

CONTENT

Law on Accreditation in Preparation	1
News from the DAR	2
Information from the ATF	2
Information about the State of Application Procedures and the Evaluation of the DAR Accreditation Bodies	2
News from Standardisation	3
News from International Organisations	4
EA Team Leader Training in Berlin	4

❖ Law on Accreditation in Preparation

In previous issues of DAR-aktuell we already reported about efforts to rearrange the German accreditation system with the aim to establish a legal basis for accreditation in Germany.

On 29 April 2004 a hearing on the "Reorganisation of German Accreditation" took place in the German Federal Ministry for Economics and Labour (BMWA). About 150 representatives from industry, accreditation and conformity assessment, from consumer organisations and other interested parties attended the hearing.

"Main points for a law on the reorganisation of German Recognition and Accreditation" which were made available to the public in sufficient time before the hearing were discussed. They covered a description of the initial situation, objectives for a reorganisation, and proposals for solutions.

In the beginning, government secretary Ulrich Becker (BMWA) realised that the German accreditation system established during the last 14 years under the auspices of the DAR can definitely mark up success. However, practical experience during the last years showed that a coordination merely based on voluntariness between the accreditation bodies operating in the mandatory and voluntary areas is getting more and more difficult.

The strong fragmentation and insufficient cooperation between recognition/accreditation bodies effect that conformity assessment bodies need for their respective field of activity a variety of recognitions/accreditation of different bodies. Due to missing legal preconditions the DAR could not adequately solve these problems.

The BMWA therefore was instructed to seek for rooms for improvement outlined in the above main points paper.

The attendees generally appreciated the legal regulations on accreditation and recognition in Germany outlined in the paper. Aims should be the debureaucratisation and the discharge of the state. Double accreditations should be avoided. The international recognition of accredited bodies shall be guaranteed and the recognition by the authorities in Germany shall be improved.

A number of precise aspects for a rearrangement of the accreditation system was

discussed, such as:

- the relationship between recognition and accreditation (accreditation as a technical service and a basis for the recognition by the authorities)
- an approval system for accreditation bodies for certain sectors without breaching the anti-trust law
- use of the mark
- transition rules

The result of the hearing was a first conclusion about what to be expected from the reorganisation of the accreditation system:

- cancellation of the separation mandatory - voluntary area
- inclusion of the voluntary area, as far as its accreditation bodies wish so
- equal requirements for all accreditation bodies
- common accreditation rules under equal conditions
- criteria are the legal obligations as well as the relevant international standards
- principle of mutual recognition (national and international)
- input for the European accreditation systems
- participation of the industry in the organisation of the system

Next steps will be:

- A first draft referee paper is drawn up based on the main points paper and the hearing.
- A consultancy circle will be established.
- A dialogue is held with the State Governments and the responsible Departments.
- A time schedule is arranged which will contain the establishment of the organisation as well as other preconditions.

The participants in the hearing left the BMWA with a positive foresight and the expectation of a further contribution to eliminate the bureaucracy in Germany.

BAM S.42 - Dr. M. Wloka

❖ Internet best addresses

The portal to the European Union law

<http://europa.eu.int/eur-lex/en/>

Single Market

<http://europa.eu.int/comm/enterprise/newapproach/>

EOTC-Homepage

<http://www.eotc.be>

❖ News from the DAR

Even though the members of the DAR intensively participate in a reorganisation of the German accreditation system there is consensus between all parties concerned that the DAR shall continue to work until a law will be passed.

We provide information about the following developments:

The legal action filed by EQC (European Quality Council) concerning incorrect statements on the DAR Websites, was dismissed by the Regional Court Mannheim as well as by the Higher Regional Court Karlsruhe.

The complaints at the Federal Cartel Office were settled amicably. The Federal Cartel Office stated - considering the German and European legislation - that market access restrictions for accreditation bodies (ABs) are illegitimate. This statement includes that competition between ABs operating in the voluntary area shall not be constrained. The European Commission has been notified about this fact. A clarification at European level is still to be expected.

In the course of this development we

already informed last year that the TGA abandoned its role as co-ordinator for the voluntary area.

Due to competition reasons and the anti-trust law a coordination body for the voluntary area will therefore not be established.

In the view of the Federal Cartel Office, a membership in the DAR may be made conditional upon the compliance with relevant international standards, which in turn may be verified by an evaluation.

As to indemnify the DAR members from potential liability risks (for this reason two accreditation bodies from the mandatory area and two authorities resigned from the DAR in 2003) the BAM will evaluate on behalf of the Chairman of the DAR those who want to become members of the DAR.

