

Eurachem2020 Virtual Workshop

Basic elements of quality assurance for university graduates

Practical needs based on a 30-year experience

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This presentation is...

a proposal for the framework of basic elements on quality assurance to be included in the curriculum of chemistry departments of universities, preferably in the 3rd year.

The duration could be 8-18 hours, depending on subjects already taught, mainly under Analytical Chemistry.

Elements listed refer to

- terminology
- understanding of aspects causing confusion
- quality assurance – where and why is it necessary?
- analysis of tools used and requirements for their adequacy
- reference to certain systems describing how quality assurance could be implemented in various activities
- the quality infrastructure in today's society.

Emphasis is given to...

industrial and laboratory activities i.e. the main orientation of graduates;

→ *the latter includes testing, calibration and sampling as well as R&D.*

It is not expected that the various aspects have to cover all needs in depth.

Continuous training and experience will anyway be required...

The society is based on Rules!

Rules provide for everything...

- Food safety - *what we eat*
- Hygiene of water - *what we drink*
- Quality of the air - *what we breath*
- Quality of medicines - *what we receive for health treatment*
- Quality of building products and constructions
- *housing infrastructure, public works etc.*
- Environmental impact assessment, pollution, energy planning
- New Approach Directives (modules - notified bodies)

The society is based on Rules! (2)

- Safety of consumer goods e.g.
 - Toys safety - *what we play with*
 - Safety of electrical appliances – *what we use for lighting, heating, cooling etc.*
 - Speed limit - *how fast we drive*
 - Medical devices – *the whole range of materials and equipment used in the medical sector*
 - Forensic investigation
 - Anti-doping control
 - DNA testing
 - Dangerous substances
 - Medical services
- ...and more*

Young graduates find difficulties...

when looking for employment in industry or in a laboratory.

Not many universities have addressed quality and quality assurance issues to the extent required so that their graduates acquire the basic knowledge to meet the needs of the market.

Quality is...

the degree to which a set of inherent characteristics of an object* fulfils requirements
(ISO 9000:2015)

**product, service, process, person, organization, system, resource*

Quality fills the gap
of language and
communication

We really need
an international
technical language!

What does this technical language include?

- Standards - Standardization
- Technical rules - legislation
- Laboratory infrastructure
- Other conformity assessment bodies (CABs)
- Metrological infrastructure
- Certification
- Accreditation

plus terminology...

Where to find terms and definitions?

- ISO/IEC Guide 99 : International vocabulary of metrology – Basic and general concepts and associated terms (VIM) /JCGM 200
- ISO/IEC 17000 : Conformity assessment – Vocabulary and general terms
- ISO 9000 : Quality management systems – Fundamentals and vocabulary
- ISO/IEC Guide 2 : Standardization and related activities – General vocabulary
- Eurachem Guide Terminology in Analytical Measurement: Introduction to VIM3
- Regulation (EC) no 765/2008

➔ *Translation into national languages as necessary*

Could we refer to quality?

- Good or bad? *(see ISO 9000:2015)*
... but, on which basis?
 - Adequate or non-adequate?
...against certain detailed criteria.
- *Such criteria are usually included in standards and specifications*

How can we be sure that...

products and services meet standards and specifications?

→ by “conformity assessment”, i.e. checking that products and services meet the relevant standards and specifications.

Conformity assessment means...

the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled*.

Conformity assessment body is...

a body that performs conformity assessment services*. This includes testing/calibration laboratories, inspection and certification bodies**.

* *ISO 17000:2020*

** *Regulation (EC) no 765/2008*

What do the following terms mean?

- standard - specification
- quality control - quality assurance
- risk-based thinking - preventive action
- repeatability - reproducibility
- precision - accuracy - trueness
- validation - verification
- internal control - external quality assurance
- traceability - metrological traceability
- procedure - method - examination
- measurement uncertainty
- certification - accreditation

Quality assurance is defined as...

part of quality management focused on providing confidence that quality requirements will be fulfilled*; it is of importance in all activities of economic interest with regard to products, services and procedures, including conformity assessment activities.

** ISO 9000:2015*

Many terms refer to quality



(for more terms and definitions, see ISO 9000:2015)

Quality assurance in various sectors

- Good Manufacturing Practice (GMP)
- Good Laboratory Practice (GLP)
- Good Agricultural Practice (GAP)
- Food industry (HACCP)
- Health services
- Laboratories
- Other CABs
- Other activities (environmental management systems)

