

Experience of the implementation of EA-4/18

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Eurachem PT Workshop, Portorož, October 2017



EA-4/18 INF: 2010 – Guidance on the level and frequency of proficiency testing participation

- **Feedback from the analytical community:**
 - **Laboratories receiving mixed messages from different assessors as to the level and frequency required**
- **To deal with the concern the EEE-PT (EA-Eurachem-Eurolab) WG undertook a survey to ascertain the experience from EA accreditation bodies.**
- **Survey sent to all EA accreditation bodies – full members and associate (47).**
- **Responses received : 26**



Principles of EA-4/18

- **It is expected that a laboratory develops a PT plan outlining their strategy for PT**
- **The plan should:**
 - **Take into account, the areas of competence (sub-disciplines) of the laboratory, other quality measures and the level of risk**
 - **State the level and frequency of participation**
 - **Cover a specific period (an accreditation cycle)**
 - **Be reviewed for its suitability on an annual basis (part of management review).**



Principles of EA-4/18

- **Laboratories need to identify their sub-disciplines or areas of technical competence.**
- **Sub-discipline: An area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related. (e.g. Determination of Arsenic in soil by ICP-MS)**



Principles of EA-4/18

- **Measurement Technique:** The process of testing / calibrating / identifying the property, including any pre-treatment required to present the sample, as received by the laboratory, to the measuring device. (e.g. ICP-MS, Rockwell Hardness, PCR, Microscopy, Force Measurement)
- **Property:** The quantity being measured (e.g. Arsenic, Fat, Creatinine, Length, Hardness, Force)
- **Product:** The item that the measurement technique is being applied. (e.g. Soil, Vegetables, Serum, Polystyrene, Concrete)



Principles of EA-4/18

- **Level of Participation:** The number of sub-disciplines that an organisation identifies within its scope, and therefore the number of specific proficiency tests that should be considered for participation
- **Frequency of Participation:** This is how often a laboratory determines that it needs to participate in PT for a given sub-discipline, this may vary from sub-discipline to sub-discipline within a laboratory and between laboratories with the same sub-disciplines



Principles of EA-4/18

- **Accreditation bodies should expect laboratories to identify groups of sets of measurement techniques, properties and products on which the outcome of a PT for one of these sets can be directly correlated to the others sets of measurement techniques, properties and products contained within the group.**
- **These groups of sets of measurement techniques, properties and products are termed a sub-discipline (or area of technical competence).**



Principles of EA-4/18

- **Once the laboratory has defined its sub-disciplines the “level of participation” can be deemed to have been defined.**
- **Accreditation bodies will also need to evaluate the suitability of a laboratories “frequency” of participation, based on level of risk and should expect a minimum frequency of participation for each sub-discipline to be set by the laboratory.**



Principles of EA-4/18

- **The classification of sub-disciplines may be different for every laboratory.**
- **Accreditation bodies should expect laboratories to be able to justify the technical arguments that have led to the laboratories decision on the “level” and “frequency” of participation in PT.**
- **It is recommended that laboratories document this justification.**



Principles of EA-4/18

- **A number of case studies have been provided to illustrate how a laboratory might review their scope of work and thus derive the number of sub-disciplines.**
- **It is for the accreditation body to discuss with each individual laboratory their PT strategy, on a case by case basis.**



Survey Question 1

Is your AB using EA-4/18 as a reference/policy document?

- If no,
 - a) What are the reasons for not considering EA-4/18.
 - b) Have you established your own guidance on level and frequency of PT
- If yes,
 - a) Do you consider EA-4/18 as an “external” informative document or
 - b) Have you included it within your own directives.



Response Question 1

Is your AB using EA-4/18 as a reference/policy document?

NO : 2 (but accepts if a laboratory uses it as reference)

- No as EA-4/18 is an informative document

YES : 24

- 17 have specifically included the principles EA-4/18 in their own policy/directives
- 7 have EA-4/18 as a reference document.

EA-4/18 is not considered as a mandatory, due to its status as informative document, so there is a risk that it is not implemented in an fully harmonised way



Survey Question 2

In the implementation of EA-4/18 have you experienced difficulties in :

- a) The understanding of the concept included in the EA-4/18
- b) The identification of sub-disciplines
- c) The assessment of the participation strategy
- d) Other



Responses Question 2

In the implementation of EA-4/18 have you experienced difficulties in :

- a) 4 AB's experienced difficulties in understanding the concept
- b) 12 AB's encountered difficulties in the identification of sub-disciplines
- c) 7AB's had some difficulties in the assessment of the participation strategy
- d) No real other problems.



Responses Question 2

- **Difficulties encountered :**
 - **Laboratories have difficulties with the understanding of the concept**
 - **Suitability of level and frequency**
 - **Time consuming discussions**
 - **Difficulties in establishing a harmonised approach**
 - **Difficulties in how the sub-disciplines can be applied**
 - **Assessment could be subjective, a lot of interpretation involved**
 - **Not always black or white**



Survey Question 3

Is the participation strategy evaluated during each assessment?

- **If yes, how much have risk factors been considered in the assessment of the laboratory PT participation strategy?**
- **If no, for which reason is this not performed?**



Responses Question 3

Is the participation strategy evaluated during each assessment?

- **YES : 24**
- **NO : 2 (1 AB not clear with the question)**
- **Participation strategy is clearly a part of the assessment, and almost every assessment, however, the degree at which risk factors are considered during the assessment varies a lot between the Accreditation Bodies.**



Survey Question 4

In assessing the laboratory PT participation strategy, what has generally been the outcome?

