Eurachem Workshop
Quality in Analytical Measurements
from Specification to Decision

Training needs to understand Quality Assurance

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A number of terms

related to Quality and activities supporting it are used; it took all of us a long time to properly understand and use them in a harmonised way.

To this task, standards and other documents e.g. VIM are quite important tools.

However…

Much more effort is required…

to ensure a common understanding of basic aspects of quality assurance and their use as tools in a common technical language for all interested parties; this refers to both the laboratories and the users of the services they provide i.e. the industry, the competent authorities, contracting authorities/organizations and individuals.

Training and awareness

is thus required at all levels so that quality assurance helps the expectations of the stakeholders and the overall quality and economic goals of the society to be met. Main issues to be addressed are

- what to look for
- how compliance with requirements is documented
- how an assessment of compliance is confirmed.

This is how quality culture is created and enhanced.

Frequently asked questions…

- What does quality assurance refer to?
- What does certification mean - Which activities are certifiable?
- What does accreditation mean? – What is accreditable?
- Is certification and/or accreditation mandatory for activities to which they apply? What is the alternative?

The scope of this presentation is…

- to refer to some examples of confusion
- to illustrate training/awareness needs on specific aspects of interest to the main parties involved in each case.

Most of these aspects refer to all conformity assessment bodies and their stakeholders; this presentation gives emphasis to laboratories.

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 17000:2004*

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

Quality Assurance is defined as…

part* of quality management focused on providing confidence that quality requirements will be fulfilled; other parts are quality planning, quality control and quality improvement. *(ISO 9000:2005)*

**planned and systematic activities implemented within the quality system, and demonstrated as needed… (ISO 8402:1995, superseded by ISO 9000)*

Quality Assurance is linked with

other terms as described in ISO 9000 and illustrated in the following diagram. The same terms apply and are of decisive importance in all activities of economic interest with regard to products, services and procedures, including conformity assessment activities.


quality management system
management
quality management
quality policy
quality planning
quality control
quality objective
quality assurance
quality improvement
continual
improvement
(ISO 9000:2005)

Quality Assurance is…

of importance not only for a particular activity but also for activities linked with it; this may include supplies, manufacture, marketing, conformity assessment, accreditation, competent authorities, customers.

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

Who introduces the requirements?

- the legislation e.g. food, medicines, New Approach Directives, construction products regulation, environmental legislation, health services
- the market
  - big organizations
  - the well informed and demanding customer
  - the competition

