

Outcomes of the EUROLAB TCQA workshop

Accreditation with Flexible Scope - Needs, Current Situation, Future Developments -

Over 50 participants representing 18 European countries, from numerous conformity assessment bodies, various industries and 8 accreditation bodies attended the workshop held at the Technical and Test Institute for Construction in Prague on November 4, 2009.

It was organized by the Technical Committee for Quality Assurance and dedicated to the accreditation with flexible scope as the follow up of the workshop organized three years before in Borås. At that time the general conclusion of the presentations and discussions highlighted the need and the benefit of a flexible scope in accreditation but there was not a full consensus on how to interpret the term flexible scope and how to implement it in practice.

The rationale of the Prague workshop was to exchange experience as well as to benchmark and promote good practices. The aim was to give documented input to the relevant interested parties, specially the community of accreditation bodies.

After a welcome address by Jiri Sobola, host of the workshop and Jean Luc-Laurent, President of Euro-lab, Jean-Marc Aublant presented the key issues of flexible scope and highlighted the conclusions from the previous workshops.

On the accreditation side, two very interesting presentations (from Martina Bednarova and Hanspeter Ischi) presented the developments and good practices at EA level. Some important developments are:

- The active role of EA LC in the discussion and harmonisation of laboratory accreditation with flexible scopes
- The document EA-4/17 (EA position paper on the Description of Scopes of Accreditation of Medical Laboratories) states that flexible scope of accreditation is preferred
- First initiative at LC level on the use of flexible scope in the environmental field. Other fields are under consideration (mechanical testing, etc.)
- Proposal for Good practices in expression of flexible scope including examples

At Eurolab level, Manfred Golze presented the results of the Eurolab Enquiry. The results of this important analysis are quite difficult to summarise. The flexible scope is sometimes only granted for specific types of laboratories (e.g. testing of food, animal diseases, pharmaceuticals, construction products, etc.). There are different levels of flexibility:

- Implementation of other standard methods
- Adaptation and extension of accredited methods
- Development of new methods

Some general comments:

- The concept of flexible scope accreditation looks promising but there is very limited information available on how it really works
- We need, above all, practical training both for laboratories and for National Accreditation Bodies (NABs) (e.g. for assessors, examples, consultations and guidelines)

The practical experiences of the laboratories were presented by Urs von Känel (in combination with the presentation of Hanspeter Ischi), Pascal Launey (French accredited calibration laboratory) and Katarzyna Rajczakowska (experience of a Polish laboratory). Some of the common views are:

- The flexible scope allows the accredited laboratories to modify the scope without having to report to the Accreditation Body in advance. The flexibility is necessary to minimise the risk of not satisfying the customer's needs but there is a risk of necessity to call back work if accreditation is not granted after Accreditation Body surveillance
- For fully flexible accreditation, there is no advertising effect for the customer looking at the scope of accreditation (the latest implemented test methods are not listed in the scope of accreditation issued by the NAB)
- Improvements can be made at different levels:
 - Data base shared by national AB and national Conformity Assessment Body (CAB) (for flexible scope)
 - European national rules, neither more nor less
 - How far has a scope to be detailed

Two presentations focused on the issue of **notified bodies (NBs)**. Jiri Sobola presented the key issues for the bodies notified in the field of CPD (Construction Products Directive), including the very interesting results of an enquiry realised within the GNB-CPD. Guy Jacques presented some proposals on the ways to define the scope of accreditation of a notified body. The proposals were based on an overview of some of the existing solutions. Both presentations highlighted the need for pragmatic consistency between the approaches.