On its last two meetings, the DAR revised its rules and adapted them accordingly to the arrangements with the Federal Cartel Office. Moreover, the DAR was requested by the BMWa to

comply with the requirements of the BMI (German Federal Ministry of the Interior) for using the DAR mark and to develop appropriate rules for admission to the DAR and for surveillance. These rules were confirmed on the last DAR meeting held in April 2004.

The DAR has the continuing ability to work and will contribute with its work to a further development of the German accreditation system.

Most notably in the interest of the accredited bodies and their clients, the DAR will contribute to a smooth transition from the current DAR system to an accreditation system operating on the basis of a law.

At no time the competence of the accredited bodies in commerce must be challenged by the reorganisation of the accreditation system. The DAR is maintaining the current system until the law will be implemented and the presently accredited bodies are transferred to the new system.

BAM S.42 - Dr. M. Wloka

❖ Information from the ATF (DAR Committee for Technical Issues)

The Committee for Technical Issues (ATF) resolved at its meeting held in autumn last year to abandon its previous position not to accredit providers of proficiency tests and therewith to follow the international trend. Applications for accreditation of providers of interlaboratory comparisons (ILCs) were already received.

The ATF supported the accreditation of providers of ILCs with an own laboratory on the basis of the ISO/IEC 17025 in combination with the ISO Guide 43 (see Minutes of the 25th ATF Meeting). In this connection, it seems to be problematic to provide proficiency tests and accreditation of providers of ILCs at the same time.

For impartiality reasons, in the meantime the DAP decided to stop arranging ILCs (DAP-News 1/2004).

It is currently under discussion, whether an accreditation of providers of ILCs is possible merely on the basis of the ISO Guide 43. This would be contradictory to the present developments in standardisation. According to standardisation, accreditation is always the determination of the competence of conformity assessment bodies to carry out specific conformity assessment activities.

I.e. providers of ILCs could only be reasonably accredited in connection with conformity assessments. (see article: News from Standardisation)

A further essential point of discussion at the last ATF meeting was the future policy with regard to a decision taken at the 12th EA General Assembly in London in November 2003, namely to delete the current reference to the fulfilment of the ISO 9001 given on the accreditation certificates.

This was considered necessary against the background of a clear separation between accreditation and certification requested by ILAC and IAF. EUROLAB, as a representative of the testing laboratories concerned, strictly objected to this request and pointed out the high significance of this reference. After a detailed discussion, the ATF decided to follow the decision taken by EA.

Until a revision of the ISO/IEC 17025, the accredited laboratories may receive an additional paper containing the reference that the laboratory has demonstrated that it operates a QM system which fulfils the requirements of the ISO 9001:2000 relevant for testing laboratories. This shall help to allow for the interests of the laboratories in the meantime. An appropriate example letter has been prepared.

BAM S. 42- Dr. G. Wermann

❖ Information on the State of the Application Procedures and the Evaluation of the DAR Accreditation Bodies

At the 39th DAR meeting held on 20th April 2004 the revised Rules of Procedures of the German Accreditation Council (DAR-2-GL-01, Version 4.0) were endorsed. They are published on the DAR Websites. The Rules require an examination of the private accreditation bodies operating in the voluntary area of the DAR.

In January 2004 a *Committee for Evaluation of Accreditation Bodies* was established. It coordinates the examination of new applicants and of the private accreditation body members in the DAR. Due to the principle of equal treatment, an analogue procedure is applied for evaluating the accreditation bodies of the DAR and the new applicants.

All persons involved in the evaluation process are sworn to confidentiality. Evaluators receive the documents submitted only after the applicants' consent and after signing the obligation for confidentiality. Currently there are four applications for admission for membership in the DAR. For applicants who are still in the course of formation a multi-stage procedure was proposed (review of the Handbook, office audit, witness audit).

BAM S.42 - Dr. J. Thiele

❖ Three standards of the 17000 standards series are in the final phase of development

ISO/IEC FDIS 17000:2004 Conformity assessment - Terms and general principles

The last draft of this standard has been put to the vote. It contains the most important terms used in conformity assessment and will replace sections 12-17 from ISO/IEC Guide 2 or from the EN 45020 standard respectively.

This FDIS has been extended by terms of trade policy, which are applied in particular in mutual recognition and in the mandatory area.

In the new ISO/IEC 17000 standard for the first time the functional approach for conformity assessment is used. The conformity assessment has the functions 'selection, determination and assessment/attestation'.

The conformity assessment itself is described as "demonstration that specified requirements are fulfilled" and includes such activities like testing, certification, inspection, and also accreditation, whereas conformity assessment bodies are bodies carrying out above activities except accreditation bodies. This is to internationally substantiate that accreditation relates only to conformity assessment bodies.