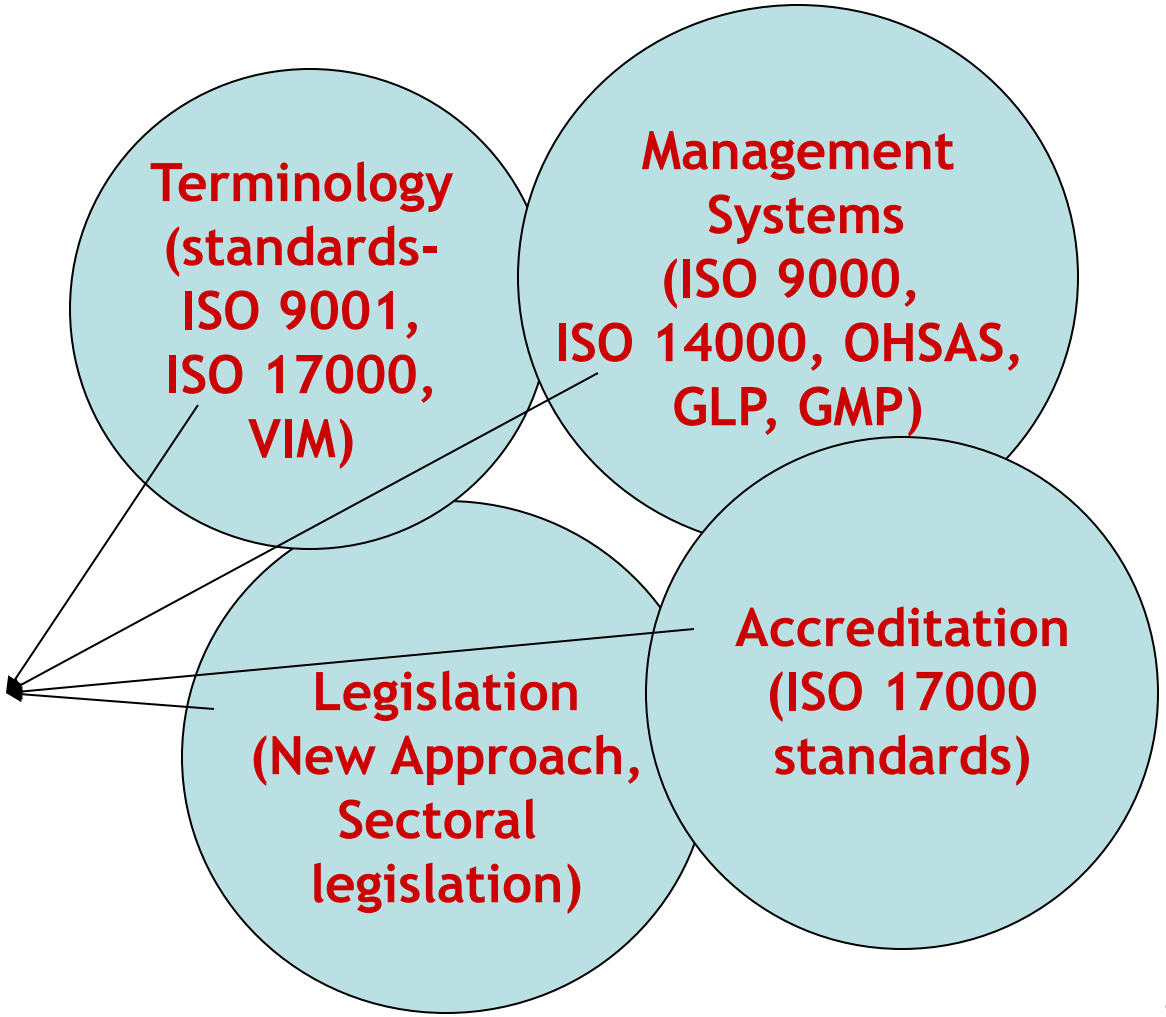
Common aspects

→ A quality management system which mainly consists of the following:

- Quality Manual
- Procedures
- Working instructions
- External documents
- Records

The main documents are…

Requirements



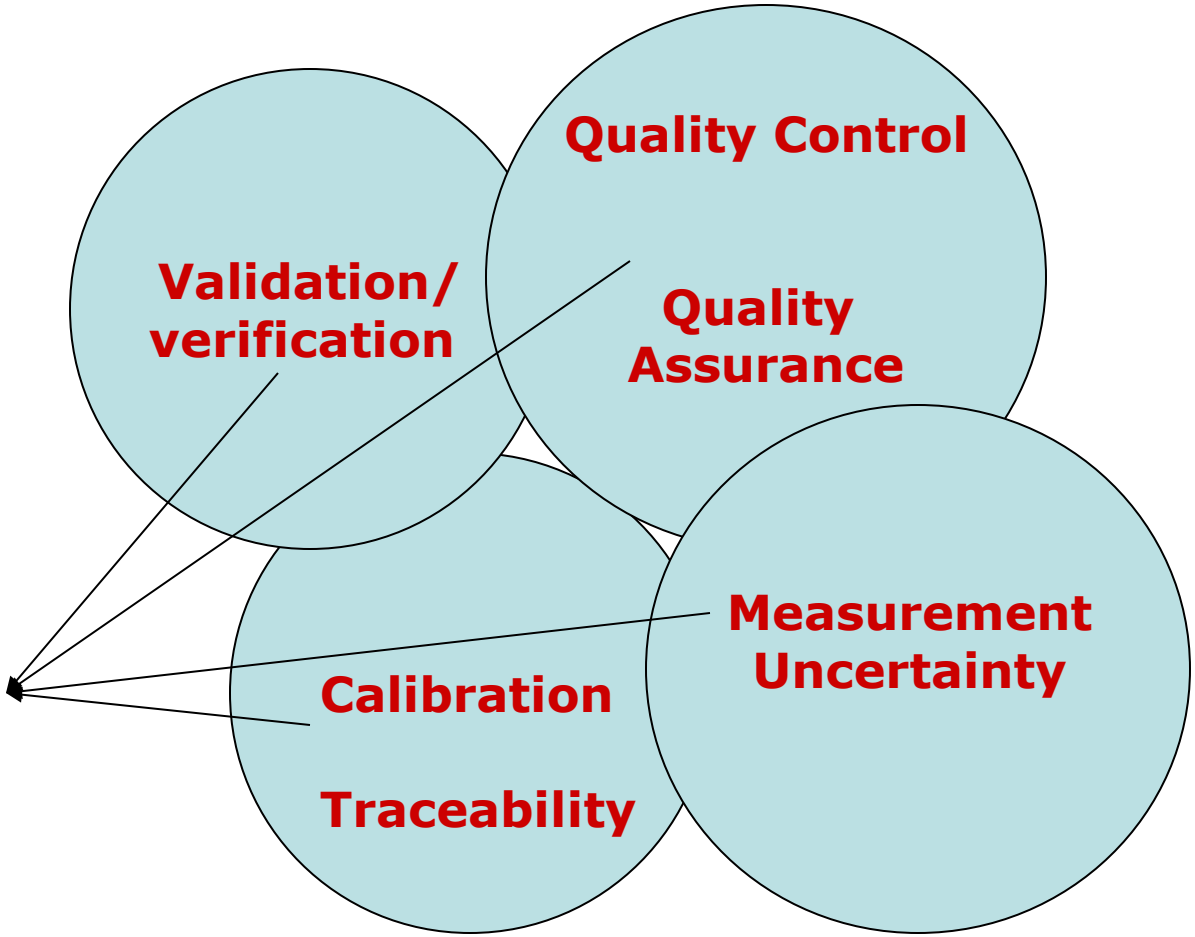
During the Workshop…

all elements of quality assurance within the laboratory have been addressed. In the case of some of them e.g. PT schemes, RMs, calibration services, the laboratory has to rely on services provided by others.

