

How do accreditors deal with providers of proficiency tests and with producers of reference materials?

Since the ILAC Conference in 1996 the issue of accreditation of both reference materials producers and providers of proficiency tests has been discussed over and over again and is still under discussion in some countries.

After a controversial discussion two Guidelines

- * ILAC-G12 Guidelines for the Requirements for the Competence of Reference Materials Producers
- * ILAC-G13 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes

were endorsed at the ILAC General Assembly in 1999. (Original documents can be downloaded from ILAC's Homepage at <http://www.ilac.org/publication.htm>, German translations from DAR's Homepage at <http://www.dar.bam.de/doc/dokumente.html>). It turned out that there are different points of views in applying these Guidelines. One reason is that in some parts of the world the aim of accreditation and the differences between accreditation and certification are interpreted in a different way.

Who can be accredited?

Discussions on the new standard ISO/IEC 17011 *General requirements for bodies providing assessment and accreditation* show that experts in Europe are pursuing to maintain one of the major aims of accreditation – the mutual recognition of results of conformity assessment bodies by recognition of competence on a comparable

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basis and connected therewith the elimination of technical barriers to trade.

From the above follows that only bodies performing conformity assessments (laboratories, certification and inspection bodies) can be accredited. To counteract any mixture between accreditation and certification, the experts want to enact this in the forthcoming ISO 17011.

Other experts, in particular from Asia and the United States, want to accredit everything the market demands from their points of view.

What is the relationship between providers of proficiency tests on the one hand and accreditation on the other hand?

Use of proficiency testing in accreditation

Proficiency tests have not been a subject of accreditation so far, but a means to perform accreditation on the basis of the rules.

Practice shows that in particular for calibration and testing laboratories operating in different fields of testing the participation in proficiency tests is an excellent opportunity to check their performance or to ensure a comparability of their results.

ISO Guide 58 or EN 45003 *Accreditation Systems for Calibration and Testing Laboratories – General Requirements for Operation and Recognition* require that accreditation bodies shall encourage the laboratories to participate in proficiency tests or in interlaboratory comparisons. Proficiency tests may be organised by the accreditation bodies themselves or by other competent bodies. Above standards are stating that the performance of laboratories in such proficiency tests shall meet the requirements of accreditation bodies. However, it is not required that the providers of interlaboratory comparisons or proficiency tests shall be accredited.

If the interlaboratory comparison test is offered by the accreditation body or by bodies associated with the accreditation body, an accreditation of the provider would easily lead to conflicts of interest. This situation should therefore be avoided.

It would be much better if the accreditation bodies were able to offer proficiency tests or if the respective Sectoral Committee selected those proficiency tests and providers meeting the requirements of the respective technical field and thus developed the preconditions for accreditation in certain technical fields.

In the field of accreditation of calibration laboratories this has been perfectly realised for many years by the DKD (German Calibration Service), that mostly uses interlaboratory comparison tests prepared by the PTB (Physical-Technical Institute) or by other metrological institutes in Europe and thus establishes a consolidated and internationally recognised basis for accreditation.

However, irrespective of an accreditation, for reasons of quality assurance in some testing fields it has been essential for testing laboratories for many years to participate in interlaboratory comparisons,.

The providers of such interlaboratory comparisons are often not associated with the accreditation. The question could be raised, whether these interlaboratory comparisons are carried out and analysed competently? So as not to complicate the system, such an analysis should be made by the team of assessors on the basis of the laboratory's documentation on interlaboratory comparisons as well as by the respective Sectoral Committee, eg on the basis of EPTIS data and the experience of the Sectoral Committee members.

To reach an international harmonisation, it would also be possible that EA and ILAC recognise providers of or procedures for interlaboratory comparisons in certain fields of testing.

Where do you find interlaboratory comparisons for specific fields of testing?

In the field of calibration interlaboratory comparisons are often provided by the accreditation bodies themselves or by national metrological institutes. However, in certain fields of testing it can be rather difficult to find a suitable interlaboratory comparison test.

That was the reason why four years ago the DAR in close cooperation with the Austrian and Swiss Accreditation Bodies mandated the BAM to establish a database with providers of interlaboratory comparison tests for different fields of testing (**IRIS** http://www.bam.de/a_s/iris). (Our 3/98 issue extensively reported about IRIS).

This database is not only of importance for accreditation, but for all laboratories - whether accredited or not - as it provides interlaboratory comparison tests to improve their own performance and efficiency and to check results.

For this significance the European Commission promoted the establishment of a European database **EPTIS** (see Supplement), which is now available to all accreditation bodies and laboratories.

