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Risk analysis approach for PT/EQA participation

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Risk analysis approach





Risk-based thinking: Basis of ISO standards

- **One of the key changes in the 2015 revision of ISO 9001 is to establish a systematic approach to considering risk.**
- **By using risk-based thinking the consideration of risk is integral.**
- **It becomes proactive rather than reactive.**
- **Risk-based thinking is not new, it is something we all do automatically in everyday life.**



Risk analysis

ISO/IEC 17025:

8.5 Actions to address risks and opportunities

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:...

- c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;**
- d) achieve improvement.**



Risk analysis

ISO 15189: The word “risk” is mentioned 80 times!!

8.5 Actions to address risks and opportunities for improvement

8.5.1 Identification of risks and opportunities for improvement

The laboratory shall identify risks and opportunities for improvement associated with the laboratory activities to:

- a) prevent or reduce undesired impacts and potential failures in the laboratory activities;**
- b) achieve improvement, by acting on opportunities;**

...



Risk analysis

5.6 Risk management

- a) **Laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement...**

“Requirements for risk management are aligned with the principles of ISO 22367 (Application of risk management to medical laboratories)”



Risk analysis approach by Accreditation bodies

- How is it approached by Accreditation bodies?



- A survey with 7 questions was sent to the EA accreditation bodies.
- Responses received : 10



Survey Question 1

Do you have an internal policy or a directive concerning the assessment of the laboratory's strategy (risk-based approach) of participation in PT?





Response Question 1

- **Accreditation bodies have a Policy regarding PT participation based on a “plan or strategy or risk based approach”.**
- **How to assess is however not included in the documents.**
- **Reference is “systematically” made to EA 4/18 (Guidance on the level and frequency of PT participation).**



Survey Question 2

During the assessor training courses, is the assessment of the strategy (risk-based approach) of participation in PT a specific topic?

If yes and your AB does not have a policy/directive, what risk-based principles are used?



Responses Question 2

- **Risk analysis always considered, but not necessarily directly associated with PT participation.**
- **EA/418 used as reference.**
- **Specific details on the risk-based principles are not addressed.**
- **This is up to the knowledge and competence of the assessors.**



Survey Question 3

ISO/IEC 17025 and ISO 15189 mention respectively “The laboratory shall monitor its performance by comparison with results of other laboratories” and “The laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories”.

How is “performance” and “performance of examination methods” understood, that is, how are the boundaries for, e.g. matrix, parameter, measurement technique, set to define what is a “method”, therefore for which a comparison of results has to be made?



Response Question 3

**A “Method” is considered as described in EA 4/18:
“Parameter measured from a matrix by a
measurement technique (As stated is scope of
accreditation)”.**

**Minimum 1 acceptable result for each type of test in
the accreditation cycle.**

Boundaries difficult to establish.

Depends on the scope (Flexibility).

Depends of the specific field.



Survey Question 4

When assessing the strategy (risk-based approach) of participation in PT, what are the 5 main risks that are considered?





Response Question 4

In general the risks included in EA 4/18 are considered (by order of importance):

- Turnover and competence of personnel;**
- Frequency of tests;**
- Stability, complexity and robustness of method;**
- Final use of measurement (Critical areas as eg. forensic, medical,...).**



Response Question 4

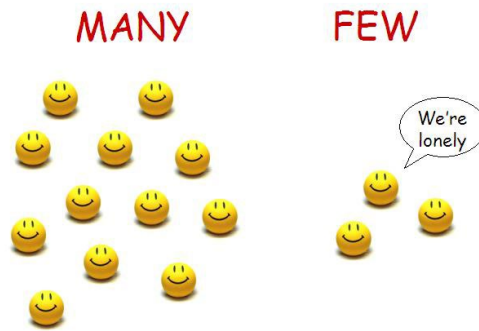
Other risks considered :

- **Participation in PT, ILC or small ILC.**
- **Frequency of use of certified reference materials or other quality control materials.**
- **Lack of internal quality controls.**
- **Previous PT/ILC results.**
- **Flexibility of the scope of accreditation.**



Survey Question 5

At which frequency is the suitability of the laboratory's strategy (risk-based approach) assessed?



Response Question 5

Every assessment.



Survey Question 6

In EA 4/18 it is mentioned: “The level and frequency of participation should be made dependent on the extent to which other measures have been taken into account”.

What are, for your accreditation body “the other measures” and how do they impact on the assessment of the risk analysis approach of the laboratory?



Response Question 6

Other measures are those stated in ISO/IEC 17025 cl. 7.7.1 (non exhaustive list).

In particular:

- **Those capable of revealing, quantifying and monitoring any bias like the regular use of (certified) reference materials.**
- **Robustness of metrological traceability.**
- **Intralaboratory comparisons (between members of staff).**



Response Question 6

“if internal quality control is showing that there is possible deterioration of the method performance and the laboratory is justifying only one PT round per year as sufficient this could be questioned”



Survey Question 7

If the strategy (risk-based approach) of participation in PT is considered by the assessment team as insufficient, is a finding raised or is a recommendation made?

nonconformity





Response Question 7

General approach:

“A finding (Non-conformity) is raised if there was enough evidence to show that the participation was not sufficient to demonstrate good overall performance of the testing in question.

There may be cases where the risk strategy is not fully substantiated but there is no evidence of poor performance, in this instance there may be grounds to raise this as a recommendation”.



Principles of EA-4/18

Revised in 2021 to take more into account the concept of risk analysis

It is expected that a laboratory develops a PT plan outlining their strategy for PT, to:

- Take into account, the areas of competence 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 areas of technical competence.**
- **An area of technical competence is defined by a minimum of one Measurement Technique, Property and Matrix, which are related. (e.g. Determination of Arsenic in soil by ICP-MS).**



Principles of EA-4/18

- **The classification of areas of competence 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 areas of competence.**
- **It is for the accreditation body to discuss with each individual laboratory their PT strategy, on a case by case basis.**



Conclusion

- **Are common risk-based principles used?**

Yes, the risks outlined in EA-4/18 are commonly considered.

- **What training is given to the assessors to ensure harmonization?**

The risk management is considered in the training of assessors, but not necessarily focused on PT participation.



Conclusion

- **What are the main risks that are considered?**
 - **Turnover and competence of personnel**
 - **Frequency of tests**
 - **Stability, complexity and robustness of method**
- **At what frequency is the suitability of the laboratory's risk-based approach (strategy) assessed?**
 - **Harmonised approach as it is verified at every assessment.**



To take home!

- **Per technical sector 1 PT participation plan will not cover all the laboratories.**
- **PT participation plan depends of the other measures used and the risks related to the laboratory.**
- **An “incorrect PT plan” can only be considered as such if there is :**
 - **No justification given by the laboratory;**
 - **Evidence of poor performance.**



Risk analysis approach for PT/EQA participation

Thank you for your attention...

