

Participation in Proficiency Testing Schemes/Inter-Laboratory Comparisons - The Cyprus Experience

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Introduction

CYS-CYSAB is...
the National Accreditation Body in the
Republic of Cyprus, designated by the
Government for the purpose of the
Regulation (EC) no 765/2008.



The aim of the presentation is...

to describe the approach of the CYS-CYSAB regarding PT/ILC comparisons and contribute to the exchange of views and experience with other accreditation bodies as well as stakeholders.

Different needs in various sectors are also discussed.

CABs accredited by CYS-CYSAB*

Activity	Standard	Number
Testing		31
Medical	CYS EN ISO 15189:2007	14
Analytical	CYS EN ISO/IEC 17025:2005	6
Microbiological		7
Construction		2
Veterinary		1
Electromagnetic		1
Calibration		2
Inspection	CYS EN ISO/IEC 17020:2004	2
Certification	CYS EN 45011:1998	2
<i>Note: one lab covers both analytical and microbiological</i>		Total 36

*30th September 2011

Standards provide as follows...

“The accreditation body shall ensure that its accredited labs participate in PT or other comparison programmes, where available and appropriate, and that corrective actions are carried out when necessary. The minimum amount of PT and the frequency of participation shall be specified in cooperation with interested parties...”. *(ISO 17011, clause 7.15.3)*

“The lab shall have quality control procedures for monitoring the validity of tests and calibrations... The monitoring shall be planned ... and may include (among others) participation in ILCs or PTs”. *(ISO 17025, clause 5.9.1)*

“Inter-laboratory comparison programmes shall be in substantial agreement with ISO/IEC Guide 43-1”. *(ISO 15189 clause 5.6.4).*

CYS-CYSAB's policy

The role of CYS-CYSAB

- dissemination of information on available PT schemes (website, leaflets etc.)
- invitations from EA and other bodies for participation in PT are distributed to selected labs (on rotation)
- organization of training courses and awareness events

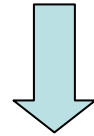
PT participation is a main aspect being assessed.

Relevant data are submitted prior to assessments.

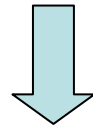
Laboratories shall...

participate in PT schemes, if available; otherwise...

document competence of the PT providers



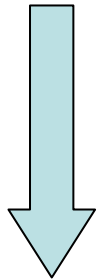
participate in ILCs or organise such comparisons; if this is not possible...



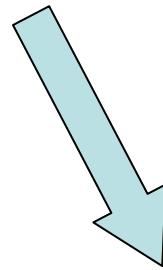
make best use of internal quality assurance/quality control measures

Minimum requirements...

