Conference/Workshop

Analytical results for decisions!

25th – 26th May 2010 in Copenhagen

Eurachem

A focus for analytical chemistry in Europe

"The consequence for millions…

of people in our society is lying in the hands of the (relatively few) experts who are responsible for making the right decisions on the rights basis!"

3

How few are we?

The answer lies in the issue put by the organisers of this challenging Workshop!
"…an attempt to look at the situation of decision making both from the side of the laboratories, from the side of those setting the limits to which conformance/non-conformance has to be decided, and from the side of those who are finally going to make the decisions!"

4

If we consider how many…

all these people are, we may conclude they are many more than the group of people deciding for much more important issues in today's World!

5

What will be illustrated…

in this presentation is that in the case of "Decisions on Conformity" there is (or, there should be) a justified and documented procedure!

6

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 made thereof - *housing infrastructure, public works etc.*

7

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*
- *And more… and more…*

8

We need to measure!

- That 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!

9

The history of measurements

goes back to the ancient times; in those days the needs mainly referred to the trade of goods and the construction activities, lengths and distances.

Pioneer scientists and famous philosophers based their considerations and inventions on various types of measurements.

10

Some examples

An examination of the Great Pyramids of Egypt and other buildings makes it clear that the Egyptians at a very early stage incorporated a measurement system, though really their system of weights and measures was fundamental to all sorts of functions and essential for the smooth running of their bureaucracy.

11

Greeks used different systems

of measuring distances and weights, partly taken from Egypt; in the Hellenistic age, Greek and Egyptian cultures were mixed. The same word could mean different lengths such as the stadion length depending when and where it is used.

12

Origins of Measurements

In ancient times, the body ruled when it came to measuring. The length of a foot, the width of a finger and the distance of a step were all accepted measurements.

- **Inch**: At first an inch was the width of a man's thumb.
- **Hand:** A hand was approximately 5 inches or 5 digits (fingers) across.
- **Span:** A span was the length of the hand stretched out, about 9 inches.

13

Origins of Measurements (2)

- **Foot:** In ancient times, the foot was 111/42 inches. Today it is 12 inches, the length of the average man's foot.
- **Cubit:** In ancient Egypt, a cubit was the distance from the elbow to the fingertips. Today a cubit is 18 inches.
- **Lick:** A Lick was used by the Greeks to measure the distance from the tip of the thumb to the tip of the index finger.
- **Pace:** The ancient Roman soldiers marched in paces, which were the length of a double step, about 5 feet; 1.000 paces was a mile.

14

Units of measurement…

Examples for the measurement of distance

FOOT
1 foot *pous* – plural *podes* (309 mm) variants from Ionic to Doric foot (296-326 mm)
6 feet = 1 *orgyia* (1.854 m) , 10 feet = 1 *akaina*
100 feet = 1 *plethron*
600 feet or 6 *plethra* = 1 *stadion* (185.4 m)

STADION
1 *stadion* (185.4 m) (Different variants of the stadion exist with around + - 30 m differences)
2 *stadia* = 1 *diaulos* , 6 *diauloi* = 1 *dolichos*

15

The need for a common…

metrological language was very early understood.

The needs for measurements have been widened through centuries. Measurements are required in all fields of economic activities, both in the regulated and no-regulated areas.

16

Quality issues are…

nowadays considered to be of highest importance as a result of increasing awareness of existing needs. This is reflected in

- legislative requirements and
- high competition on quality aspects

17

About Quality…

- Good or bad?
  … but, on which basis?
- Adequate or non-adequate?
  …against certain detailed criteria.

→Such criteria are usually included in standards and specifications

18

How can we be sure that…

products and services meet the specifications?

→ By "conformity assessment", i.e. checking that products and services meet the relevant standard´s specifications.

