

International News

Letter from **EUROPE**

Quality in measurement, chemical analysis, and testing is of interest to metrologists worldwide. This *Letter from Europe* reports about quality issues, which were discussed at EUROLABs National Members Meeting, which took place in Athens, Greece, November 4, 2008. (For a general overview on the development and activities of EUROLAB, the reader is referred to the *Letter from Europe* in the October 2008 issue of the **me-trol'o-gist**.)

Quality issues are the work scope of the TCQA, EUROLABs Technical Committee on Quality Assurance. The TCQA consists of members from various EU countries, both from public and private labs, as well as from industry and research and testing institutes. Some of the current strategic and practical aspects of quality issues relevant for the conformity assessment community can be sketched in brief as follows:

Quality issues: on the usefulness of strategic positions

When EUROLAB, and its committees and representatives in various bodies, have to consider the evolution of the European conformity assessment system, actions from the accreditation bodies, and the development of standards and guidance documents, it may be of value to have established a set of *strategic positions* in addition to the general strategy. This is helpful because it makes it simple for everybody to act consistently and uniformly, hence giving a greater impact on the development, and in line with the strategy. It is also a help for individuals in up-coming situations to have a set of rules-of-thumb, instead of having to make decisions from a new line of thought over and over again.

In order to illustrate what is meant by strategic positions, a few examples were given by Hans Andersson, SP Sweden, Past Chairman of the Technical Committee on Quality Assurance:

The role of the conformity assessment system is to increase competitiveness and innovation in industry by facilitating free trade of safe products. Accreditation bodies, laboratories and certification and inspection bodies are **service providers** to this system. They act as a link between industry and authorities, with loyalties to both.

Accreditation services must be internationally harmonised and transparent, in order to offer a level playing field to the international market of conformity assessment system stakeholders, and have systems to show efficiency. The fact that accreditation bodies are national monopolies puts special requirements on them to be efficient, i.e. to offer services without delay and to costs, which are comparable to corresponding services in the private sector.

The basis for accreditation should be international standards, with a minimum of interpretation documents implying additional requirements, and with a fit for purpose implementation. Considering that accreditation is a sampling process, that perfection is infinitely expensive, that any system can be compromised, and that there is redundancy in the standard requirements, accreditation bodies should concentrate on important issues and a holistic view, and put more weight to assessment of personal competence and company culture.

Since EUROLAB comprises members from laboratories as well as inspection and certification bodies it is necessary that actions do not create conflicts of market interests, which may weaken the joint activities to support members. It is important to create an understanding that a unified strategy and actions is beneficial to all, and that activities from accreditation and authorities to split and weaken laboratories and other conformity assessment bodies should not be accepted as a basis for internal competition between EUROLAB members.

Quality issues for laboratory practitioners: The EUROLAB "Cook Book"

The *EUROLAB Cook Book* contains a set of informal EUROLAB documents intended to assist laboratories in their efforts to comply with the requirements of the ISO/IEC 17025 standard. They are based on experience and extensive discussions in the EUROLAB TCQA, but they are not in any way formally endorsed and must not be followed strictly.

An example of the contents of the Cook Book, an excerpt
of VALIDATION OF TEST AND CALIBRATION METHODS



The EUROLAB "Cook Book"

A compilation of short documents on Quality issues for laboratory practitioners

Factors to consider the validation of test and calibration methods:

When planning a validation much work can be saved by having technical competence available and by use of a systematic approach. One aim is to judge which factors are of most importance and

deserve most attention. Three main stages could be used:

- Distinguish between method of test, and of producing and processing the specimen, including sampling
- Consider the test or measurement factors (equipment and calibration, handling of specimen, testing or measurement procedure, analysis and form of results)
- Consider supplementary changing factors (environment, education and experience of operator, frequency of use of the method).

- Already available at www.eurolab.org are:
- Validation of test and calibration methods
 - Criteria for the selection of a proficiency testing scheme
 - Use of interlaboratory comparison data by laboratories
 - Handling of untestable samples
 - Management reviews for laboratories
 - Conflict handling within the accreditation process
 - How to assess the competence of staff
 - Determination of conformance with specifications or limit values with particular reference to measurement uncertainties—possible strategies

Information on the Cook Book can be obtained from Manfred Golze, Chairman of EUROLABs TCQA (Email: manfred.golze@bam.de).

The Technical Committee on Quality Assurance of EUROLAB is continuing the work on this series, e.g. concerning *Internal audits*, and *Electronic recording of data*.

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Sudoku

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9			3					
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The documentation should clearly describe which factors are of significance and why, and how they are treated in the validation. Conditions and limitations should be described.

The two main principles for validation which are used often in combination, are:

- Use scientific knowledge and acknowledged experience to describe and demonstrate the validity of factors involved. Example: Time to obtain thermodynamic equilibrium in a climate chamber may be assessed either by dimensional analysis of the laws of heat flow, or by experience from measurements in similar situations.
- Use, if possible, interlaboratory comparison, proficiency tests or reference materials to show that the complete chain of testing or analysis gives the stated result, including uncertainty, and in the range of interest.

Example: Chemical analyses by "black box" equipment may be validated by reference materials and proficiency tests.