

Visit of the Chair and Vice Chair of the European Cooperation of Accreditation (EA) at the DAR

On 23rd January 2006, Lorenzo Thione, EA Chair (SINCERT, Italy) and Graham Talbot, EA Vice Chair (UKAS, UK), visited the Offices of the German Accreditation Council to get informed about its activities and to discuss future advanced tasks of EA as well as possibilities to improve EA's work.

On the German part, the following representatives took part: Dr. H.-U. Mittmann (DAR Chair); the managing directors Prof. K. Ziegler (DAP); Dr. T. Facklam (TGA/DATech); Dr. W. Bosch (DKD); Dr. A. Steinhorst (DACH); Mr. H. Meierhofer (Chair of the Coordination Group of the Mandatory Area KOGB); Mr. D. Moritz (Federal Ministry of Economics and Technology BMWi); Dr. M. Wloka (managing director of the DAR Secretariat,) and Dr. J. Thiele (DAR Committee for International Cooperation DAR-AIZ).

The EA Chair briefly introduced the „EA Position Paper “EA and its relation to the European accreditation policy, 20th January 2006”. This paper provides EA's ideas when accepting additional tasks on behalf of the EU Commission for implementing the EC Directives of the New Approach. This Paper was already handed over to the European Commission and the Senior Officials Group of Standardization (SOGS) and is a response to the SOGS Paper N524 introduced in the November 2005 Issue of DAR-aktuell.

Mr. Thione explicitly thanked Dr. Facklam who as the former Vice Chair of EA had an essential part in accomplishing the EA Position Paper, which is currently being discussed with the European Commission, Directorate Enterprises, and the Vice Chair of the European Parliament. According to the opinion of the European Commission, accreditation is a service for the public interest and should not be subject to competition.

In the EA Position Paper it is stated that EA may take over international rules of ILAC and

IAF if they are in line with the specifications of the EU Commission.

It was established that in view of the new objectives the improvement of the evaluation process is considered to be necessary.

Mr. Meierhofer introduced the structure of the governmental accreditation bodies and their activities in the mandatory area.

He informed that in Germany there are about 100 notified bodies; these are 10% of all notified bodies within the EU. Only about 10% of them were accredited by the five governmental accreditation bodies operating under the umbrella of the DAR. The main part of them is accredited and approved outside the DAR system.

As to the current revision of the New Approach, the KOGB supports among others the following concepts:

- Accreditation shall be understood as a service of general interest leading to further acceptance of accredited conformity assessment results both reached by the authorities and the free market.
- Accreditation shall be performed free from competition ensuring and maintaining its public character.
- National authorities responsible for implementing the New Approach shall adequately be represented in EA to appropriately consider the regulatory aspects in accreditation.
- To provide the legal basis to the re-oriented EA, it shall closer be tied up to the Commission.

Subsequently, the KOGB considered the following issues:

- Establishing a committee of representatives from the authorities of the member states that supervises the rules and conductance of the Peer Evaluation system in view of the notified bodies;

In this Issue:

Visit of the Chair and Vice Chair of EA at the DAR Offices	1
Information from Standardization	2
13th Tutors' Exchange of Experience, 28th March 2006	3
Information from the DAR	3
Discussions on Technical Issues	4

Topics in this Issue:

- ♦ *EA Chair's visit at the DAR*
- ♦ *Tutors' Exchange of Experience*
- ♦ *ISO Guide 43*
- ♦ *ISO/IEC Guide 65*
- ♦ *Presumption of conformity when applying harmonized standards*
- ♦ *Need for interpreting the ISO/IEC 17011*
- ♦ *Accreditation in the EU Commission*
- ♦ *What can be accredited?*
- ♦ *Evaluation of the DAR accreditation bodies*
- ♦ *DAR policy on accreditation of PT providers and producers of RM*



From left to right: Dr. T. Facklam/TGA, Dr. M. Wloka/DAR, G. Talbot/Vice Chair EA, L. Thione/Chair EA

- Assessment of competence and independence of the notified bodies;
- Harmonization of accreditations and promotion of confidence in the conformity assessment system;
- Accreditation under the guidelines of the New Approach by authorities or legally responsible institutions considering their political and legal responsibility in implementing the guidelines of the New Approach with respect to health protection, public and technical safety, data security, consumer and environmental protection.