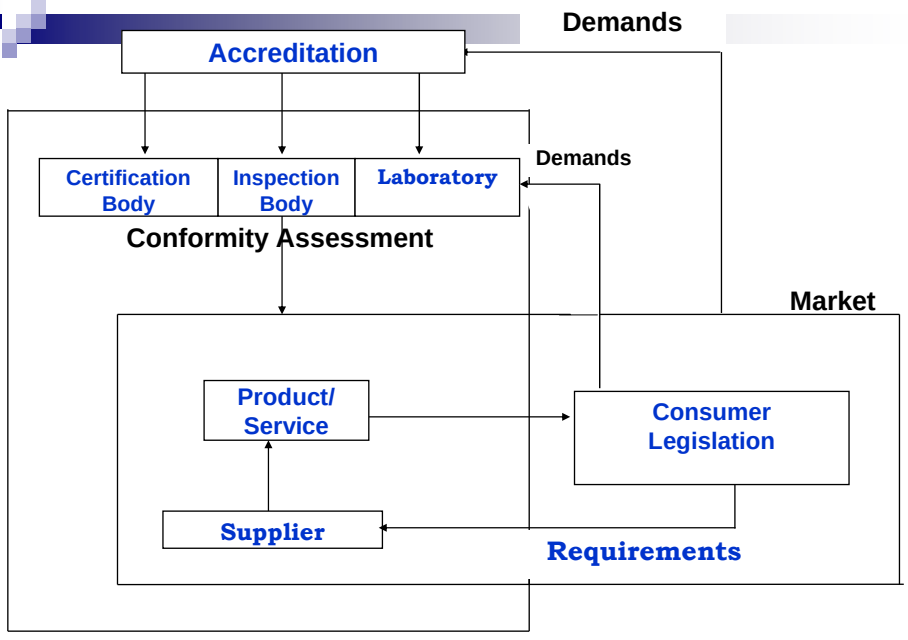
19

Conformity assessment is

any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.

Bodies conducting conformity assessment (CABs) comprise an infrastructure of decisive importance for the operation of the Single Market and furthermore for the removal of trade barriers all over the World.

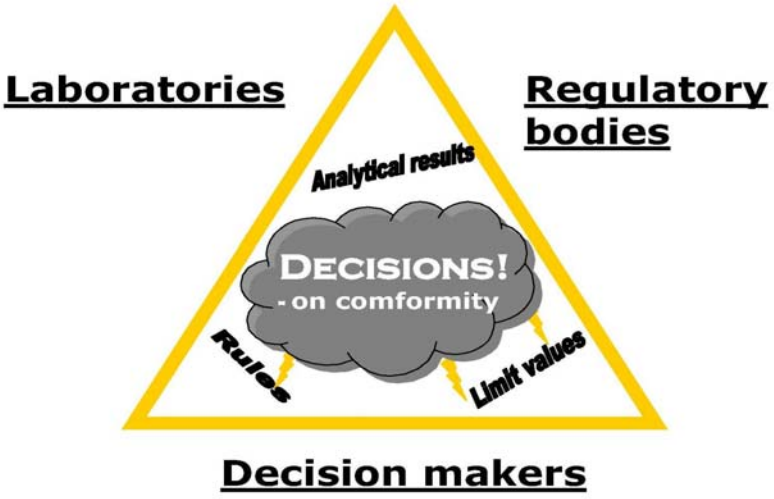
20



Correlation of various activities and the role of the stakeholders

21

The Decision Triangle



Some basic pre-requisites…

- A common basis does exist
- The rules are adequately justified
- Conformity assessment infrastructure is available
- Measurement techniques and suitable equipment have been developed
- Qualified personnel

23

The role of measurements is…

different
→ in regulated areas, where we evaluate compliance of products with specifications set either in legislation or in other normative documents
and
→ in non-regulated areas, where we need to illustrate that product and services meet the expectation of the buyers and users

24

How requirements are set?

- In mandatory areas e.g. health protection, environmental studies, safety issues, relevant requirements are discussed and decided by competent authorities and a network of scientists and standardisers, on the basis of detailed studies, epidemiology surveys etc. where measurements represent a decisive tool.

25

In other areas

a similar approach is followed with a minor role of legulators.

- In case the product/service under consideration represents a priority in the standardization activities, the outcome of this work is reflected in standards
- In other cases it remains at company level or as a document used by professionals in a certain sector

26

Specific needs in some sectors

- food (GMOs, HACCP, chemical analysis, microbiological testing, organic products)
- water resources
- health care services (medical laboratories, anti-doping control, HIV etc.)
- molecular biology (DNA testing)

27

Specific needs in some sectors (2)

- environmental impact assessment, pollution, energy planning
- New Approach Directives (modules - notified bodies)
- dangerous substances
- forensic science
- building materials and construction

28

In the case of the health services

the cost of reliable measurements e.g. in medical laboratories is less than the cost for non-reliable or lack of measurements.

29

Who pays the cost of Quality?

The customer, the end user and the society, depending on the case.

Why pay an additional cost?

30

A lot of examples exist where…

the advantage of compliance with quality requirements justifies the additional cost.
In any case, the cost of products or services is not only the initial one but the overall cost during the whole life-cycle of products or services.