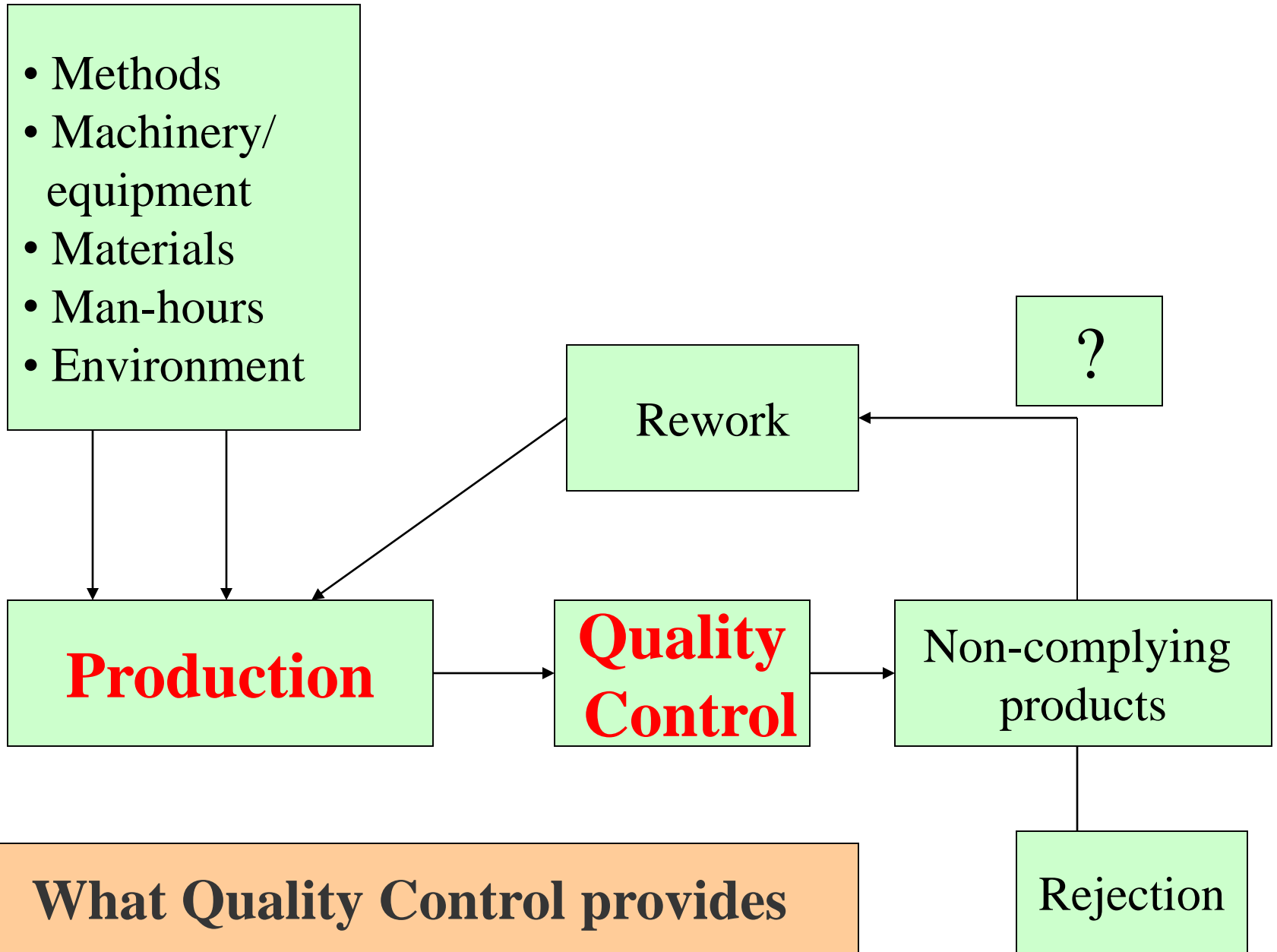
A quality management system

- Quality Manual
 - Documents (procedures, work instructions etc.)
 - External documents
 - Non-conformities
 - Corrective-preventive actions
 - Internal Audit
 - Records
 - Management review
- ➔ Audit/assessment by an authorized body

What is necessary in each case...

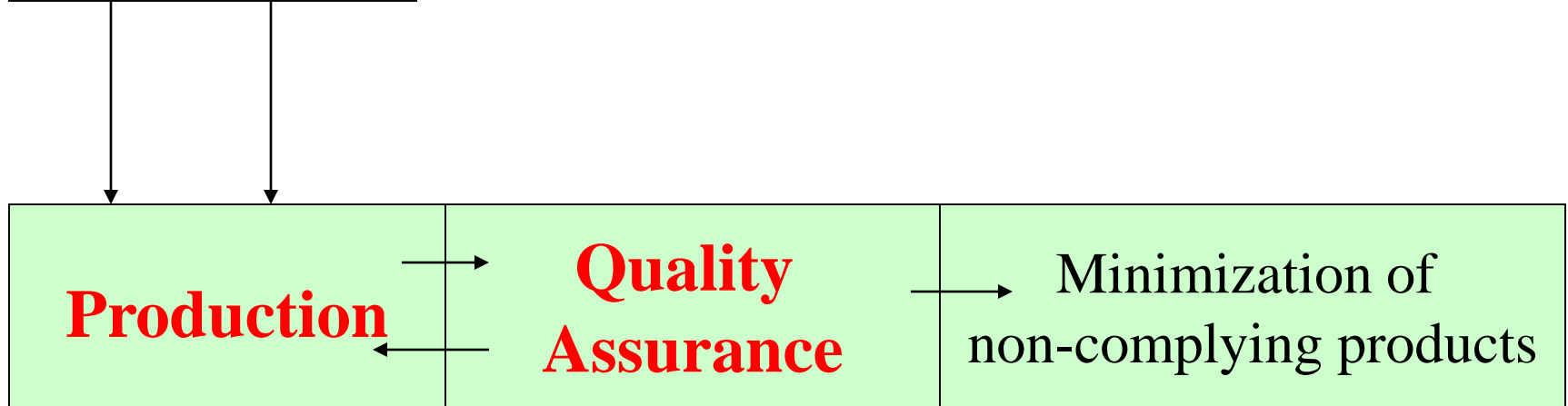
is to define the detailed content of quality assurance, appropriate to the specific requirements with reference to

- the nature of the activity and related products and services
- the use of the outcome of that activity
- the legal and other requirements



What Quality Control provides

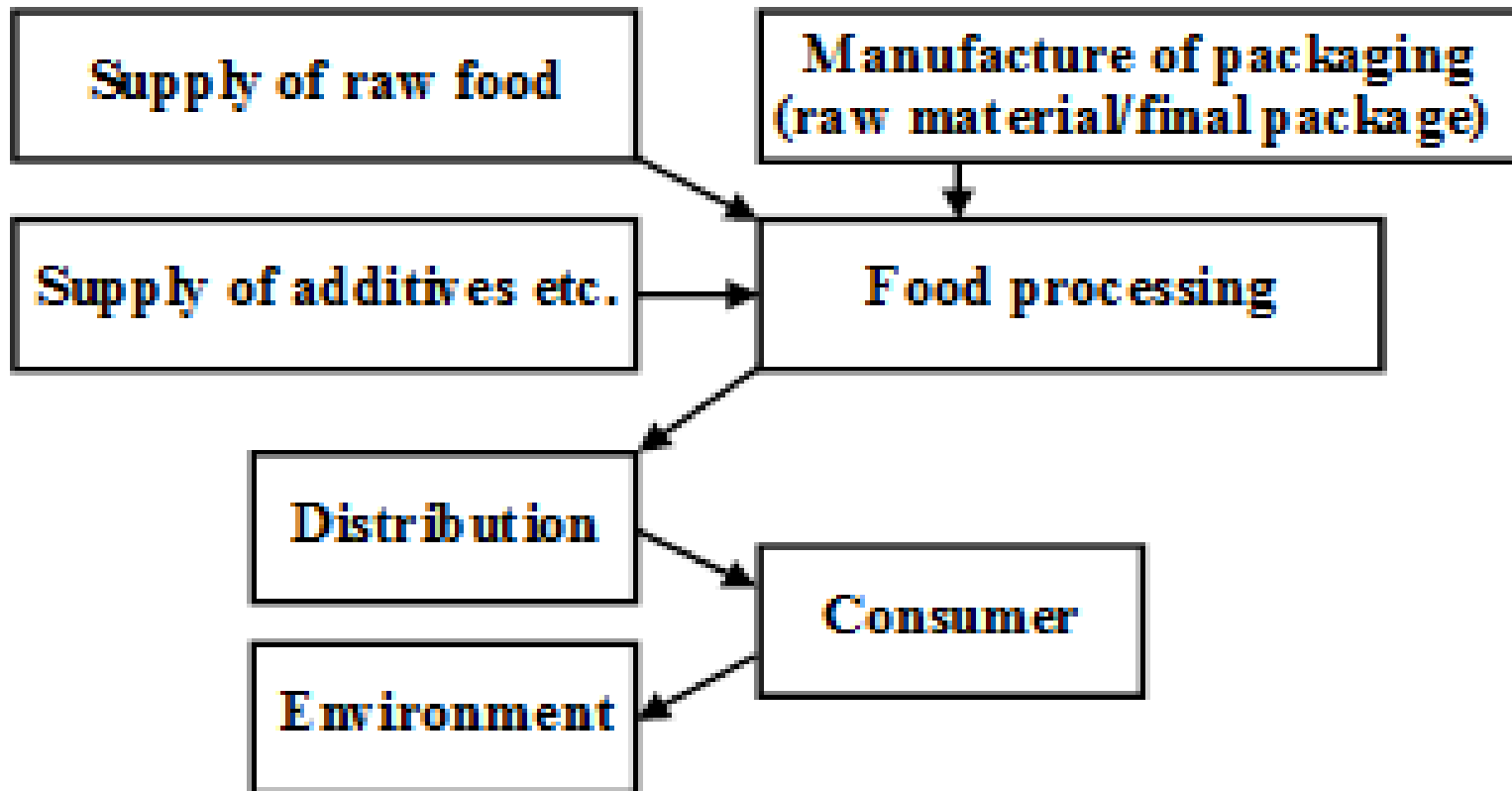
- Methods
- Machinery/
equipment
- Materials
- Man-hours
- Environment