View harmonised in EA in using providers of interlaboratory comparison tests in accreditation

It has been difficult for many years to effect a compromise in EA on the issue "How to deal with providers of interlaboratory comparisons and their accreditation or non-accreditation". Discussions held on this issue were mainly characterised by a strong argumentation of the DAR against an accreditation.

On its Meeting held in Brussels in May this year, the EA Advisory Board discussed this issue and recommended EA not to encourage the accreditation of providers of proficiency tests either. It rather recommended EA to harmonise rules how to deal with new requirements and how to launch new accreditation programs in a concerted way.

The harmonised view found in EA is described in the paper ***EA Policy on the Accreditation of Providers of Proficiency Testing Schemes***:

1. Each EA member is free to offer accreditation services to PT providers. Accreditation bodies which do not wish to offer such services and which may prefer other means of recognition of PT providers shall not be prohibited to do so.
2. If formal accreditation is granted by an EA member, the *ILAC Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes* (ILAC-G13) shall be used as accreditation criteria.
3. EA does not intend to establish a specific mutual recognition agreement on accreditation of PT providers.
Note: It is the responsibility of the national accreditation body to establish confidence in the PT providers they accept for their own accreditation purposes.
4. The existence of accredited PT providers in some countries should not prevent EA from designating any non-accredited provider to organise an EA interlaboratory comparison if considered appropriate by EA-C2.
5. The existence of accredited PT providers should not prevent accreditation bodies from developing and operating their own proficiency testing for any of the following purposes:
 - To assess laboratories' performance before accreditation is granted;
 - To survey the performance of accredited laboratories;
 - To organise EA interlaboratory comparisons as a means to establish confidence among EA members.
6. Accreditation bodies which develop and operate their own proficiency testing schemes as mentioned under item 5 shall not be obliged to be accredited for these services.

Discussions on this issue are still in progress. The Joint Group EURACHEM/EUROLAB/EA on Proficiency Testing (EEE-PT) is currently agreeing on a paper *Use of PT as a Tool for Accreditation in Testing* which describes how results obtained in proficiency tests are treated in accreditation and which are the requirements of accreditation bodies with regard to participation in interlaboratory comparisons.

To summarise the discussion: As ISO Guide 43 complies with the current international consent, providers of interlaboratory comparison tests should take this Guide into consideration. If a recognition is deliberately required by the accreditation bodies too, a close cooperation should be designed (eg via Sectoral Committees) and the interlaboratory comparison tests should be preferably provided in EPTIS.

The discussion held on the accreditation of providers of interlaboratory comparisons and proficiency tests will be continued in future.

Accreditation of producers of reference materials?

The discussion on this issue is also an international matter in dispute.

To avoid the introduction of new accreditation programs it was generally agreed in DAR and EUROLAB not to favour accreditations of producers of reference materials. It is feared that the costs for reference materials and therewith the costs for accredited tests would raise without effectively increasing quality in testing.

Which papers on this issue are currently valid?

On its last General Assembly held in October 1999 ILAC endorsed the *ILAC Guideline for the Requirements for the Competence of Reference Materials Producers*. After intensive discussions in the respective Committee consensus was reached on the following wording given in the Preamble to this document: "If the producer of reference materials is a laboratory, the assessment according to these *Guidelines* can be done by a laboratory accreditation body in connection with an accreditation according to ISO/IEC 17025.

Otherwise, the assessment by a product certification body, accredited for this purpose, may be more appropriate."

In the meantime the new ISO Guide 34 "*General Requirements for the Competence of Reference Materials Producers*" has been published. ILAC will examine up to what extent the ILAC Guide 12 will still be required.

In its comments to the ILAC Guide the DAR pointed out that producers are not to be accredited, but only conformity assessment bodies. The view harmonised now has the advantage that

1. no new accreditation program has been launched;
2. laboratories characterising reference materials and having been accredited may receive – if they wish so – an extension of their scope for this characterisation as well as for further laboratory related activities;
3. quality and manufacture of products used as reference materials may be certified by a product certification body in accordance with EN 45011. This prevents a competition between accreditation and certification.

The DAR Committee for Technical Issues (ATF) discussed this topic again on its Meeting held in June 2000. However, results of this discussion have not finally been settled. The accreditation bodies operating under the umbrella of the DAR generally agreed that they do not wish accreditations of reference materials producers. The accreditation should be performed as a laboratory accreditation according to ISO/IEC 17025. It is pointed out that the expenditure for the accreditation of laboratories should be kept as low as possible, i.e. whenever possible the scope of accreditation should be extended. The accreditation of product certification bodies for reference materials has not yet finally been discussed. It is intended to elaborate a German position paper which shall be introduced to EA and ILAC. We will keep you informed about further progress and trends in this discussion in our next issues of DAR-aktuell.

