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Can PT Participation reduce surveillance visits?

The view of an accreditor who has not forgotten his laboratory origin

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- **the author :**

10 years member of Austrian AB BMWA; Assessor (technical, system, team leader); EA Peer Assessor (TL and TM);

more than 25 years experience as Laboratory Manager in Food Chemistry and Microbiology; Legally authorized expert at court; Food expert according to Austrian Food Act

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University lecturer at Montan University Leoben;
Trainer (national and international) on Accreditation, Quality Assurance and Global Approach;
Contributions to meetings and workshops

Regular participation in PTs as laboratory
Organising PTs in the field of food chemistry and microbiology
Organising and evaluating PTs as accreditor

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Member in different workings groups

national and international

- Food Investigations,
- Standardization,
- Accreditation,
- Proficiency testing

- EEE-pt
- EA-LC
- DAR-ATF
- GÖCH and ASAC
- FNA 205

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EEE-PT , the joint working group of EA, EUROLAB and EURACHEM on Proficiency Testing issued a paper on the "Trade-off" issue between participation in PT and the Level and Frequency of Surveillance Activities.

EEE/pt(03)14; EA/LC(04)58

Final Position Paper on the "Trade-off" issue between Participation in Proficiency Testing and the Level and the Frequency of Surveillance Activities

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Intention of the document :

To provide a framework for ABs to implement a flexible assessment regime for laboratories depending on their proficiency testing activities

It is not the intention to replace all surveillance activities by increased proficiency testing.

It does not state that PT is the only quality measure that should be taken into account by accreditation bodies in formulating their assessment activities for individual laboratories

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The goal of this document thus is to influence EA or ILAC policy taking into account good performance in PT/EQA*-activities of laboratories when estimating the frequency and extent of surveillance activities.

* *EQA= External Quality assurance*

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- Accreditation bodies are requested to consider and take into account proficiency testing of laboratories as important part of the accreditation process.

- The discussions about this topic feature include: sufficient frequency, availability, appropriateness and good performance.

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„**Good**" performance in PT as (one possible) measure for accreditation is described in various documents: e.g.

- EA-3/04 Use of Proficiency Testing as a Tool for Accreditation in Testing (EEE-PT)
- EA-3/09 EA Policy for Surveillance and Reassessment of Accredited Organisations
- ISO/IEC 17011 "Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies"

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ISO/IEC 17011:

The accreditation body shall ensure that its accredited laboratories participate in proficiency testing or other comparison programmes where ***available*** and ***appropriate*** and that corrective actions are carried out when necessary. The minimum amount of proficiency testing and the frequency of participation shall be specified in cooperation with interested parties and be appropriate in relation to other surveillance activities.

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Trading-off dependent upon technical sector only relevant in sectors with enough proficiency testing schemes available.

- Internet Databank EPTIS (European proficiency testing information scheme) www.eptis.bam.de
- COEPT

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2 important questions to be answered:

- What means good performance?
- What is appropriate?

Good performance

One of many possible definitions:

A laboratory must obtain a set percentage of satisfactory results over a period of time.

Disadvantage : Likely to put pressure on Laboratory

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Appropriateness

- Material/Matrix
- Measurands
- Levels
- Frequency
- Statistical protocol

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- Material/Matrix:

  The sample material/matrix is as close as possible to that normally tested by the laboratory

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Measurands:

- The measurands in the test samples or materials include as many as reasonable of those normally measured by the laboratory in that sample type.

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- Levels: The levels of these measurands are broadly within the range usually measured by the laboratory in that sample type.

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Frequency:

- The frequency of rounds of the scheme is sufficient as recommended in EA-3/04 in connection with the other means of quality applied by the laboratory for the respective test (method, measurand, material/matrix)

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Statistical protocol:

- The statistical protocol for evaluation of participants' performance is considered to be appropriate for the measurands and test methods covered

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Accreditation of laboratories:

- The establishment and maintenance of quality management systems is intended to guarantee safeguarding technical competence as a daily and ongoing routine and this process is valid for both laboratories and accreditation bodies.

