

CONTENTS

**The countdown has begun –
Accreditations to
EN 45001 valid only until
the end of 2002** 1

**Practical experiences of labo-
ratories in implementing the
ISO/IEC 17025** 2

**Will the ISO/IEC 17025:2000
"General Requirements for
the Competence of Testing
and Calibration Laboratories"
be reviewed again?** 3

**The approval of the ISO
19011 is imminent** 3

**ILAC/IAF Conference
Berlin, September 2002** 3

**Information from ILAC APC,
12th Meeting,
20/21 February 2002** 4

The countdown has begun – Accreditations to EN 45001 valid only until the end of 2002

As already reported in several issues of DAR-aktuell, the EN 45001 was replaced by the ISO/IEC 17025 in 2000. In the meantime many Seminars and Workshops have been arranged and the accreditation bodies provided their accredited bodies with useful information on how to implement the new standard.

Which are the regulations for the transition period? On international scale (ILAC and EA) an agreement was reached that the accreditation bodies require their accredited bodies to fulfil the requirements of the ISO/IEC 17025 until 31 Dec. 2002. Only under these conditions the accredited bodies are continued to be kept in the multilateral agreement on mutual recognition. The way to get there should not cause any additional surveillance activities both to the accreditation and the accredited bodies. Moreover, the accreditation bodies should rather use the regular surveillance or reaccreditation visits to confirm the competence to their laboratories that they also fulfil the requirements set out in ISO/IEC 17025.

The DAR Homepage provides comprehensive information on the implementation of the ISO/IEC 17025. In particular a Checklist for self-assessment of laboratories provides a useful tool to check to what

extent the laboratories meet the requirements of the ISO/IEC 17025. No laboratory which has an accreditation to EN 45001 and which carries out its tasks competently, will abandon its competence with the implementation of a new standard. However, it is important to verify how the accredited bodies implement those requirements which go beyond the EN 45001, e. g. in view of measurement uncertainty. The compliance to the requirements of the ISO/IEC 17025 by the laboratories can best be examined during an on-site assessment. This imposes special demands upon the accreditation bodies during the next surveillance or reaccreditation. After that there will be nothing against a respective confirmation to the laboratory.

If you are an accredited laboratory and if you have not made any plans so far to involve the new ISO/IEC 17025 in your fields of activity, you should turn to your accreditation body as quickly as possible and prepare for these tasks.

If you have any further questions, you may at any time turn to the DAR Secretariat as well.

In the following this issue provides details on practical experiences of laboratories gained in implementing this standard.

BAM S.42 – M. Wloka

Practical experiences of the laboratories in implementing the ISO/IEC 17025

Generally said the German accreditation bodies were and are not confronted with serious problems in implementing the ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories". As all accreditation bodies operating under the umbrella of the DAR carry out their assessments on the basis of a harmonised Checklist, which is filled out by the laboratories and handed over prior to the on-site assessment, the assessments can be focused on the most significant issues.

To ensure a concerted action in implementing the standard of all accreditation bodies in Germany operating under the umbrella of the DAR, the DAR Committee on Technical Issues (ATF) held a special session and dealt thoroughly with the content, issues and open questions.

Essential experiences with individual problems:

1. Measurement uncertainty (Section 5.4.6.2)

In line with the standard, a laboratory shall determine and apply a procedure for estimating the measurement uncertainty. Here you presently find the greatest unsureness. A helpful tool for the laboratories is a German Guideline (DAR-4-INF-08 *Requirements for Testing Laboratories and Accreditation Bodies in Terms of Estimation of Measurement Uncertainty according to ISO/IEC 17025*) for a step-by-step qualification of the laboratories' level. This Guideline can be downloaded from DAR's Homepage (www.dar.bam.de), see button DOCUMENTS.

As a first step the accreditation bodies should verify during the surveillance visit, whether e.g. a survey exists specifying the most significant points in terms of uncertainty. Step by step these works are elaborated by the laboratories and are subject to a surveillance in the follow-up assessments.

2. Preventive measures (Section 4.11)

Quality assuring measures, such as the use of reference materials, the keeping of control charts and the participation in interlaboratory comparisons, should be considered as preventive measures. Measures such as risk analysis, fault tree analysis and statistical process control can be possible and useful, but are not required.

3. Opinions and interpretations (Section 5.10.5)

The laboratories appreciate that the new standard provides the possibility to give opinions and interpretations (O+I) in test reports. This corresponds to the practice and is often required by clients in conjunction with their order. O+I used to be possible only with special documents, which caused higher efforts (e.g. comply with the Drinking Water Regulation or not). In this context it is important that O+I are clearly marked in the test report. The qualification of the personnel authorised for giving O+I is verified during the assessments.