On the other hand the user of the laboratory services may not be adequately aware of all aspects related to quality and quality assurance.

For reliable measurements…

Reliable measurement



Confusion and misunderstanding*

Some examples

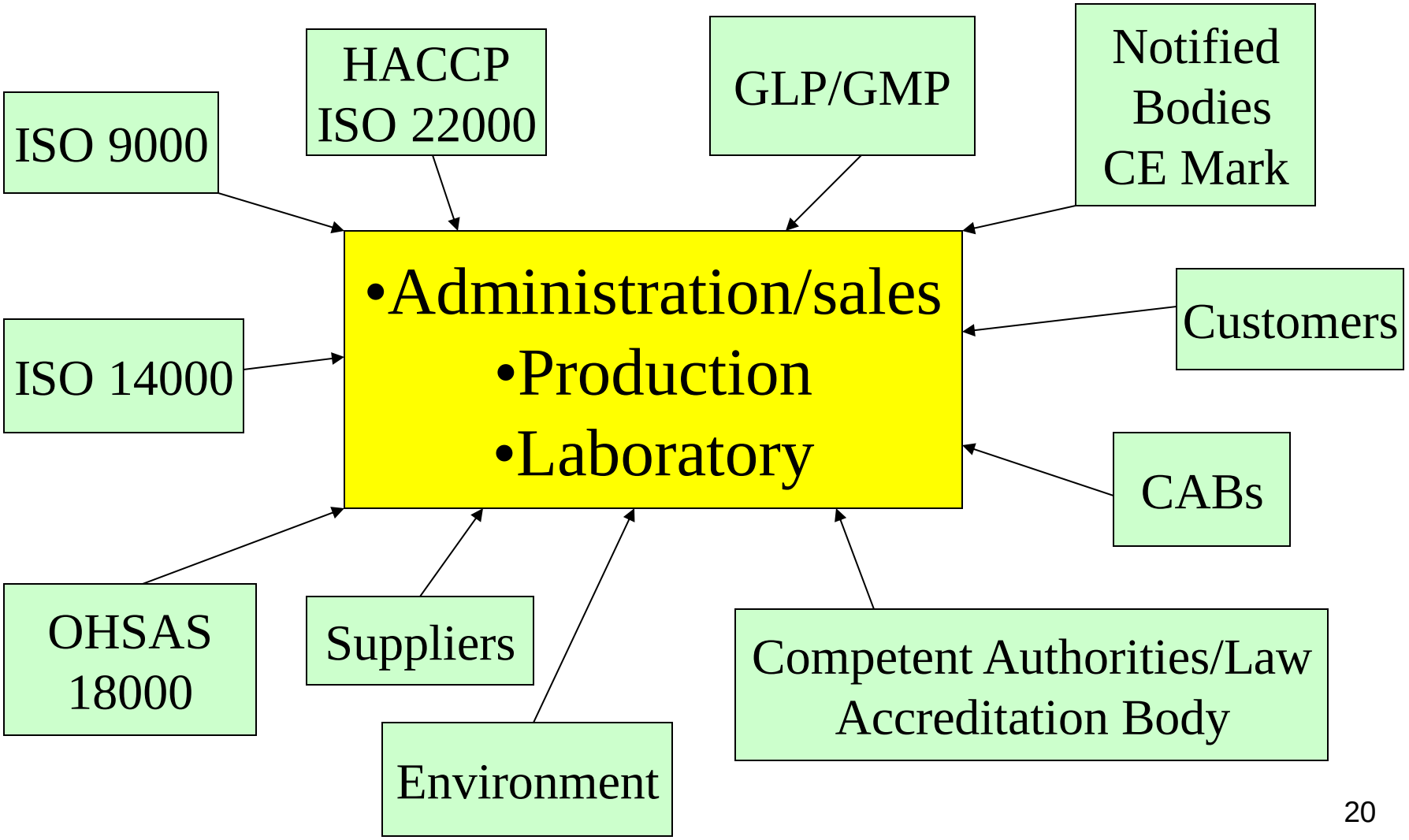
- Accreditation or certification?
- Are hospitals accreditable?
- Who grants accreditation?
- What about the interaction between a calibration laboratory and its customers
- The scope of accreditation
- The scope of regional/global recognition
- Certification Body: Accredited or not?
- PT schemes: Training and competence tool

