

BMW i Assumed International Representation of the German Accreditation System

On 21 August 2006 the *German Accreditation Advisory Council* was appointed at the Federal Ministry of Economics and Technology (BMW i). This Council will provide advice to the BMW i, in particular concerning all questions as to the representation of the German accreditation system at international level.

Thus the BMW i assumed the commitment to represent the German accreditation system abroad.

Initial point for establishing such a Board was the new development in revising the European legislation on product directives (DAR-aktuell already reported about this topic in previous issues), the European regulation on accreditation to be expected, and the increasing request of the accreditation and recognition bodies operating in the mandatory area to actively take part in the work of EA and other international organizations through the BMW i.

The DAR which so far used to represent the German accreditation system in EA, ILAC, and IAF decided at its 44th Meeting on 21 June 2006 to transfer this task to the BMW i.

The DAR therefore modified its Rules of Procedure that will be put into force after founding and establishing the working capacity of the above Accreditation Advisory Council.

As to ensure the continuity of work in European and international accreditation committees the BMW i will fall back on the German representatives who have been already actively participating in the work of these international organizations.

The members of the Accreditation Advisory Council were appointed by the BMW i. These are 21 representatives from accreditation bodies, the Federal Government and the Lander governments, industry and consumer associations and from conformity assessment bodies as well as 21 deputy members.

Prof. Dr. Manfred Hennecke, President of the Federal Institute for Materials Research and Testing (BAM), was appointed Chairman of the German Accreditation Advisory Council. Gunther Beer, Siemens AG, accepted the position as Deputy Chairman.

The Secretariat was established at the BAM, Berlin (www.akkreditierungsbeirat.de).

By having taken this action, the BMW i demonstrated that it will fulfil its responsibilities as to the German accreditation system. The BMW i therewith smoothed the way for a German law on accreditation which will be prepared after adopting the European regulations in Germany.

BAM S.2—M. Wloka

Revision of the New Approach

Since the Council decision in 2003, intensive efforts have been taken to revise the New Approach that led to a proposal of the European Commission for a horizontal act of law available as SOGS documents N560-1 and N560-2 (Annexes) (see also http://ec.europa.eu/enterprise/newapproach/review_en.htm). This horizontal act will make basic provisions to be bindingly applied to all Directives. Horizontal aspects in the Directives that became necessary due to the historical development of the individual sectors shall thus be harmonized.

Basic principles of the New Approach of 1985

The New Approach (Council decision dated 7th May 1985 on a new conception in the field of technical harmonization and standardization; ABL C 136 dated 04/06/1985 pp. 0001 -

0009) is based upon the following **four basic principles**:

- The harmonization of the approximation of laws is limited to the determination of basic safety requirements (or other requirements for the public benefit) within the frame of the Directives according to Article 100 of the EEC Treaty;
- The standards committees are instructed to develop technical specifications for manufacturing and placing of products on the market that meet the basic requirements defined in the Directives;
- The technical specifications will not receive any obligatory nature, but remain voluntary standards;
- For products manufactured on the basis of harmonized standards a compliance with the “basic requirements” as defined in the Directive is presumed (presumption of conformity).

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New Approach as a regulatory instrument

The **New Approach has been and will remain a regulatory instrument** to exercise the duties of the signatories to the EEC and EU Treaty, a. o. the duties as to the approximation of the laws resulting from this EU Governmental Treaty – Art. 100 and 100a. A few excerpts taken from the Articles:

„Chapter 3; Approximation of the laws; as of: 24th December 2002, ABL C 325

Article 94 (ex-Article 100)

* The Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, issue directives for the approximation of such laws, regulations or administrative provisions of the Member States as directly affect the establishment or functioning of the common market.

Article 95 (ex-Article 100 a)

* The Council shall, acting in accordance with the procedure referred to in Article 251 adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

* If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

* ...If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

* The harmonization measures referred to above shall, in appropriate cases, include a safeguard clause authorizing the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure."

Scope

The New Approach has been and will be defined by Article 5 of the EEC-/EU-Treaty:

– „The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein.

– In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

– Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty."

– By **applying the New Approach for approximation of laws** in each possible area, the Commission aimed in 1985 at preventing an undue increase of over-technical single Directives for each product. The scope of the Directives with "reference to standards" should be determined based on product categories and the types of risks to be covered.

Duty to supply information

The emergence of new barriers to trade by approving technical standards and provisions in the EU member states that differ from each other may be prevented through a procedure specified in the **Directive 98/34/EC**. According to this procedure, the member states are committed to notify the technical provisions and standards drafts to the Commission and to the other member states.

Essential aspects as to revision

As the aims and provisions of the New Approach were to some extent differently interpreted in practice a revision of the following aspects became necessary and they are therefore taken into consideration in the present revision:

– Improvement of the exchange of information and experience among the notified bodies;

– Harmonization of the requirements for notified bodies as well as of the notification procedures;

– Improvement of administrative cooperation in terms of market surveillance;

– Acceleration of the safeguard clause procedure;

– Safeguarding CE marking.