Accreditation is a confirmation that a "third-party attestation related to a conformity assessment body convey formal demonstration of its competence to carry out specific conformity assessment tasks."

These definitions shall help to make clearer the differences between accreditation and certification.

The clearly prescribed terminology in the new ISO/IEC 17000 will result in a new discussion of this topic.

A problem appearing in this connection is the accreditation of providers of proficiency tests (PT providers) and producers of reference materials which has been intensively discussed lately in EA and ILAC.

As mentioned above, the DAR-ATF formed an opinion, however at international level it is a common practice of accreditation bodies to accredit PT providers (e.g. RvA and NATA), even though they are no conformity assessment bodies.

ISO/IEC FDIS 17011:2004 Conformity assessment - General requirements for bodies providing accreditation of conformity assessment bodies

According to recent information, the draft standard was adopted by 86%. The terms were aligned with those described in the draft ISO/IEC 17000 standard. Thus the scope of this standard starts from the assumption that only conformity assessment bodies providing services, calibration, testing, and certification are accredited. So the activity of accreditation is clearly delimited from other activities.

A general résumé of this draft is that it reflects the current international practice in accreditation.

It unites the requirements for accreditation bodies operating laboratory accreditation (at present ISO Guide 58), for certification bodies (at present ISO Guide 61) and for inspection bodies (at present TR 17010) and thereby considers also international guidance papers of ILAC and IAF. The issue of impartiality of an accreditation body, which has been under heated discussion for a long time, is now defined in the above draft in that way that an accreditation body may not perform any other conformity assessment activities.

We will report about this new standard more comprehensively in our next issue.

ISO/IEC FDIS 17025:2004 Conformity assessment - General requirements for the competence of testing and calibration laboratories

In the last year an Amendment 1 to ISO/IEC 17025:1999 was prepared and discussed which in particular focused on aligning the ISO/IEC 17025:1999 with the requirements set out in ISO 9001:2000. The ISO/CASCO Secretariat prepared a new draft which includes the contents of the Amendments, but represents a revised version of the ISO/IEC 17025.

At the end of June 2004, ISO/CASCO WG25 will hold a meeting in Geneva at which further proceedings will be discussed. It is proposed to put the new draft to the vote and to apply it during the next five years.

BAM S.42 - Dr. M. Wloka

❖ Upcoming Revision of the 9000 Standards Series Presumably until 2007/2008

The ISO 9000 standards series is shortly before its first revision. The first planning started at the ISO/TC 176 session held in Bucharest 2004.

In the beginning of the year 2004, ISO initiated a survey made accessible for participation at the following Internet site www.isotc.iso.ch/webchest/tc176/index.htm.

The German Institute for Standardisation (DIN) offers a special cooperation via the German-speaking mirror committee of ISO/TC 176, the NQSZ-1.

The revision aims at a further adaptation of the standard to the users' needs. It is assumed that after analysing the survey, the revision of the standard will be commenced in 2005 and a completion of this work cannot be expected before 2007/2008.

BAM S.41 - Dr. R. Schmidt

❖ ISO 10001 to 10003: New Amendment Series to the ISO 9000 Standards Family on Consumer Protection

Parallel to the revision of the ISO 9000, a series of further supporting standards is being developed, which in particular should allow for the interests of consumer protection. It concerns three standards with a series of guidelines with the designation ISO 10001 to 10003.

As Final Draft as well as in a first translated German version already exist:

ISO 10002: „Quality management - Customer satisfaction – Guidelines for complaint handling in organizations“ – a first translated German version of the DIN, currently available as DIN ISO 10018, which will however be adapted.

First Working drafts, WD1:

ISO 10001: „Quality management - Customer satisfaction – Guidelines for Codes of Conduct“

ISO 10003: „Quality management - Customer satisfaction – Guidelines for disputes Resolution“

Useful guidance is given for companies and business establishments who have little experience in complaint management, including templates suitable to be applied as complaint forms, e.g. for an effective registration and handling of complaints. However, the standards contain numerous repetitions and partly sections which hardly offer any new information, in particular for companies who have already a modern complaint management.