M. Wloka, BAM-S.42

News from the DAR

Survey of accreditation systems - Europe, Asia, Australia, America, Africa -

The DAR Secretariat has updated a survey of accreditation systems around the world and made it available on DAR's Homepage at <http://www.dar.bam.de/asi/>. You may either download the entire Brochure as PDF file or select the description of a single country.

Accreditation systems not mentioned in this survey are encouraged to send their descriptions to the DAR Secretariat to be included in this survey and thus be represented on the Internet. It is intended to update the information quarterly provided that the accreditation bodies notify about any changes without request.

S. Stobbe, BAM-S.42

Outcome of the 7th Tutors' Exchange of Experience

From 16th to 17th March 2000 the 7th Tutors' Exchange of Experience – an annual event of the D-A-CH-countries – took place at BAM, Berlin, with guests from Austria, Latvia, Slovakia and Estonia.

Main topics under discussion were the implementation of the ISO/IEC 17025 and a consistent practice within the transitional period as well as the transition of accreditations to the new requirements of the standard.



Among others the following topics were discussed:

1. ISO/IEC 17025 in accreditation on the basis of the DAR-ATF recommendation, the ILAC Draft "Guidance to ILAC members for accreditation to ISO/IEC 17025" and the proposed transitional solutions
2. Elaboration of a common Checklist on ISO/IEC 17025, which should be used both in the mandatory and the voluntary areas for self-assessment of laboratories and for use by the assessors
3. Information on current activities of EA, ILAC, ISO/CASCO
4. Reference to the assessment of interlaboratory comparisons in accreditation
5. Information on the use of EA rules on surveillance of accredited bodies in Switzerland, in particular after the first re-accreditation, and efficiency of internal auditing
6. Information on IRIS and EPTIS
7. Approach in implementation of and transition to the new ISO 9000 standards in accreditation of certification bodies

N. Bendix, BAM-S.42

Economic aspects and effects of the accreditation of testing laboratories and certification bodies for products

What about the relationship between costs and benefit of an accreditation? This is one of numerous questions bodies operating in testing and certification are faced with in accreditation. Companies often regard "Accreditation" as a key word in the market economy sense. What are the facts from real life? The difficulties arising with an accreditation are the subject of a doctoral thesis handled at BAM. The thesis among others deals with the following main topics:

- Motives for an accreditation on the part of testing laboratories and certification bodies;
- Qualitative and quantitative effects of accreditation on: trade, trade relations, the technical competence, operating cycles, performance/effectiveness, price-to-performance ratio;
- Staff costs and financial expenditure for accreditation on the part of the testing laboratories and certification bodies in comparison to the economic benefit;
- Problem of harmonisation (Multilateral Agreement);
- Expectations of testing laboratories and certification bodies to the accreditors etc.

To cover all these aspects and effects of accreditation of testing laboratories and certification bodies for products, 1200 accredited testing laboratories, 60 accredited certification bodies and all accreditation bodies operating in Germany under the roof of the DAR were interviewed by means of questionnaires. The questionnaires were similar in structure so that a comparable analysis will be possible. During the next weeks the clients of testing laboratories and certification bodies will be interviewed (on-site visits) on some significant issues in accreditation.

The aim of this study is to make an analysis based on consolidated source material which allows to draw conclusions on the present situation in accreditation as well as on tendencies/trends in Germany and Europe. Results of the entire survey will be available by the end of 2000. It is intended to publish the results.

Doctoral candidate: Mrs. Katrin Schüttpelz (formerly Großhans), BAM, Master's degree in industrial engineering.
Tutors: Prof. Dr.-Eng. J. Herrmann, Technical University, Faculty Science of Quality, Dr. M. Golze, BAM.

K. Schüttpelz, BAM-S.42

Imprint:

Editor: Bundesanstalt für Materialforschung und -prüfung (BAM), DAR Sekretariat, Unter den Eichen 87 D-12205 Berlin, GERMANY, PHONE ++49-30-8104-1942, Responsible for redaction: Dr. Monika Wloka, BAM-S.42
September 2000, ISSN 1436-2082

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DAR-aktuell

4 (4)

Nr. 1/2000 (18)

<http://www.dar.bam.de>

E-mail: dar@bam.de