The competence of notified bodies which is currently different in the various sectors was emphasized; improvement potentials are existing in the EU.

In the mandatory area, there are attempts to use accreditation more and more as an efficient tool. This includes the technical cooperation among authorities and accreditation bodies emanating from positive experience gained at DAP, AKS, DAU, DACH and DATech.

To improve EA's structure and operation, the German party suggested:

- to aim the general assemblies more at the establishment of a European opinion to be represented in international organisations;
- to aim at the homogeneity of accreditation in Europe as a big development target;
- to focus the Committees' work upon a few main points;
- to approve new projects by the General Assembly and the Advisory Board prior

to their commencement;

- to restrict the discussions at the General Assemblies to a few main points; certain members will give their purposeful opinions on these topics prior to the meetings to reach a benchmarking based on their experience;
- to identify new trends early enough and to discuss them in anticipation of the meetings;
- to organize exchanges of experience among the leading accreditation bodies. Positive experience gained at the annual DAR Tutors' Exchange of Experience is useful.

With regard to the improvement of the Peer Evaluation process the following questions were discussed:

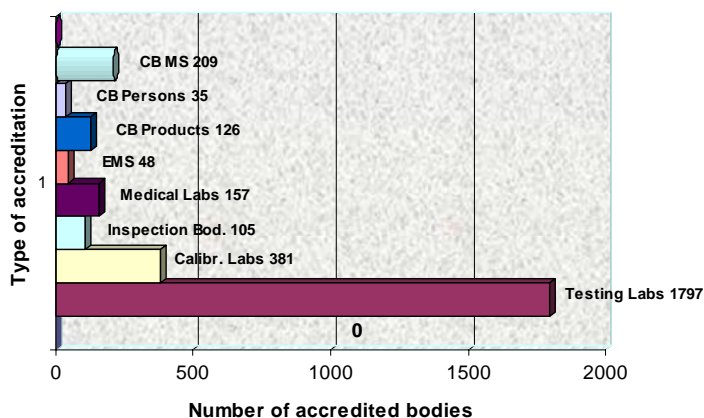
duration, size of the team, number of team leaders/team members, deepening of the evaluation, number of witness audits, feedback system, relation to international systems, establishing a European opinion etc. as well as the question „What can be accredited?“.

From the German point of view, an additional EA MLA Mark would be reasonable and would have a positive effect only if a relation to the European Commission could be established.

Dr. Mittmann handed over to the EA Chair a first draft of the EA WG Training of Evaluators "How to improve the Peer Evaluation process". The training of evaluators has to be upgraded by modules on legal aspects resulting from the European Directives.

Information was provided about the number of bodies accredited by accreditation bodies operating under the umbrella of the DAR.

Number of accredited bodies in the DAR (2006-05-19)



All parties concerned considered this meeting to be fruitful for the future work and the tasks to be solved in future.

BAM S.2 - J. Thiele

Information from Standardization

Proposal on revision of ISO Guide 43

ILAC made a proposal to ISO/CASCO to transform the ISO Guide 43 „Proficiency testing by interlaboratory comparisons“ into a standard. The majority of the ISO/CASCO members agreed to revise this ISO Guide. The revision will be commenced in 2006. A respective mirror board in the DIN Standards Committee NA 147-00-03 (former NQSZ-3) will be established.

Revision of the ISO/IEC Guide 65

ISO/CASCO was requested to revise the ISO/IEC Guide 65 (identical in wording with the EN 45011) „General requirements for bodies operating product certification systems“ earlier than scheduled, as it is the last standard to be incorporated into the 17000 standards series.