BAM S.41 - Dr. R. Schmidt

❖ EA MLA Inspection

In October 2003 twelve accreditation bodies became signatories to the MLA for Inspection after having successfully passed an evaluation:

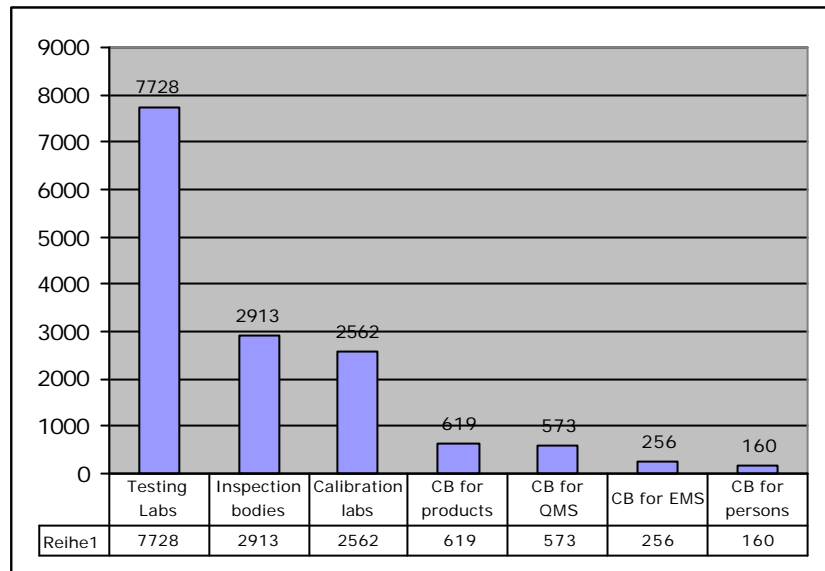
- BELTEST/Belgium
- CAI/Czech Republic
- COFRAC/France
- ENAC/Spain
- FINAS/Finland
- NA/Norway
- RvA/The Netherlands
- SAS/Switzerland
- SINCERT/Italy
- SNAS/Slovakia
- SWEDAC/Sweden
- UKAS/United Kingdom of Great Britain

In March 2004 the following bodies became signatories to the EA MLA for Inspection:

- EAK/Estonia
- ESYD/Greece

DAR accreditation body members accrediting inspection bodies among others are currently successfully evaluated by an international evaluation team.

With the extension of the EA MLAs to inspection, EA comes up to the increasing needs for mutual recognition of the high number of inspection bodies accredited. Until the end of December 2003 the EA member accreditation bodies accredited 2913 inspection bodies. The following diagram shows the relation of accredited inspection bodies in comparison to all the other bodies accredited within EA.



❖ Basic Principles for an MLA Inspection

The current normative basis for the work of the accreditation bodies to accredit inspection bodies is the DIN V 55390:1999 "General requirements for bodies providing accreditation of inspection bodies" (identical in wording with the ISO/TR 17010:November 1998 "General requirements for bodies providing accreditation of inspection bodies"). This standard will be replaced shortly and after an appropriate transition period by the EN ISO/IEC 17011:2004 "Conformity assessment - General requirements for providing accreditation of conformity assessment bodies" (ISO/IEC 17011 "General requirements for bodies providing assessment and accreditation of conformity assessment bodies").

❖ Developments of a Worldwide MLA for Inspection

The 7th ILAC General Assembly held in Bratislava in September 2003 took the decision to draw up in a joint ILAC-IAF Working Group guidance documents on the ISO/IEC 17020 "General criteria for the operation of various types of bodies performing inspection" (identical in wording with the DIN EN 45004:1995 "General criteria for the operation of various types of bodies performing inspection"). An ILAC/IAF Multilateral Mutual Recognition Arrangement (MLMRA) for accreditation bodies operating accreditation of inspection bodies is in preparation.

The joint ILAC-IAF Committee on Closer Cooperation, JCCC, was instructed to develop mechanisms for a separate "Inspection Arrangement Council" as well as technical criteria based on existing harmonised ILAC and IAF evaluation procedures. A logo/mark to be used by the inspection bodies accredited under the MLMRA will be developed.

In November 2003 APLAC signed an MRA for inspection among four accreditation bodies: NATA/Australia, HKAS/Hong Kong, IANZ/New Zealand, SAC/Singapore.

BAM S.42 - Dr. J. Thiele

❖ EA Team Leader Training in Berlin

A refresher training for evaluator team leaders performing evaluations and assessments within the scope of the process of mutual recognition of accreditation bodies within EA took place at the BAM, Berlin, on 3 and 4 June 2004.

15 team leaders as well as representatives from international institutions, such as ILAC MRA and APLAC MRA, took part. The international process of harmonising the evaluation process between the regions was continued.

The training contents based upon the new requirements of the ISO/IEC FDIS 17011, a revised version of the Key Performance Indicators (KPIs), and upon other modified evaluation documents.

The numerous notes provided by participants experienced in practice shall be introduced in the upcoming revision of the EA evaluation rules (EA-2/02).

BAM S.41 - P. Keitzl
(EA MAC WG Training, Secretariat)