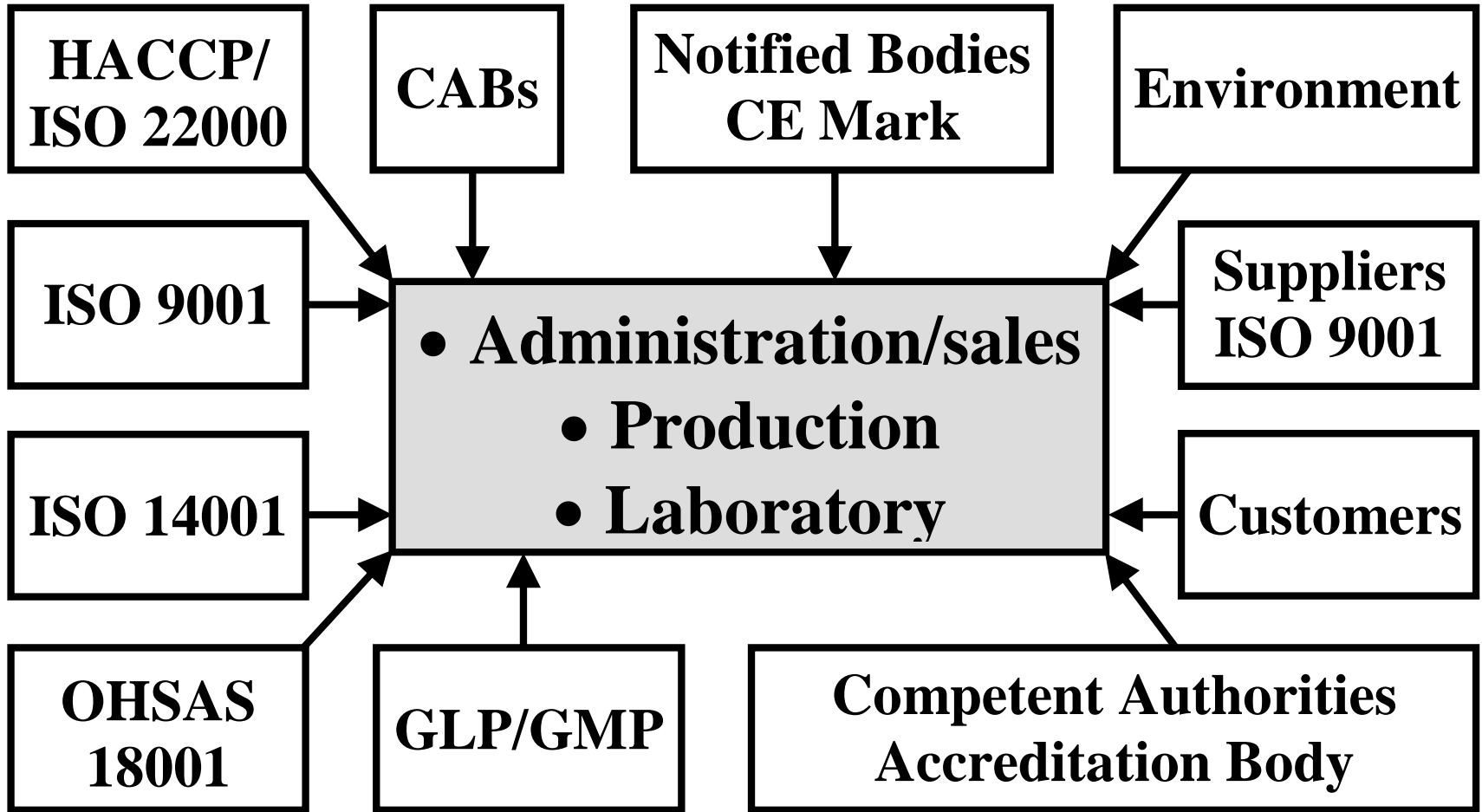
What Quality Assurance provides

Quality Assurance is...

of importance not only for a particular activity but also for activities linked with it; an example: Food industry



Interactions of an industrial activity



We need to measure!

- This means we need to compare an unknown value of a material substance with a known one
 - Thus we need an **appropriate method**, **qualified personnel** and **equipment** operating in a suitable environment
- measurement and testing are required to assess for compliance!
- *The history of measurements goes back to ancient times...*

To achieve Reliability...

