Measurement uncertainty: Requirements set in the accreditation standards

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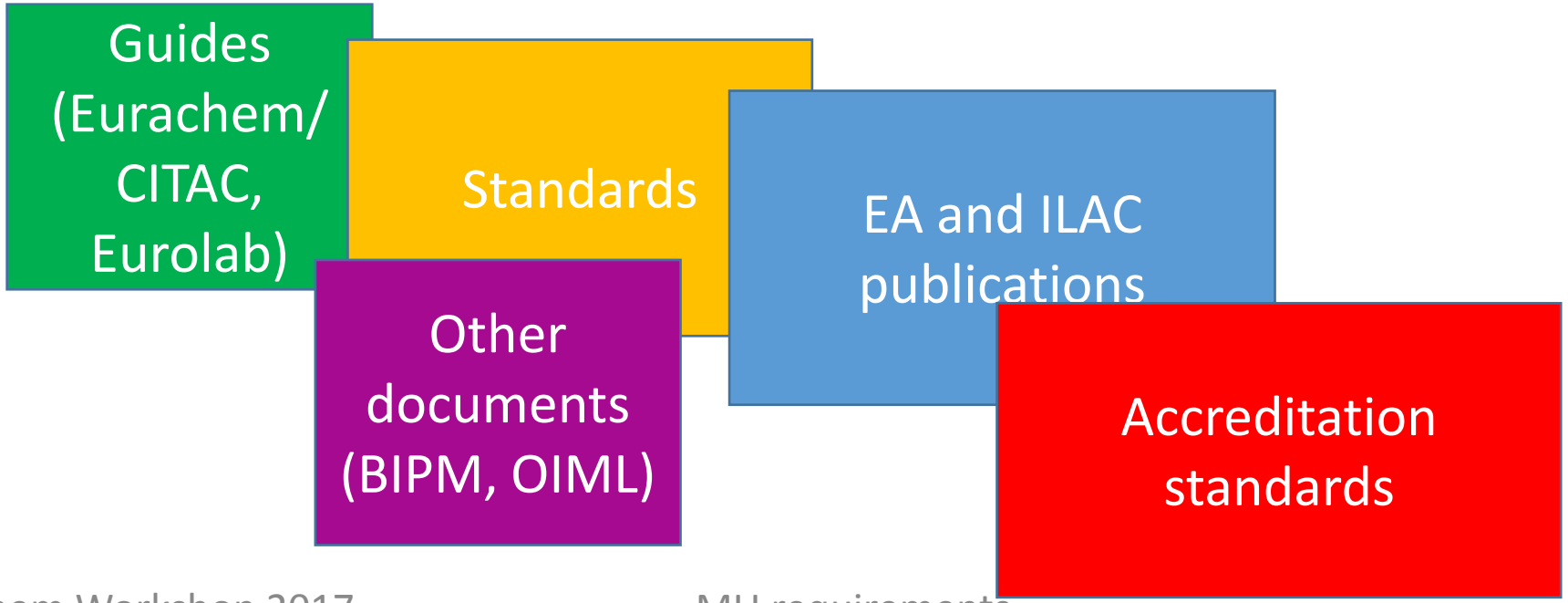
Accreditation standards

- ISO/IEC 17025 (2005) General requirements for the competence of testing and calibration laboratories
- ISO/IEC DIS 17025 General requirements for the competence of testing and calibration laboratories
- ISO 15189 (2012) Medical laboratories – Requirements for quality and competence
- ISO/IEC 17043 (2010) Conformity assessment – General requirements for proficiency testing
- ISO 17034 (2016) General requirements for the competence of reference material producers
- ISO/IEC DIS 17011 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