participation* in at least one PT / ILC activity relating to each sub-discipline



prior to granting accreditation



per year after granting accreditation

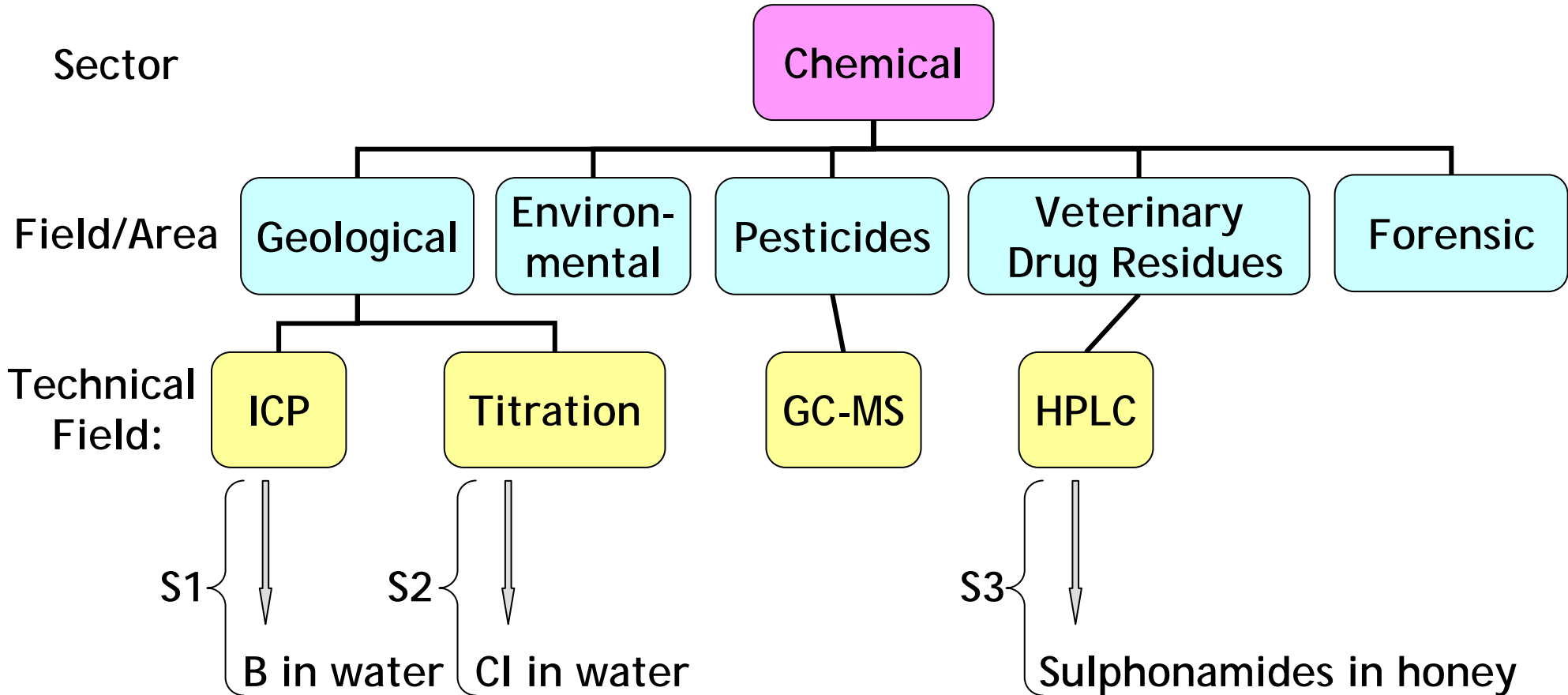
**upon availability*

Sub-discipline: A tool for efficient planning

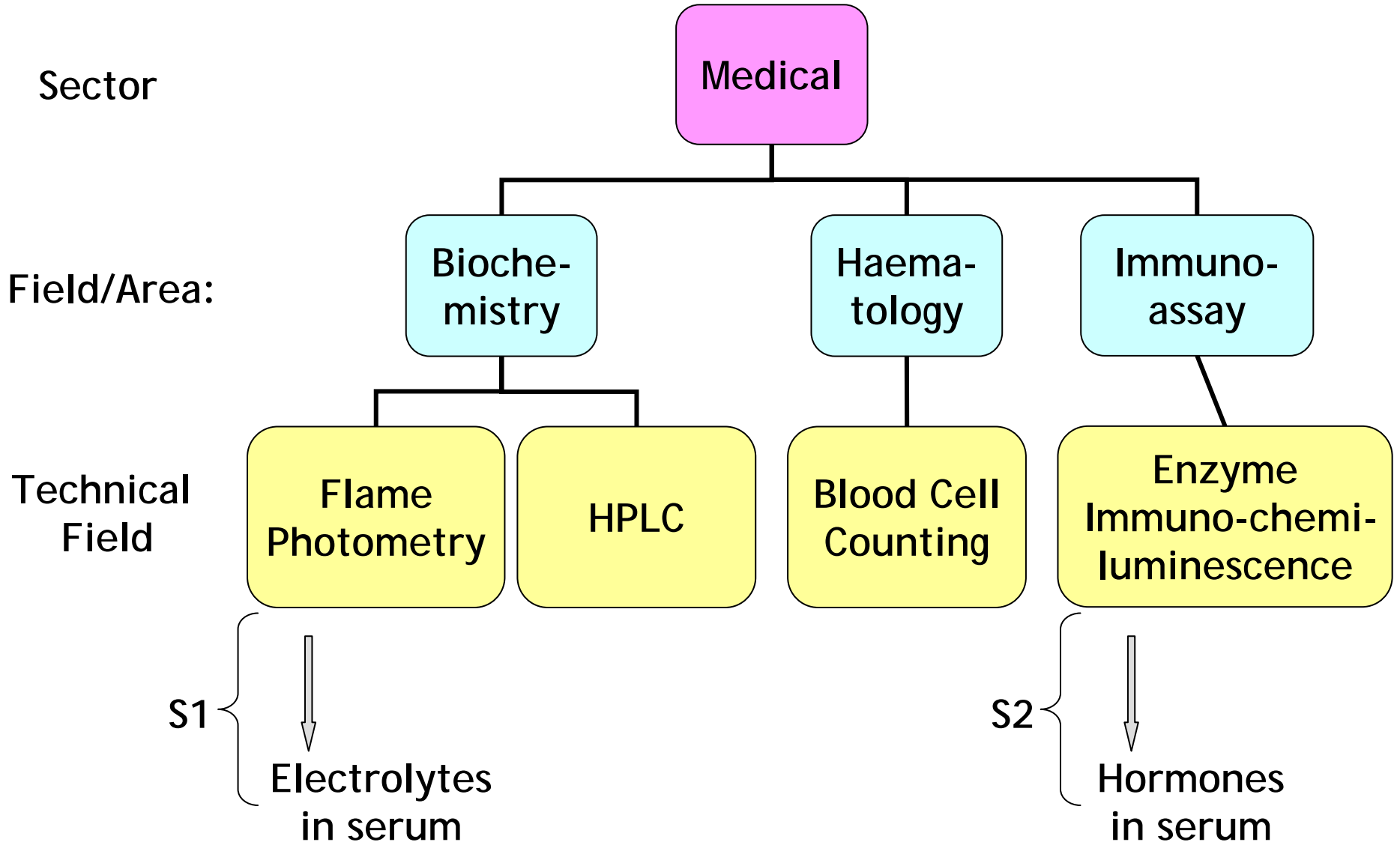
The sub-discipline refers to an area of technical competence defined by a minimum of one measurement technique, property and product which are related.

How to define a sub-discipline?

Example (1)



Example (2)



A discipline does not include...

all parameters. However, rotation of all of them is expected and assessed during surveillance visits, so that the whole scope of accreditation is covered during the 4-year accreditation cycle.

In medical labs, the participation per sub-discipline covers all parameters.

Labs' policies/procedures shall include

- participation plan (including all sub-disciplines, level and frequency)
- acceptance criteria for results
- evaluation of results
- non-conformity policy in cases of unsuccessful or otherwise questionable results
- investigation/ corrective actions
- notification to the customer, as appropriate
- additional measures
- documentation

Discussion

Table for the participation of laboratories in PT schemes

PT provider	Scheme	Accredited? Y/N	Method/ Equipment	Matrix/ Parameter	Analyst	Result	Comments*

**refer to corrective actions for unsatisfactory/questionable results*

The laboratories in Cyprus

- utilize also their results (expressed as z-score or otherwise) as a quality indicator of their performance,
- review their performance in correlation with defined % targets for satisfactory results (e.g. $|z| \leq 2$) and specify new % targets.

Assessment Teams evaluate both...