- In the field of CPD, it was highlighted that flexibility is a basic requirement due to the fact that the directive only applies to products for which hEN (harmonised European standards) or ETA (European Technical Approval) exist. There is a (not too long) transitional period and NBs are expected to serve industry first day after the end of the period. Some of the practical proposals are:
 - The accredited bodies have to be allowed to follow the position papers established at European level. Even if they are, by nature not included in the standard they define the state of the art
 - If a specific test procedure is accredited for a specific product, it should be easily (without long delays and detailed assessment) accepted for another product.
- As far as the scope of accreditation is to be considered Guy Jacques made some proposals on the possible ways to go forward:
 - Basic principles
 - A. The relation between the scope of accreditation and the scope of notification should be unambiguous. The notifying authorities should not have to guess which modules and which products are covered by the accreditation
 - B. The direct reference to harmonised product standards in the accreditation scope may be possible for some directives (there are only 9 harmonised standards for the toys directive) but is highly hypothetical when it goes about directives supported by 1, 2 or 3 hundred standards
 - C. The identification of categories of products covered is sometimes possible and useful (Construction products, machinery, Personal protective equipment, etc.) sometimes irrelevant (Pressure equipment directive, etc.)
 - D. Since none of the accreditation standards is perfectly fit for any module, several combinations are possible for the same purpose. The important issue is principle A.
 - Practical consequences, content of the scope of accreditation (NoBos)
 - A. Reference to the European (and possibly national) regulatory acts
 - B. Reference to the applicable modules. Depending on the policy of the accreditation bodies/notifying authorities, several accreditation standards may be needed to support an accreditation on a wide range of modules.
 - C. Reference (when applicable) to the categories of product covered. Use of the wording of the directive to define the category.
 - D. Reference to harmonised standards if and when it brings added value.

A fruitful **debate on the conclusions** to be drawn up was introduced by a presentation made by Magnus Holmgren on the gap analysis between the current situation and future needs.

- During the presentation it was confirmed that there were different levels of flexibility, from possibility to adopt new versions of methods to the possibility to develop totally new methods. These different levels are reasonable but the need for an equal level of playing field has to be taken into account and there is a need to harmonise
- For laboratories, there is almost always a general limitation "it is not allowed to introduce new measurement principles". This limitation is reasonable
- There is a need to clarify the situation if something goes wrong (this might be related to the personal feelings of one auditor). Harmonised rules should be established at EA or ILAC level.

The way forward (conclusions)

As stated by one of the speakers, we must handle the flexible scope with flexibility

- It is neither necessary nor useful to create rigid rules for formal harmonisation of the way the scope is expressed.
- What is important is an alignment of good practices showing the ways to go forward in practice. The initiatives of EA LC are welcome. Calibration might be an issue of further development and harmonisation for the EA LC as the concept of flexible scopes is still used rarely in this field.
- Illustrations of bad practices can also be a good driver to help conservative auditors to consider new ways of thinking.
- There is also a sectorial issue for the laboratories. A rigid scope is not a problem in a lot of cases because the customer does not really care about the scope of accreditation. But it becomes a real problem when the activities of the laboratories are directly or indirectly connected to regulatory purposes (food safety, construction products, medical/pharmaceutical laboratories, etc.).

The concept of flexible scope must be discussed further in Europe keeping in mind the international context as led by ILAC and IAF. The "European way" of flexible scope implementation must be promoted internationally e.g. in ILAC. To support harmonization of practices with a view to the New Legislative Framework for Goods EA and the European Commission must promote the concept of flexible scope to accreditation bodies that do not grant it yet. This must also be broadened to other conformity assessment activities, e.g. inspection, product certification.

EA and its stakeholders must develop the concept of flexible scope to make it better understood and more harmonised throughout the laboratory and accreditation communities. EUROLAB must take a leading role in this development and also participate in handling tricky situations based on case studies together with EA. The problem with countries where the accreditation bodies are not able or do not want, whatever the reasons, to grant flexible scope to a national laboratory-conformity assessment body or notified body applying for must be solved.

The focus and the culture of accreditation and its assessors must change from documentation to competence. And the quality assurance activities of a laboratory must be and stay under its own responsibility.

Paris, November 24, 2009