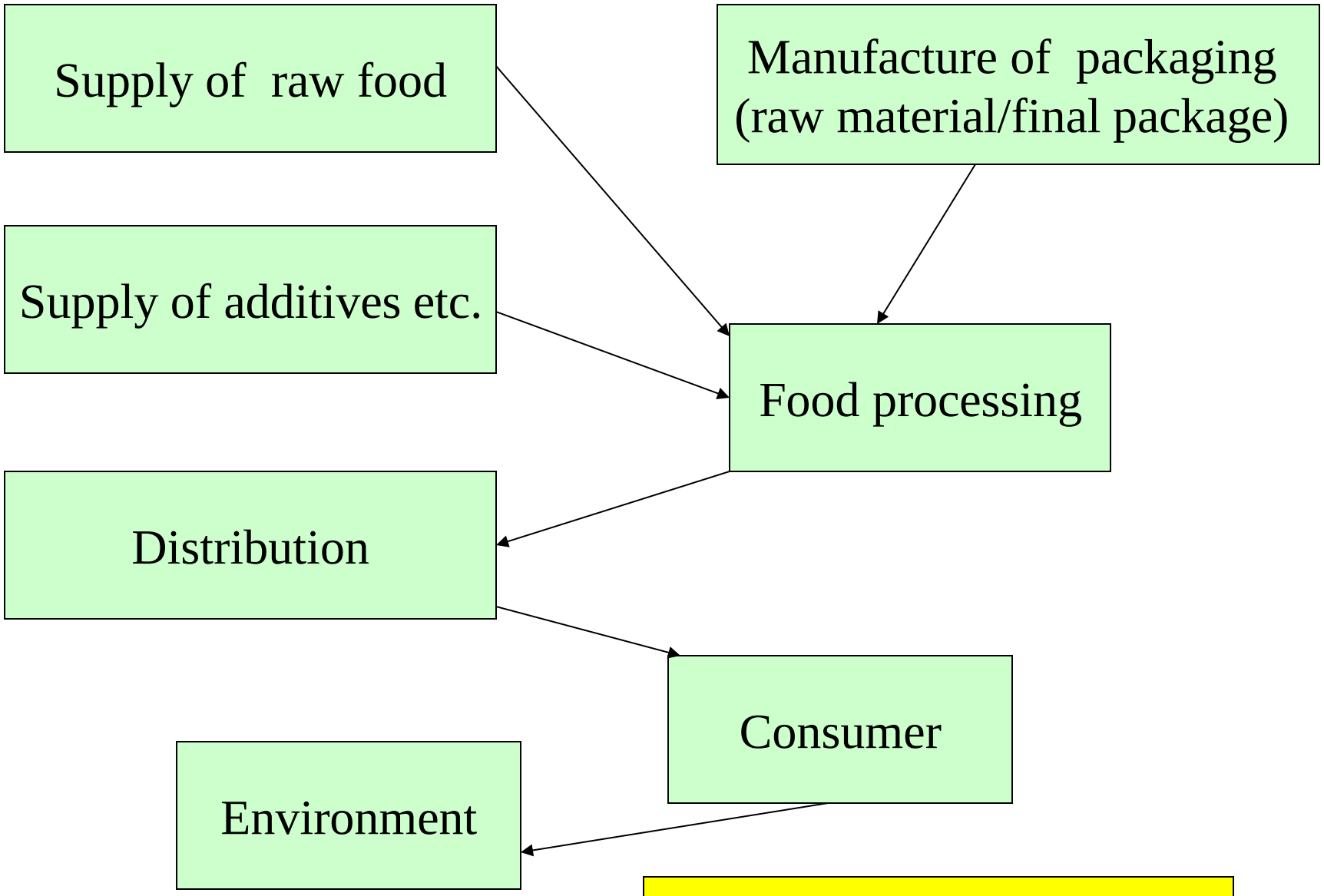
** based on the experience gained within the Cyprus Accreditation Body*

Some examples

- Industrial activity
- Food supply
- Testing/calibration laboratory
- Medical Laboratory

Industrial unit consideration




Supply of raw food
Manufacture of packaging (raw material/final package)
Supply of additives etc.
Food processing
Distribution
Consumer
Environment
Roles and responsibilities

Certification is…

Third-party attestation related to products, processes, systems or persons. *(ISO 17000 cl. 5.5)*

Note: applicable to all objects of conformity assessment EXCEPT for conformity assessment bodies themselves to which accreditation is applicable

Is certification mandatory?

→No!

However, the increasing needs of the market (e.g. invitation for tenders) and, in some cases, the legislation have made it strongly preferable.

This is the easiest way to meet the needs of the customer looking for an evidence of the effective implementation of a quality assurance system.