- a) **Systematically adequate**
- b) **Frequently adequate**
- c) **Occasionally adequate**
- d) **Rarely adequate**
- e) **Never adequate**



Responses Question 4

In assessing the laboratory PT participation strategy, what has generally been the outcome?

- a) Systematically adequate : 5**
- b) Frequently adequate : 16**
- c) Occasionally adequate : 2**
- d) Rarely adequate : 0**
- e) Never adequate : 0**

Outcome consistent with other points of the accreditation standards assessed.



Responses Question 4

In assessing the laboratory PT participation strategy, what has generally been the outcome?

- Omitted for extensions**
- Level and frequency not considered over the full cycle**
- Adequate after a few assessment**
- Documented risk-based evaluations of participation strategy not sufficient**
- Choosing “small” ILC’s (between few laboratories) instead of available and appropriate PT schemes.**



Survey Question 5

In assessing the laboratory PT participation strategy, do you accept other QA measures being taken into account (i.e. use of CRM, internal quality control measures)?

- a) Yes**
- b) No**



Responses Question 5

In assessing the laboratory PT participation strategy, do you accept other QA measures being taken into account (i.e. use of CRM, internal quality control measures)?

All Accreditation Bodies accept other quality assurance measures in assessing the PT participation strategy



Survey Question 6

If the laboratory has not implemented an adequate PT participation strategy, what is the outcome from the AB?

- a) Major finding**
- b) Minor finding**
- c) Recommendation/remark**
- d) No comment**



Responses Question 6

If the laboratory has not implemented an adequate PT participation strategy, what is the outcome from the AB?

- a) Major finding : 10**
- b) Minor finding : 3**
- c) Recommendation/remark : 0**
- d) No comment : 0**
- A lot of Accreditation bodies responded : it depends on the finding**
- Major because PT participation is an important element for proving competence**



Survey Question 7

In which circumstances do you accept economic reasons put forward by a laboratory that an available PT is not considered appropriate?



Responses Question 7

In which circumstances do you accept economic reasons put forward by a laboratory that an available PT is not considered appropriate?

- **Never : 10**

In a general view if a PT is appropriate and available, a laboratory has to participate

- **Accepted : 15**
 - **If solid alternative resources to prove technical competence are in place**
 - **Very expensive (e.g. stack emission the laboratory has to go on-site)**
 - **If the costs of PT participation have a significant influence on the price of the test**



Survey Questions 8/9

Has the implementation led to changes in the level and frequency of PT participation by laboratories?

- **If yes, to what extent have the changes been for :**
 - the level of participation?
 - the frequency of participation?

- a) Reduction in the level/frequency
- b) Increase in the level/frequency
- c) Same level/frequency



Responses Questions 8

Has the implementation led to changes in the level and frequency of PT participation by laboratories?

- **If yes, to what extent have the changes been for :**
 - the level of participation?

- a) Reduction in the level : 1
- b) Increase in the level : 9
- c) Same level : 14
 - Can vary according to the technical fields
 - Has promoted participation in some fields, where few or no PT schemes are available
 - Increase linked with a good understanding of the sub-disciplines



Responses Questions 9

Has the implementation led to changes in the level and frequency of PT participation by laboratories?

- **If yes, to what extent have the changes been for :
- the frequency of participation?**
 - a) **Reduction in the frequency : 3**
 - b) **Increase in the frequency : 3**
 - c) **Same frequency : 15**
 - d) **No opinion: 3**
- **Can vary according to the technical fields**
- **Depends on the offer**
- **More structured**



Survey Questions 10

Do you consider, there is a need to :

- a) **Revise EA-4/18. What changes need to be made?**
- b) **Withdraw EA-4/18. For what reason?**
- c) **No change**



Responses Questions 10

Do you consider, there is a need to :

- a) **Revise EA-4/18 : 17**
- b) **Withdraw EA-4/18 : 2**
- c) **No change : 6**

Withdraw EA-4/18 :

- **ILAC P9 is the reference document**
- **No added value as it is an informative document only**



Responses Questions 10

Do you consider, there is a need to :

Revise EA-4/18 :

- **Case studies useful, add genetics**
- **Develop the risk approach on level and frequency of participation**
- **Take into consideration the changes of ISO/IEC 17025 and ISO 17011**
- **Clarify the levels of participation with the minimum tolerated and what must be accepted as a minimum in a strategy of participation**
- **Terms like availability, economic and technical adequacy must be defined**



Responses Questions 10

Do you consider, there is a need to :

Revise EA-4/18 :

- Inclusion of risk and other QC measures influencing the level and frequency needs further guidance
- Incorrect assumptions
- More examples, including calibration
- Add criteria for determining the frequency of participation within sub-disciplines
- Add more information about how a laboratory can demonstrate equivalence



Conclusion

- EA-4/18 is largely used as a reference document by ABs
- As an informative document, the level of rigour in its application varies between the ABs
- Difficulty to define sub-disciplines
- Difficult to establish a harmonised assessment approach of the PT participation strategy
- Understandably laboratories can have the impression that they are treated differently
- A majority of ABs are in favour of a revision of EA-4/18, meaning that the document is considered as useful in the accreditation process



Experience of the implementation of EA-4/18

Thank you for your attention...

