Use of in-house Methods

Rasha El-Khadem
ISTA Accreditation and Technical Department
Outline

• Validation Study
• The ISTA Proficiency Test Programme
• Accreditation and Audit Programme
• Reporting of Results
• Legal Aspects
Validation Study

• Will the validation follow (in principle) the ISTA Method Validation Programme? Yes

• (At least three laboratories to participate. Can any laboratory apply to participate?)

• Will the validation study be published and be available to all members? Available upon request? Available to GER, STA, Accreditation? Yes
Validation Study

• If the in-house method is published does this mean that also laboratories that did not participate in the validation study, can use this method?

Not sure... – I think no, otherwise why not make it an ISTA method published in the Rules?
Proficiency Test Programme

• Should/must the in-house method be used for the PT participation?

Yes, the PT is the monitoring tool for the uniformity of results (regardless where and how the laboratory tests - as long as following the Rules)
Proficiency Test Programme

The list of in-house methods and the laboratories using them (if limited?) must be available for the Accreditation staff. (Reason: while entering the PT results, we enter if a method indicated is an ISTA method)

As a consequence the results obtained using an in-house method will be used to calculate the overall mean.
Proficiency Test Programme

• What are the consequences if a laboratory using in-house method obtained a “BMP”?

Risk of the laboratory, the PT administration will not be able to accept a retest.

If consistent the related Committee should be informed and the validation study should be reviewed, with a possible consequence to reject the method.
Accreditation and Audit Programme

• Which test will be reviewed during the ISTA audit?

Those that are regularly performed. If the in-house method and a reference method is used, both must be demonstrated during the audit.
Accreditation and Audit Programme

• How will the technical auditors be able to prepare themselves?

On the application for reaccreditation, the laboratory should clearly indicate the use of in-house methods. The related documents (e.g. SOP, validation study?) shall be submitted for review.
Accreditation and Audit Programme

• Should the use of in-house methods be indicated on the Scope of Accreditation?

Not sure:

It will be helpful for the Accreditation Body.

It might be interesting for applicants.
Reporting of Results

• How shall laboratories report the results obtained using an in-house method?

Very transparent reporting including details of the method (e.g. first/final count, description of substrate, temperature, etc.)
Legal Aspects

• What happens in the case of an arbitration?

Not sure
Conclusion

Implementation will make the process more complex but it is possible.