

WG 4 – 10.05.2016: Method validation under flexible scope of accreditation

Some introduction words :

- Flexible scope is a possibility offered to conformity assessment bodies by the accreditation bodies
- General provisions for implementation established by EA (document EA-2/15)
- Valid for all types of conformity assessment bodies but mainly implemented for and by testing laboratories
- Objective: better service to the clients – faster response to their expectations and to the evolution of the market
- **Key issue : competence of the laboratory to develop / implement new methods under accreditation, in a well defined technical area, without preliminary assessment by the accreditation body**

4 THEMES FOR DISCUSSION

Specific / additional requirements for method validation in order to get accreditation with flexible scope or to extend the limits of flexibility? (groups 1 and 4)

How to define the limits of flexibility of the accreditation scope of a testing laboratory ? (groups 2 and 5)

**Specific / additional requirements for the competence of the laboratory personnel in charge of method validation under accreditation with flexible scope?
(groups 3 and 6)**

Challenges experienced in different areas? (all groups)

Specific / additional requirements for method validation in order to get accreditation with flexible scope or to extend the limits of flexibility? (groups 1 and 4)

- General principles of validation apply but a global validation procedure is needed
- Prepare and explain in advance what will be done in relation with validation or verification of activities that fall within your flexible scope
- Define your groups within your flexible scope to work out a validation strategy (groups of parameters, groups of matrices...)
- Everything, that has been undertaken to include an activity under accreditation, has to be documented
- It is up to the laboratory 'to defend' its validation strategy

How to define the limits of flexibility of the accreditation scope of a testing laboratory ? (groups 2 and 5)

- Flexibility can be related to matrices (products) and/or parameters (analytes)
- How flexible can you go within 'matrix or analyte flexibility': is depending on several factors (e.g. how much is the performance of the method influenced by the matrix)
- The lab has to choose its own "range of flexibility" in relation to matrices or analytes, thereby considering the expectations of its customers
- In some countries, accreditation bodies will also consider the following situations to be included in the concept of 'flexibility':
 - Updates of standard methods used
 - Extension of measurement range
 - Referring to several similar standards
 - Developing in house methods

Specific / additional requirements for the competence of the laboratory personnel in charge of method validation under accreditation with flexible scope? (groups 3 and 6)

- Two main keywords :
 - Knowledge: particularly in relation with the technique used & the products analysed as this knowledge will be needed to define an adequate validation strategy
 - Responsibilities : who, within the management, is responsible for every steps for the implementation of the flexible scope (e.g. who approves the validation of a 'new matrix')
- Having a flexible scope can be an advantage in e.g. training investments (training people in relation to "groups of activities")

Challenges experienced in different areas? (all groups)

How to fix the limits of my flexible scope?

Think in function of the global experience of the laboratory and the needs of the customers

How to design a good validation strategy?

A good validation strategy will allow for limited extra validation efforts & costs when implementing a new test under the flexible scope

How to redesign a fixed scope to a flexible scope?

The starting point is the identification of the different analytical techniques

When will a laboratory have enough experience to apply for a flexible scope?

Be ready to demonstrate your competence...