Accreditation

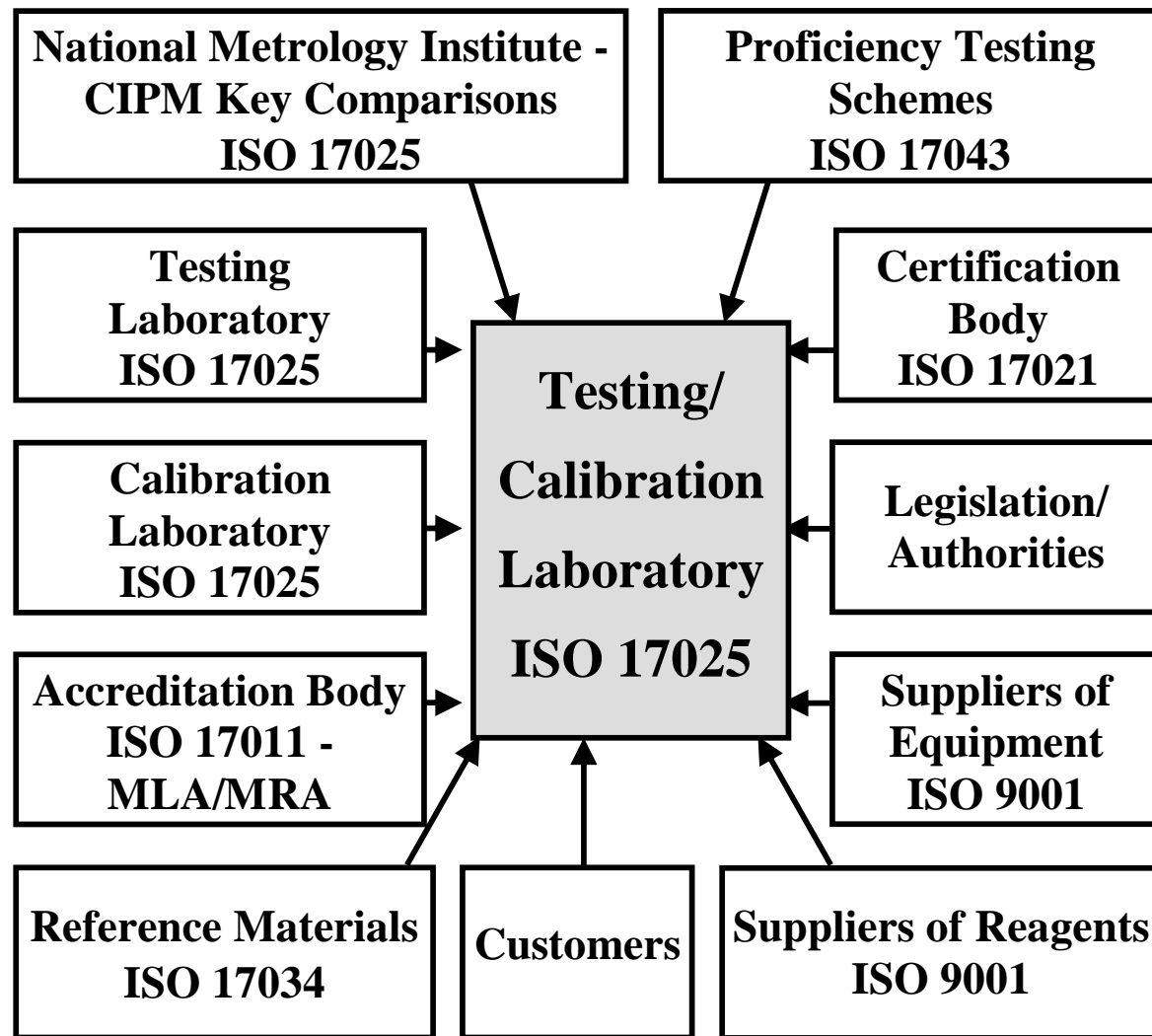
Technical
competence

Reliability

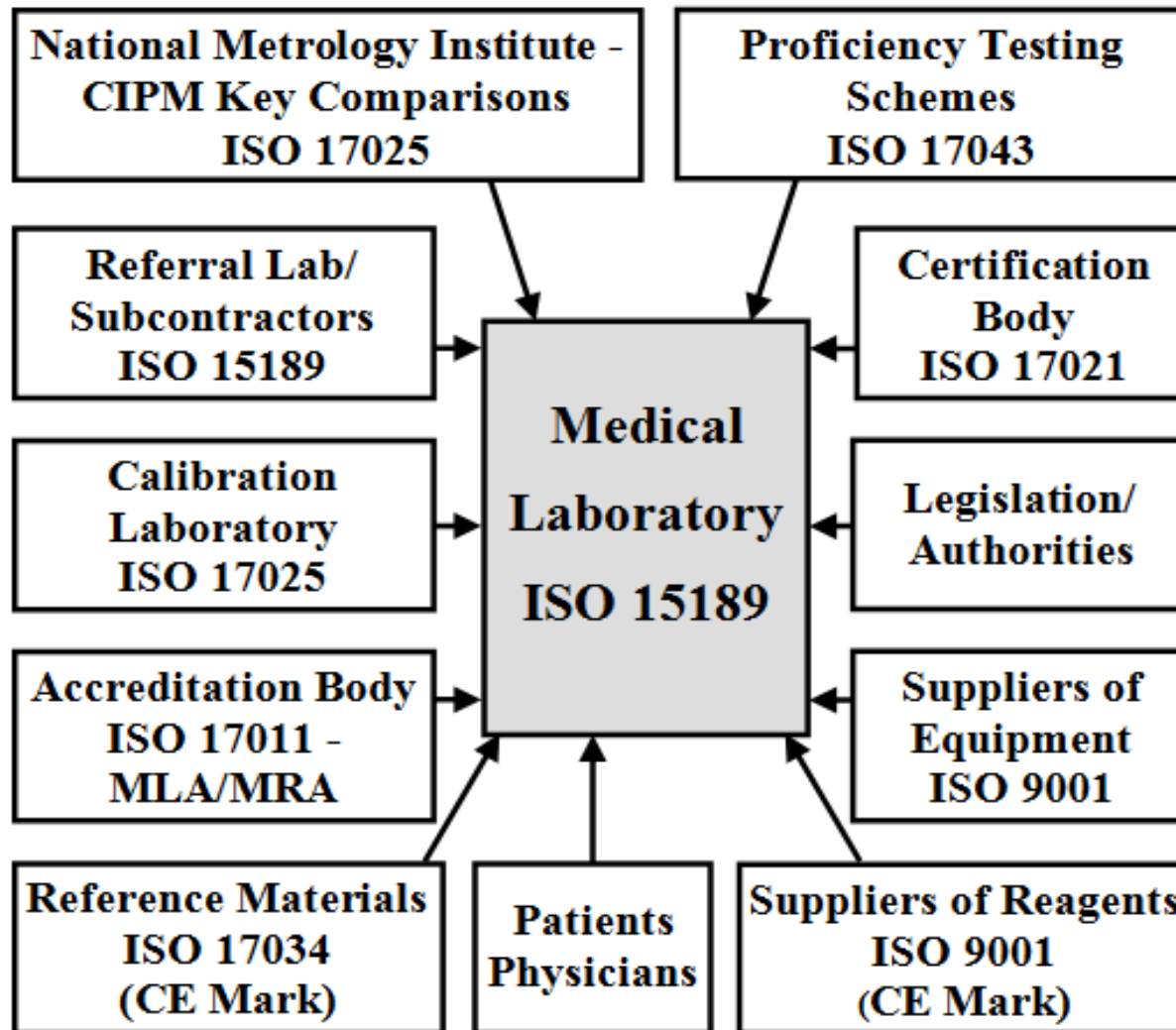
- Competence of personnel
- Suitability of equipment
- Metrological traceability
- Internal quality control
- Interlaboratory comparisons
- Method validation/verification
- Measurement uncertainty

Quality Management System (→ Certification?)

