

VALUE ADDING AUDITING – A TWO WAY COMMUNICATION: WHAT LABORATORIES CAN CONTRIBUTE

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The safe car driver

Getting your licence:

- Always walk around the car before driving to check lights
- Never exceed speed limits
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Driver



Safe and efficient driving:

- The lighting is redundant, and anyhow lamps are impossible to change...
- Follow the rhythm of the traffic on busy highways to avoid unsafe braking or overtaking
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Safe and efficient laboratory services

To get an accreditation:

Document systems and routines, following standards literally, as implemented in accreditor's guidance documents and interpreted by accreditation officers

Laboratory staff



To satisfy customers:

Perform assignments with cost efficiency, safely, and with flexibility and adjustments to innovative products and customer's needs



Hypothesis

Laboratories are in the crossing between theory and practice.

They should be able to build management systems fulfilling requirements and still being robust, simple and fit for purpose

and

transfer this knowledge to accreditors

and

contribute to coming revisions of standards and guides



Example: Flexible scope

This concept is very useful to support industry in **innovative areas** with new products coming up frequently, where **complicated products have varying design**, and in fields with **many similar methods**

Fire testing: Flexible methods based on standards for fire and /or heat resistance, fire protection ability, function in conjunction with fire, and load-bearing ability

EMC testing: Similar for methods from generic standards for sustainability to electromagnetic fields, injected current or voltage, or transients.

EX-safety: Methods for varying design of products by combination of parts of standard methods already accredited.



Example: Flexible scope (continued)

Chemical analysis: New methods similar to accredited methods, methods in new product standards based on accredited methods, and non-standard methods based on combinations of accredited methods etc.

Key problems solved in co-operation:

- **Definition of flexibility**
- **Contacts with accreditation body**
- **Validation procedure**



Example: Measurement uncertainty

This is a long, sad and continuing story but of great importance. The main problem is **lack of a combination of knowledge and perspective**. Statisticians do not know about reality as regards e.g. customer needs in product testing, and many laboratory staff have forgotten everything they learnt in school about statistics.

Discussions with accreditation staff (also at dedicated meetings), and discussions with technical experts during assessments have successively resulted in a considerably improved understanding of pragmatic, customer oriented solutions for

- **how uncertainty can be assessed**
- **how uncertainty can be stated in reports**

in a still correct way



Example: Working at the customers´ site

This can be of great practical importance, for effectivity, and sometimes to enable the test is performed at all (very large, and seldom occurring tests)

It has been possible to find practical solutions for requirements on the customer´s equipment, competence, responsibility etc



Example: Use of Computers and IT

Guidance documents and practical routines have been developed mainly by laboratories

This has resulted in fit for purpose requirements and efficient use of computers and IT-solutions



Major learnings (1)

Accreditation is a sampling process, repeated annual assessments always reveal new things to correct

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It must be accepted that an accredited system contains deviations from some requirements, *and still it functions well and customers can be safely satisfied*

Several requirements are either redundant or of minor importance

Accreditors could learn from laboratories to have a holistic view, and distinguish between the big and the small

[The 17025 standard was intentionally written as a "buffet" from which different types of labs should be able to "fill their plate" in a tasty way]



Major learnings (2)

Standard requirements can be implemented in different ways, and it is not sure that the most meticulous way gives the best resulting quality (customer satisfaction)

In daily work it is necessary that the essential process is followed by all staff

⇒ The system should be simple and robust, and be communicated (available e.g. on the Intranet, with check lists, forms etc)

Accreditors and labs can learn together the properties of a well functioning quality system

Example: Introduction of differentiated routines for contract review, and expression of uncertainty in reports



Major learnings (3)

Knowledge, attitude and experience of staff are essential for a well functioning laboratory service

⇒ Laboratories have programs for continued training, and build sustainable teams of "critical size", and have programs for building a company culture supporting quality

Laboratories can show accreditors how to take these issues into account to a greater extent

Example: Systems for personnel development and attitude building are integral parts of the quality system, and are assessed



Major learnings (4)

Customer needs must be merged with standards requirements in a fit for purpose quality system

⇒ The quality system must reflect this in its various routines

Laboratories can show accreditors how this can be made safely

Examples:

- Laboratories need to perform both accredited and non-accredited (novel, more advanced) services by the same team
- Validation of seldom used methods can be made by taking also personal competence and experience into account



Corollaries

Co-operation between labs and accreditors is more important than separation, for an optimal function of quality in labs

Laboratories are very eager, for market reasons, to avoid errors and complaints



Mementoes

Experience, from many cases:

Many (small) laboratories are actually afraid of the accreditors (repressive actions) and do not dare to take up discussions with accreditor´s staff.

Accreditors are sometimes self-sufficient and unwilling to accept that they are not always right to the letter.

Accreditors sometimes think that co-operation and mutual learning are compromising them.

Both parties have to work on this on a long term basis

