

Gap analysis between current situation and future needs

Magnus Holmgren
SP, Technical Research Institute of Sweden



My background concerning flexible scope

- Flexible scope possible in Sweden for over ten years
- Different approaches, e.g. notified body, calibration, testing
- The positive experience
 - Possible to quickly answer to the customer's needs
 - New way of thinking, competence and systems instead of documents
 - Better focus on quality and competence within the organisation
- The negative things
 - Internal and external increase of costs
 - The decision, the visibility of the competence of a laboratory



I am a strong supporter of the concept of flexible scope and I am also very happy with the way SWEDAC has handled the issue in Sweden!

I should not say this! Please do not tell SWEDAC!



Background

- The concept of flexible scope in accreditation has been discussed for over ten years
- It has been asked for by
 - Laboratories (as well as other CAB ex. notified bodies)
 - Industry
 - Authorities
 - Accreditation bodies
- It has now been introduced in many European countries
- But there are still differences, even though there have been a lot of improvement
- There is a need to take the next step



The future for accreditation needs flexible scope!!

If not flexible scope will be a natural part of the service granted by ABs, accreditation will not be able to answer to the many of its customers' and their customers' needs.



Gap analysis between the present situation and the future needs

I have used EUROLAB questionnaire. Thanks to all involved.



Flexible scope granted

Present situation

- Many of the accreditation bodies grant accreditation with flexible scope but there are still ABs that refuse.

Future needs

- It must be possible for laboratories in all European countries to apply for accreditation with flexible scope. This is for the good of the customers and to avoid market distortion (to have a level playing field).



Types of laboratories and technical fields

Present situation

- In many countries all types of laboratories are granted accreditation with flexible scope
- That is also the situation for all technical fields
- But that is not the situation in all countries

Future needs

- All types of European laboratories must have the possibility to apply for accreditation with flexible scope in all technical fields
- This is valid for testing but also for other activities e.g. calibration, notified body, inspection, certification



Calibration

Present situation

- Calibration laboratories are not granted accreditation with flexible scope in all countries. However, a majority of the European accreditation bodies are granting calibration laboratories accreditation with flexible scope

Future needs

- Also all European calibration laboratories must have the possibility to apply for a accreditation with flexible scope. There are no big difference between calibration and testing in the view of flexible scope.



Notified body

Present situation

- Flexible scope are granted for notified body activities in few countries

Future needs

- The concept of flexible scope should be a possibility also for notified bodies. The notified body activities are not much different from testing and certification (product)



Levels of flexibility

Present situation

- Different levels of flexibility, from possibility to adopt new versions of methods to the possibility to develop totally new methods
- There is almost always a general limitation “it is not allowed to introduce new measurement principles”

Future needs

- Different levels of flexibility is reasonable, but also here must the level playing field be taken into account and there is need to harmonise
- The limitation concerning new measurements principles is reasonable



Restrictions

Present situation

- There are in most countries some restrictions e.g. minimum number of test methods in the field of competence, the time with fixed scope accreditation and the number of employees

Future needs

- It is reasonable to have some restrictions considering the flexible scope needs special competence. However also here must the level playing field be kept



Additional requirements

Present situation

- There are additional requirements for accreditation with flexible scope e.g. competence, validation, contract review, documentation and reporting and others (e.g. competence list, quality control procedures, staff training)

Future needs

- Additional requirements are of course needed. But it is strange that requirements for documenting and reporting as well as for contract review are increased when the flexible scope accreditation is used. It is not reasonable.



Costs

Present situation

- There are in most cases an increase in costs, both internal and external, when flexible scope is introduced
- Even though flexible scope is focusing on the competence it seems like there are an increased focus on documentation during some assessments

Future needs

- A reduction in external costs should be seen, especially since the flexible scope in the long run should be easier to handle for the ABs
- The assessments should focus on the competence of the CAB
- The concept of flexible scope will probably mean a small increase in internal costs due to increased requirements for validation, internal audits, training etc.

Assessments

Present situation

- The laboratory community seem to be content with the present assessment efforts from the AB

Future needs

- Flexible scope must in the long run lead to increased external cost, since more of the quality assurance activities are performed by the laboratory and therefore the AB assessment should decrease or at least not increase
- The main focus during the assessment should be on competence and not so much on documentation

Awareness

Present situation

- Not all assessors are familiar with the concept of flexible scope
- Few of the customers are familiar with the concept

Future needs

- As long as there are enough assessors (to perform assessments of flexible accreditation) with sufficient knowledge about the concept of flexible scope there is no problem if the rest of the assessors are not aware of the concept

Awareness cont.

Future needs

- When the laboratory have contact with the customer, the concept of flexible scope and what it means to the customer is easily explained. It is a more problematic situation when a customer is searching for a laboratory which is able to perform a specific test and that is not showed on the decision document and/or not on the accreditation body's homepage. The issue of how to inform customers about the possibility for a laboratory with a flexible scope to perform special tests must be further discussed.



If something goes wrong!

Present situation

- It is not clear what will happen when something goes wrong e.g. a laboratory perform tests with a new measurement principle

Future needs

- There is a need for agreement about flexible scope and also for harmonised rules (EA? ILAC?)



Broader application and new areas

- Product certification
- Inspection
- Notified body activities
- Sampling
- Other certifications (system and personnel)?
- Broadening concerning new methods, parameters, objects, product etc.



Fixed scope vs.. flexible scope

Flexible scope is a wonderful thing but we must not forget that there will be a lot of (majority) of the European laboratories that will continue with a fixed scope!

We must not forget the needs of these laboratories. One possible and pragmatic approach is to “easier allow” incorporation of new versions of standards also for laboratories with fixed scope, especially since ISO 17025 require that the latest version of a standard is used.

We must however not mix up the terminology!

There no difference in value between reports from laboratories with flexible scope compared with reports from laboratories with fixed scope accreditation.



The way forward

- The concept of the flexible scope must be discussed further in Europe, and EA and the Commission must promote the concept to ABs that are not granting it.
- EA and its stakeholders must develop the concept of flexible scope to make it more harmonised and also to be able to handle tricky situations. EUROLAB must take a leading role in this development.
- The problem with countries where the ABs are not able/do not want to grant flexible scope must be solved.
- The concept must be broadened to other conformity assessment activities, e.g. inspection, notified body
- The "European way" must be promoted internationally e.g. in ILAC



Conclusions

- The flexible scope is considered as very positive among laboratories
- Not all European ABs grant flexible scope
- There are in some countries still limitations concerning
 - Types of laboratories, e.g. calibration
 - Technical fields
 - Other activities, e.g. inspection, notified body
- The present situation with increased costs (both internal and external) must be handled. With a flexible scope the laboratory is much more active in its quality assurance activities.
- There is a need for harmonised rules for e.g. formulation of the decision document, how to handle problems etc.
- The market distortion will be considerable if nothing is done.



We must handle the flexible scope with flexibility!

Harmonisation is wanted and preferred but can not be archived in all parts and area!



The focus must change from documentation to competence! And the quality assurance activities of a laboratory must be the laboratory's responsibility!

Thank you for your attention!