The environment of a laboratory



A slightly different case: A medical laboratory



Is the method appropriate?

- In some cases the method to be used is specified either by a legislative document or by the customer
- In other cases it is within the role of the laboratory to choose which method is appropriate for a certain task; to this end, the quality features of the method have to be considered

The laboratory may prefer...

to use a standard method (or one which is well recognised). This gives the advantage of the method being validated and also ensuring a common basis in communication and understanding with the customers and other users of the laboratory results.

If this is the case, verification is required; otherwise, validation is required.

Is the equipment to be used...

appropriate for the method to be implemented and give results within the specified quality performance?

- *The equipment needs to be properly maintained and calibrated with justified frequency*
- *Appropriate environmental conditions need to be ensured*

Calibration of equipment...

needs to be organised and carried out in a way to adequately document metrological traceability; this refers to the methods used, the frequency, the level in the metrological hierarchy;

→ *Calibration laboratory accredited for the specific parameter (preferable) or otherwise assessed.*

The competence of the personnel...

for the tasks undertaken needs to be demonstrated, both prior to their authorization and afterwards, on continual basis.

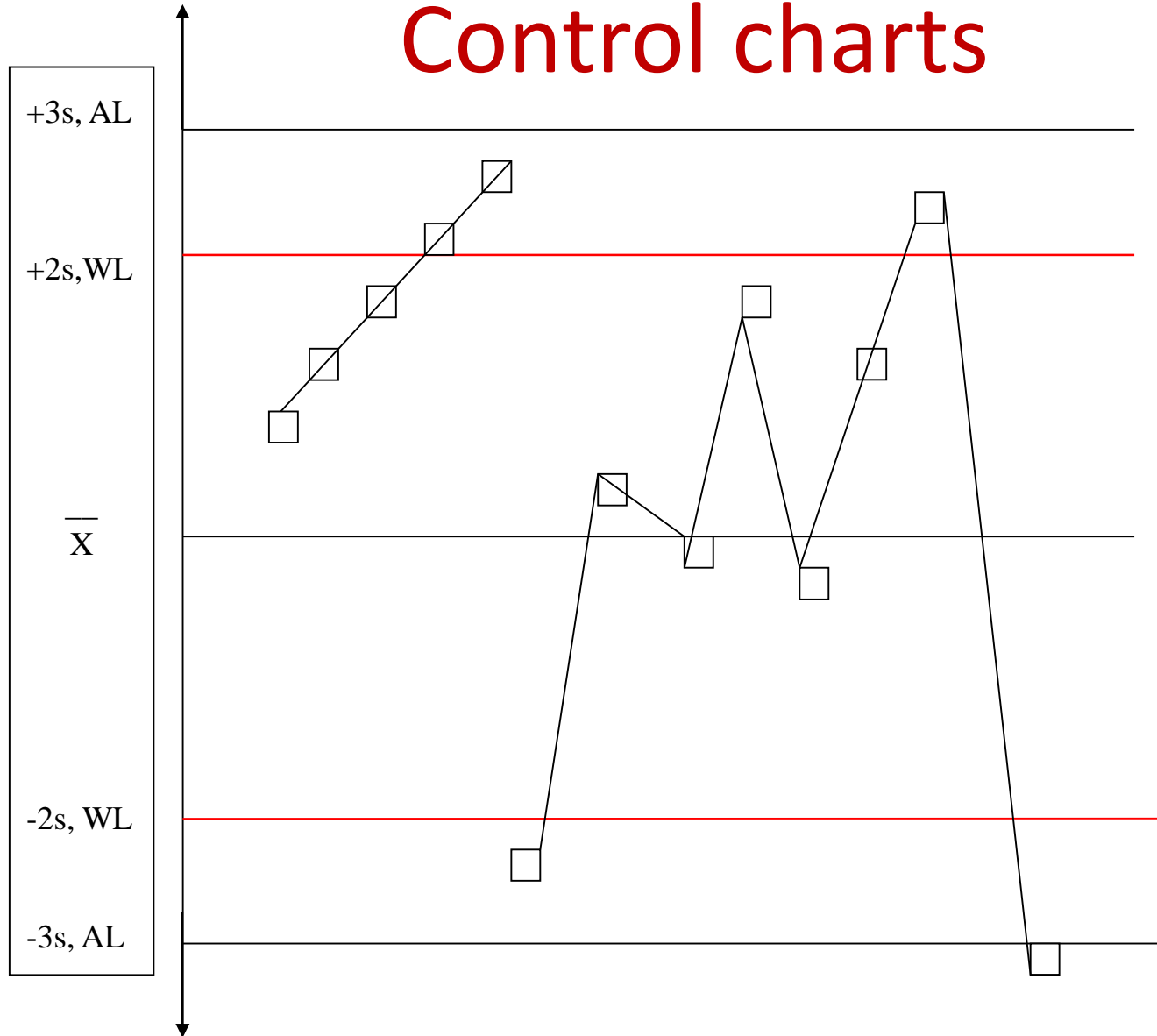
→ *Relevant criteria refer to academic background, experience and training, successful participation in external quality assurance schemes*

Internal control...

provides an efficient tool to monitor the laboratory's performance and illustrates trends and deviations from the set limits (warning limit - WL, action limit - AL)

→ *Control samples covering the whole range of measurements need to be used in each case.*

Control charts



Specific requirements

are set for the (certified) reference materials used (traceability) and the service provided by their suppliers (ISO 17034)

Is the internal control adequate?

Could we detect any systematic error?

Possibly No! Reference to medical laboratories!

This is why we need

to have also external quality control.

A number of laboratories participate in the measurement of samples distributed by proficiency testing providers.

Specific requirements...

are set for the proficiency testing (PT) schemes and their providers (ISO/IEC 17043). In case such conditions are not met...

Interlaboratory comparisons (ILCs)

could be organised by a number of laboratories, based on a protocol describing

- sampling, distribution of samples
- method(s) to be used
- criteria for the analysis of the results.

→ *In all cases (PT and ILC) all personnel authorised for a method needs to be involved on rotation, based on an appropriate plan.*

Participation in PT schemes...

is a tool for

- competence (initial and on-going)
- improvement
- training
- confirmation of reliability

- How sure are we about the reliability of a measurement?
- Which is the cost of a non-reliable measurement?
- In a number of cases, mainly but not only in the health sector, this cost is not only economic!
- the cost of reliable measurements is less than the cost for non-reliable (or lack of measurements)

The meaning of uncertainty...

