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Guidance on the level and frequency of proficiency testing participation

PURPOSE

The aim of this paper is to promote harmonization between accreditation bodies on how the level and frequency of participation in PT is evaluated and to assist laboratories in determining their own levels and frequency of participation.

Authorship

This document has been prepared by the EEE-PT Working Group “Proficiency Testing in Accreditation”.

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1. INTRODUCTION

The standard ISO/IEC 17025:2017 [1] General requirements for the competence of testing and calibration laboratories (7.7.1) establishes that the laboratory shall have a procedure for monitoring the validity of results and that this monitoring shall be planned and reviewed.
In 7.7.2 it is required that the laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;

NOTE ISO/IEC 17043 [2] contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 [2] are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing.

In addition, ILAC [3] has established specific policy regarding participation of laboratories in PT activities. This paper, which has been prepared by the joint stakeholder working group, EEE-PT, on proficiency testing in accreditation is the result of extensive discussions and helps the accreditation bodies in their implementation of this policy. This paper provides guidance to accreditation bodies with the aim to promote harmonization between accreditation bodies on how the level and frequency of participation in PT is evaluated and to assist laboratories in determining their own levels and frequency of participation.

For the purpose of this document, “measurement” covers also testing, calibration, analysis, investigation, examination, determination, assay and other concepts commonly used to describe core laboratory work.
Furthermore, the term laboratory used in this document covers all organizations that provide information on items based on experimental observation, including testing, calibration, examination and sampling. Thus, the principles described in the document are applicable to any accredited organization when performing laboratory activities.

Note: This document is also applicable to medical laboratories and when used in such instances reference to ISO/IEC 17025 [1] should be read as ISO 15189 [4].

2. TERMS AND DEFINITIONS

The definitions below which do not have a specific reference, have been written for the purpose of this document in order to provide clarity for its implementation.

Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2010, definition 3.7) [2].

Proficiency testing (PT) scheme: proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection (ISO/IEC 17043:2010, definition 3.11) [2].

Interlaboratory comparison (ILC): organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions (ISO/IEC 17043:2010, definition 3.4) [2].

Measurement process: The process of measuring the characteristic, including any pre-treatment required to prese he sample, as received by the laboratory, to the measuring device.

Characteristic: The ameter being measured.

Product: The item to which the measurement process is being applied.

Area of technical competence: Field of expertise defined by a minimum of one measurement process, characteristic and pr ct, which are related
Example: amount of arsenic in soil by ICP-MS.

Level of participation: The number of specific activities that an organisation identifies within its scope of accreditation, and t efore the number of specific proficiency tests that should be considered for participation.

Frequency of participation: The number of proficiency tests per unit of time, in which a laboratory participates for an activity as specified in their scope of accreditation.

Scope of accreditation: specific conformity assessment activities for which accreditation is sought or has been granted (ISO/IEC 17011 [5], 3.6).

Small interlaboratory comparison (small ILC): An interlaboratory comparison organised by, and among seven or less laboratories (EA-4/21 INF:2018 [6])

3. GENERAL ASPECTS

The following aspects should be taken into consideration by accreditation bodies when determining the suitability of a laboratory's "level" and "frequency" of participation in proficiency testing:

(1) The laboratory should define the level and frequency of its participation after careful analysis of its other quality assurance (QA) measures to ensure the validity of the results (especially those that are able to disclose, quantify and follow the development of bias of a stated magnitude). The level and frequency of participation should be made dependent on the extent to which other measures have been taken into account. QA measures can include, but are not limited to:

- Regular use of certified reference materials and/or reference materials.
- Comparison of analysis by independent techniques.
- Participation in ILCs for method development/validation and/or reference material characterisation studies.
- Use of internal quality control (IQC) measures.

- Other inter/intra – laboratory comparisons e.g. analysis on blind samples within the laboratory.
- Robustness of the metrological traceability chain. (Are instruments calibrated under the same conditions as routinely used versus assumptions on e.g. influence factors or secondary parameters)

Note: Other approaches to ensuring the validity of the results can be found in ISO/IEC 17025:2017 (7.7.1) [1] and ISO 15189:2012 (5.6) [4].

