

The Establishment of the New Accreditation Body is Under Progress

The implementation of the law on establishing an accreditation body - AkkStelleG – is on schedule with regard to the organisation of the national accreditation body in Germany

The law on establishing an accreditation body (AkkStelleG) of 31 July 2009 has been in force since 7 August 2009. This provides now a legal basis in Germany for conducting accreditations under the Regulation (EC) No 765/2008.

With the Regulation that will come into force on 01 January 2010, the accreditation of conformity assessment bodies to be carried out by the national accreditation body has become a sovereign task of the Federal Government.

Yet, who or what is the national accreditation body? And what about the thousands of accreditations which were previously issued by the German accreditation bodies?

In order to resolve the many questions as quickly as possible, the BMWi (German Federal Ministry of Labour and Technology) as the responsible federal ministry commenced its preparatory work immediately after the enactment of the AkkStelleG. There is not much time left till the end of this year - and so there is an ambitious schedule that requires a lot of support to launch the national accreditation body in due time. At its next meeting on 9th December 2009, the DAR will decide on a concept for transferring the tasks to the new national accreditation body.

In its overall responsibility, the BMWi has begun to establish this project and gathered experts from various organisations, authorities, the DAR, and accreditation bodies in a project team. On 10th August 2009, the project team began its work to establish the national accreditation body. The priorities in this project team work may be outlined as follows:

Legislative activities to implement the AkkStelleG

This includes among others the establishment of an accreditation body as a private limited company which fulfils the preconditions for authorisation as laid down in the AkkStelleG and may be authorised by ordinance with the consent of the Federal Council of Germany. Following the vote on the ordinance on authorisation of accreditation services (AkkStelleGBV), further contracts will be coordinated. As the BMWi announced at an information session held on 3rd November 2009, a multistep process was chosen for the formation of the private limited company, i.e. initiating the integration of the German Calibration Service (DKD) and the merger with

the largest German private accreditation body „Deutsche Gesellschaft für Akkreditierung mbH“ (German Association for Accreditation / DGA, a merger of the former DACH, DAP, and TGA). This way, the German Accreditation Body (DAkKS) was established whereof the German State will have a share of two thirds. The remaining one third is represented by industry. Furthermore, for implementing the AkkStelleG, a fee regulation and a regulation on the protection of the new accreditation symbol are to be adopted.

Structure and organisation of the national accreditation body

The DAkKS' internal organisational structure is set up in such a way to provide both voluntary and mandatory accreditations under Article 3 of the Regulation (EC) No 765/2008. It was decided to organise the departments of the DAkKS subject-oriented, thus bringing together the mandatory and voluntary areas structurally visible. The fact that the DAkKS will have multiple locations had to be taken into account. Against this background, the DAkKS will be composed of six departments:

- Department 1 „Construction / Transport / Materials engineering“
- Department 2 „Safety equipment and plant safety / Telecommunications / EMC“
- Department 3 „Health / Forensic“
- Department 4 „Consumer health, agriculture and environment“
- Department 5 „Metrology“
- Department 6 „Certification of systems / Persons“

Transfer of personnel and involvement of external persons for ensuring the necessary human resources in the national accreditation body

The transfer of rights associated with the merger into DAkKS also ensures the existence of a solid basis of qualified personnel. However, solely because of the extent of its scope, the DAkKS depends on further expertise and personnel from other organisations which were previously dealing with accreditation and will be integrated in the DAkKS in various ways.

For example, the AkkStelleG contains specific guidelines for integrating the authorities who grant authorisation, in particular in the fields of medical products, genetic diagnostics, safety technology as well as nutrition, agriculture, and consumer protection including food safety, which - in the context of the development work - are complied with specific rules.

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Provision of the required infrastructure

The DAkKS will make its regulations, the list of accredited bodies based on the well-known DAR database, and any further information available on its websites. Information on the DAkKS will presumably be available at the following website www.dakks.de. For a transitional period, the headquarters of the DAkKS will be located at the BMWi. The DAkKS will have offices in Berlin, Frankfurt/Main and Brunswick which are to be connected to each other.