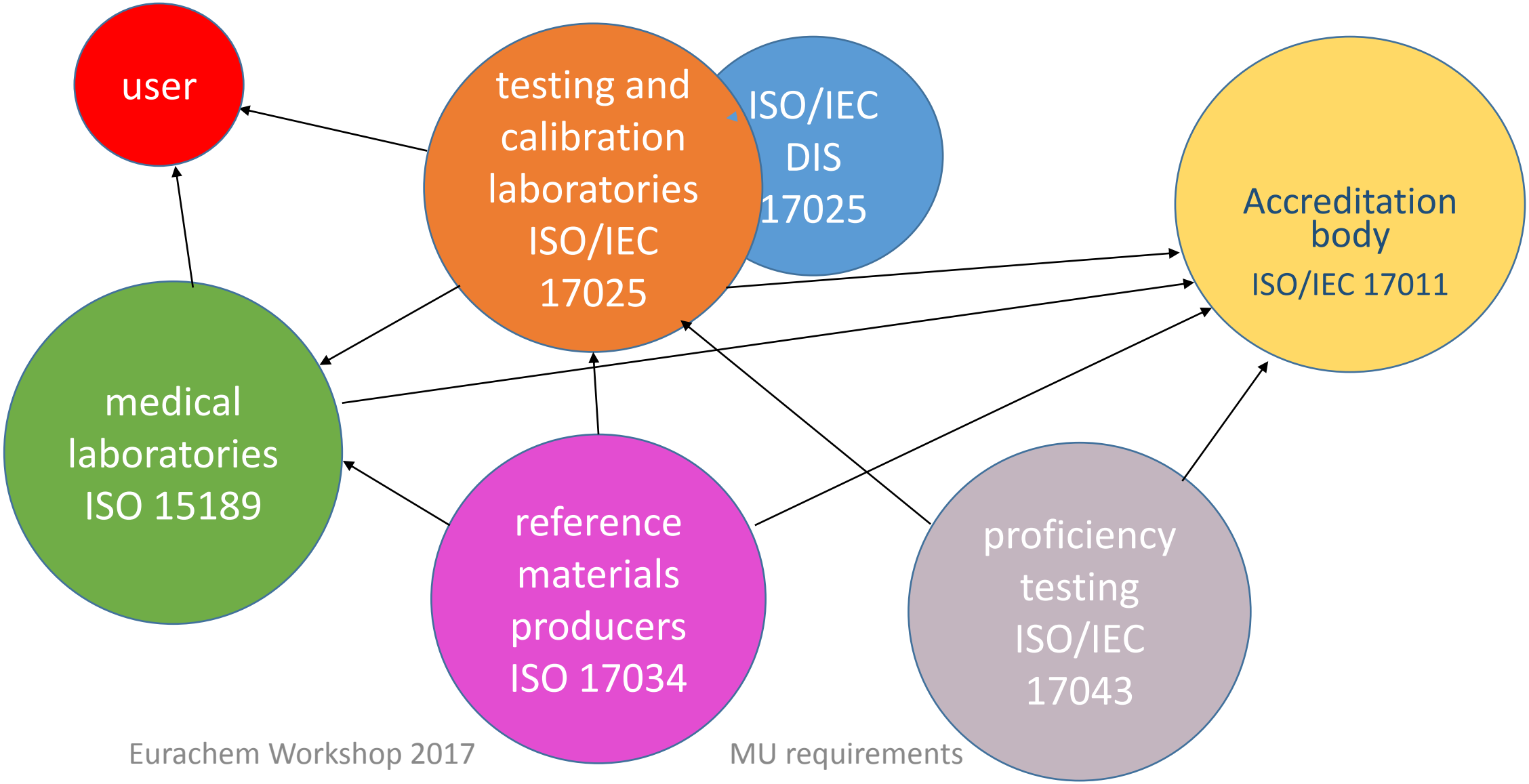
➔*Eurachem/CITAC Guide on R&D and non-routine analysis (under revision)*

The Accreditation Standards…

are generally applicable and they do not address all specific needs in each field; therefore additional documents are necessary to provide guidance and explanations to laboratories…