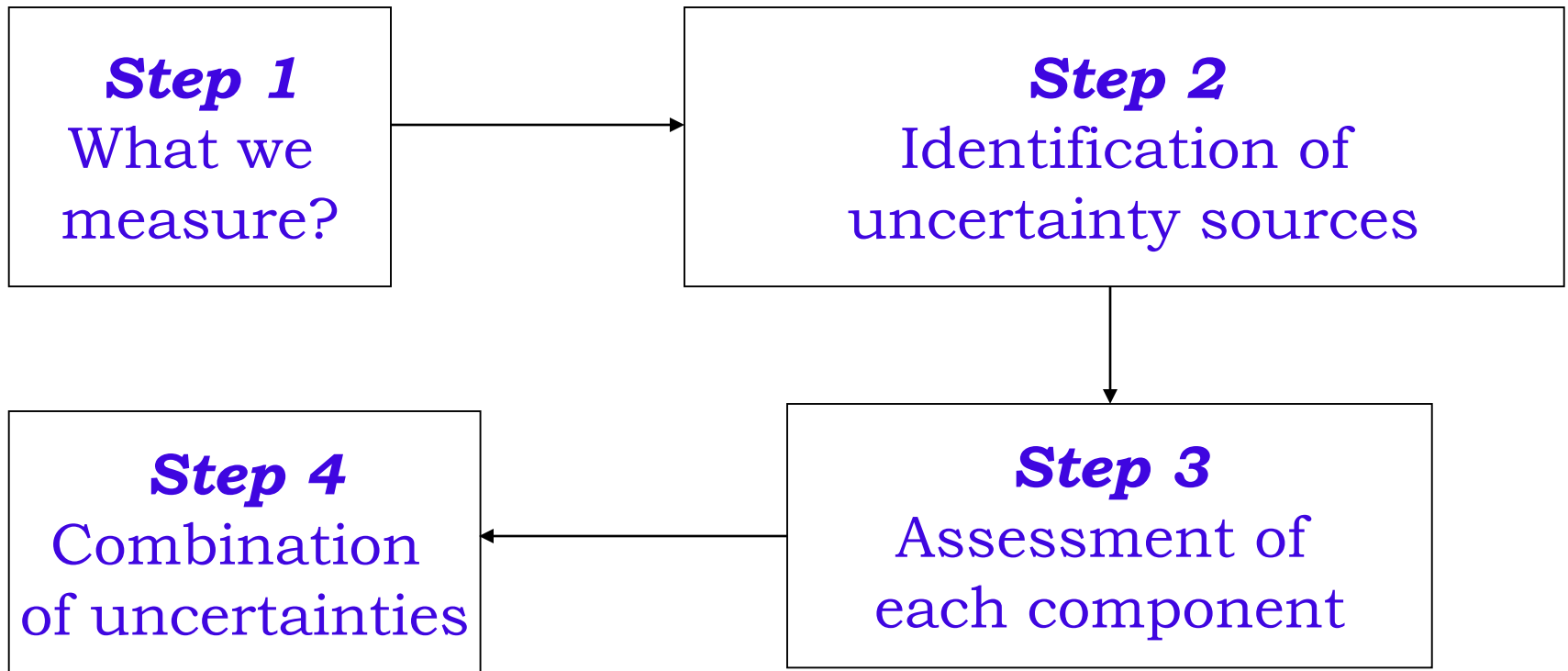
is still not well conceived by the customers.

Not all of them are prepared to pay for a result that is “uncertain to a quantified extent”.

They do not realise that expression of measurement uncertainty is required to illustrate reliability, provided that it is evaluated correctly!

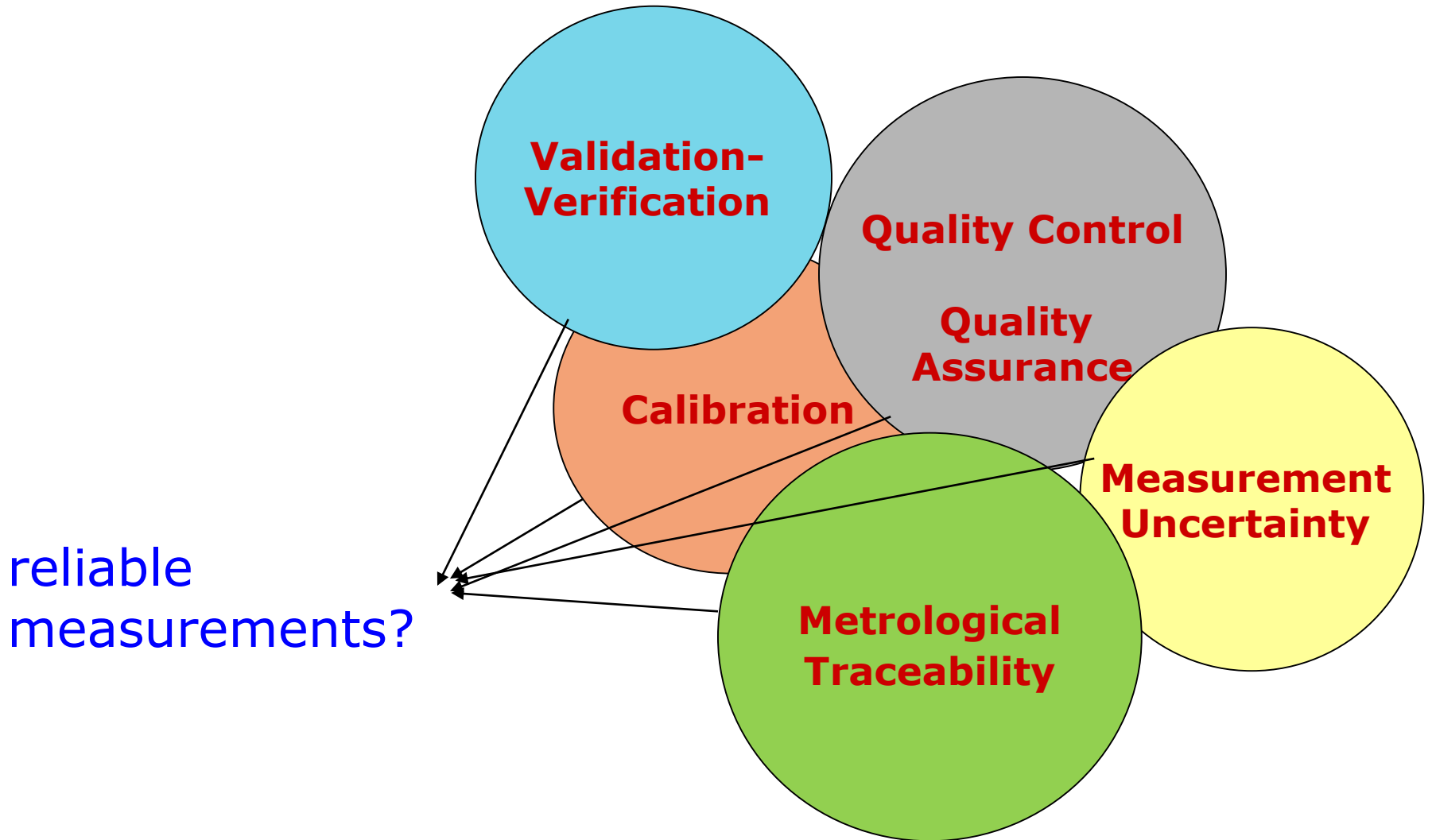
What about uncertainty?

