

What are the Changes in the German Accreditation System?

After the foundation of the German Accreditation Advisory Board at the BMWi - we reported about it in our last issue of DAR-aktuell - we received many enquiries, in particular from accredited bodies, concerning possible consequences in view of the validity of their accreditation. We also were faced with misinterpretations by our foreign contact partners. Colleagues from EA even talked already about a „closure and cancellation of the DAR“. So as to avoid further confusion we want to use this opportunity to correct this false information.

The DAR continues to be the national coordination body for its members. The private accreditation bodies operating under the aegis of the DAR have been evaluated in the frame of an evaluation system in view of their compliance with ISO/IEC 17011. In our last issue of DAR-aktuell we informed that the DAR members DACH, DAP, DATech and TGA successfully passed the evaluation procedure, comply with ISO/IEC 17011 and the corresponding requirements of the DAR and are therewith entitled to remain members in the DAR and to issue the DAR certificate. For one DAR member the evaluation procedure is still in process.

The bodies accredited by the DAR member accreditation bodies are entitled to keep on using the DAR logo; it has been protected according to the German Trademark Act until the end of 2017 as a visual mark to indicate the accreditation status.



The accredited bodies continue to be registered in DAR's database of accredited bodies accessible at the Homepage of the DAR, so that an accredited body is able to demonstrate everywhere in the world for which scope and by which accreditation body it has been accredited provided it uses the DAR logo in combination with the registration number.

The present changes in Germany are associated with the revision of the New Approach and an increased responsibility of the member state for the accreditation of conformity

assessment bodies. The technical performance of an accreditation is not subject to any changes. In the first draft of the European legislative provision both the German Federal Government and the European Union act on the assumption that the international standards of the 17000 standards series are to be complied when performing an accreditation, so that the technical rules developed within the DAR and based upon the international standards continue to be valid.

The European act of law about which we also reported in our last issue of DAR-aktuell is expected to be issued in its first draft version open to discussion presumably in February this year. The German Federal Government will take decisions on how to implement these legal provisions, which will also concern accreditation matters. From today's point of view, this will not concern the technical performance of assessments of accredited bodies, but rather organizational issues associated with the accreditation bodies.

Until that time, the DAR will continue to exist and realize its tasks with the exception of the international representation in line with the Rules and Procedures represented at DAR's Homepage (www.deutscher-akkreditierungsrat.org). The central DAR register of accredited bodies will continue to be maintained and kept updated by the DAR Secretariat. The Secretariat of the DAR is permanently available to all interested parties seeking support and information. It closely cooperates with the KOGB, the Coordinating Group of Accreditation and Recognition Bodies Operating in the Mandatory Area; its Secretariat is located at the Bundesnetzagentur (Federal Network Agency for Electricity, Gas, Telecommunications, Postal and Railway Markets).

The bodies concerned pointed out again and again — both in the DAR and in the Accreditation Advisory Board of the BMWi (AKB)—that the future structure of the German accreditation system shall in no case have an affect on the performance of the accreditation or the status of the accreditations granted. The framework to be established for the German accreditation system shall focus on cooperation (merging, if necessary) of the German accreditation bodies so as to reach equivalence of accreditations in all areas.

BAM S.2—N. Bendix

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New Standard for Bodies Providing Auditing and Certification of Management Systems

ISO/IEC 17021:2006

ISO/IEC 17021 „Conformity assessment – Requirements for bodies providing auditing and certification of management systems“ was published on 15th September 2006. The German translation has been available since December 2006.

ISO/IEC 17021 supersedes the following standards:

- ISO/IEC Guide 62:1996 (or EN 45012:1998 respectively) „General requirements for bodies providing assessment and certification/registration of quality management systems (QMS)“
- ISO/IEC Guide 66:1999 General requirements for bodies providing assessment and certification/registration of environmental management systems (EMS)“

This means that in future we will have harmonized requirements for certification bodies at international level providing auditing and certification of any type of management systems.

The aim of the ISO/CASCO Working Group WG21 in developing this standard was to put down in writing all requirements for certification bodies providing certification of different types of management systems. If possible, all IAF recommendations should be included to avoid any additional guidance papers.