(2) The level of risk presented by the laboratory, the sector in which it operates or the methodology it is using. This can be determined, for example, by considering:

- Number of measurements undertaken.
- Frequency of tests at a different concentration level.
- Number of different calibration intervals.
- Turnover of technical staff.
- Experience and knowledge of technical staff.
- Source of metrological traceability (information and availability of reference materials, national measurement standards, etc.).
- Known stability/instability of the methodology.
- Complexity and robustness of the methodology.
- Significance and final use of measurement data (e.g. forensic science represents an area requiring a high level of assurance).
- When statements of conformity are required and changes in related specifications are made.
- Risks and opportunities associated with the laboratory activities, in particular those that will prevent, or reduce, undesired impacts and potential failures in the laboratory activities and achieve improvement.
- Extent of validation and/or verification.

(3) Different types of ILCs that can be used by laboratories, and which should be accepted by accreditation bodies as PTs, include:

- ILC organised by a sufficient number of laboratories as a one-off or continual exercise.
- Organisation of, or participation in, an ILC with a small number of participants.

  Note: Organisations that organise a small ILC among themselves should apply the appropriate requirements of ISO/IEC 17043 [2], and EA-4/21 INF [6] if the results and evaluation of performance are to be used as a tool to monitor and demonstrate the validity of their results.

(4) It must be recognised that there are sectors where participation in PT may be difficult, due to the technical characteristics of the measurement, the lack of PT schemes, the

low number of existing laboratories in the sector, etc. For innovative fields PTs may not yet exist for some fields. PT may only be possible or economically feasible for parts of the measurement undertaken. In these areas the suitability of other QA/IQC measures is paramount.

(5) Any requirements for frequency and type of PT participation from other sources, e.g. legislation, customers, etc.

4. LEVEL AND FREQUENCY OF PARTICIPATION

The first step for a laboratory is to consider their scope of accreditation concerning the measurements for which it is accredited.

Ideally, a laboratory would participate in a specific PT for every measurement process it uses and for every characteristic measured in every product. However, it is acknowledged that this is unlikely to be feasible, both logistically and economically. Therefore, accreditation bodies should expect laboratories to identify areas of technical competence comprising sets of measurement processes, characteristics and products on which the outcome of a PT for one of these sets can be directly correlated to the other sets of measurement processes, characteristics and products contained within their accreditation scope.

An area of technical competence, as mentioned above, may contain more than one measurement process, characteristic or product as long as the equivalence between the combined measurement processes, characteristics or products can be justified. Different technical competences can usually be identified by the need for different qualifications, training, and use of different equipment, knowledge or experience.

When determining an area of technical competence, it may be helpful to consider a stepwise approach working up from measurement process through characteristics to products. This is because it is more likely that there will be several products and/or characteristics associated with one measurement process within a given area of technical competence than vice versa:

(i) With reference to the **measurement process**: It is possible but not common to include different measurement processes in the same area of technical competence.

(ii) With reference to the **characteristic** to be measured or identified: It may be possible to include more than one characteristic in the same area of technical competence.

(iii) With reference to **products** to be measured: It may be possible to include different products in the same area of technical competence provided that the items included are of equivalent nature.

Once the laboratory has defined its areas of technical competence the “level of participation” can be deemed to have been defined. The AB should assess the suitability of the laboratory´s risk based approach for determining its participation frequencies in different technical areas, and how it takes into consideration the extent and character of other quality control initiatives.

Therefore, once the “level” and “frequency” of participation have been established, this will be included in the laboratory’s overall quality control strategy.

It is recommended that the PT participation plan, resulting from the establishment of the various “levels” and “frequencies” of participation, covers, at least, one accreditation cycle (period between full reassessments), and is reviewed with the overall PT strategy by the laboratory for its suitability, usually on an annual basis during the formal management review.

Note: If unsatisfactory results are obtained from the PT participation, this may also influence the ongoing strategy.

5. REFERENCES

1 ISO/IEC 17025:2017: General Requirements for the competence of testing and calibration laboratories.
2 ISO/IEC 17043:2010: Conformity assessment — General requirements for proficiency testing.
3 ILAC-P9 (Current Version): ILAC Policy for Participation in National and International Proficiency Testing Activities.
4 ISO 15189:2012: Medical laboratories. Requirements for quality and competence.
5 ISO/IEC 17011:2017: Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies.
6 EA-4/21: 2018-03: Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

6. CASE STUDIES

It is for each individual laboratory to consider how many areas of technical competence will adequately cover the scope of their work and thus define their “level” and “frequency” of participation in PT, which should be detailed in their PT strategy. Six studies have been provided to illustrate how a laboratory might review their scope of work and thus derive the number of areas of technical competence. However, these case studies are only examples of how this could be approached and should not be regarded as a benchmark. Specific frequencies are for illustrative purposes only.

