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REFERENCE
LABORATORIES IN
THE FIELD OF
TESTING

Position Paper

EUROLAB POSITION PAPER :

Reference laboratories in the field of testing

The intention of this document is to clarify the role of reference laboratories in the field of testing, as established so far, and to promote the idea to establish others.

This should not be mistaken as an effort to promote new regulations – on the contrary: EUROLAB advocates self-organisation of the testing community. Here networks of reference laboratories provide an opportunity for field laboratories to trace back their test results to sound references on a voluntary basis.

1 Background

Tests which are carried out in different laboratories should yield comparable results taking measurement uncertainty into account. Consequently traceability of measurement results, as referred to in ISO/IEC 17025, is an important element not only for calibration laboratories but also for testing laboratories. Comparability of test results presupposes in general not only the use of the same test methods but also the availability of stated references to which the test results may be traced back.

While for physical measurements there is an efficient network of national metrology institutes and accredited calibration laboratories ensuring the traceability of measurement results, in the field of testing such an infrastructure is largely missing. In some areas, however, e.g. analysis of foodstuffs and laboratory medicine considerable efforts are being made internationally to develop an appropriate traceability infrastructure, where reference laboratories play a key role.

Although the term *reference laboratory* is increasingly used in various fields, currently neither a generally accepted definition, nor a commonly accepted concept of the tasks and functions of reference laboratories are available. The present paper thus serves a double purpose:

- to define the term and outline the typical tasks and functions, which determine the requirements for the competence of such laboratories;
- to promote the idea of reference laboratories as an important part of a consistent traceability structure for test results, also in those fields where traceability to SI units is not possible.

2 Tasks of reference laboratories

The core task of a reference laboratory is assigning *reference values* to materials or products to which test results may be related or traced back and whose quality is fit for that purpose.

This could e.g. be:

- safety properties of pure substances;
- characteristics of defined materials;
- property values of reference materials;
- property values of quality control samples;
- assigned values of proficiency test items.

As far as the materials or products are not generally known or accessible, the provision of reference values includes the provision of respective reference samples or specimens.

In general the provision of reference values falls under wider fields of activity such as

- development and use of reference procedures;
- preparation of reference materials and objects;
- organisation of interlaboratory comparisons.

The tasks of reference laboratories outlined above are similar to the task of providing measurement standards. In general the activities as a reference laboratory cover only a small part of the entire activities of a testing laboratory, which are often carried out by the research & development section.

Reference values must be reliable and comparable. In order to guarantee this reference laboratories must take appropriate quality assurance measures, e.g.

- participation in interlaboratory comparisons at an international or supraregional level;
- traceability to SI units as far as possible or to other accepted references;
- evaluation of measurement uncertainty.

Reference laboratories have substantial knowledge and experience in the respective field of testing. Besides the provision of reference values and related activities, the scope of activities as a reference laboratory will include

- pre-normative research for the development of standard test procedures;
- performance evaluation of standard test procedures, in particular concerning the uncertainty of test results;
- organisation of intercomparisons for testing laboratories for voluntary self-assessment of proficiency;
- transfer of know-how (e.g. by publications, courses etc.);
- providing technical expertise for accreditation.

3 Requirements for reference laboratories

Reference laboratories must be competent in their respective field of activity. In addition, they must have the specific competence to provide reference values. This means that the general technical requirements of ISO/IEC 17025 for testing laboratories must be fulfilled. In addition, with regard to establishing measurement traceability and determining measurement uncertainty of reference values, reference laboratories must comply with the additional technical requirements of ISO/IEC 17025 for calibration laboratories.

Reference laboratories must operate a quality management system in their specific field, e.g. according to ISO/IEC 17025, GLP or ISO 15195. A formal recognition, e.g. accreditation, is desirable but not mandatory.

4 Establishment and operation of reference laboratories

If for economic or scientific reasons there is a need for reference laboratories, such laboratories will be appointed in agreement with a sectorial or regional association of testing laboratories for a specific area, specific tasks and a specified period. In general such an appointment will be made with the consensus of the laboratory community; a formal designation or recognition by an appropriate body is desirable but not mandatory.

Reference laboratories may also be appointed on the basis of a guideline or other official resolutions or a decision of an accreditation body.

Reference laboratories are obliged to be impartial and to avoid conflicts of interests which might develop in connection with other testing activities.

Reference laboratories are obliged to make their work transparent by documentation and publication of their activities, so as to ensure recognition of traceability to the reference values provided.

5 Proposal for definitions

The following definition is proposed to characterise the tasks and functions of a reference laboratory:

Reference (testing) laboratory: Testing laboratory which – in agreement with a specified laboratory community or through appointment by a competent organisation – provides reference values in a specific technical field, i.e. property values of materials or products to which test results can be related or traced back and whose quality is fit for this purpose.

Note 1: In general the provision of reference values is part of broader fields of activity, such as

- development and use of reference procedures;
- preparation of reference materials/objects;
- organisation of interlaboratory comparisons

The term reference value is defined as follows:

Reference value (testing): Property value of a specified material or product that has been determined with an accuracy fit for use as a source of traceability of test results obtained on comparable materials or products.

Note 1: The material or product must be accurately defined such that the residual uncertainty in the definition will not significantly contribute to the uncertainty assigned to the reference value.

Note 2: Unless reference values are related to generally known and accessible materials or products, the provision of reference values includes the provision of respective reference samples or specimens.