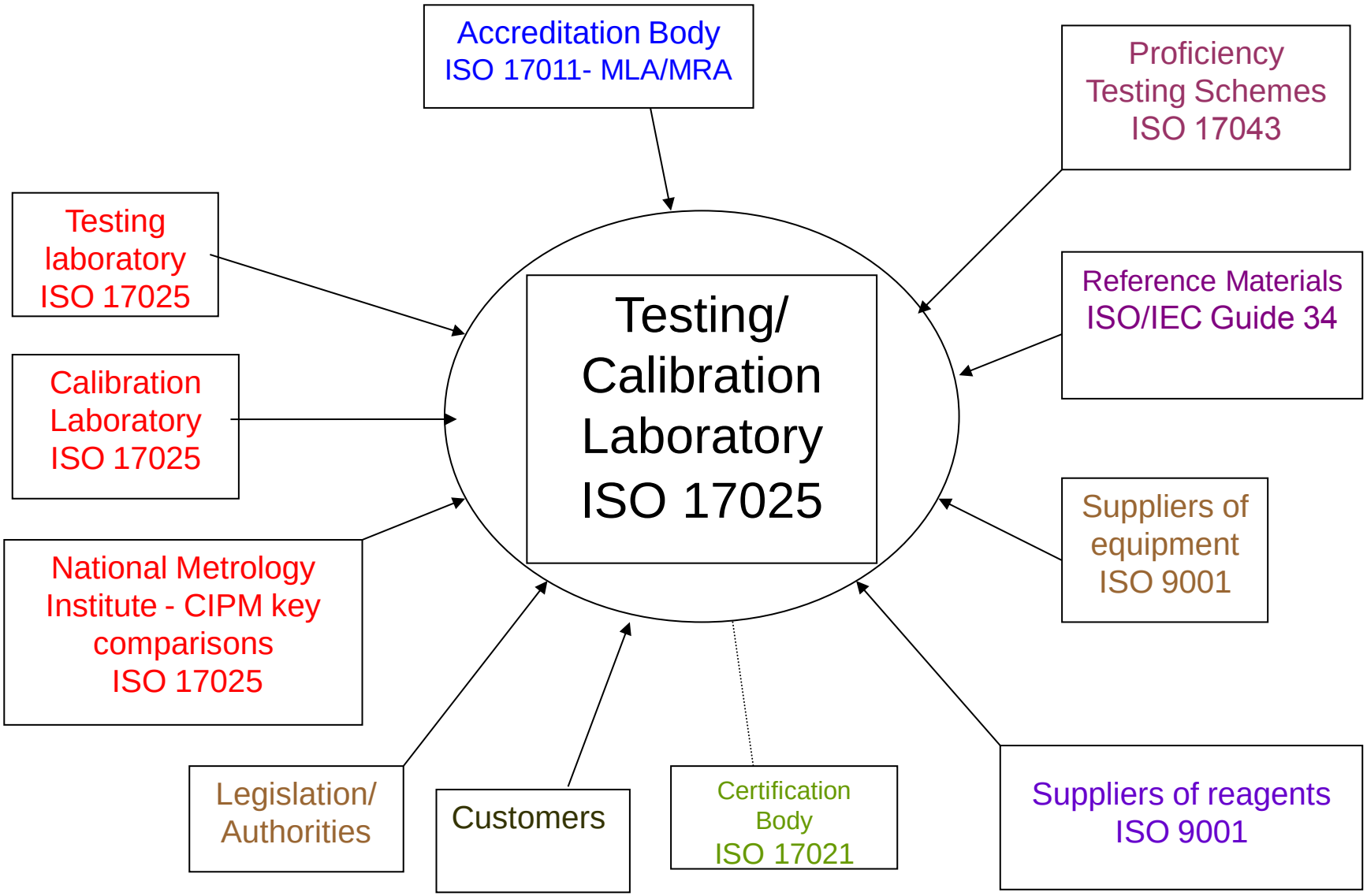
For this evidence to be safe, the certification body needs to be accredited!

A testing / calibration laboratory…

is not isolated from its environment. It is committed to offer the services required by the customers according to their needs as well as the relevant legislative provisions.

In the following diagram, all interfaces of a testing /calibration laboratory and the inherent requirements to be met in each case are illustrated.