Case Study 1 – Environmental Chemistry Testing Laboratory

Accredited measurements performed by the laboratory

- Polychlorinated Biphenyls (PCB) by GC-MS in soils and sewage sludge
- Polyaromatic Hydrocarbons (PAH) by GC-MS in soils and sewage sludge
- Volatile Organic Compounds (VOC) by Purge and Trap GC-MS in waters
- Metals by ICP-MS in soils, sewage sludge and waters
- pH in soils, sewage sludge and waters

Considerations for determinations of areas of technical competence

- For pH the laboratory identifies that it utilises the same ISO method for all three matrices (soils, waters and sewage sludge). This ISO method has been validated against all three matrices and therefore the laboratory identifies this as one area of technical competence.

- For the analysis of metals, the laboratory identifies that it uses the same measurement process (ICP-MS) for all three matrices (soils, waters and sewage sludge). However, the preparation of water samples compared to soils and sewage sludge is significantly different. As such, the laboratory identifies that it cannot declare this as one area of technical competence, but as the methodologies for soils and sewage sludge are demonstrably comparable, they can be. Therefore, the laboratory identifies two more areas of technical competence.

- For PAH and PCB analysis the laboratory identifies that it uses the same measurement process (GC-MS) and the extraction of the matrices (soils and sewage sludge) is identical for both matrices. However, via its initial validation of the methods it is apparent that PCB and PAH are effected in different ways by variations in the methodology and therefore acceptable performance or problematic performance on PCB would not necessarily mean the same for PAH (and vice versa). Therefore, the laboratory identifies two more areas of technical competence.

- For its VOC method, the laboratory only has one matrix (water) to consider. However, the laboratory is aware that the method analyses several different parameters that could potentially react in different ways to problems with the method. Through its method validation data, the laboratory has demonstrated that the differing parameters react in comparable ways to variations in the method. Therefore, the laboratory identifies one more area of technical competence.

Resulting areas of technical competence from this exercise

- Polychlorinated Biphenyls (PCB) by GC-MS in soil and sewage sludge
- Polyaromatic Hydrocarbons (PAH) by GC-MS in soil and sewage sludge
- Volatile Organic Compounds (VOC) by purge and trap GC-MS in water
- Metals by ICP-MS in soil and sewage sludge
- Metals by ICP-MS in water
- pH in soil, sewage sludge and water

Considerations for determining frequency of participation

For the various areas of competence, the laboratory has defined the following frequencies:

- For the analysis of PCB and PAH, the laboratory uses certified reference materials once a year, one at the lower level of the typical concentration range and one at the higher level. It has decided to participate twice a year in PT as it enables the laboratory to cover the rest of the concentration range over a period of three years.

- For VOC analysis, it does not use a certified reference material, and therefore it participates in a PT four times a year even though the PT provider also provides the possibility of participation twice a year. It has selected the higher frequency because the two technicians responsible for this analysis have only just been trained and thus are reasonably inexperienced.

- For measurements made by ICP-MS, the laboratory has four technicians that undertake the analysis, but since there is not enough PT items to do more than one determination, the laboratory participates four times a year, so that each technician can participate once per year. In addition, the level of concentration of the certified reference materials do not correspond to the level of concentrations usually analysed. The level of concentrations proposed by the PT provider cover adequately the levels of concentration analysed by the laboratory, so the emphasis is made on PT participation rather than the use of certified reference materials.

- For the determination of pH, the laboratory participates once a year as it uses a pH meter that it calibrates internally, and the pH measurement is not a critical value.

Summary Table

	Characteristic	**Measurement process**	**Product**	**Frequency**
1	PCB	GC-MS	soil/sewage	1 CRM; 2 PTs
2	PAM	GC-MS	soil/sewage	1 CRM; 2 PTs
3	VOC	GC-MS	water	4 PTs, all technicians
4	Metal	ICP-MS	soil/sewage	4PTs, 1 technician/PTs
5	Metal	ICP-MS	water	4 PTs
6	pH		soil/sewage/water	1 PT

Case Study 2 – Microbiology Testing Laboratory

Accredited measurements performed by the laboratory

- Enumeration of *Escherichia coli* in meat
- Detection of *Salmonella* in meat
- Enumeration of *Escherichia coli* in vegetables
- Detection of *Salmonella* in vegetables
- Enumeration of *Escherichia coli* in dairy products
- Enumeration of *Escherichia coli* in drinking water
- Enumeration of *Escherichia coli* in swimming pool water

Considerations for determining areas of technical competence

- For the enumeration of Escherichia coli, the laboratory identifies that it uses the same method for the analysis of both meat and vegetable samples. This method has been validated for these two sample matrix types and therefore the laboratory identifies this as one area of technical competence. Since this method has not been validated for the analysis of dairy products, the laboratory uses a different method for such sample matrices. Thus, this is identified as an additional area of technical competence.