IAF Instructions for Use

From today's point of view, this has been realized. At its last General Assembly in November 2006, IAF decided not to draw up any IAF guidance on ISO/IEC 17021. The Technical Committee is currently verifying whether the Annexes to the IAF Guidance Documents 2 and 6 will continue to exist as independent IAF application rules. These Annexes concern recommendations for accreditation, such as scope of accreditation, audit time, certification of several locations and transfer of the accredited certification.

Transition Period

In the Foreword to the standard it is stated that the previous standard needs to be withdrawn until March 2007. At the last IAF General Assembly in November 2006 the transition period for accredited certification bodies was fixed to 24 months after publication of the standard by ISO.

The DAR followed this decision. This means that after September, 15th 2008, accreditations against the previous EN 45012:1998 are no longer accepted.

I.e., in future the accreditation bodies in Germany will begin to accredit against ISO/IEC 17021.

News at a glance

1. Scope

This standard is applied to any type of management systems, such as e.g. ISO 9001 QMS, ISO 14001 EMS, ISO 27001 ISMS, ISO 22000 Food Safety MS, ISO 13485 Medical Devices MS.

It means for the accreditor to clearly indicate the scope of accreditation of the certification body. As stated in ISO/IEC 17011, the accreditation body shall already require the certification body to clearly describe in its application for accreditation the management systems for which it wishes to have the competence certified.

2. Principles

Para. 4 of the standard describes the principles. These principles are no requirements, but the requirements in the standard are based upon these principles. Therefore, they do not establish a basis for an accreditation, but can be recommendations and serve as guidances for unexpected situations.

Principles are described concerning impartiality, competence, responsibility, confidentiality, openness and responsiveness to complaints.

3. Impartiality

The topic of impartiality has been discussed by the WG21 for a long time: whether the term „related body“ should be defined and specifications be made about the way in which the certification body shall arrange its relationships with its related bodies. They arrived at the conclusion that the relations between related bodies and certification bodies are too complex and different, as if they could be clearly written down in a standard. For this reason, it was deviated from a definite definition and definite specifications. The standard requires each certification body to identify and analyse the risks for its impartiality caused by related bodies or by other activities and to draw respective conclusions from this analysis. The top management of a certification body shall publicly commit to impartiality, control conflicts of interest and ensure objectivity. In doing so, it is supported by the committee for ensuring the impartiality, that—in addition to other tasks—has to evaluate the analysis of impartiality.

Moreover, the standard defines that a certification body shall not outsource audits to a consultancy organization for management systems. The certification body or parts of the same legal entity shall not offer or provide internal audits to its

certified clients. A certification body shall not certify a management system on which it provided internal audits within two years following the end of the internal audits.

Furthermore, the standard pointed out that personnel records shall contain all relevant consultancy services made available by the personnel of the certification body. In the same way, the organization to be certified shall make available information in its application for certification about which consultancy services in view of the management system were used and received.

4. Competence of the audit team

The certification body shall perform a competence analysis for the personnel involved in the certification activities. In the same way, a review of the application is necessary, whether the certification body has the required competence to execute the certification tasks. Rationales for decisions concerning the acceptance of the application are to be maintained. The selection of the audit team should also be based upon the required competence.

5. Legal responsibility

As in all other standards on conformity assessment, it is precisely confirmed in this standard that the certification body needs to be a legal entity or part of a legal entity and that it can be held legally responsible for all its certification activities. It is also stated that a governmental certification body is considered as a legal entity due to its regulatory status and that the authority shall define the part which is considered to be the certification body; it shall furthermore prevent any potential conflicts of interest with other parts of the respective governmental institution.

6. Certification process

Based on a functional approach, the certification process has been clearly defined in the standard:

- Planning the audit
- Conducting the audit
- Preparing the audit report
- Evaluation and decision concerning the certification

For an initial certification, the standard requires an audit consisting of two stages. The audit of stage 1 aims at preparing the actual on-site visit. Audit stage 1 requires 7 objectives. It is recommended that at least parts of the audit stage 1 are to be conducted in the premises of the audit client, however this is not explicitly required.

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Subject to the conditions, the certification body shall reasonably determine the audit time and maintains records about it.

The flexibility to adapt the audit programme is based upon the verified effectiveness of the organization's management being certified.

In general, audits are conducted based on ISO 19011.

7. Certification documents

In the standard, it is referred to the expiration date that is in line with the re-certification cycle and which shall be stated in the certification document.