Analysis of various steps



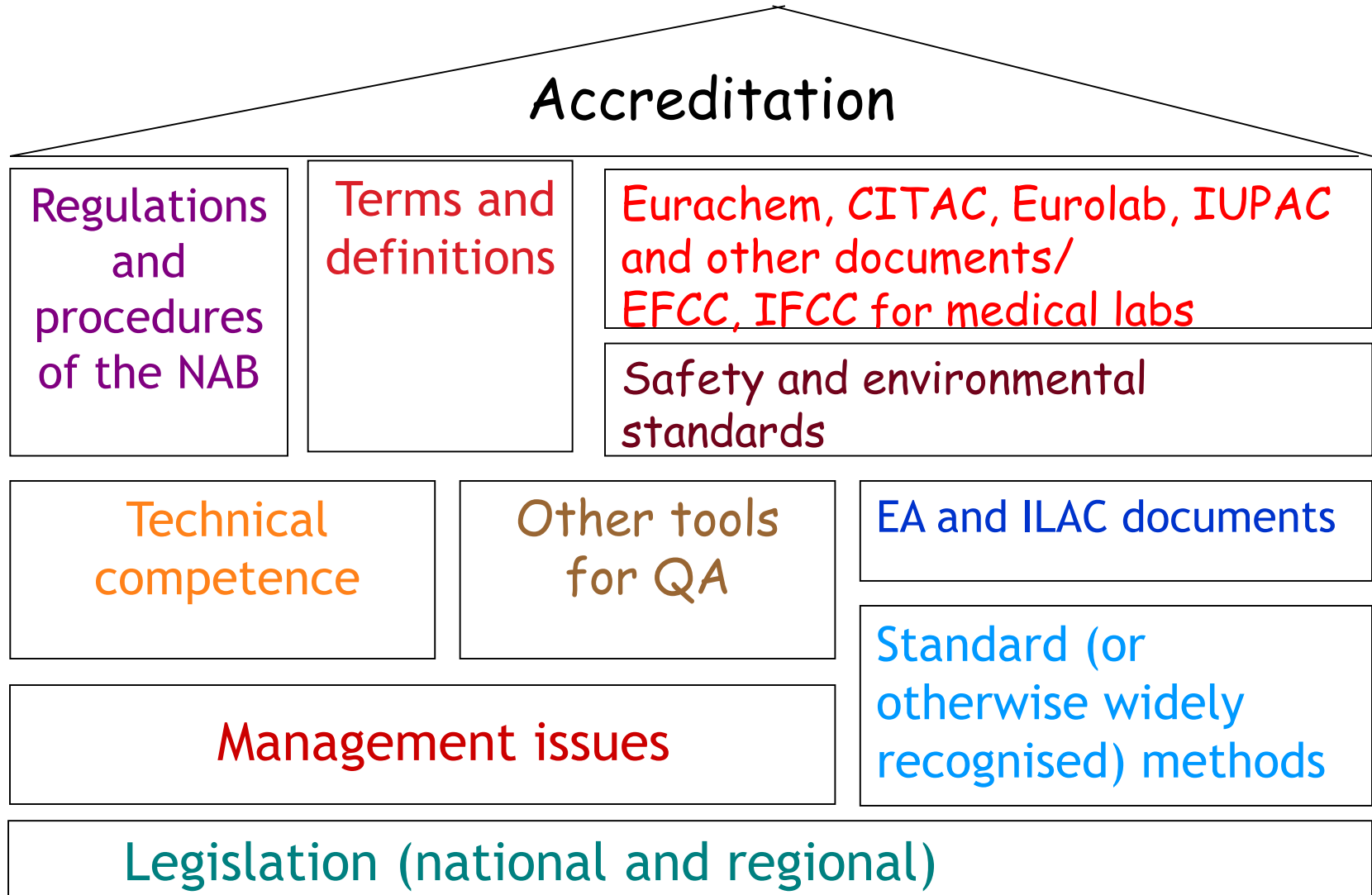
Evaluate measurement uncertainty → increase of reliability