- The method used by the laboratory for the detection of Salmonella has been validated for both meat and vegetable matrices, and thus the laboratory identifies this as one additional area of technical competence.

- For the enumeration of Escherichia coli in water, although different sampling and pre-treatment techniques are used for the collection of the samples, the method used (which is different to that used for the food products) has been validated for both drinking water and swimming pool water, so this has been identified as one additional area of technical competence.

Resulting areas of technical competence from this exercise

- Enumeration of *Escherichia coli* in meat and vegetables
- Enumeration of *Escherichia coli* in dairy products
- Detection of *Salmonella* in meat and vegetables
- Enumeration of *Escherichia coli* in drinking water and swimming pool water

Considerations for determining frequency of participation

For the various areas of competence, the laboratory has defined the following frequencies:

- The laboratory carries out the analysis of a high volume of meat and vegetable samples every week for both the enumeration of Escherichia coli and the detection of Salmonella. There are no certified reference materials available for use, so the laboratory is very reliant on PT participation to monitor its performance. Therefore, the laboratory decides to participate at the maximum frequency offered by the PT provider which is once a month. Furthermore, since there are four different microbiologists, that undertake the analysis and

there is sufficient test material provided, each microbiologist participates in the PT each month.

- For the enumeration of Escherichia coli in dairy products, the laboratory only receives a small number of samples to test each month. Therefore, it has decided to participate in the PT four times a year. However, again since there are four microbiologists that undertake the analysis, they all participate each quarter.

- A different department than that for food undertakes the enumeration of Escherichia coli in drinking water and swimming pool water. The monthly volume of samples received for testing is not that high and two microbiologists undertake the work. Whilst based on the volume of samples tested it would be sufficient to participate four times a year, there is a high turnover of staff in this team, so the laboratory has selected to participate every month with both microbiologists participating in the PT.

- For the different areas of technical competence, the laboratory has chosen PT programs that cover a high variety of different matrices to ensure that over an accreditation cycle all the parameters and matrices are considered.

Summary Table

	Characterisitic (μ-organism)	**Measurement process**	**Product**	**Frequency**	**Comment**
1	Salmonella	Detection	Meat/ vegetables	Once/month every microbiologist	High number of samples
2	E coli	Enumeration	Meat /vegetables	Once/month every microbiologist	High number of samples
3	E coli	Enumeration	Dairy	4 PTs every microbiologist	Low number of samples
4	E coli	Enumeration	Water	Once/month every microbiologist	High turnover of staff

Case Study 3 – Medical Laboratory

Accredited measurements performed by the laboratory

- Screening for drugs of abuse in blood by ELISA (Enzyme-Linked Immunosorbent Assay) and Liquid EIA (Enzyme Immunoassay)
- Screening for drugs of abuse in urine by ELISA and Liquid EIA
- Confirmation of Amphetamine in blood and urine by GC-MS (Gas Chromatography-Mass Spectrometry)
- Confirmation of Amphetamine in urine by GC-MS
- Confirmation of Codeine in blood by GC-MS
- Confirmation of Codeine in urine by GC-MS
- Confirmation of Diazepam in blood by LC-MS/MS (Liquide Chromatography – Mass Spectrometry
- Confirmation of Diazepam in urine by LC-MS/MS
- Confirmation of Cocaine in blood by LC-MS/MS
- Confirmation of Cocaine in urine by LC-MS/MS
- Confirmation of EDDP (2-ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine) in blood by LC-MS/MS
- Confirmation of EDDP in urine by LC-MS/MS
- Confirmation of Buprenorphine in blood by GC-MS/MS
- Confirmation of Buprenorphine in urine by GC-MS/MS
- Confirmation of Tetrahydrocannabinol in blood by GC-MS/MS
- Confirmation of Tetrahydrocannabinol in urine by GC-MS/MS

Considerations for determining of areas of technical competence

- The two methods used for the screening for drugs of abuse are different, however both have been verified for use with both blood and urine samples. Thus, the laboratory identifies these as two areas of technical competence.

