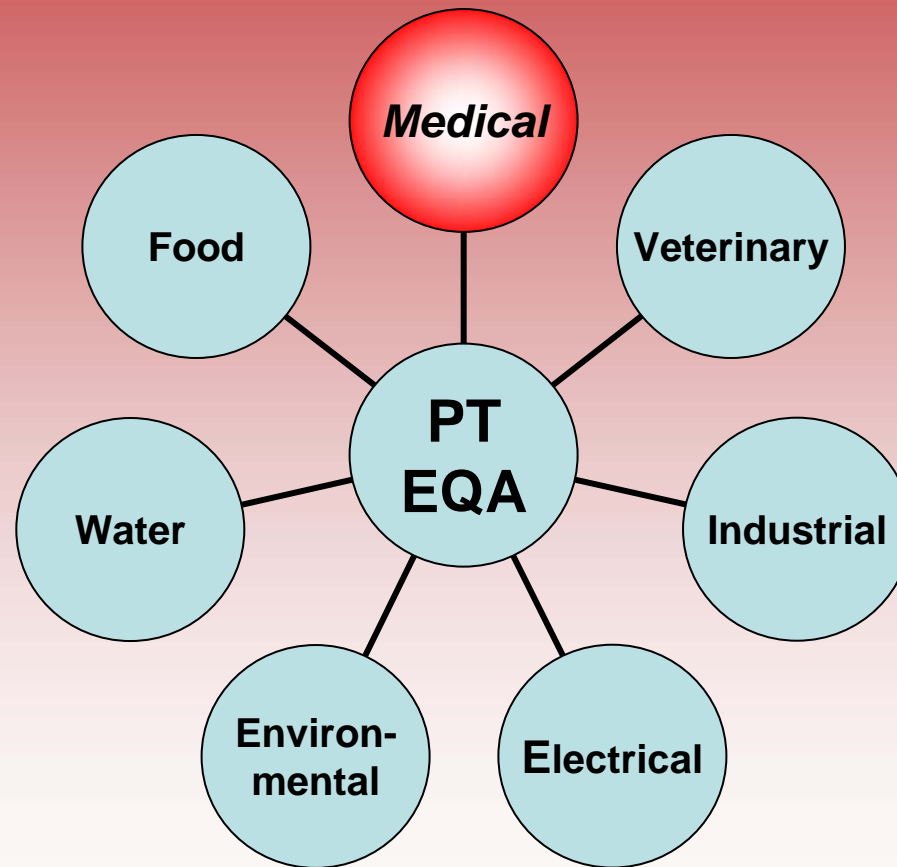
Addresses Measurement Uncertainty as a statistical issue only as it applies to calculation of **assigned values** and **stability**.

Does not address the estimation of factors that can have an impact on sample uncertainty.

Also does not demonstrate the benefits of calculating measurement uncertainty.

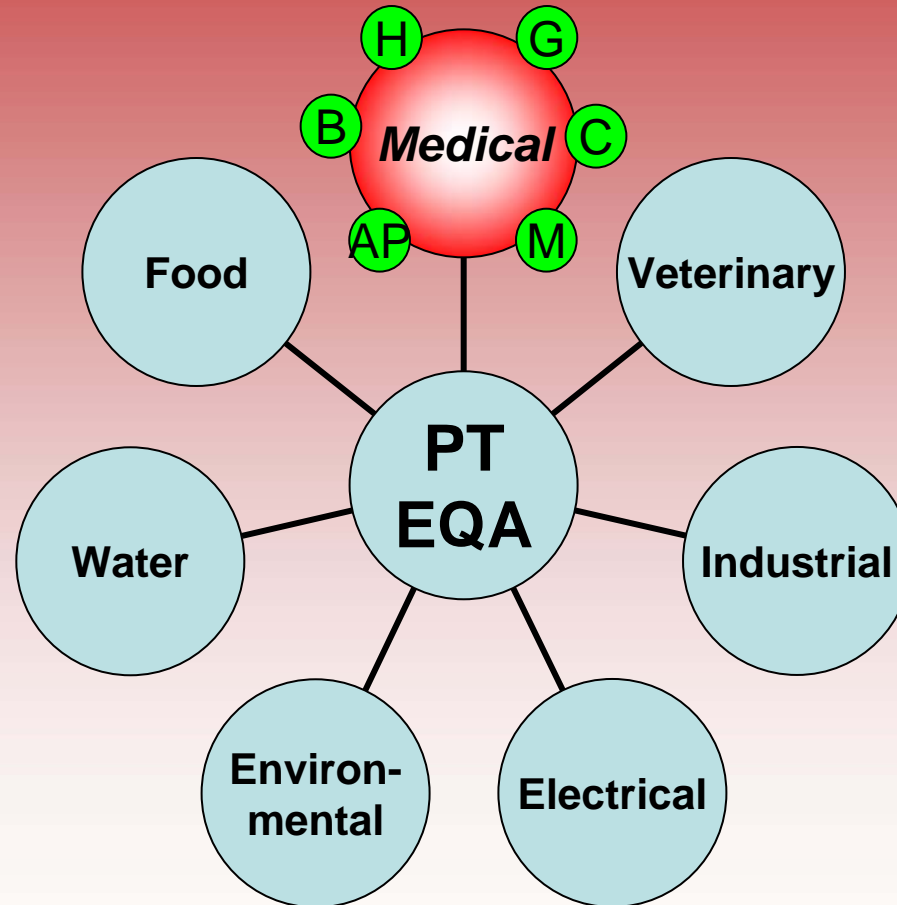


# Why ISO 17043 provides so much flexibility in its requirements.





# Why ISO 17043 provides so much flexibility in its requirements.



# Challenges for ISO17043

- Application
  - Is it better than Guide 43-1?
  - Where does it fit with ISO9001:2008?
- Cost
- Confidence in Assessment Process.
  - Knowledge and Interpretation
  - Bias
  - Competence



# Challenges for ISO17043

- Application

- Is it better than Guide 43-1?