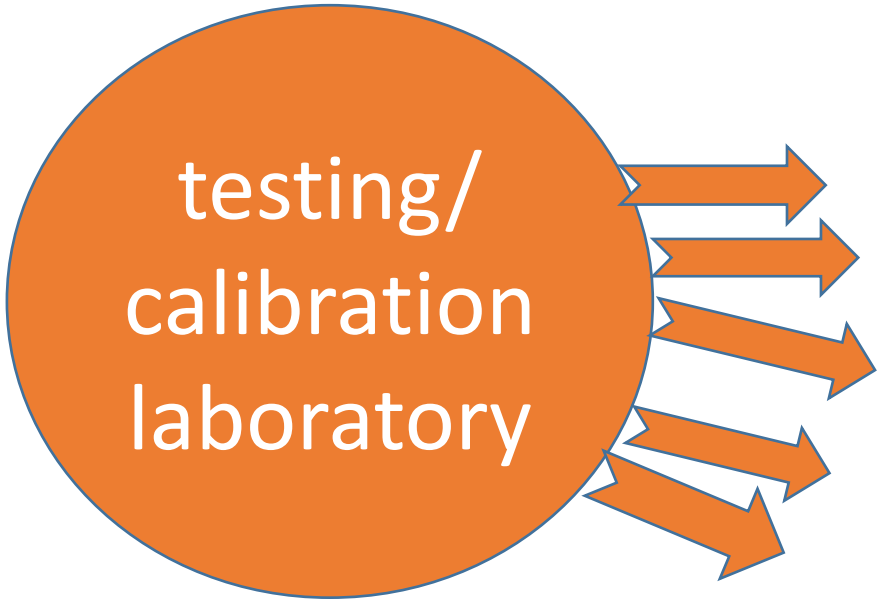
Requirements for measurement uncertainty



The accreditation body

- Shall follow the requirements of EA e.g. EA 4-02 M, EA 4-16 G (or, other regional body) as well as those of ILAC i.e. P 10, P 14, G 17. Such documents comprise the basis for the EA MLA/ILAC MRA. Laboratories need to be aware of these!
- Further to these, the national accreditation body may prepare additional documents, both informative of their policy and guidance to the laboratories in the country.

Who is the user of laboratory services?



- testing laboratory
- calibration laboratory
- manufacturer
- competent authority
- consumer

How is uncertainty used? Is it well understood?

- Laboratories need to take the stated uncertainty into account when evaluating the uncertainty of their results.
- Competent authorities need to consider the stated uncertainty to correlate the result with a legislative limit.
- The manufacturer can decide on adjustments needed bearing in mind contractual commitments already undertaken.

(continued)

How is uncertainty used? Is it well understood? (2)

- The consumer may find it difficult to understand what this "uncertain component" of the result may mean

➔ *All users need to understand the meaning of uncertainty stated on testing reports and calibration certificates and, if necessary, ask for clarifications.*