This request was discussed in the DIN Standards Committee NA 147-00-03. Although the Committee members are of

the opinion that this standard should be revised a short-term revision was rejected, as the standard is considered to be of great importance in connection with the notification of conformity assessment bodies in Europe. It shall be avoided at any case that the new standard would not fulfil the requirements of the authorities in Europe and that a different standard would have to be elaborated by CEN/CLC.

Presumption of conformity when applying the harmonized standards

NA 147-00-03 discussed how to reach a mandating by the EU Commission of the standard ISO/IEC 17021 „Conformity assessment—Requirements for bodies providing audit and certification of management systems“ (currently at the FDIS stage). This shall help to justify and establish the presumption of conformity concerning compliance with the EC Directives. With regard to a further development of the New Approach, it was emanated from

the concepts of the EU Commission provided in the SOGS Paper N529.

While other EU countries don't see any call for action, in Germany the representatives of the mandatory area pointed out that the standard should be designed in that way that when complying with the requirements the title „regulatory acceptance“ may be granted. This is of vital interest for the industry.

Therefore a representatives of the mandatory area worked out a compilation which will ask for sources of problems occurring in connection with the presumption of conformity, i.e. which parts of the draft standard would probably not be accepted by the mandatory area.

This compilation will be used for the Final Draft of the ISO/IEC 17021. However, the German representatives shall in general address this problem in the international standards committee.

BAM S.2 - M. Wloka

13th Tutors' Exchange of Experience, 28th March 2006

35 participants took place in the 13th Tutors' Exchange of experience, mainly from these accreditation bodies training their tutors based on the DAR Framework Program agreed upon by the D-A-CH countries (Germany, Austria, Switzerland).

Alongside with the exchange of experience from the last year, the aim of the event was to enable the circulation of information to the tutors relevant for further training courses from the field of accreditation and standardization. Short and also more detailed discussions were held on all topics listed. All contributions on the topics introduced can be received from the DAR Secretariat.

The agenda of the meeting included the following topics:

- Utilization of the Framework Program for structuring the training courses in the (DAR-)accreditation bodies;
- State of revision of the New Approach in particular in view of the European accreditation policy and the role of the EA in this context with regard to a possible use of EA's experience and the EA structures;

- Current state of the standards and standards drafts;
- Implementation of the requirements of the standard EN ISO/IEC 17011 in the mandatory area and the voluntary mutual system evaluations within this area;
- Ongoing and results from the international organisations, a.o. current state of the mutual recognition arrangements in EA, IAF, ILAC (MLA/MRA);
- DAR policy on the accreditation of manufacturers of reference materials (RM) (Draft);
- DAR policy on the accreditation of providers of proficiency tests (PT) (Draft);
- Revision of the technical DAR documentation 2005/2006;
- Interrelation and cooperation of the German Federal States with the accreditation bodies concerned in the field of environmental protection, above all "Water", "Pollution Control", "Soil/Contaminated Sites", "Waste";
- Examples of the way in recognizing subcontracting testing laboratories by an accredited product certification body in case the laboratory has no official accreditation based on ISO/IEC 17025;
- State of implementation of the Measuring Instruments Directive (2004/22/EC) in Germany;
- Approach of the individual accreditation bodies in categorization/classification of nonconformities and findings;
- Minimum requirements for electronic testing and inspection reports and their handling as well as maintenance;
- Handling results gained in interlaboratory comparisons (ILCs), in particular in conducting ILCs in the fields of drinking water, soil, food, measurements at workplace and the subsequent synopsis of the results in the context of the European Project (01/2003—06/2005) CoEPT (Comparability of the Operation and Evaluation of European Proficiency Testing Schemes in the Chemistry Sector).

BAM S.2 - N. Bendix

Information from the DAR

Membership in the DAR

The German Accreditation Body for Petroleum and Related Products (DASMIN) finished its membership in the DAR. Its activities will be realized in future by the German Accreditation Body for Chemistry (DACH). Bodies accredited by DASMIN will be supervised in future by the DACH.