The laboratory environment

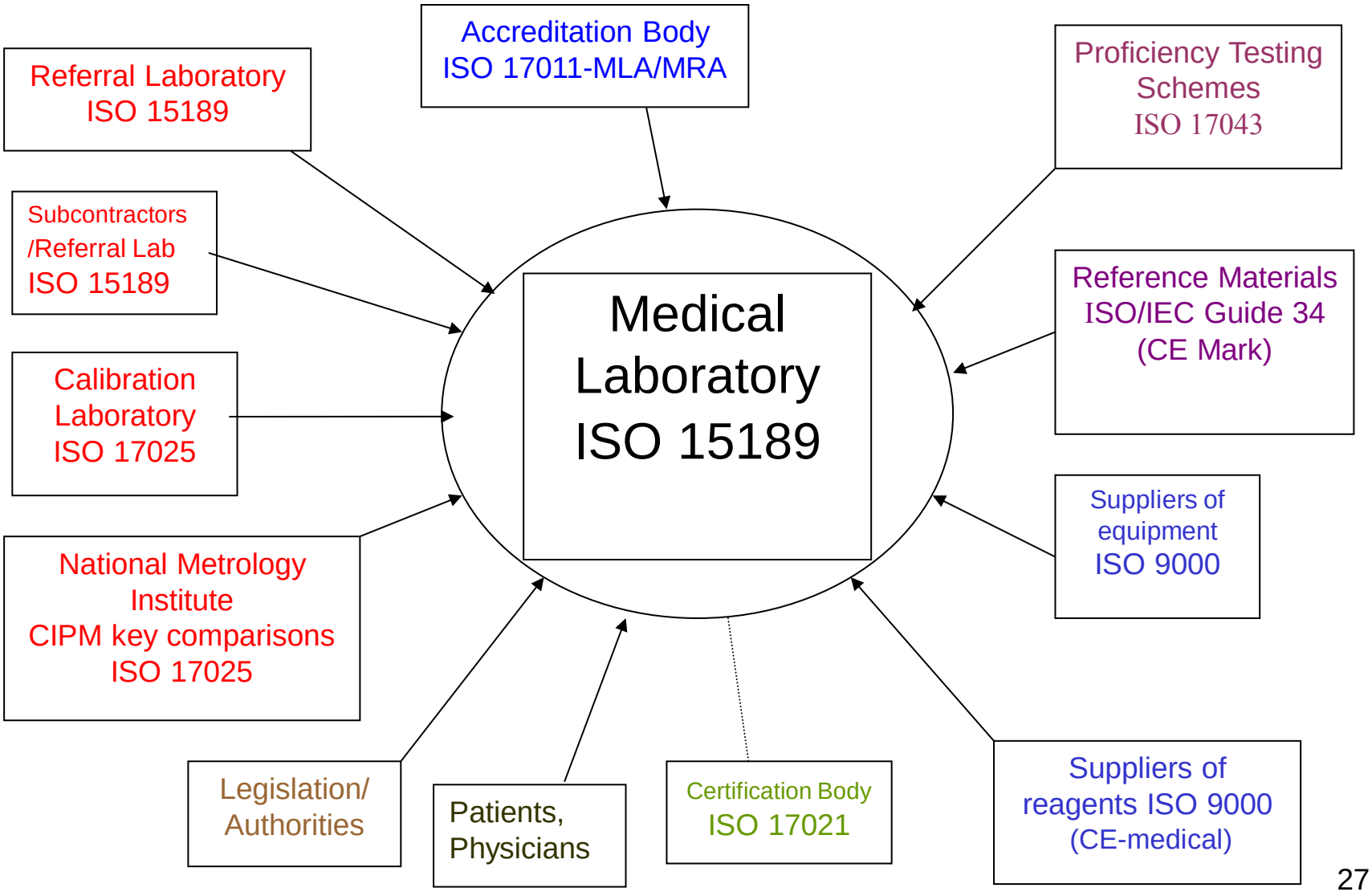


In the case of medical laboratories

the diagram is adjusted to reflect particular needs of this sector referring to

- the accreditation standard
- the legislation

The medical laboratory environment



Accreditation is

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. *(ISO 17000, cl.5.6)*

Is accreditation mandatory?

In general, accreditation of a laboratory is only voluntary; however, there are cases where the legislation, either european or national, specify accreditation as a requirement.

A non-accredited laboratory

can implement itself all aspects addressed by the accreditation standard; it may further document its operation and the quality assurance it implements.

What is missing is the independent confirmation which could be provided only by the accreditation body.

This gap is quite significant for marketing reasons. It is upon its customers to elaborate and accept that the services provided can meet their expectations.

The figure that follows

- illustrates all elements to be considered by the customer/user of laboratory services in the absence of accreditation
- gives, in an illustrative way, the answer to the question, still creating some confusion, “Accreditation or Certification for laboratories”

Anyway the answer to this question is already given in ISO 17000:2004 (see definition of certification given therein)

To achieve Reliability…

Accreditation

Reliability

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

Quality Management System (→Certification?)

All accreditation certificates

clearly refer to the detailed scope for which the laboratory has been accredited; usually this does not cover the whole range of activities of the laboratory.

The customer should be

- well aware of the scope of accreditation
- adequately informed on accredited or non accredited results (indication on test reports)

→ *particular care is required in the case of calibration certificates*

The use of the accreditation symbol

- Accredited or not?
- The use of the accreditation symbol on test reports and (even on) calibration certificates is not mandatory; how can the user recognise whether the results do come from accredited methods being implemented?
- The difficulty is bigger in the case of calibration certificates (calibration or performance check/ verification?)

In case non-accredited services…

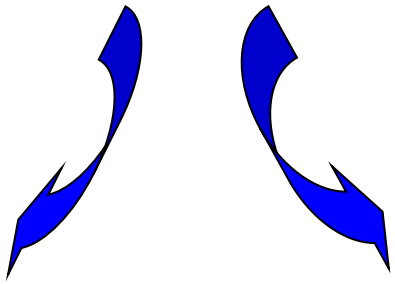
are preferred, it is necessary that customers and competent authorities are well aware of the main aspects they will need to look at in order to assess the reliability of the services offered.

Whatever is the case…

the laboratory needs to document the technical competence of its suppliers, namely:

- Calibration services (ISO 17025, ILAC P10)
- Testing laboratories (ISO 17025/ISO 15189)
- Proficiency testing schemes (ISO 17043)
- Reference materials (Guide 34)
- Equipment, reagents (ISO 9001)

Medical Sector



Laboratories

testing of samples
from human body
(reliability of results)

Hospitals

overall service
to patients
*(management
and organization)*

There are different needs in each case, thus a different approach is required

Therefore, in the medical sector…

Accreditation

competence to carry specific tasks

appropriate for laboratories

Certification

assurance of conformity to specified requirements

appropriate for hospitals/clinics

To this end…

the use of the term *accreditation* for hospitals and clinics referred to on papers issued by some certification bodies is not appropriate and not correct at all!