The SOGS documents N560-1 and -2 describe these aspects in detail. The overall 71 Articles (N560-1) and 7 Annexes (N560-2) with detailed implementation procedures explain a. o. the basic principles and the commitments resulting from them as well as the necessary transparency.

In this context discussions are resumed about an extension of the New Approach,

i.e. the application of the same principles and rules to further product areas.

The act of law is planned to be implemented in terms of an ordinance and will focus on the following points:

– The individual directives will be reduced to essential sectoral requirements. In order to prevent disadvantages to the technical progress, they will contain only protection goals, but no reference to specific technologies. As hitherto, an essential role will come up to the European standardization.

– Responsibilities and duties of manufacturers, salesperson and importers will be defined in order to enable the path followed by the products to be traced back along the entire supply chain. This need to be coupled with an efficient market surveillance.

– Basically, the single modules in terms of conformity assessment procedures that include a comprehensive quality assurance and relate to all stages up to the completion of the product will be maintained.

– In future, the conformity assessment bodies will be notified according to a procedure based on a formal accreditation. Only in well-founded exceptional cases it may be deviated from this procedure. Furthermore, the exchange of information and experience will be intensified by including the Commission, the notified bodies, the authorities, and accreditation bodies.

– By revising the New Approach, the accreditation will be granted the role as the last supervisory level in conformity assessment. It will be defined as a governmental task for the public benefit and shall be free of any commercial competition.

When further developing the **European accreditation infrastructure**, the Commission will rely upon the long-term experience gained in the EA.

As to the national accreditation infrastructure, the document SOGS N560-1 (Chapter VII Accreditation, Article 32, General Principles, 4.) requires that only **one national accreditation body** be established. This requirement is much stricter than in the previous documents where there was alternatively mention of an accreditation system.

However, these provisions will exclusively relate to the scope of the „old“ and the „new“ approaches, i.e. to the legally regulated (mandatory) and not to the voluntary area.

BAM S.2—N. Bendix

Source: Interview with Mr. McMillan, Head of Unit, Legal aspects linked to the internal market“ at the DG „Enterprise and Industry“ of the European Commission; KAN Letter 3/06

Information from Standardization

ISO/IEC 17021 – Requirements for bodies providing audit and certification of management systems

The ISO/IEC 17021 Final Draft was adopted by ISO, although four national ISO members argued against its adoption (Germany, UK, Norway, and Austria). This standard will supersede the ISO Guide 66 (General requirements for bodies operating assessment and certification/registration of environmental management systems) and the EN 45012 or the ISO Guide 62 respectively (General requirements for bodies operating assessment and certification/registration of quality systems).

With this standard, ISO meets a very practical need, as many certification bodies provide certifications of different kinds of management systems, among others also quality management systems.

The adoption of this standard will be discussed during the next General Assemblies of EA and IAF. The DAR will also consider how to apply this standard by the accreditation bodies.

Part 2 of ISO/IEC 17021

A Work Item Proposal was put on the vote among the ISO members. It is proposed to develop a Part 2 for the ISO/IEC 17021 titled „Conformity assessment – requirements for third party auditing of management systems“. This Work Item Proposal was accepted with the exception of Germany, the US, Denmark and Norway.

A main reason why a few ISO members rejected this Work Item Proposal was the fact that the ISO 19011 would suffice to put requirements to auditors and to the organization of the audits. According to a statement given by the ISO/CASCO WG 21—that dealt with drafting the ISO/IEC 17021 and will now also develop Part 2—such a Part 2 is now welcomed by the industry and also by the authorities, as the requirements for auditors and for the management of audits for certification shall be formulated sector-specific, so as to ensure the competence of the auditors and also to increase the acceptance of certified management systems.

The WG 21 decided to develop in Part 2 of the ISO/IEC 17021 only the framework in which criteria and requirements shall be determined by the competent ISO TCs or other standards bodies or by the authorities based on the sector-specific requirements.

On the part of the DIN, a German representative will also be included in the Working Group to develop Part 2.

Revision of ISO Guide 43

As already reported in our last issue of DAR-aktuell, a decision was taken to revise ISO Guide 43 and to publish it as ISO/IEC 17043. This work will be commenced in December 2006. It is expected that in the standards committee ISO/CASCO WG 28 dealing with this project also the question will be discussed under which conditions providers of proficiency testing can be accredited.

BAM S.2 - M. Wloka

Information from the DAR

Membership in the DAR

After having successfully finished the evaluation procedure, according to a recommendation of the BAM Evaluation Committee the German Accreditation Association e.V. (GA-A; www.ga-a.de) based in Bonn was accepted as a member of the DAR with effect from 01 May 2006.

The GA-A is an accreditation body operating accreditation of certification bodies for environmental and quality management systems as well as persons.

Results from the BAM Evaluation of DAR Accreditation Bodies Operating in the Voluntary Area

The DAR member accreditation bodies DACH, DAP, DATech, and TGA have proved evidence of their compliance with the binding DAR Rules of Procedure (DAR-2-GL-01) through the BAM evaluation procedure performed by independent assessors. The requirements set out in the EN ISO/IEC 17011 are part of these Rules. These accreditation bodies therewith have the continuing right to stay a member of the DAR and to issue the DAR certificate.