31

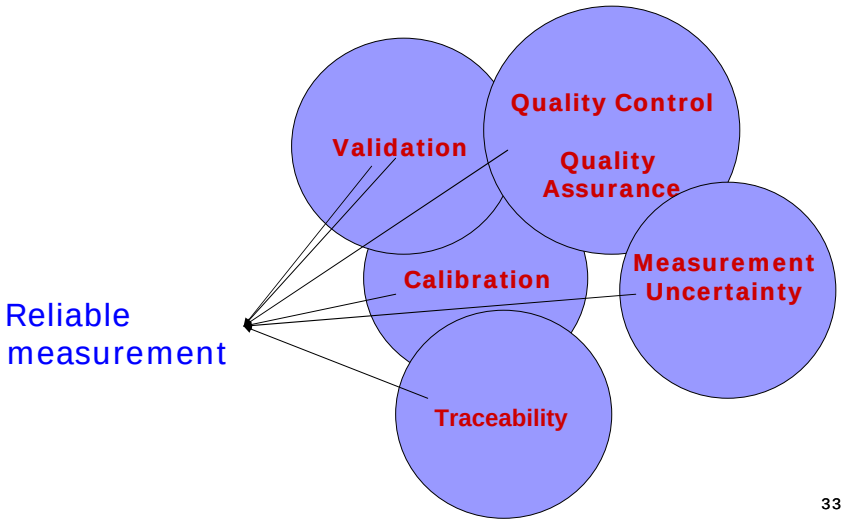
What is a measurement?

Process of experimentally obtaining one or more **quantity values** (*number and reference together expressing magnitude of a quantity*) that can reasonably be attributed to a **quantity** (*property of a phenomenon, body or substance where the property has a magnitude that can be as a number and a reference*)

(VIM 3 : 2008)

32

For reliable measurements…



33

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

34

The laboratory may prefer…

to use a standard method (or, one which is widely recognised). This gives the advantage of the method already being validated (note: however, verification is still required); this also ensures a common basis for the communication and understanding with the customers and the other users of the laboratory results.

35

The equipment to be used…

is one with which the method could 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

36

Calibration of equipment…

needs to be organised and carried out in a way to adequately document traceability; this refers to the methods used, the frequency, the level in the metrological hierarchy – accreditation of the calibration laboratory for the specific parameter or otherwise assessed.

37

The qualified personnel…

needs to demonstrate its competence for the tasks undertaken, both prior to their authorization and afterwards, on a continual basis.

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

38

With all necessary tools available…

the Laboratory needs to build its self-confidence for the reliability of its measurements.

What about each individual measurement which leads to the issue of a test report?

39

Laboratories need…

to demonstrate their technical competence and reliability

→to this end they also need to have policies on how to estimate the uncertainty of their measurements

40

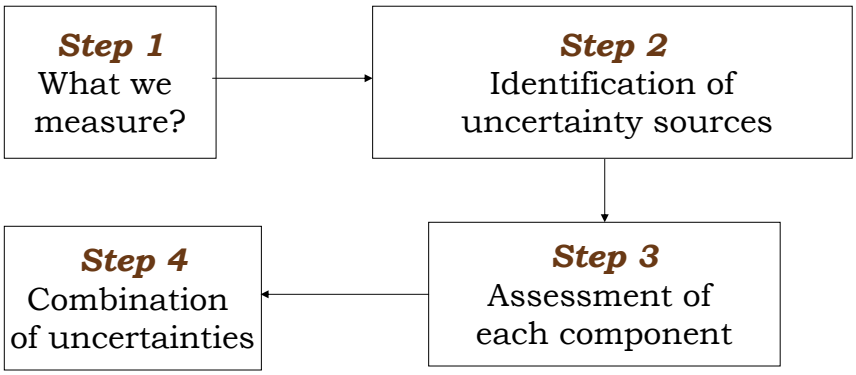
The meaning of uncertainty…

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".

41

Analysis of various steps



Knowing uncertainty ➔ increase of reliability

42

Some questions arise…

- How the results of successive measurements made by the same analysts, the same day and under the same conditions (method, equipments, environmental conditions) are compared? How much they deviate from each other?

43

Let´s follow a practical approach

to illustrate how things are in routine work : In the case of a small laboratory employing one analyst, measurements carried out by him/her with the same instrumentation may still vary, even in repeatability conditions (same day, same environmental conditions).

44

As we move to

to less simple but more realistic situations, we could go to more and more factors affecting the results: more analysts in different days with deviating environmental conditions, not using the same equipment (intra-reproducibility conditions).