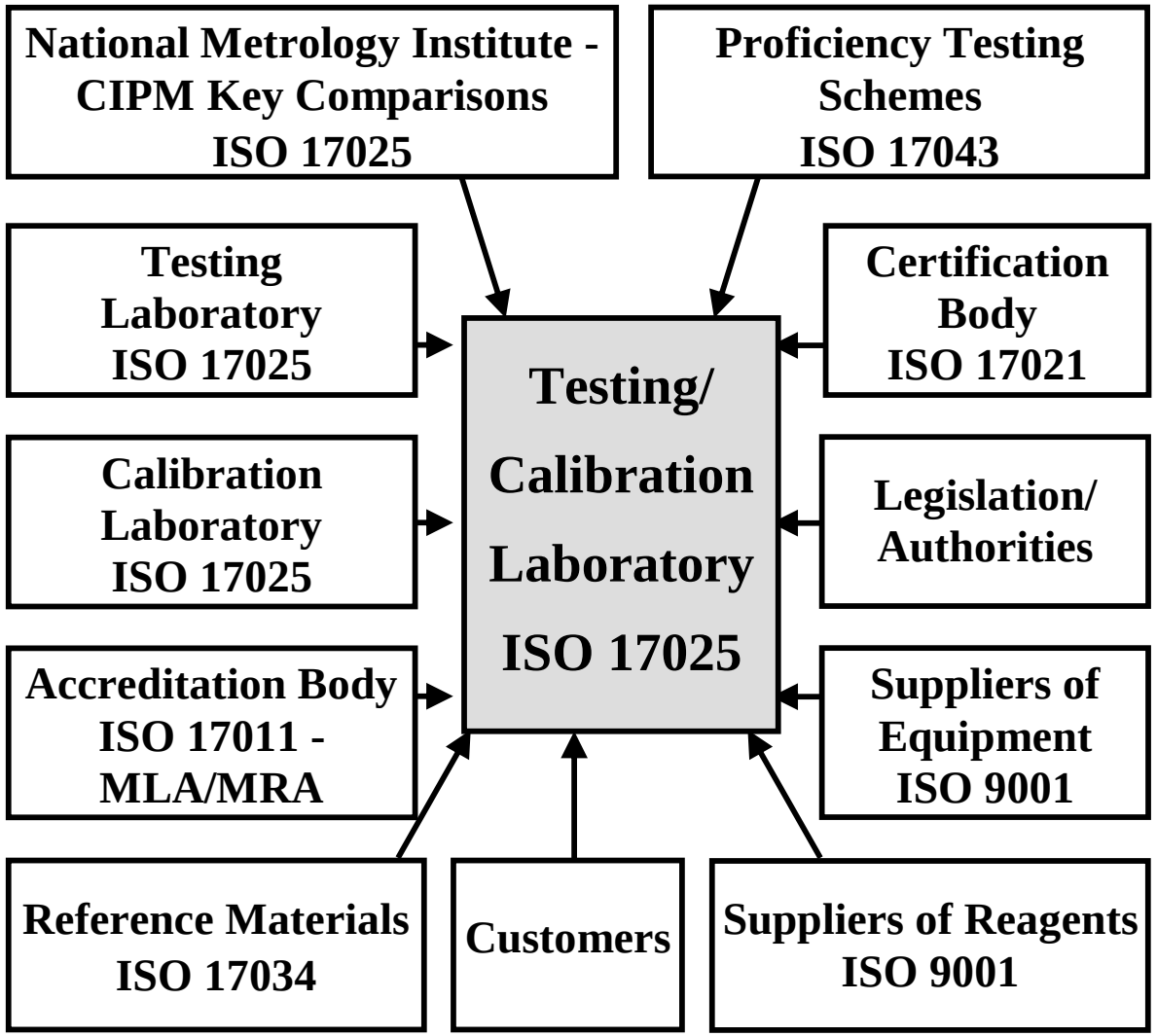
A laboratory is supported by…

a series of different suppliers; their selection shall be based on set criteria related to the specific supply and address the provisions of the Standard.

➔ Are laboratories aware of accreditation standards applying to their suppliers and the requirements included therein?

➔ Are these standards included in the list of external documents and are controlled as appropriate?

The environment of a laboratory



ISO/IEC 17025:2005 indicates that…

The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations.

What are the needs regarding measurement uncertainty (MU)…

Accreditation standards specify…

that the laboratory shall evaluate the measurement uncertainty of their results; this is the case with both ISO/IEC 17025 and ISO 15189.

Furthermore, ISO 17025 provides for the reporting of the results…

ISO/IEC 17025 specifies that…

for calibrations

laboratories (both calibration and testing) shall apply a procedure to estimate the uncertainty of measurement for all calibrations they carry out

for testing

similarly as for calibrations; in case this is not possible, laboratories shall at least attempt to identify all the components and make a reasonable estimation

➔In both cases all uncertainty components of importance shall be taken into account

When reporting…

a statement of the estimated uncertainty shall be included where necessary for the interpretation of results (ISO/IEC 17025)

- Testing laboratories, when
  - relevant to the validity or application of test results
  - required by the customer
  - it affects compliance to a specification limit;
- Calibration laboratories, in relation to a statement on compliance with an identified metrological specification

The ISO/IEC DIS 17025

- No significant change regarding MU
- Reference to sampling; it has been included in laboratory's activities
- Description how MU to be presented
- Reference to the "decision rule" (describing how MU will be accounted for when stating conformity with a specified requirement)

Reporting of results

ISO/IEC DIS 17025 lists common requirements for all types of laboratory activities; when referring to a laboratory involved in sampling (for subsequent testing or calibration), it indicates that, where necessary, relevant information regarding sampling shall be taken into account in the estimate of MU.

In parallel, ISO 15189 specifies that…

medical laboratories shall

- determine measurement uncertainty for each measurement procedure
- define the performance characteristics for each case
- regularly review estimates of measurement uncertainty
- consider measurement uncertainty when interpreting measured quantity values

➔Upon request, the laboratory should make its estimates of measurement uncertainty available to laboratory users

Three types of services

are of particular importance, affecting the overall uncertainty budget of the laboratory:

- Calibration
- Reference materials
- Proficiency testing

Metrological traceability…

Are relevant criteria well defined and clear to laboratories?