- Even though the three techniques used for the confirmation of various drugs of abuse are very different, each has been validated for both blood and urine matrices. Furthermore, each different detection system is considered to belong to a separate group of areas of technical competence. The drugs, although coming from different families of products, are considered as equivalent from a competence point of view. Thus, the laboratory identifies that their confirmation tests consist of three additional areas of technical competence.

Resulting areas of technical competence from this exercise

- Screening for drugs of abuse in blood and urine by ELISA
- Screening for drugs of abuse in blood and urine by Liquid EIA
- Confirmation of Amphetamine and Codeine in blood and urine by GC-MS*
- Confirmation of Diazepam, Cocaine and EDDP in blood and urine by LC-MS/MS*
- Confirmation of Buprenorphine and Tetrahydrocannabinol in blood and urine by GC-MS/MS*

*Note: although the different drugs have been combined into one area of technical competence for each detection system in terms of being equivalent from a competency point

of view, this does not suggest that they are equivalent in terms of method and laboratory performance. Therefore, the laboratory would be expected to undertake such PTs specifically covering all the drugs in their scope on a periodic basis. This would be expected to be clearly detailed in their proficiency testing strategy.

Considerations for determining frequency of participation

For the various areas of competence, the laboratory has defined the following frequencies:

- For the screening of drugs of abuse, the laboratory recognises that whilst their methods are different, they are applicable to both blood and urine. The PT scheme available covers both ELISA and Liquid EIA methods and covers both matrices on a monthly basis. Therefore, the laboratory has decided to participate monthly for both methods but to alternate the matrix being used i.e. participates six times a year for blood and six times a year for urine.

- For the confirmation tests, the volume of samples that are tested are much lower than the screening tests. However, it is recognised that whilst the groups of drugs can form one area of technical competence for a particular technique, it is important to ensure that PT participation does encompass all the drugs over an agreed period. Furthermore, the results of these tests inform critical decisions. Therefore, the laboratory decides to participate on a monthly basis for both blood and urine for each of the techniques, in a PT scheme that provides sufficient coverage of all the drugs requiring confirmation on an annual basis.

Summary Table

	Characteristic	**Product**	**Measurement process**	**Frequency**
1	Drugs	Blood, urine	ELISA (screening)	6 PTs for blood 6 PTs for urine
2	Drugs	Blood, urine	Liquid EIA (screening)	6PTs for blood 6 PTs for urine
3	Amphetamine, Codeine	Blood, urine	GC-MS (Confirmation)	monthly, for each matrix, for each technician
4	Diazepam, Cocain,EDDP	Blood, urine	LC-MS/MS (Confirmation)	monthly, for each matrix, for each technician
5	Buprenorphine, Tetrahydrocannabinole	Blood, urine	GC-MS/MS (Confirmation)	monthly, for each matrix, for each technician

Case Study 4 – Mechanical Testing Laboratory

Accredited measurements performed by the laboratory

- Fracture toughness and fatigue crack growth of metals and metal alloys (ASTM E 399)
- Tensile and compression testing of metals and metal alloys (example: ISO EN 6892-1)
- Tensile and compression testing of plastics (ISO 527-1)
- Hardness test according to Brinell (ISO 6506), Vickers (ISO 6507), and Rockwell (ISO 6508)
- Charpy impact test according to ISO 148-1
- Determination of grain size (ISO 643)
- Optical emission spectrometry (Quantification of chemical elements in steel matrix, in house procedure)

Considerations for determining areas of technical competence

Many accredited laboratories perform these named activities in the field of mechanical testing. ISO, EN or ASTM standards describe the test methods. The standards usually define the required equipment and other test related parameters. The named test activities are performed using the same or different types of equipment requiring a specific calibration status and specific knowledge of the staff performing these tests.

- The same measurement process is used for examining fatigue crack growth and fracture toughness and the method (ASTM E 399 [1]) has been validated for metals and metal alloys. Therefore, the laboratory identifies this as one area of technical competence.

- Tensile testing and compression testing for metals and metal alloys are based on the same measurement process [2]. However, the testing of fatigue crack growth encompasses the measurement capability of tensile/compression testing and so the laboratory has identified no need to undertake additional PTs for metals and alloys. (Note: participation in a PT for tensile and compression testing would not be sufficient to cover the testing of fatigue crack growth).

