



9th PT/EQA Workshop - Portoroz 2017

Report from WG 5



Experience of the implementation of EA-4/18

- Convenors:
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- Objectives: Consider the experience of the implementation of EA-4/18 since it was published in 2010



Composition of Group

- 22 participants
 - 7 Accreditation Bodies
 - 13 PT Providers
 - 1 Laboratory
 - 1 consultant/assessor/trainer

- Italy, Czech Republic, Spain, Iran, UK, US, India, Turkey, Germany, Poland, Switzerland, France, Jordan 7 China



How useful is this document

- For the Laboratories
 - Useful guide for laboratories to plan their PT participation
 - Helps to reduce the number of participation's due to formation of sub-disciplines; but it is confusing
 - Not easy for labs to understand without assistance of accreditation bodies
 - Helps set plan of PT participation – can refer to the document
 - Some labs use risk approach but did not know of the document



How useful is this document

- For Laboratories
 - Labs in medical field have no idea regarding frequency – could there be a minimum number?
 - Fields and sub-fields should be clearer as to minimum requirements
 - Point made that the EEE-PT WG did not set a minimum frequency because every lab is different
 - APLAC have set a minimum frequency by sector in their document because many of their member are less well established than in Europe.
 - In the US medical field the frequency is regulated



How useful is this document

- For the PT Provider
 - Helps with harmonisation between lab, PT provider and accreditation body
 - Useful as allows PT provider to change/vary the matrix and analytes and plan in line with participants requirements?
 - By using the document, to help know what the labs need, the PT provider can make it more affordable



How useful is this document

- For the Accreditation Body
 - Makes the assessment more difficult, it is complicated to draw up the sub-discipline and train the assessors.
 - Drives labs looked across their whole participation and sub-disciplines, leading to PT areas they were covering
 - Will enhance PT participation in long term
 - Starting to relate the scope of accreditation to the sub-disciplines – harmonise approach
 - Drives labs to think about other quality measures



Has this guidance changed the level and frequency of PT/EQA participation?

- No a simple question, depends on the area
- Yes in some cases due to formation of sub-disciplines
- BUT has increased in other areas i.e. where PT was not being done
- Has increased due to AB policy or ILAC P9 rather than this guide



What are the challenges of preparing the strategy for PT/EQA participation?

- Confusion of sub-disciplines – would likely to revise
- Equivalence, lack of technical knowledge often; labs not sure how to justify
- Often differences of opinion between the lab and the assessor
- Labs do not understand risk approach



To what extent is risk assessment taken into account:

- No in all cases both from the lab and the assessor
 - Better on the medical field since ISO 15189 has elements of risk approach
 - The new ISO/IEC 17025 will drive greater awareness
 - Most of the labs do not yet understand fully
 - More detail required in 4/18 on how to use risk based approach



Is the implementation of this guidance harmonised:

- Some laboratories have been told by assessors that they had to do less?
- Differences in sub-disciplines and how they are applied
- Greater understanding is required



Should the requirements of the document be mandatory rather than guidance?

- Should have a higher status than information document
- Should be training at EA Level



What needs to be changes in a revision?

- Better definition of frequency, sub-disciplines, availability and appropriate PTs
- More details on risk analysis
- More details on forming sub disciplines
- How to justify equivalence
- More examples
- Workshop to help ABs implement