The BAM evaluation procedure of the German Accreditation Association (GA-A) - which applied for membership in the DAR - was accomplished with a positive result. With effect from 1st May 2006, the GA-A has been a new member of the DAR. It will operate accreditation of certification bodies for quality management systems and persons.

Need for interpreting Para. 4.3.6.a of the ISO/IEC 17011

The DAR made a decision on the interpretation of Para. 4.3.6.a of the ISO/IEC 17011 (*„The accreditation body shall not offer or provide any service that affects its impartiality, such as a) those conformity assessment services that CABs perform, or b) consultancy...“*), the requirements of which - in accordance with international custom - have to be applied in such a way that the accreditation bodies operating under the auspices of the DAR shall not execute conformity assessments carried out by conformity assessment bodies.

Developments in accreditation in the EU Commission

The New Approach is considered to be an important tool for facilitating trade that has to have effective structures. An essential document on the revision of the New

Approach is the SOGS N529. The following elements are of special importance:

- Accreditation results from a governmental task, but may also be carried out by a private body.
- Competition among accreditation bodies shall not exist.
- Accreditation bodies shall not execute activities performed by conformity assessment bodies.
- As a general rule, the notification of bodies shall be based upon an accreditation.
- The accreditation bodies shall comply with the requirements set out in ISO/IEC 17011.
- Authorities assessing the competence of bodies to be notified shall comply with the essential requirements set out in the ISO/IEC 17011.

Consensus was reached on these accreditation chapters in N529. The SOGS will not continue discussing them. To implement this document, a bye-law will be worked out having the advantage of the direct legal effect for the member states. The DAR appreciates the contents of N529. The field of activity of an accredited body may not inevitably need to be in the public interest.

The EU Commission has the idea to utilize EA. It is therefore required that EA will have additional structures and an appropriate legal form in order to meet the

requirements of the mandatory area. There is a strategy paper in which EA agrees to taking over the tasks described in N529 and also agrees to re-organize its structure. Each country is currently allowed to speak with one vote in the EA General Assembly as well as in the corresponding Committees. Ways shall be found in Germany allowing to include non-members of the DAR, e.g. from the mandatory area, in the process of forming opinions. EA needs structures that allow to implement even governmental interests/concerns and in which stakeholders are equally represented.

What can be accredited?

This issue debated in an ILAC Working Group was discussed at the last DAR meeting. This Working Group examines whether the interpretation papers of the standards result in binding conclusions, in particular in view of the accreditation of producers of reference materials and providers of proficiency tests. This topic has not yet been discussed exhaustively.

Results from the BAM evaluation of the DAR accreditation bodies

The evaluations of the DAR members DACH, DAP, TGA and DATech were finished successfully. Confirmation was given to these accreditation bodies that—after having solved the nonconformities found during the evaluation—they meet the requirements of the standard ISO/IEC 17011 and of the DAR and therefore are entitled to remain members in the DAR and to continue using the DAR accreditation certificate.

Imprint: Editor:
Dr. M. Wloka, DAR
German Accreditation Council
c/o BAM, S.2
Unter den Eichen 87
DE-12205 Berlin / GERMANY

Phone: ++49-30-8104 1942
Fax: ++49-30-8104 1947
E-Mail: office@deutscher-
akkreditierungsrat.org
May 2006
ISSN-1436-2082

DAR policy on accreditation of providers of proficiency tests and producers of reference materials

In Europe and at international level about 30% of the accreditation bodies accredit producers of reference materials according to ISO/IEC 17025 in connection with ISO Guide 34.

The DAR holds the view that only the laboratory parts of providers of proficiency tests and producers of reference materials may be accredited. A producer of a reference material cannot be accredited as a whole and in its entirety. Its QM system could be certified.

Just as the service of a provider of a proficiency test cannot be accredited, but only the part of conformity assessment that is necessary to install such a proficiency testing program.