- PT/ILC results and actions taken by the lab
- investigation by the lab, appropriateness of corrective actions and their effectiveness
- occurrence/percentage of unsuccessful results

Based on the above, not as the sole criterion, the Team may propose

- a limited scope or not granting accreditation (in initial assessment/extension)
- suspension, reduction of scope or withdrawal of accreditation (in surveillance)

FAQs (*Frequently Asked Questions*) on PTs (1)

Is it expected that the best analysts in the lab are to be involved?

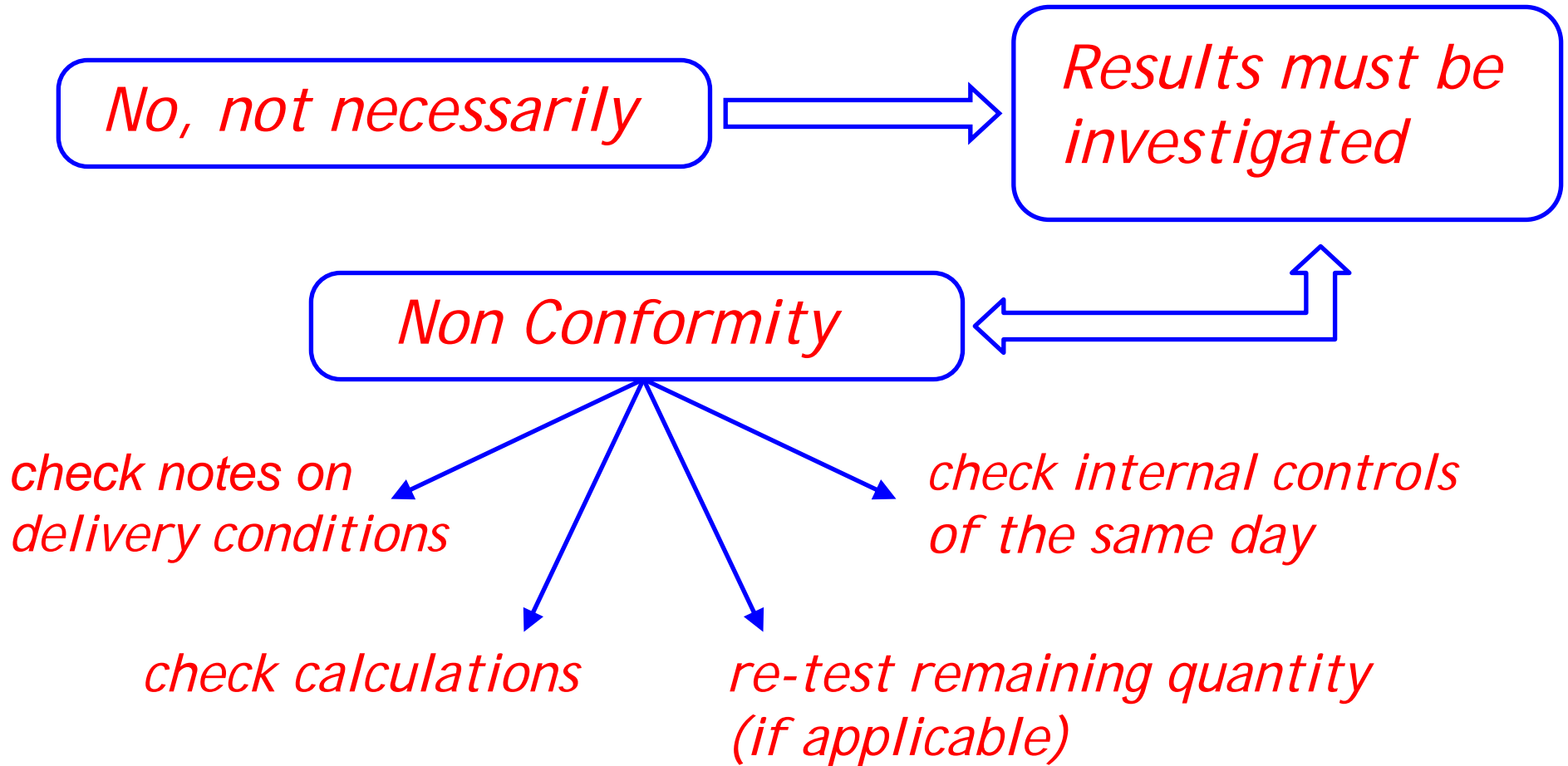
- *No, rotation of analysts, as part of the documentation of their maintained competence.*

Is particular care taken to ensure that the PT sample is tested in the most reliable way?