- For tensile test on plastics, a similar test system can be used, but usually a lower load capacity is necessary. The supplementary equipment is different because of the high ductility of plastics. Additionally, the definitions of the characteristics that are determined are different in ISO 527 [3]. The equipment must be calibrated once a year and the use of reference material is limited to a small number of laboratories. Therefore, the laboratory identifies this as an additional area of technical competence since this uses a different method.

- In the hardness tests according to Brinell (ISO 6506 [4]), Vickers (ISO 6507 [5]), a ball or a pyramid is used to make an indentation in a surface of a steel material. After this step, the diagonals of the indentation are measured and the hardness of the material is calculated. In the related ISO 6506-1 [4] and 6507-1 [5] series, the requirements on the direct calibration status of the equipment (load, indenter, length measurement device) are defined. They must be repeated once a year, and the use of certified reference material

prior to a test is mandatory. Thus, the laboratory identifies an additional area of technical competence for these two methods.

- The Rockwell (ISO 6508-1 [6]) hardness test uses a different measurement procedure compared to Brinell and Vickers. According to ISO 6508 [6] different types of indenters can be used to make an indentation on a metal's surface under pre- defined loading conditions. In this test, the depth of the indentation is measured using the specific test procedure. The ISO standard requires calibration and the use of certified reference material. Therefore, this is identified as an additional area of technical competence by the laboratory.

- The Charpy impact test standard, ISO 148-1 [6], defines the specimen dimensions. The test equipment is calibrated once a year, and the Standard requires additionally specific reference material for indirect calibration of the whole test setup. The impact energy is measured. Thus, another area of technical competence is identified by the laboratory.

- For the determination of grain size (ISO 643 [8]), the surface of a steel is prepared in a specific way, grinding, polishing, etching to mark the grain boundaries of the material. After this preparation step, a microscope with calibrated magnification is used to measure the size of the grains and calculate the relevant parameters according to the standard. The laboratory identified this as another area of technical competence.

- Optical emission spectrometry is used by many laboratories to identify steel alloys. Certified reference materials and secondary in-house standards are used to calibrate the equipment. This is identified by the laboratory as an additional area of technical competence.

Resulting areas of technical competence from this exercise

- Fracture toughness and fatigue crack growth of metals and metal alloys
- Tensile test on plastics
- Hardness test by Brinell or Vickers
- Hardness test by Rockwell
- Charpy impact test
- Determination of grain size
- Optical emission spectrometry

Considerations for determining frequency of participation

For the various areas of competence, the laboratory has defined the following frequencies:

- The laboratory does not have a high throughput of samples for the majority of the tests, with even less samples tested by optical emission spectrometry. The laboratory has experienced technicians who have been undertaking the tests for many years. Given that some customers for this test come from, for example, the nuclear industry, which is a critical area, the laboratory feels that participating in a PT scheme four times a year enables them to guarantee towards their customers the validity of their performance. If the

customers did not come from critical areas, then participation in a PT scheme once or twice a year would be sufficient.

- The laboratory recognises the particular criticality of the fracture toughness and fatigue crack growth about decisions made on health and safety, and so has decided to increase the frequency for these tests to six times a year, otherwise a frequency of once a year could be considered sufficient. It is also important to ensure the comparability in testing of the different staff members performing these tests.

- Given the much lower number of samples for testing by optical emission spectrometry, the laboratory decides it is sufficient to participate twice a year for this area of technical competence.

References

1 ASTM E399-20a: Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness of Metallic Materials

2 EN ISO 6892-1:2019 - Metallic materials. Tensile testing. Method of test at room temperature

3 ISO 527-1:2019: Plastics — Determination of tensile properties – Part 1: General principles

4 ISO 6506 series: Metallic materials — Brinell hardness test

5 ISO 6507 series: Metallic materials — Vickers hardness test

6 ISO 6508 series: Metallic materials — Rockwell hardness test

7 ISO 148-1: 2016: Metallic materials — Charpy pendulum impact test — Part 1: Test method

8 ISO 643: 2019: Steels — Micrographic determination of the apparent grain size

Case Study 5 – Medical Laboratory (Matrix Approach)