The inspection part of providers of proficiency tests may be accredited as an inspection body.

In view of the developments in the EU, the DAR will have thoroughly to check what can be accredited. With regard to the new accreditation law, this issue will be under further discussion.

Joint ILAC-IAF-ISO Communiqué on ISO/IEC 17025

The Joint Communiqué of ILAC, IAF and ISO on the relation between ISO/IEC 17025 and ISO 9001 was discussed; a text to be given on the accreditation certificate was proposed. The aim of this Communiqué is to enable accredited laboratories to demonstrate that they do not need any additional certification of their QM system according to ISO 9001.

Technical documents of the DAR

The DAR endorsed the revised version of EA-4/16 *EA Guidelines on the Expression of Uncertainty in Testing* as well its German translation (*EA Leitfaden zur Angabe der Unsicherheit beim quantitativen Prüfen*) as DAR-4-EM-07.

DAR-4-EM-02 The *Guideline for the Assessment of Measuring and Testing Equipment in Testing Laboratories in View of Calibration and Measurement Traceability to SI Units* has been withdrawn.

BAM S.2 - S. Stobbe

Discussions on Technical Issues of Accreditation - Information from the DAR-ATF

The spring meeting of the DAR Committee ATF (Technical Issues) took place at the Federal Institute of Materials Research and Testing (BAM), Berlin, on 2nd March 2006. The Committee members discussed among others how to assess from DAR's point of view the strategy of EA concerning a European database of accredited bodies and whether such a database can be designed in compatibility with the German system. In this context, it was also considered how to adapt the structuring of descriptors used in the DAR database on the basis of which the accredited bodies in the DAR are registered and which enables the search for particular product groups or technical fields in the database. Basis of the re-structuring will be the NACE code. The results of this discussion will be brought to an EA Working Group.

A further issue of discussion was an application of ILAC—received from ISO/CASCO—for a *New Work Item Proposal* on the revision of the ISO Guide 43 and its transformation in a standard of the 17000 standards series. In view of accreditation, the necessity of a revision was considered in detail. The members expect from the German part to actively take part in this development.

During the exchange of experience, it turned out that the accreditation bodies categorize nonconformities found in assessments in a different way. This does not mean that the accreditation bodies assess the competence in a different way, but simply that the systematic classification of nonconformities is different. Insofar, a short-dated need for harmonization is not arising.

The requirements as to the certificates for a laboratory accreditation to ISO/IEC 17025 and valid until the expiration of the transitional period were checked thoroughly. Assurance is provided that from 1st January 2007, reference is given only to the new standard ISO/IEC 17025:2005.

The Committee also agreed upon how to implement the standards requirements for testing and inspection reports prepared electronically. The electronic forwarding of reports and partial reports is accepted on certain conditions, such as the previous agreement with the client, the protection of confidentiality, the sending/forwarding by authorized persons as well as the assurance of the report's authenticity.

In the context of a permanent update of the technical DAR documentation, special issues on the translation and implementation of the EA-IAF/ILAC Guidance on ISO/IEC 17020:1998 were treated and clarified. The *DAR Glossary* (on technical terms relating to accreditation, metrology, etc.) as well as the *Checklist on ISO/IEC 17025:2005* are currently under revision as well as the *Procedures on Accreditation of Testing Laboratories with Several Locations*. The representatives in European and international technical committees informed about main points, such as the development of the Guidance on ISO/IEC 17011, the revision of the ILAC G13, the development of criteria for the accreditation of producers of reference materials as well as the harmonization of scopes of accreditation in inspection bodies.

S.2 - G. Dudek

DIARY:

Next EA GA:

- 07 to 08 June 2006, Riga, Latvia
- June 2007, Sofia, Bulgaria

Next ILAC/IAF GAs:

- 06 to 14 November 2006, ema, Mexico
- 2007, NATA/JAS-ANZ, Australia

Further events:

- Polydays 04 to 06 October 2006, Berlin (Bi-annual meetings on Polymers)