Example:

The establishment of the metrological traceability. For part of the task, a testing or calibration laboratory relies on services provided by a calibration Laboratory. For a long time it was unclear which should be the requirements to be met by the calibration services supplier…

Is the calibration laboratory accredited?

- If YES,
  - is the property included in the accreditation scope?
  - is the calibration and measurement capabilities (CMC) declared fit for purpose?
- If NO,
  - how does the calibration laboratory demonstrate its metrological traceability?
  - is the laboratory to be served aware that it has to evaluate the situation and adequately document it?
- Does the national accreditation body (NAB) have clear policy to support
  - the said task of the laboratory
  - the assessment of the laboratory
  - the evaluation of the NAB by EA?

These questions were answered by….

ILAC P10:2013, a policy document prepared to support the ILAC MRA.

It clearly indicates the need for an accredited calibration laboratory (although not as the only route).

Recently, the DIS 17025 seems to follow the same lines.

➔ ILAC P14:2013 on the policy for uncertainty in calibration is also important.

Three types of services

are of particular importance, affecting the overall uncertainty budget of the laboratory:

- Calibration
- Proficiency testing
- Reference materials

According to ISO/IEC 17043

The PT provider shall document and provide information for a series of issues, including the origin, metrologicαl traceability and measurement uncertainty of assigned values, taking into account all factors including problems in homogeneity and stability.

One of the purposes of interlaboratory comparisons is the validation of uncertainty chains

PT schemes…

- in calibration shall have assigned values with metrological traceability, including MU
- in testing metrological traceability and associated MU shall be determined taking into account specified requirements

The competence of the PT provider

for the development of PT schemes refers to meeting the requirements of ISO/IEC 17043.

- In case the provider/scheme is accredited, competence is documented.
- If this is not the case, the laboratory shall look for other means to confirm the required competence.

Laboratory accreditation standards do provide some support…

What is expected from laboratories?

- in DIS 17025* it is noted that proficiency test providers meeting the requirements of ISO 17043 are considered as
- competent *(it should be considered as referring to the particular scheme)*
- ISO 15189 notes that the (medical) laboratory should participate in schemes that substantially fulfil the requirements of ISO/IEC 17043

**ISO/IEC 17025* does not refer to any requirement on this issue*

Three types of services

are of particular importance, affecting the overall uncertainty budget of the laboratory:

- Calibration
- Proficiency testing
- Reference materials

Reference materials are used

in all stages of the measurement process, including

- Method validation
- Calibration
- Quality control

➔ They are also used in interlaboratory comparisons

ISO 17034 specifies that…

the reference material producer (RMP) shall address, among others, the following:

- establishing uncertainty budgets and estimating uncertainties of certified value(s)
- defining acceptance criteria for measurand levels and their uncertainties

Furthermore, the RMP shall provide…

- evidence of the metrological traceability of the certified value to a stated reference
- identify the uncertainty contributions to be included in the assigned uncertainty
- document the factors affecting the uncertainty of the certified value

The competence of the RM producer

refers to meeting the requirements of ISO 17034.

- In case the producer is accredited, competence is documented.
- If this is not the case, the laboratory shall look for other means to confirm the required competence.

Laboratory accreditation standards do not provide much support…

Reference materials

- Only ISO/IEC DIS 17025 recommends the use or reference materials from producers that meet ISO 17034
- ISO/IEC 17025 and ISO 15189 do not make any reference to ISO Guide 34 which was used as the basis for the competence of RMP until recently when ISO 17034 was published.

A laboratory uses information

provided by PT schemes and RMP taking into account when estimating its uncertainty budget. Their technical competence required is the main selection criterion.

➔Are they accredited? Does the particular activity fall within their accreditation scope, if any?