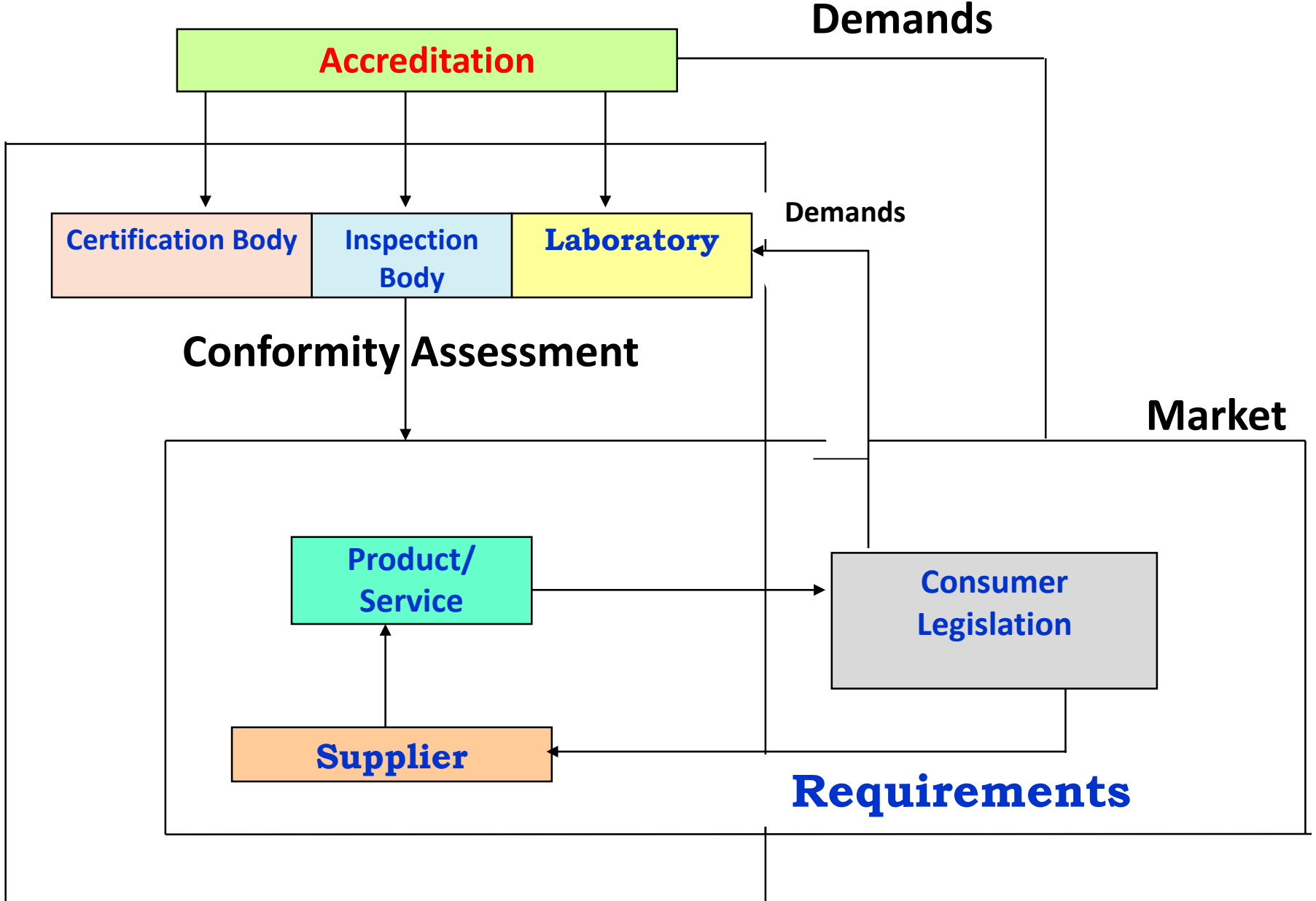
What is needed



reliable
measurements?

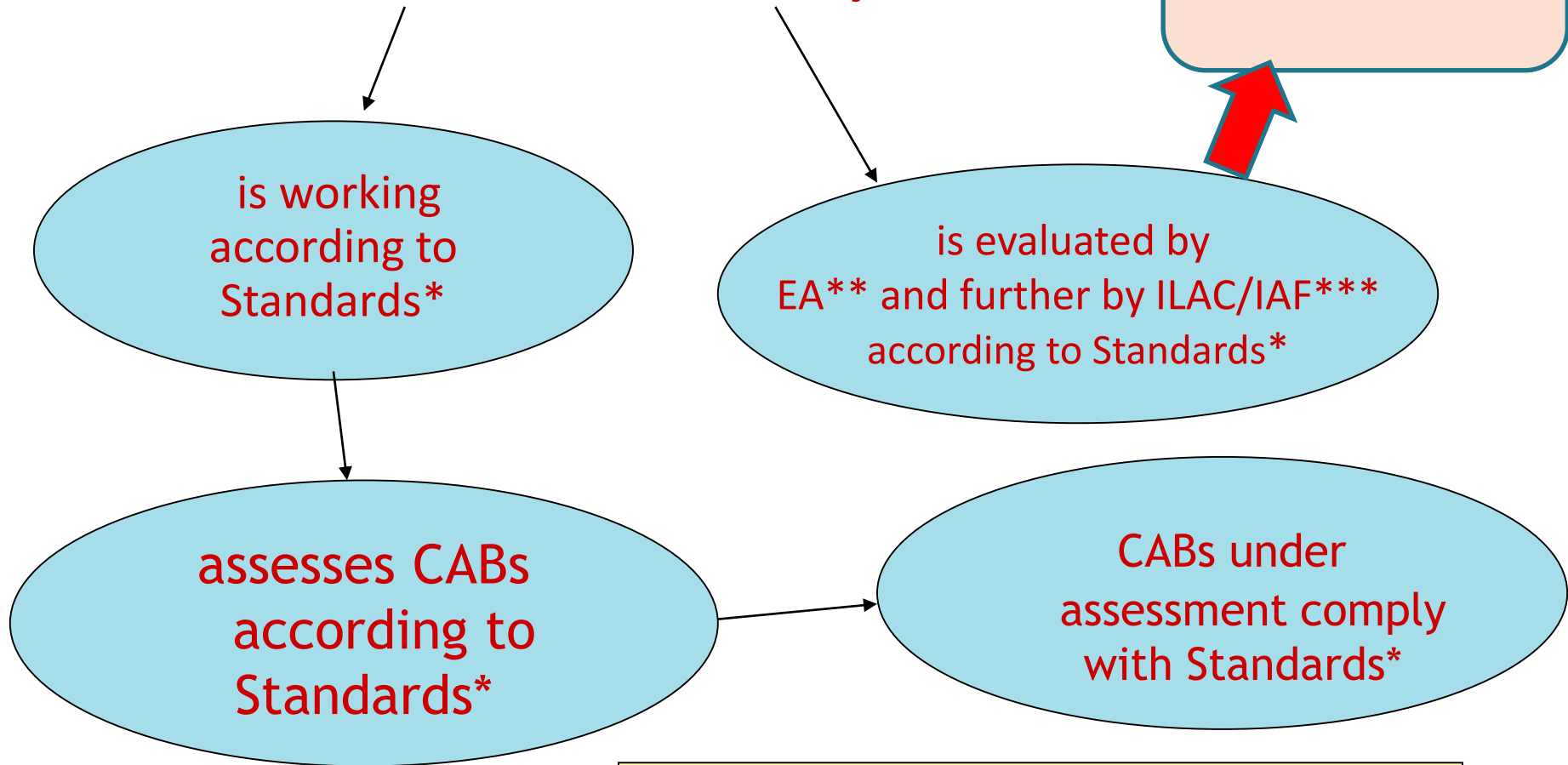
How to “build” a laboratory





The quality infrastructure in today's society

An Accreditation Body...



- * european/international
- ** European cooperation for Accreditation
- *** International Accreditation Organizations

Sources of information

- www.european-accreditation.org
- www.eurachem.org
- www.eurolab.org
- www.ilac.org
- www.irmm.jrc.be
- www.iso.org
- www.bipm.org

It is very useful to ensure...

an adequate interaction with the students. To this end, students could be given some tasks to find information in the literature - Eurachem, Eurolab, EA, ILAC etc. and submit comprehensive reports.

➔ *This makes them familiar with the main sources of information and have a better understanding.*

This proposal is supported...

by a 30-year experience gained through a wide range of training and awareness activities...

- *with widely varying audience from under graduate students to accreditation assessors and*
- *the involvement in the work of Eurachem and other networks*

as well as a successful pilot implementation in the Chemistry Department of the University of Cyprus.

Thank you for your attention

....and your questions