Accredited measurements performed by the laboratory

- FSH (Follicle-stimulating Hormone) by Chemiluminescence in blood
- LH (Luteinizing Hormone) by Chemiluminescence in blood
- Folic acid by Chemiluminescence in blood
- Calcium by Electrochemistry in blood and urine
- Potassium by Electrochemistry in blood and urine
- Cryoglobulins by Electrophoresis in blood
- Carbamazepine by Immunoassay in blood
- Ciclosporin by Immunoassay in blood
- Transferrin by Nephelometry in blood and urine
- α2 Macroglobulin by Nephelometry in blood and urine
- ALAT (Alanine Aminotransferase) by UV-Visible spectroscopy in blood
- ASAT (Aspartate Aminotransferase) by UV-Visible spectroscopy in blood
- Magnesium by UV-Visible spectroscopy in blood and urine

Considerations for determining areas of technical competence

In order to determine its areas of technical competence, the laboratory lists all the measurement processes it uses within its scope, all the characteristics, which can be individual characteristics or areas of technical competence of equivalent characteristics.

From the defined measurement processes, characteristics and products, the laboratory, for each individual characteristic, links it to one measurement process, one group of characteristics and one product.

Resulting areas of technical competence from this exercise

- Hormones by Chemiluminescence in blood
- Vitamins by Chemiluminescence in blood
- Electrolytes by Electrochemistry in blood and urine
- Specific proteins by Electrophoresis in blood
- Drugs by Immunoassay in blood
- Specific proteins by Nephelometry in blood and urine
- Electrolytes by UV-Visible spectroscopy in blood and urine
- Enzymes by UV-Visible spectroscopy in blood

The laboratory takes into account the decision threshold (example: for therapeutic decision) because it can be different according to the product. For example, if the blood and urine tests are correlated, they can only be considered as belonging to the same group if, among the test items proposed by the PT, there are concentrations close to each threshold. The test items have to cover measuring ranges of the two products.

Note: Although the different products have been combined into one area of technical competence for each detection system in terms of being equivalent from a competency point of view, this does not suggest that they are equivalent in terms of method and laboratory

performance. Therefore, the laboratory would be expected to undertake such PTs specifically covering all the products in their scope on a periodic basis. This would be expected to be clearly detailed in their proficiency testing strategy.

Considerations for determining frequency of participation

The medical laboratory is regulated by national government legislation in that it needs to participate in PT at least twelve times a year i.e. a monthly participation. Since the PT provider selected offers both blood and urine test materials on a monthly basis, and the sample volume throughput is very high at the laboratory coupled with the criticality of the measurements, the laboratory decides to take test materials for both blood and urine on a monthly basis. Since there is a large team of analysts and a range of different instruments that are used, the laboratory utilises the multi analyst/instrument reporting offered by the PT provider within the limitations of the sample size. Thus, although not all analysts/instruments participate in every round, the laboratory has developed a strategy where every analyst/instrument participates at least four times a year.

Summary table

	Characteristic	**Measurement process**	**Product**	**Frequency**
1	Drugs: Carbamazepine, Ciclosporin	Immunoassay	Blood	Monthly
2	Electrolytes: Calcium, Potassium	Electrochemistry	Blood	Monthly
3	Electrolytes: Calcium, Potassium	Electrochemistry	Urine	Monthly
4	Electrolytes: Magnesium	UV-Vis	Blood	Monthly
5	Electrolytes: Magnesium	UV-Vis	Urine	Monthly
6	Enzymes: ALAT, ASAT	UV-Vis	Blood	Monthly
7	Hormones: FSH, LH	Chemiluminesence	Blood	Monthly
8	Specific proteins: Cryoglobuline	Electrophoresis	Blood	Monthly
9	Specific proteins: Transferrine, α2 Macroglobulin	Nephelometry	Blood	Monthly
10	Specific proteins: Transferrine, α2 Macroglobulin	Nephelometry	Urine	Monthly
11	Vitamins: Folic acid	Chemiluminescence	Blood	Monthly

Case Study 6 – Calibration Laboratory

Accredited calibration activities performed by the laboratory:

- Geometric measurement equipment (from gauge blocks to handheld tools)
- DC and LF electrical measurement equipment (from calibrators to handheld DMMs)
- Temperature (measurement systems and sensors in liquid baths and in air)

Considerations for determining areas of technical competence:

Many accredited calibration laboratories have a scope covering several areas of competence, and unless these share traceability, e.g. through internal calibrations, they should be handled separately with regards to PT/ILC programmes.

In the present example, a relatively small scope is considered.

For a calibration laboratory, regular calibration of reference equipment is essential and a strict requirement to ensure documented traceability. The accredited scope is defined through a specification of a “calibration and measurement capability (CMC)” specifying measurand, measurement range (including any secondary parameters), measurement uncertainty, method (typically locally defined) and type of instruments[1].