Granted, suspended or withdrawn certifications shall be made know to the public in the same way.

8. Management system requirements

The WG21 has discussed the management system requirements for a long time. The result of these discussions: the certification body has two alternatives. Either it complies with the requirements of ISO 9001:2000 or it complies with the general management system requirements set out in alternative 2.

In both cases it is pointed out that a mere fulfilment of the requirements set out in ISO 9001 is not sufficient, as the customer orientation must not only focus on the certification body's direct contract customers. The certification body shall deal with the needs of all parties concerned using the audit and certification services (e.g. also those of the authorities or the market).

It is a general requirement for management systems of conformity assessment bodies not only to be focused on the needs of its clients, but also to consider the general requirements of the market or of other clients using the services.

The criteria described in this standard can be used for the accreditation, peer assessment or for other audit processes. For certification bodies it is more favourable to focus only on one standard. However, the possible flexibility requires the certification body to be concerned about the competence of its auditors, to establish provisions about its competence, i.e. which management systems it plans to certify and also be prepared for how to extend its scope, if new management systems come into the market against which the certification body plans to certify.

BAM S.2 – M. Wloka

Information from the DAR

At its 45th meeting held on 24th November 2006 the members of the German Accreditation Council were informed about the foundation of the German Accreditation Advisory Board (AKB) established at the BMWi (German Federal Ministry of Economics and Technology). Based on decisions taken previously and after the Advisory Board has constituted, the tasks concerning the international representation of the German accreditation system were transferred to the BMWi.

As a consequence of this, the Committee for International Cooperation (DAR-AIZ) was closed. In future this work will be realized by the AKB.

The System Description of the DAR was revised accordingly and adapted to the new circumstances. It can be inspected in its revised and updated version on DAR's Homepage.

The following document changes were endorsed by the DAR and can be downloaded from DAR's Homepage:

*** DAR-3-EM-16 „Accreditation of Conformity Assessment Bodies with Several Locations“.**

***ILAC-G21 „Cross-Frontier Accreditation, Principles for Avoiding Duplication“** was translated into German and endorsed by the DAR as DAR-3-INF-01. It contains the ILAC policy on Cross Frontier issues.

*** DAR-3-EM-23 „Annex: ILAC Laboratory Combined MRA Mark; Sublicense Agreement“.**

ISO/IEC 17021 was included in the DAR Rules and Procedures as an obligatory standard. The transition period has been fixed for 2 years (see article page 2).

On 21st March 2007, the next Tutors' Exchange of Experience is going to be held in Berlin. The accreditation bodies may use this opportunity to exchange experience on how to inform the assessors about new developments and technical documents.

BAM S.2—S. Stobbe

Information from International Organizations

In November 2006, the ILAC and IAF General Assemblies took place in Mexico. The Joint General Assembly showed that a large part of the work is done in joint working groups or committees.

The following groups currently exist:

*** Joint Arrangement Management Committee:** Organization of the evaluations of accreditation bodies

*** Joint Working Group on Training of Evaluators:** Joint training of evaluators in ILAC and IAF

*** Joint Working Group on A-series:** Working on the documents to be used for the evaluation of accreditation bodies and on maintaining the Multilateral Recognition Arrangements of ILAC and IAF

*** Joint Working Group for Inspection:** Development of papers on the accreditation of inspection bodies and on the establishment of a Multilateral Arrangement

*** Joint Developing Support Committee:** Joint work on supporting the developing countries

*** Joint Working Group on Guidance on ISO/IEC 17011:** Development of an interpretation paper on ISO/IEC 17011 in ILAC and IAF

Basic results:

A joint ILAC/IAF MLA in the field of inspections will only be established after the guidance on ISO/IEC 17011 has been approved in both organizations.

The evaluations of accreditation bodies are

revised with the aim to improve the mutual recognition as well as the recognition of the accreditations on the international markets.

In both organizations a so-called Cross Frontier Policy Paper has been discussed. The point is to control cases in which foreign laboratories or certification bodies seek to be accredited. In this case, the Multilateral Recognition Arrangement shall be applied and the national accreditation body shall be used reasonably.

In ILAC the issues of accrediting PT providers and establishing an MLA were postponed until a standard has been developed in ISO/CASCO.

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A guidance paper to be used for accreditation against ISO 15189 is being developed.