- *No, just as a normal routine sample.*

FAQs on PTs (2)

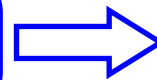
Does an unsuccessful result mean failure?



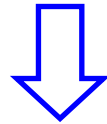
FAQs on PTs (3)

What can the lab do in case no PT scheme is commercially available?

Inter-laboratory comparison

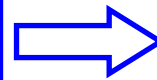


with one lab (at least)



protocol describing

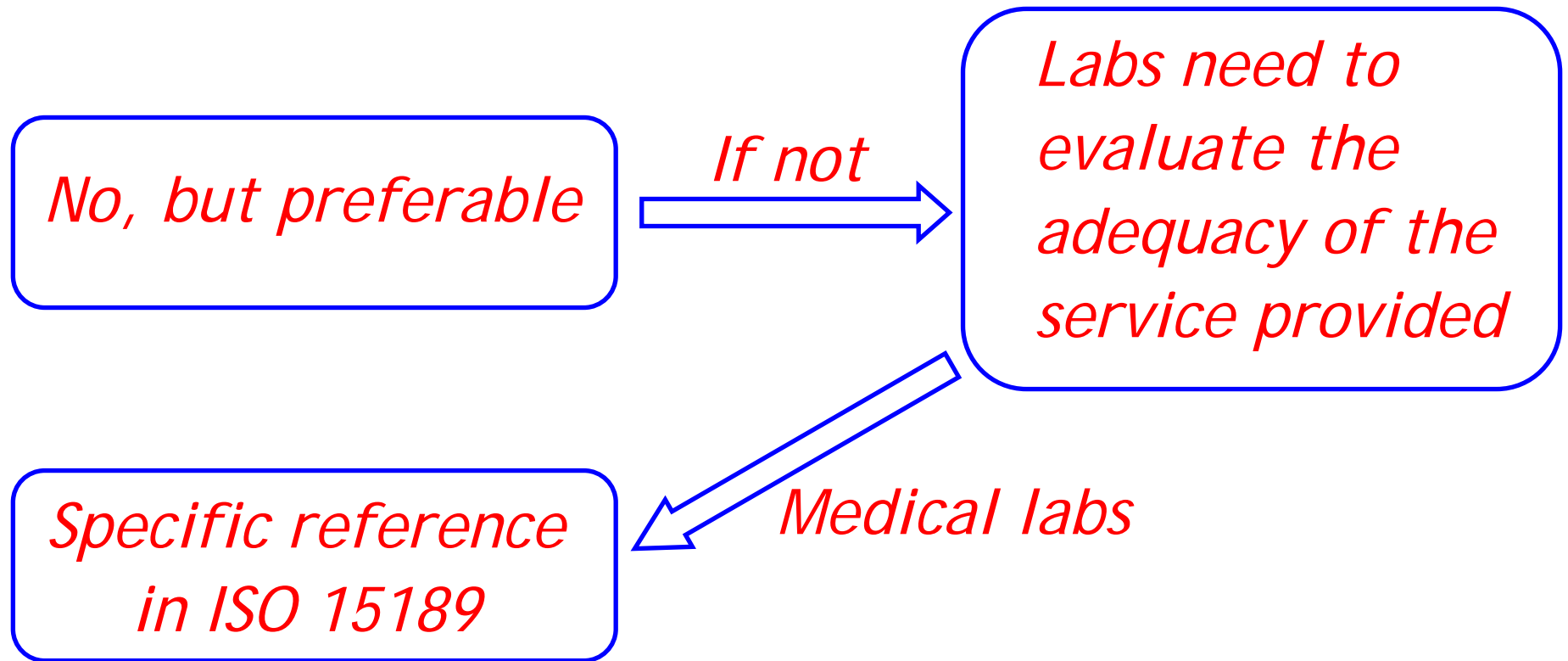
- *time planning*
- *sampling*
- *methodology*
- *analysis of results*
- *criteria for their evaluation*



homogeneity and stability issues need to be elaborated.