It should be noted, that in the field of calibration very few regularly organised PT schemes exist. Most PTs (in the form of ILCs) are organised in a semi-regular fashion by a number of national metrology institutes or laboratory collaborations as a side business, some of which are accredited against ISO/IEC 17043. Because ILCs in calibration most often are based on the circulation of a single or a very limited number of test items, which need to be monitored over the time period of the ILC, only a limited number of participants is possible, reducing further the availability.

Hence, most calibration laboratories must devise more extensive internal quality assurance measures and engage in collaborations with other laboratories to organise e.g. bi- or tri-lateral comparisons. An important aspect is to seek comparisons of measurements using a different traceability route than that used by the laboratory, and to take into consideration the need for adequacy for the best uncertainties and over the widest possible range (including low and high limits, if possible.

When organised PTs do not exist, assessment by the accreditation body will focus on the relevance of the comparison protocol defined by the participants and the laboratory’s own analysis of results of comparisons, including criteria and actions taken when results fall outside these criteria.

[1] ISO/IEC 17011:2017, 7.8.3.c

A constructed example of considerations:

Geometry: Metrological traceability is established through reference gauge blocks calibrated at the National Metrology Institute (NMI) which participates in the CIPM MRA. The laboratory maintains two sets which are calibrated in turn every fourth year. Each set is only used for internal calibrations of working sets. Further standards include internal and external diameter (ring gauges), step-gauges, tapers, glass scales, roughness standards and more. They are calibrated by an accredited calibration laboratory.

Because a large number and brands of geometric measurement tools are covered, the areas of technical competence are broken down to five areas:

- Length standards and tolerance tools (gauge blocks, step gauges, tapers, …)
- Manual length measuring devices (calipers, micrometers, etc.)
- Length measuring apparatus (tape measures, laser length indicators, …)
- Surface measurement (roughness, optical flats, …)
- Other geometric equipment (profile projectors, ring gauges, …)

Electricity: Traceability is established via a reference high-end transfer multimeter, which is calibrated twice a year and used for internal calibrations of calibrators and digital multimeters (DMMs).

A set of discrete reference and working resistors are maintained mainly to support temperature.

Because the main tasks handled by the laboratory are DMMs, calibrators and simulators to support temperature measurements, the technical competence is focused on the areas:

- Precision DMMs (6+ digits)
- Resistance measurement

Temperature: Traceability is established by two SPRTs calibrated in turn annually. Two fixed points are maintained at WTP (0,01 °C) and Ga (~ 39 °C). Calibrations are not performed using these, only internal monitoring of two reference SPRTs. Calibrations are performed in liquid baths as comparison to SPRT and temperature sensors can also be calibrated in air using an air bath and comparison with reference thermometer.

- Temperature measured in liquid bath in the range 0 °C to 40 °C
- Calibration of temperature sensors in air

Considerations for determining frequency of participation:

Geometry: The laboratory has set up internal gauge block comparisons and maintains data on measured differences between blocks in the two sets of references. In this manner, an indirect comparison with the NMI is performed every two years, and the possibility of checks exists for secondary measurement equipment.

The laboratory seeks to participate in ILC on geometric measurement tools every second year, rotating the type of equipment among the five main groups, mainly based on the comparisons available. As an alternative, if a suitable ILC is not available, an agreement with a similar laboratory has been established to swap and calibrate internal standards or equipment and compare results.

The group of calibration technicians can compare their competences in the instances when an ILC is available.

Electricity: The laboratory participates in an organised ILC on calibration of multimeters once every 4-5 years, as these are offered from various sources, and otherwise engages with laboratories with a similar scope and level in bi-lateral comparisons every 2-3 years (exchange of test units - e.g. reference multimeter and high end resistors - and subsequent exchange of calibration certificates). Because organised ILC's in the field seek a "low common denominator", e.g. 4 ½ digit DMM, the laboratory must seek other collaborations to tests its better measurement capabilities.

Temperature: The laboratory compares its SPRTs internally after each calibration and compares final calibration results of standard PRTs performed by different technicians. SPRTs are regularly tested in the two fixed points and the results monitored over time.

As an external comparison activity, the laboratory requests a SPRT from another laboratory, determines SPRT parameters (R_0 and W_{Ga}) for the main usage range (0 °C – 40 °C) and compares to the assigned values.