The definition of accreditation and who accredits is clearly provided on a legal basis i.e. Regulation (EC) no 765/2008.

What about calibration services?

- Does the calibration services supplier need to be accredited?
- ✓ This is not a requirement of ISO 17025 (nor of ISO 15189) but a strong preference after ILAC P10:2013
- ✓ In case no accredited calibration services for a particular parameter are available in the country, it is upon the customer to ask for adequate evidence that traceability is ensured
- ✓ In case a calibration laboratory provides a certificate for a parameter within its scope of accreditation without the accreditation symbol being displayed, this might be confusing/ misleading to the customer
- ✓ What about contract review?
- ✓ How does the customer “read” the calibration certificate?

What about PT providers?

- Does the PT provider need to be accredited?

✓ This is not a requirement of ISO 17025; however, as the number of accredited PT schemes is increased, laboratories may prefer the ones which are accredited. Otherwise, the laboratory needs to use appropriate criteria for the selection of PT providers to fit the purpose; relevant documentation is required

✓ ISO 15189 specifies the need for PT providers to comply with the requirements of ISO 17043. In case accreditation is not there, it is upon the laboratory to look for evidence for such a compliance and document it as appropriate.

With regard to PT participation

it is not always clearly understood that this represents a tool for

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

Reference materials producers

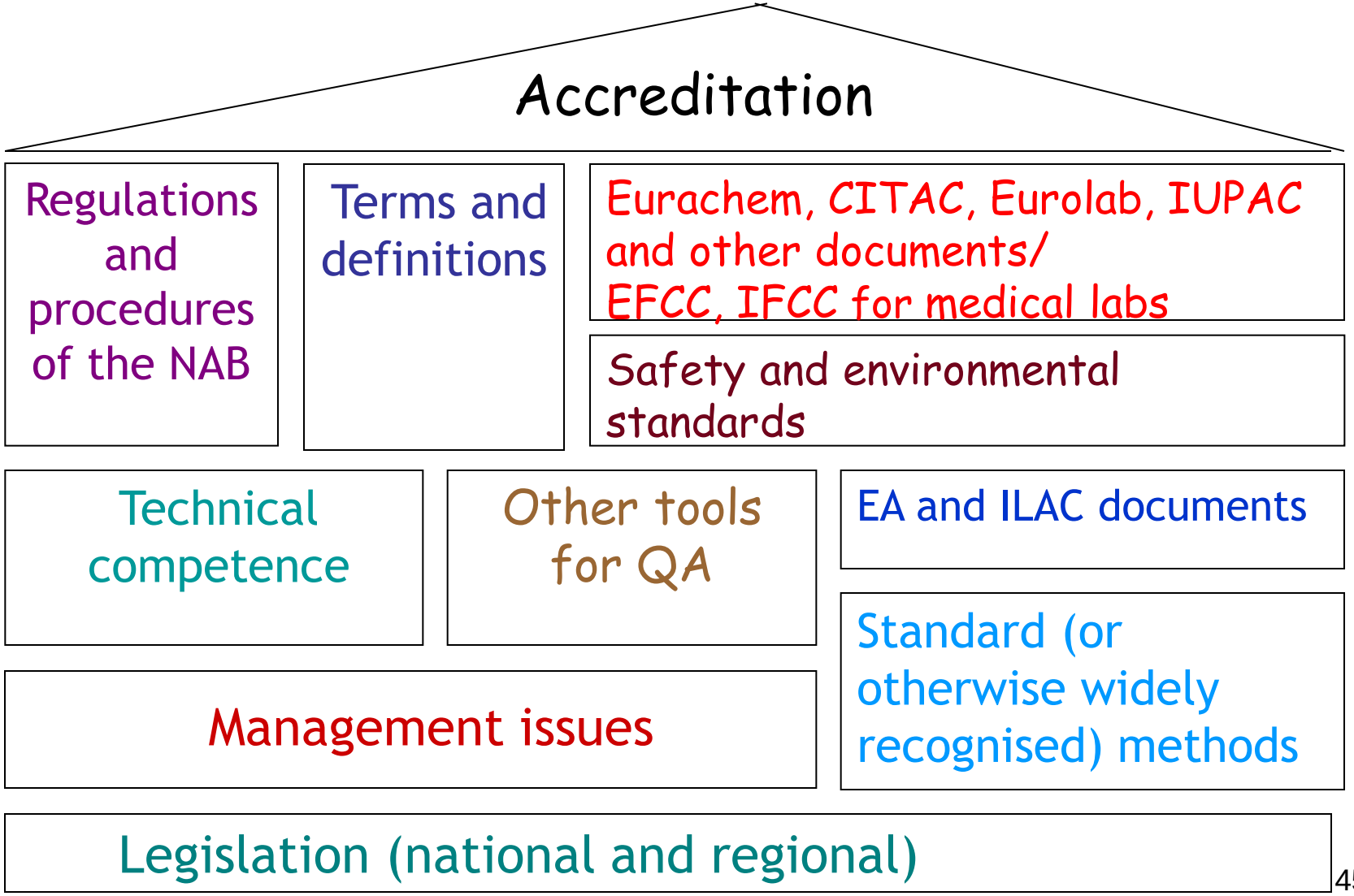
- For the moment, no requirement for their accreditation
- Accreditation was until recently based on ISO 17025 and ISO/IEC Guide 34; this has now been changed – only ISO/IEC Guide 34 is to be used
- Further work is under way
- The documented selection contributes to the illustration of traceability
- Specific requirements in the medical field *(EC Directive on in-vitro diagnostics - CE Mark)*

The meaning of uncertainty…

is still not well conceived by the customers. They may not choose a laboratory which produces results that are “uncertain” to some extent!

