CURRENT PRACTICES AND FUTURE CHALLENGES IN METHODS VALIDATION – NEW AREAS OF APPLICATION

THE POINT OF VIEW OF AN ACCREDITATION BODY

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Methods validation and the evolution of

- The accreditation standards
- The role and responsibilities of the laboratories

Some current / future challenges for the laboratories ….. and the accreditation body

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THE EVOLUTION OF THE ACCREDITATION STANDARDS

EN 45001 – ISO Guide 25 :
no explicit mention of the concept of validation of methods

ISO/IEC 17025:1999: new requirements !
Keywords **:**

- Fit for purpose !
- Validation of certain types of methods : non-standardised , in-house developed , modified standard methods
- Validation file – documentation
- Identification of performance characteristics
- Notes : validation of sampling process – balance costs / efficiency

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THE EVOLUTION OF THE ACCREDITATION STANDARDS

ISO/IEC 17025:2005 no changes

ISO 15189: 2007
In-line with ISO/IEC 17025 with respect to the requirements on validation of (examination) methods

ISO 15189:2012 new explicit requirements !

- Introduction of the concept of verification (« validation » of standardized methods used as such)
- New validation in case of modification of an already validated method

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THE EVOLUTION OF THE ACCREDITATION STANDARDS

ISO/IEC 17025 CD 2 :2016

some significant changes / clarifications are proposed :

- Introduction of the concept of verification (alignment with ISO 15189)
- Consistency of methods performance characteristics with customer's needs and specified requirements
- Specific attention for sampling process , reporting statements of conformity -> **links with requirements on validation**

The revised version of ISO/IEC 17025 is expected to be issued in 2017.

What is already achieved: validation remains a core issue !

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THE ROLE AND RESPONSIBILITIES OF THE LABORATORIES

The role of the laboratory is to provide reliable test results but its function as « conformity assessment body » is given more and more emphasis , especially for the laboratories active in sectors regulated by

- National authorities (market surveillance , activities as notified body or as subcontracting party for a notified body in the framework of the European harmonization legislation
- International organizations such as WADA

Requirements on « Statements of conformity « have been explicitly introduced in ISO/IEC 17025 CD 2 :2016

Decision rules need to be documented , based on validation data including measurement uncertainty.

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THE ROLE AND RESPONSIBILITIES OF THE LABORATORIES

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Decision rules need

- to be documented , on the basis of validation data including measurement uncertainty;
- to be decided in cooperation with and communicated to the customer
- to be taken into account for the formulation of the test report

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VALIDATION: SOME CURRENT / FUTURE CHALLENGES

Challenge 1: Validation and measurement uncertainty:

Which level of validation in case of a «slightly modified« standardised method ?

- ISO/IEC 17025: « The validation shall be as extensive as is necessary to meet the needs of a given application »
- *The dilemma of the accreditation body :* can the test method be presented in the accreditation documents with reference to the test standard if the performance characteristics are not affected by the modification ?

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VALIDATION: SOME CURRENT / FUTURE CHALLENGES

Challenge 2: Validation and measurement uncertainty: *contribution of the sampling process* ?

This statement looks obvious but …… few examples of implementation up to now

- ISO/IEC 17025: **Note**: « Validation **can** include procedures for sampling, handling and transportation »
- Only applicable when the laboratory is responsible for the sampling stage -> *different performance characteristics including measurement uncertaintiesfor the same test method depending on responsibility for sampling (laboratory or not)!!!!!*

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Challenge 3: Validation and measurement uncertainty: *how to implement the general requirements in case of a flexible accreditation scope ?*

- Flexible scope : possibility for a laboratory to be accredited for a specific « testing field » and to include new tests under this « testing field » without specific assessment by the accreditation body.
- *Challenge for the laboratory*: to document a general validation process that will serve as basis for the validation of the individual tests under the « testing field » . Objective: to be able to limit the validation work to what is strictly needed in case of development of new tests within the given flexibility

These examples are only part of the everyday experience of an accreditation laboratory …… and the list is far from being limitative !

They demonstrate that validation is a core issue for the laboratories and for the accreditation body . The input of scientific associations as EURACHEM for the development of guidelines for implementation is essential …… for the final benefit of the users of laboratories services.

Thank you for your attention !