FAQs on PTs (4)

Is it necessary to find an accredited PT scheme?



Medical labs (1) the “black box” problem

There are additional needs for external quality assurance due to the fact that all main factors affecting the results (equipment, controls, calibrators, reagents) are usually supplied by the same source.

Further to this...

Medical labs (2)

particular features

- Small medical laboratories in the private sector are encouraged to participate in PT schemes in accordance with their normal patient testing requirements.
- For accredited parameters that are not part of the routine workload, the frequency for PT participation can be lower; however regular internal control is required.
- Participation in PT schemes is done according to the method and equipment used by the lab.
- PT participation is monthly or bi-monthly depending on the type of examination and the PT scheme the lab participates.

Medical labs (3) particular features

PT schemes provide clinically relevant samples to check the entire examination process including pre- and post-examination procedures.

- Non availability of an appropriate PT scheme is rather exceptional
- Examples as yet:
 - CK-MB in biochemistry and
 - faecal occult blood in microbiology

In these cases, ILCs were organised by the labs according to well defined pre-determined conditions.

Chemical and Microbiology Labs

- They participate in PT schemes for each activity of their scope of accreditation once or twice a year depending on the type of examination and the PT scheme the lab participates in.
- The participation in PT activities of accredited parameters or products tested with the same technique (*sub-discipline*) may not necessarily include all of them each time.
- Coverage of all accredited parameters/products, by rotation within the four-year cycle is required.

The new standard ISO 17043:2010

Shall be implemented by all parties as from 1.2.2012

Will apply to PT providers for testing and calibration laboratories and inspection bodies

Specifies requirements, both technical and management, for PT providers

In case PT provider/scheme is not accredited then the lab shall evaluate the compliance with ISO 17043

Problems of non-availability of PT...

are faced in some sectors i.e. construction products, calibration (volumetric).

In the case of some construction products, namely concrete cubes, PT schemes provided from outside Europe presented problems:

- high cost,
- use of other regional standards.

Calibration

- Only two (2) calibration labs have been as yet accredited by CYS-CYSAB
- Due to non-availability of PT schemes (within a realistic timeframe), bilateral comparisons with EIM (the Hellenic NMI) were planned and carried out to serve the purpose

Participation in PT schemes

Since 2006, CYS-CYSAB has been disseminating information received from EA, APLAC, IMEP and other bodies inviting laboratories to participate in relevant schemes. Laboratories accredited, either by CYS-CYSAB or other accreditation bodies, were encouraged to participate in such PT Programmes; there was participation in 26 schemes.

Benefits from PT participation

The Cyprus experience

- Monitor and improve quality of measurements
- Reliability of results
- Evaluation of laboratory's performance
- Greater process control
- Demonstrate competence to customers
- Determination and monitoring of the personnel competence, development and training
- Monitor methods and equipment

References

- CYS EN ISO/IEC 17011:2004 - Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
- CYS EN ISO 15189:2007 - Medical laboratories - Particular requirements for quality and competence
- CYS EN ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories
- EN ISO/IEC 17043:2010 - Conformity assessment - General requirements for proficiency testing
- EA-4/18 - Guidance on the level and frequency of proficiency testing participation, June 2010
- Eurachem Guide: Selection, Use and Interpretation of Proficiency Testing (PT) Schemes, 2nd Edition, 2011
- Minutes of the EA LC meeting, Paris, 9-10 March 2011