Not all of them are prepared to pay for a result that is “uncertain to a quantified extent”. They do not realise that the expression of uncertainty is required to illustrate reliability, provided that it is estimated correctly!

How to “build” a laboratory

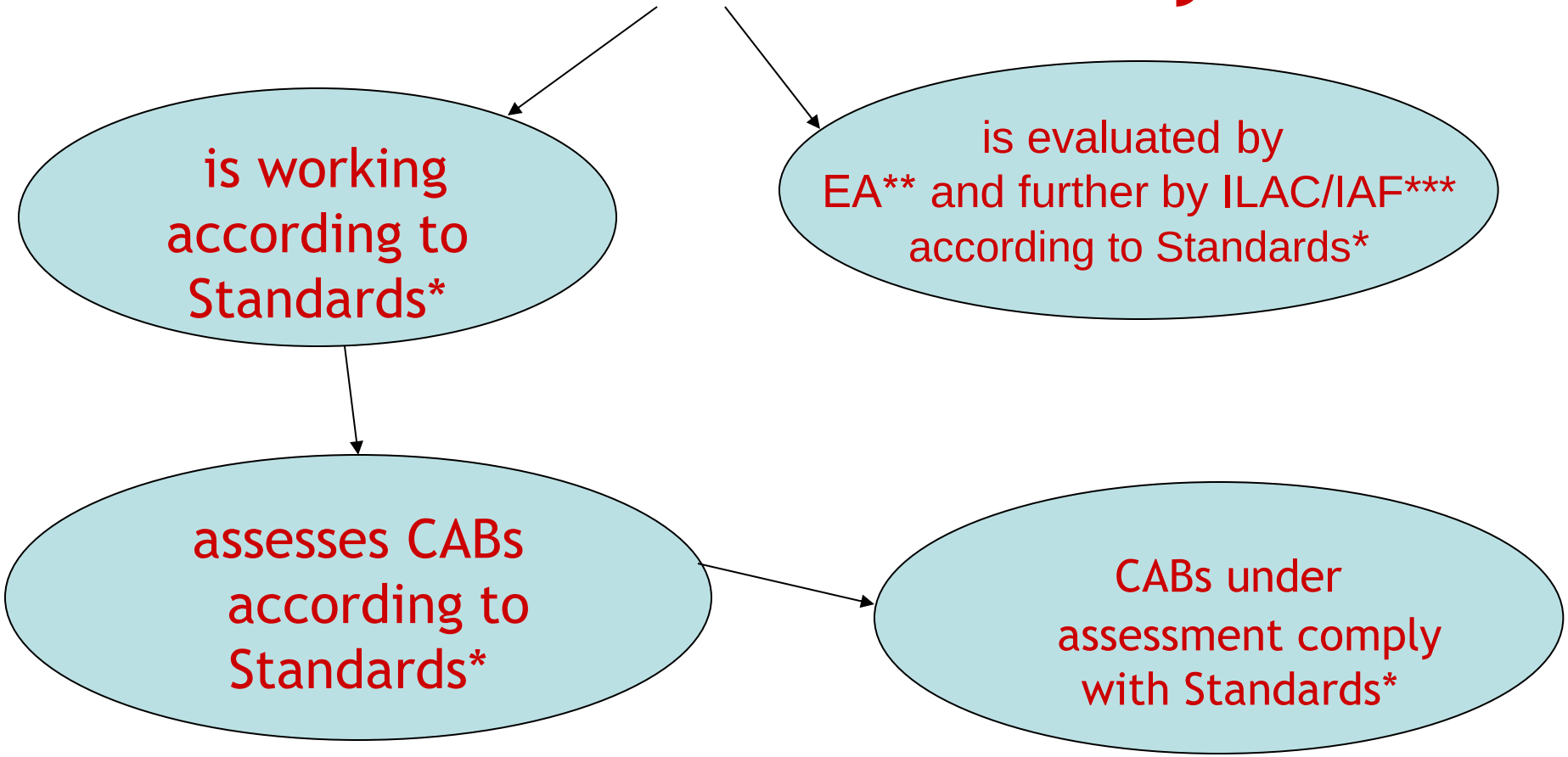


Accreditation Bodies offer

equally confident services, based on the peer evaluation carried out by the regional accreditation organizations, based on which they are globally recognised as well. This may or may not cover the whole range of their activities.

According to the Regulation (EC) no 765/2008, only accredited conformity assessment bodies can become notified under the condition that the accreditation body has been successfully peer evaluated for the particular scope.

An Accreditation Body...



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

Thank you for your attention!

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