It is not always realistic

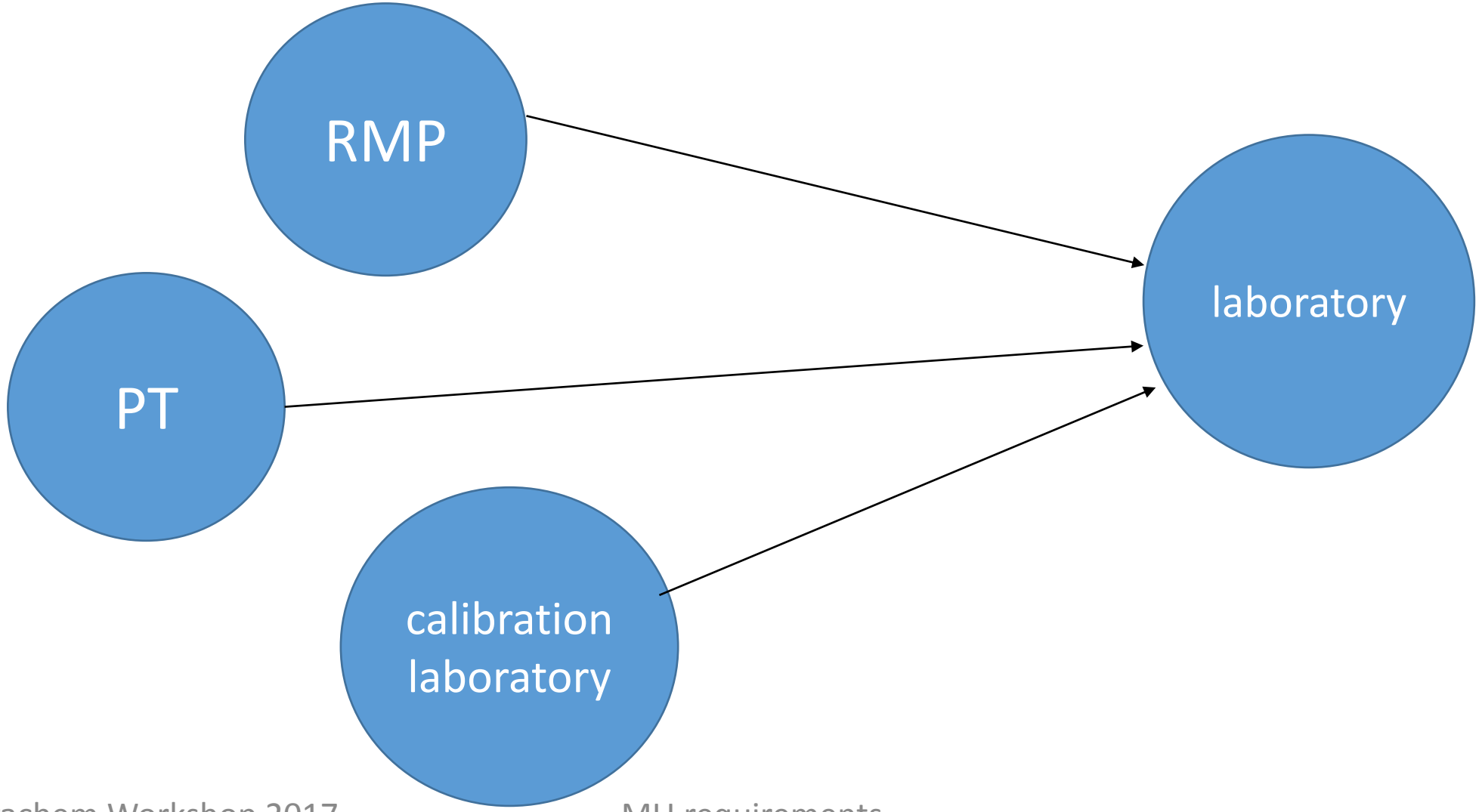
to find accredited suppliers in every field, especially RMP;
the accreditation standard ISO 17034 has been published quite recently (replacing ISO Guide 34), thus not many RMP are accredited as yet.

➔In case of no accreditation status, which evidence does exist for their compliance with relevant standards?

In case these suppliers are not accredited

- The laboratory should take an additional role of considering the competence of the supplier
- Further to this and regardless of how the supplier demonstrates competence, the laboratory should be in a position to adequately communicate and make best use of the information the supplier provides

The laboratory at the end of the route…



What is necessary for a laboratory…

either accredited or being prepared towards its accreditation?

The most probable answer is “the requirements of the relevant standard i.e. ISO/IEC 17025 (or, ISO 15189)”.

- Is this answer enough?
- Is it the only relevant to the laboratory and its activities?

It is expected that accreditation…

now covering all types of conformity assessment bodies as well as other bodies supporting them will be more and more used as a tool.

In case all partners/players are accredited against the corresponding standard, this would speed up the harmonisation procedure regarding conformity assessment!

Thank you for your attention

…and your questions!