4. Purchasing services and supplies (Section 4.6)

Regulations on purchasing quality relevant supplies, a list of suppliers and a supplier evaluation shall be available. It turned out that the first two points do not become a problem, because generally only suppliers who were working satisfactorily over a longer period have a chance and therefore are well known. Because supplier evaluations are often not performed or only performed incompletely or imperfectly, nonconformities shall be formulated during the accreditation. In laboratories where the quality is regularly monitored by the head of the laboratory the suppliers are already assessed exemplarily.

5. Test and calibration methods and validation (Section 5.4.2, 5.4.4) as well as sampling (Section 5.7)

Due to the requirements of governmental measures, these requirements have already been implemented in particular by many chemical laboratories.

6. Management reviews (Section 4.14)

The extension of the requirements of the standard (9 items) has proved to be worthwhile. The laboratory management is therefore obliged to thoroughly deal with the quality of tests.

7. Accreditation to 17025 with reference to ISO 9001:2000

Synopses 17025/9001 and 9001/17025 carried out have shown that the ISO/IEC 17025 adequately

contains all relevant requirements of the ISO 9001 with regard to the performance of tests (see following article). An ISO/CASCO Working Group 25 was established for the alignment of this standard with the new ISO 9001:2000.

8. Further provisions of the DAR-ATF on a harmonised implementation of the standard

- Control of data (Section 5.4.7.2)
Commercially purchased software and software of/in tests shall not be validated. Software for specific purposes developed by the laboratory itself or by external companies shall be validated. Corresponding records are to be demonstrated. See also document DAR-4-INF-07 (previously DAR-INF6).
- Reporting the results (Section 5.10.1)
In case of tests or calibrations performed for internal clients and in case of a written agreement with the clients, the results may be given in reports. The reports shall at least contain the test/calibration results and shall uniquely be identified by an identification number (e. g. number of the sample, of the test report or of the order).
- Independence (Section 1.2, 4.1.4)
There should not be an accreditation as a so-called First (supplier), Second (purchaser) or Third Party (independent third party) laboratory and therewith an identification on the accreditation certificate.
- Subcontracting (Section 4.5.2, 5.10.6)
In line with the standard, the laboratory shall advise in advance the client in writing about any subcontracting. It is deemed to satisfy, if the laboratory makes a reference in its supplies or service specifications that it subcontracts certain tests. The results gained by the subcontractor shall uniquely be identified in the laboratories' test reports as subcontracted tasks. A statement of the name and/or address of the subcontracting laboratory is not required.

BAM S.4 – J. Pritzkow

Will the ISO/IEC 17025:2000 "General Requirements for the Competence of Testing and Calibration Laboratories" be reviewed again?

The proposal to align the ISO/IEC 17025 with the new ISO 9001:2000 has been accepted by most of the ISO/CASCO members. This proposal does not include a revision in respect of content, but rather refers to a correction of the sections relating to the previous ISO 9001:1994. The first ISO/CASCO WG25 meeting revealed that the majority

of the members wishes to modify as few sections of the standard as possible. Agreement was reached that the ISO/IEC 17025

- is not a sector-specific application of the ISO 9001,
- contains all requirements of a modern quality management system as set out in ISO 9001:2000,

has to be reviewed only in those parts that relate to the modified sections of the ISO 9001:2000.

A Working Group (under the head of Peter van de Leemput, RvA/NL) has been set up, which shall reveal the correspondence between the ISO/IEC 17025 and the ISO 9001:2000. Results to be expected will be discussed half-way through this year.

BAM S.42- S. Stobbe

The approval of the ISO 19011 is imminent

After approving the standards ISO 9000 ("Quality Management Systems – Fundamentals and Vocabulary"), ISO 9001 ("Quality Management Systems – Requirements") as well as ISO 9004 ("Quality Management Systems – Guidelines for Performance Improvements"), the fourth key standard of the new ISO 9000 standards series is shortly before its approval.

This fourth key standard concerns the ISO 19011 ("Guidelines on Quality and Environmental Auditing"). It replaces the existing standard ISO 10011, parts 1-3, as well as the ISO 14010,

14011 and 14012 from the ISO 14000 standards series.

These Guidelines were developed in a close international and national cooperation between the respective Subcommittees on Standardisation in the respective subjects quality and environment (in Germany: NQSZ-1.3 and NAGUS) which first established a basis for planning and conducting joint audits. This means that a trend towards integrated management systems is more strongly taken into account for audits as well.

Furthermore, these Guidelines increase the importance and the significance of internal audits in companies, in particular in view of the qualification and further education of the auditors employed. The practical approach should adequately consider the size of the company and the industrial sector.

The final standard draft for voting (FDIS) has been issued in April 2002. After approval of the Guidelines, they are expected to be published in July/August 2002.