- Where does it fit with ISO9001:2008?



- Cost



- Confidence in Assessment Process.

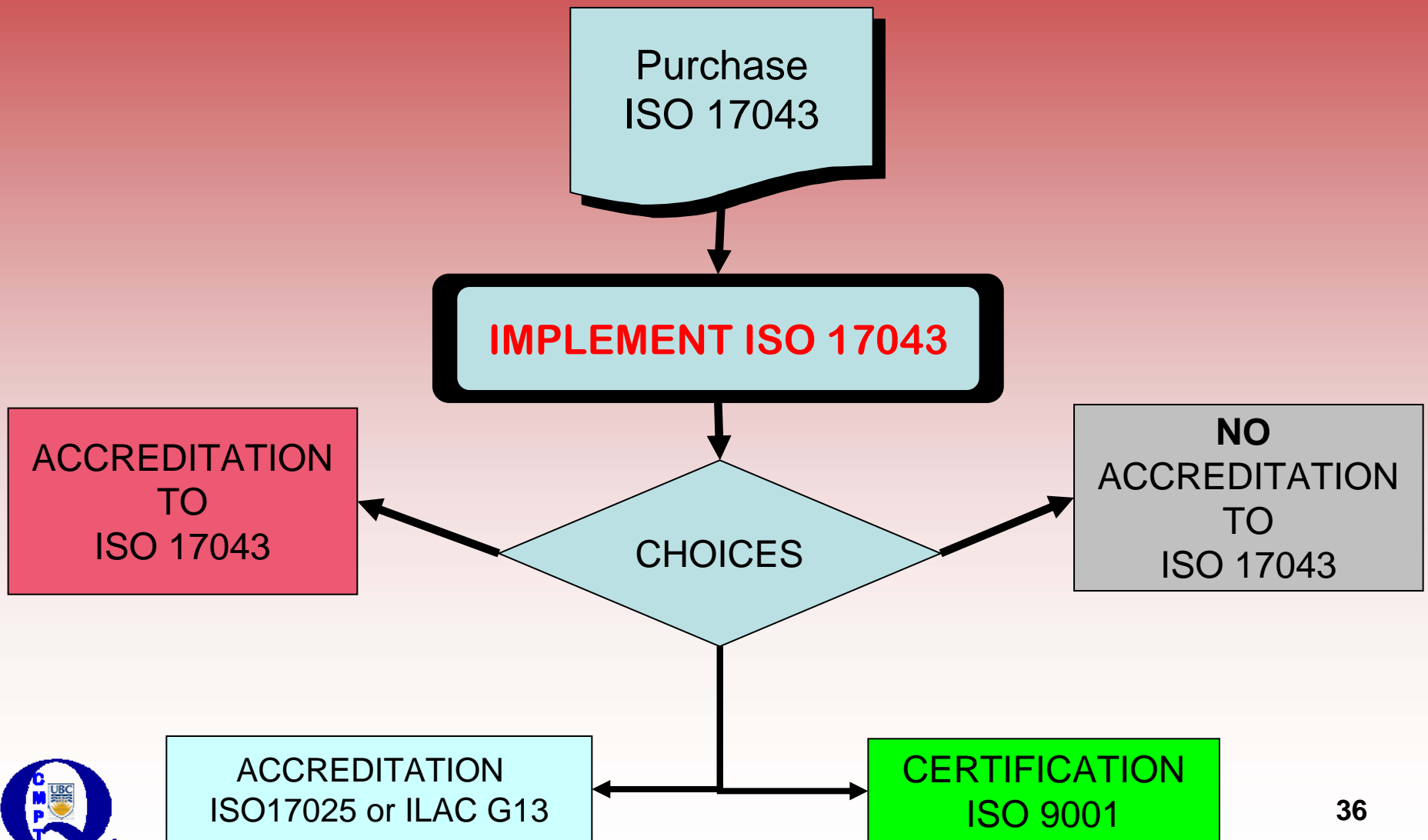


- Knowledge and Interpretation

- Bias

- Competence

# Strategy for Going Forward



# Accreditation or Not Accreditation

## Reasons for Accreditation

- External Validation
- Demonstration Value
- Business Opportunities
- Public Relations

## Reasons for Not Accreditation

- Availability
- Cost
- Business Realities
- Accreditation Body Competence.



# Do Laboratories Care?

- *Some might.*

- Local factors are very important

- Government authority

- Accreditation bodies

- Laboratory personal factors

- » *How well are the laboratorians informed and knowledgeable about quality?*

- » *"If we **have** to, you **have** to."*



# Alternatives to Accreditation Depends on the Reason

## For External Validation or External Audit

- International committee of peers
- Quality Consultant Group
- National accreditation body for unofficial visit

## For Accreditation or Certification Certificate

- NONE



# To sum up ISO17043:2010?

- Not a big jump from existing documents
  - ISO 17043 is better organized
  - More current
  - More relevant
  - Lots of good practice
  - Lots of flexibility
  - Addresses measurement uncertainty narrowly.
- *A document that I can work with at CMPT*





## *in summary...*

- Proficiency Testing Providers are a valuable Quality Partner for medical laboratories.
- Proficiency Testing Providers will soon have their own ISO standard for quality assessment (ISO 17043).
- Working to meet Quality Assessment requirements should be a goal for all Proficiency Testing Providers.
- The decision to seek accreditation is *different* from the decision to meet quality requirements.



# and finally final.

- Whether or not you decide to consider accreditation, you should follow the recommendations in ISO17043 because...

**It is the RIGHT thing to do.**