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control mechanisms for ABs:

- Enquiries by the AB
- Reporting by the laboratories
- Assessing the laboratory's performance including proficiency testing
- In normal practice the conduction of surveillance visits by the accreditation body is the most important tool.

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- Rules for the performance, including the frequency of these visits:
- The international standard ISO/IEC 17011 "Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
- and ILAC G 10 " Harmonised Procedures for Surveillance and Reassessment of accredited laboratories".

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- The intervals between surveillance visits 12 months after the first accreditation,

  later these intervals can be expanded, but should not exceed 2 years.
- The ILAC-document recommends a 12 months period after the first assessment and then later an approximate time of 18 months

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These are more or less recommendations only

The peculiarities of the accredited body has to be considered

But it is very convenient to stick to very stricts rules

This is valid also for Peer Assessments

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My personal view:

- The application of quality management systems are only then worth the efforts which have to be undertaken to implement and maintain them if common understanding ("the simple common sense") has enough room to move.
- The implementation of quality management requires living organisations with enough freedom to change, to develop, to improve.
- Off course rules are necessary, but the application of too strict rules is not advantageous

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Aspects of QS :

- Internal surveillance of the consistency of the measurement, e.g. control charts
- Internal audits
- Comparison with internal standards
- Comparison with "external" standards, i.e. certified reference materials
- External comparison of results
  - with other laboratories (ILCs, PTs)
  - with materials of an assigned value (ILCs, PTs)
- External audits, e.g. within a notification or accreditation process

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All these aspects have to be considered when formulating

Trading off

Survey of EEE-pt

Majority of ABs reacted on non satisfactory

But did not react on successful participation in PTs

why

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Trade off performed by considering

- Reduction of surveillance time on site
- Increasing the intervals between 2 surveillance visits
- Reduction of assessment laying more emphasis to the quality management part and reduce technical assessment
- Reduction of assessment applying fewer technical assessors (only for special fields where technical competence is not sufficiently covered by PT)

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- Reduction of preparation time for AB and assessors involved and by this reduce costs
- Reduction of post assessment activities if necessary and by this also reducing costs
- Reduction in cost for prefixed price offers (if the accreditation body performs that way)
- Reduction of assessment: the parts of the scope covered by PTs sufficiently surveilled only by a document review instead of an on-site visit

Depending on case-by-case situation

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Preconditions :

The laboratory's scope of accreditation is covered well by its PT participation and the quality system of the laboratory and its competence are well implemented and stable,

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1:

alternate surveillance visits can be replaced by desk audits of PT results, their review of these results, any investigations, corrective actions and evidence of efficacy of these actions, together with any further documents or information required by the assessor for the audit.

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2:

Increasement of period between surveillance Visits to 2 years

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But:

Where this information indicates a problem within the laboratory's quality system, the accreditation body has the right to conduct a subsequent on-site surveillance visit immediately,

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Concentrate technical assessment to parts not covered so well by PT-participation with a desk assessment as supplement or even perform assessment of quality system only

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Conclusions (summary ?) my personal opinion:

- I like idea of taking succesfiul pt-participation into account
- I dislike too strict accreditation regimes, so to say overruled
- I like to create deeper understanding of quality management in laboratories
- I like to create the „feed-back approach"

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BUT :

Every laboratory is a unique case !!

PT participation of the entire scope will be seldom and don´t forget :

- The pt must be:
- appropriate
- covering the scope of the laboratory to a reasonable extent
- evaluate pt-activities over a longer period (statistical approach)
- The participation in pts of the laboratory must be:
- good
- enough frequent
- evaluate pt-activities over a longer period (statistical approach)

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Consequences :

If preconditions are fulfilled

AB has to evaluate corresponding policy

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This could lead to :

Fewer technical assessors

concentration to technical sectors not covered so well

Laying more emphasis on QM-part of standards

Do not prolong evaluation periods over 2 years

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Surveillance and pts have some similarities:

3rd party assessment

Learning effects

Therefore combine them to improve quality of laboratories