BAM S.41 – R. Schmidt

ILAC/IAF Conference, Berlin, September



On invitation of the German Accreditation Council for the first time a joint scientific Conference of ILAC and IAF will be held in Berlin from 23 to 25 September 2002, in conjunction with the General Assembly/Plenary of both organisations as well as Meetings of several Working Groups and Committees. Pursuant to the worldwide requirement "Tested once – accepted everywhere", the "International ILAC/IAF Conference on accreditation in global trade" turns to accreditation bodies, manufacturers, authorities, laboratories, certification and inspection bodies.

It will provide an unprecedented concentration of information and communication means for an intensive and controversial exchange of opinions and experiences on political as well as technical issues of accreditation. Information relating to the program and to organisational issues of the Conference are published at the Conference Homepage www.ilac-iaf-2002.de, which moreover offers the possibility to register for this event (until 15 July 2002 at a special price).

BAM S.42 – A. Nickel/S. Deperade

Information from the ILAC Accreditation Policy Committee (ILAC APC), 12th Meeting, 20th /21st February 2002

ILAC as an international organisation of accreditation bodies for laboratories is anxious to increase the effectiveness of the agreement on mutual recognition of accreditations (MRA) and to convey this to its clients to a greater extent. Therefore cost effectiveness, consumer needs and a close cooperation with IAF as well as the regional accreditation groups play a major and decisive role.

Two models of cooperation between ILAC and the regions have been discussed.

Model 1 considers ILAC a strong organisation, in which all general activities of the region are centrally organised,

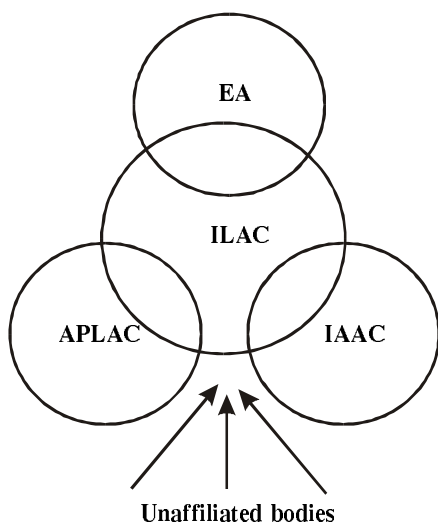
developed and harmonised to take some off the loads of them.

Model 2 considers ILAC only a small platform for exchange of experience and with minimal services for support and maintenance of the agreement on mutual recognition.

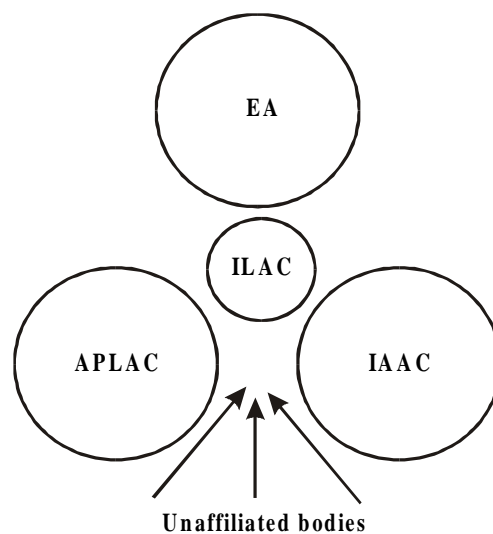
ILAC APC favours Model 1. It presupposes that optimal communication channels between the regions and ILAC are going to be developed.

To an increasing degree more and more international organisations are applying for a membership in ILAC.

Model 1



Model 2



(Unaffiliated bodies: single accreditation bodies not being members in regional groups)

They are interested in accreditation and a worldwide mutual recognition. With regard to membership ILAC wants to stay open, flexible and non-discriminating and would like to offer a home to all accreditation bodies, without abandoning its identity. If ILAC will not manage to fulfil this, the market will be disarranged by an increasing number of new and non-harmonised accreditation bodies, the value of accreditation will be reduced and the charges imposed on the laboratories will be increased by multiple accreditations.

In future experiences of IAF (International Accreditation Forum, Inc.), the international organisation for accreditors for certification bodies, will be more and more taken into account. For a longer time associated stakeholder members have been involved in all activities, including those concerning and affecting the MLA.

ILAC is anxious to closer cooperate with authorities. To facilitate this, ILAC is holding a worldwide survey and collecting examples for the acceptance of accredited laboratory reports by national authorities.

This important topic was an issue on the Agenda of the "Industry Cooperation on Standardisation and Conformity Assessment" Meeting (ICSCA) held in Berlin on 27 February 2002. At this meeting a Memorandum of Understanding was signed on the cooperation between ILAC and ICSCA.

The document "Cross-frontier accreditation – principles for avoiding duplication" endorsed by the ILAC General Assembly in November 2001 has been published in the ILAC-News 1/2002 as well as on the ILAC Homepage www.ilac.org.

BAM S.42 – J. Thiele