A Memorandum of Understanding (MoU) has been signed between ILAC and OIML.

The nomination of both chairs for ILAC and IAF were confirmed. IAF – Dr. Facklam from Germany and ILAC – Daniel Pierre from France.

BAM S.2—M. Wloka

EUROLAB-D Survey on the DAR Accreditation Certificate

ISO/IEC 17025 in its 2005 version includes a quality management system (QMS) for testing and calibration laboratories which complies with the principles of ISO 9001:2000. The laboratory associations, such as EUROLAB, committed themselves worldwide to clearly indicate this fact on the accreditation certificates, after the international accreditation associations ILAC and IAF agreed at the end of 2003 to cease using respective information on the accreditation certificates. The international standards organization ISO as well as ILAC and IAF reached a compromise in June 2005 to sign a Joint Communiqué which clarifies the relation between the QMS against ISO 17025:2005 and ISO 9001.

EUROLAB-D performed an e-mail inquiry among the testing and calibration laboratories accredited in Germany and asked for their view on this matter; in particular concerning the laboratories' satisfaction with the current DAR accreditation certificate or if they wish an additional clear statement on the QMS and its equivalence with ISO 9001:2000. For the second case, two options were offered:

- * Reference to the ISO / ILAC / IAF Communiqué or
- * (for the long term) again a direct reference to ISO 9001.

The survey was launched at the end of May 2006. The EUROLAB-D Secretariat received 304 responses (response rate: 19.6%), 18 of which contained only general comments which could not be included in the regular evaluation. Among the remaining 286 laboratories just 42 explained to be satisfied with the presently used DAR accreditation certificate. The vast majority, however 244 laboratories, emphasized their wish to have an additional statement on their accreditation certificate concerning their QMS. 26 laboratories felt an explicit reference to the ISO/ILAC/IAF Communiqué to be sufficient. 100 laboratories favoured (at least for the long term) a direct reference to ISO 9001. 115 laboratories agreed with both options. The results of this survey are explained in detail in the Technical Report 1/2006 of EUROLAB-D and were made available on the Homepage (www.eurolab-d.bam.de).

Based on these results, EUROLAB-D will continue in its attempts, first with the German accreditation bodies, to reach a short-term solution in the interest of the laboratories concerned.

Beyond this, it has to be checked, whether through negotiations at the European and international level a further solution could be reached that makes clearer the relation between the two standards concerning the QMS of the laboratories compared with the other participants in the market.

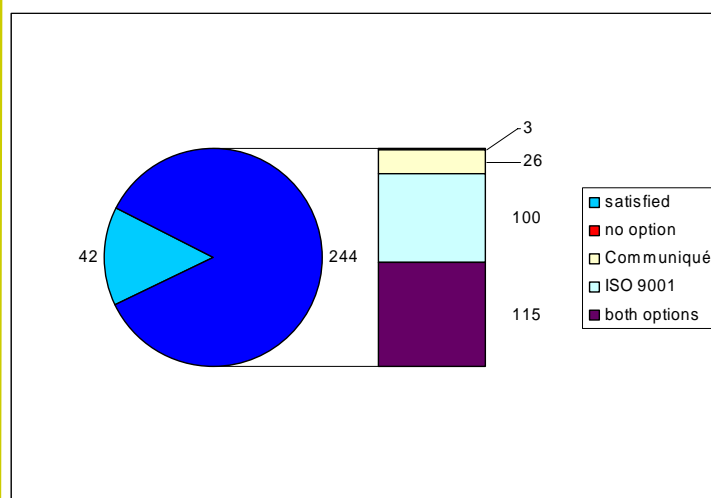


Fig. Survey results

BAM S.1 – R. Nüsser / EUROLAB-D

DIARY:

Next EA GA:

- 30/31 June 2007, Sofia, Bulgaria
- 20/21 November 2007, Cyprus
- June 2008, Estonia
- November 2008, Portugal
- Spring 2009, Luxembourg
- Autumn 2009, Belgium
- 2010 possibly in Jordan

Next EA MAC meetings:

- 28/29 March 2007, Praha, Czech Republic
- 27/28 September 2007, Bern

Next ILAC/IAF GAs:

- October 2007, NATA/JAS-ANZ, Australia
- 2008 Stockholm, Sweden