Continuation of the Discussion on „What Can Be Accredited?“

This issue has already been discussed in DAR-aktuell 1/2006 (in connection with the accreditation of manufacturers of reference materials and providers of proficiency tests). Although the ISO/IEC 17011 clearly defines the scope and states about what can be accredited according to this

standard, finding an international consensus seems to be rather difficult. Currently there are discussions in the international organizations ILAC and IAF about the criteria based on which a positive list could be established. The following simple rule shall be applied: Everything what can be certified must not be accredited.

The positive list to be established in IAF and ILAC will be submitted to the EU Commission; a clear definition about what can be accredited and what is an accreditation for the public and general benefit shall thus be enabled.

The discussions on this issue will be continued. The outcome is to be expected from the revision of the ISO Guide 43 both in ILAC and IAF and in the European Commission as well as in ISO/CASCO.

Study „Conformity Assessment in Germany“

A study commissioned by the BMWi (German Federal Ministry of Economics and Technology) was introduced to the public in July 2006 within the frame of a presentation at the BMWi. Interested parties may see the study at www.bmw.bund.de/BMWi/Navigation/Service/bestellservice,did=143658.html

Certificates of Conformity according to ISO/IEC 17025 for Subcontractors of Certification Bodies for Products

The accreditation bodies operating accreditation of certification for products within the DAR are requested to exert influence

on their accredited certification bodies for products with regard to a clear presentation of the confirmation of the subcontracted laboratories. This confirmation must not be mixed up with an accreditation according to ISO/IEC 17025.

Certification bodies for products need to assure themselves of the laboratories' competence, if they use them as subcontractors. This is a requirement of the EN 45011. The subcontracted laboratory shall comply with the requirements of the EN ISO/IEC 17025 in terms of those tests that will be performed for the certification bodies for products. The subcontracted laboratories wish to receive from the certification body for products a confirmation that they fulfil the certification body's requirements (demonstration of competence). There are various possibilities to do so: recognition of the laboratory's accreditation without any further activities through the certification body; recognition of the laboratory, in case it has no accreditation, but has already performed the same test method and has been recognised by another certification body; in case of missing evidence concerning the compliance of the ISO/IEC 17025 through the laboratory, the certification body shall assure itself of the laboratory's competence.

The confirmations of the laboratories' competence through the certification bodies need to be designed in such a way that they cannot be mixed up with an accreditation certificate.

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Withdrawal of Documents

The DAR decided to withdraw the following obsolete documents:

- DAR-3-EM-17 Harmonized Procedures for Surveillance and Reassessment of Accredited Laboratories
- DAR-4-EM-04 Recommendation for the Statement of the Scope of Accreditation for Testing Laboratories
- DAR-4-EM-05 Guidance for Accreditation to ISO/IEC 17025

Reference on the DAR Certificate on Compliance with ISO 9001

A request submitted by Eurolab-D to take over the words of the ILAC-IAF-ISO Communiqué on the accreditation certificate was not granted. On request of the clients, the Communiqué or an information letter may be distributed along with the certificate.

For reasons of a mix-up of accreditation and certification according to ISO 9001, the accreditation bodies did not see any need to indicate a respective note already on the accreditation certificate. Further information about this topic see www.dar.bam.de/newse.html

BAM S.2 - S. Stobbe

EA Evaluators' Training at the BAM



About 60 Team Leaders (TL), Team Members (TM) as well as observers from the EU Commission, from the EA Advisory Board and the mandatory area took part in this year's EA evaluators' training held from 27th to 29th September 2006 at the BAM, Berlin.

The first Workshop day, which was dedicated solely to the TL, focused—as already in the previous years—on the improvement of the evaluation process and served the exchange of experience.

Within the following Workshop days, along with the below improvements, the developed Cross Frontier Policy and the evaluation of conformity assessment

schemes were introduced in a joint TL-TM evaluators' training. Syndicate work on the topics KPI, Reporting and assessment of findings topped the meeting off.

The following proposals were introduced to the EA-MAC meeting held on 5th/6th October 2006 in Brussels:

- Introduction of a Deputy TL: He/she will accept parts of the TL's work and act in place of him/her during the evaluation in case of illness. A build-up of the evaluation team will not take place, as the Deputy TL will take the place of a TM.
- Rating sheet:
TL and TM assess each other after completion of the evaluation; the filled in questionnaires are forwarded to the EA-MAC Secretariat for analyzing purposes.
- Payment of the evaluation team by the body to be evaluated on the basis of a man-day rate still to be fixed.

BAM S.009—B. Abraham

DIARY:

Nächste 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 presumably in Jordan

Next EA MAC Meetings:

- 28 to 29 March 2007, Prague, Czech Republic
- 27 to 28 September 2007, Berlin, Germany

Next ILAC/IAF GAs:

- 19—31 October 2007, NATA/JAS-ANZ, Australia
- 08 to 18 September 2008, SWEDAC, Stockholm, Sweden
- 2009 CAEAL (Canadian Association of Environmental Analytical Laboratories), Vancouver, Canada