45

This variation of measurements

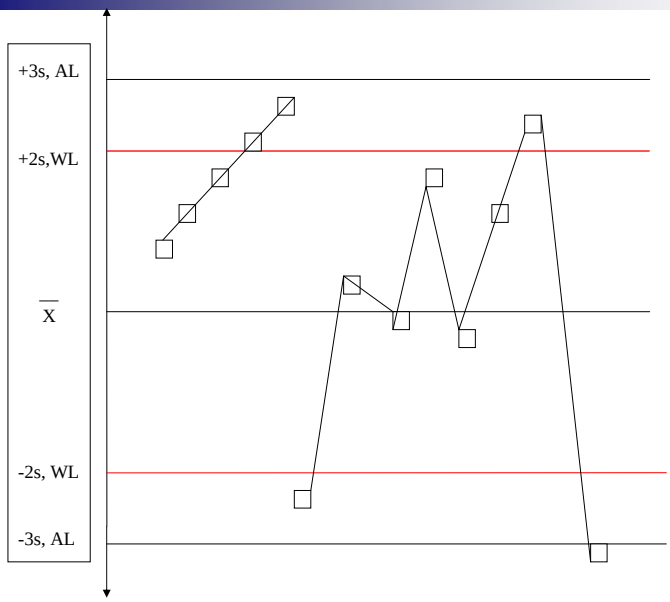
illustrates the range in which measurements may lie in routine work, thus providing the basis for the estimate of the uncertainty of measurement; however we need to take into account other factors out of the control of the laboratory (calibration, reference materials etc.) for which relevant information could and should be achieved from their suppliers

46

Are the variations in the laboratory

acceptable? Which are the criteria?
The internal control charts [based on measurements of (certified) reference materials] provide an efficient tool to monitor the laboratory performance.

47



48

The criteria to be used

usually refer to the behaviour of successive measurements with reference to the Action Limit (AL) and the Warning Limit (WL).

49

Specific requirements

are set for the (certified) reference materials used (traceability) and the service provided by their suppliers. Accreditation against ISO/IEC Guide 34 and ISO 17025 is being promoted.

Is the internal control adequate?

Could we detect any systematic error ? No!

50

This is why we need

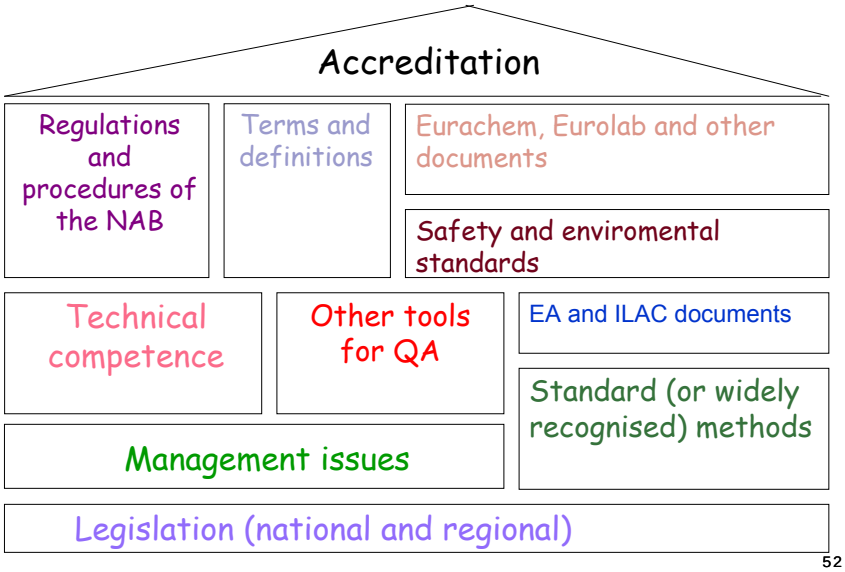
to also have external quality control. A number of laboratories participate in the measurement of samples distributed by proficiency testing providers. Laboratories are expected to analyse any deviations (I z-score I >2) and take appropriate corrective and preventive actions.

Specific requirements…

are set for the proficiency testing schemes and their providers (ISO/IEC 43-1 and, now, ISO 17043).

51

How to "build" a laboratory



52

Sources of information

- www.european-accreditation.org
- www.eurachem.org
- www.eurolab.org
- www.ilac.org
- www.irmm.jrc.be
- www.euromedquality.org
- www.eptis.bam.de

53

Thank you for your attention

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54