Accreditation procedures in accordance with the AkkStelleG, the Regulation (EC) No. 765/2008 and the DIN EN ISO/IEC 17011

The DAkKS will do its work on a non-profit basis, and with regard to its sovereign activity the DAkKS will be subject to the

German administrative law. As a result of this, the DAkKS will execute these accreditation activities as an authority. Thus, compared to the previously performed accreditation procedures, there will be formal changes which result among others from the Administrative Procedure Act. For this reason, the DAkKS will be issuing decisions on accreditation from January 2010. Furthermore, the DAkKS will be under the technical supervision of the competent federal ministries.

The supervision will be designed in such a way that independence and impartiality of accreditation decisions will be guaranteed. However, the technical depth and the well-proven method of how to conduct assessments will hardly be changed. As usual, the DAkKS will also be issuing accreditation certificates. The sovereign activities of the DAkKS will be provided on the basis of the

fee regulation.

Membership of the DAkKS in the European and international accreditation organisations

Prior to the formal entrustment of the DAkKS, the consent of the EA members was obtained to transfer the EA membership of the DGA and the DKD to the new national accreditation body DAkKS. At the EA General Assembly held from 25th to 26th November 2009, the EA members were informed about the current status and asked to take a decision in this respect.

Even though many detailed issues still need to be clarified, the development work in the BMWi is proceeding at a great pace so that the DAkKS may be entrusted by the end of this year and can take up its work in due time in January 2010.

BMWi – G. Dudek

News from the DAR

50th Meeting of the DAR

On 9th December 2009, the DAR will hold its 50th meeting.

The main topic will be the "Transfer of the responsibilities to the new accreditation body". The aim will be to manage and secure the currently existing accreditations appropriately.

The accredited bodies have already been informed by their accreditation bodies about the situation after the 1st January 2010 and may decide - in case their accreditations are voluntary - in which way they wish to continue their accreditations

after expiration of their validity.

DACH, DAP, and TGA merged into the DGA mbH (German Association for Accreditation)

With regard to the necessary reorganisation of the German accreditation system, the three major accreditation bodies DACH (German Accreditation Body Chemistry), DAP (German Accreditation Body Testing), and TGA (Association for Accreditation) took an important step and merged into the DGA (German Association for Accreditation).

After its merger, DACH, DAP, and TGA were listed in the commercial register as DGA mbH.

Since the DGA mbH is the legal successor of the three individual accreditation bodies, the existing contracts and arrangements will be continued. The DGA mbH runs offices in Berlin and Frankfurt/M. Further information about the DGA mbH will be provided on the internet under the following link www.dga-mbh.de.

BAM S.2 – S. Stobbe

Eighth and Last Meeting of the Accreditation Advisory Board (AKB) at the BMWi

The 8th meeting of the Accreditation Advisory Board took place at the BMWi in Berlin on 30th September 2009. At the meeting, the following topics were discussed: the report on the Law on Establishing a Single National Accreditation Body and the current state of implementation, the merger of the private accreditation bodies, developments at EA, IAF and ILAC, EU/SOGS, and the AKB Sub-Committee.

The present Accreditation Advisory Board will continue to exist until 31st

December 2009 and carry out its work as usual until that date. This mainly includes provision of advice and assistance to the BMWi in issues related to accreditation, coordination and external representation of the German accreditation system, and the drafting of opinions regarding the German position in European and international committees. The 8th meeting was the last meeting of this Board according to schedule.

Mr. Barz from the BMWi and Professor Hennecke as Chairman of the Accreditation Advisory Board expressed

their thanks to the members for their active participation and the successful realisation of tasks as well as to the staff of the office for providing and coordinating information and establishing transparency.

The BMWi is presently developing the concept for the new Accreditation Advisory Board required by the Law on Establishing the Accreditation Body, and is preparing its authorisation which scheduled for January 2010.

BAM S.2 – F. Behrens

News from International Organisations



IAF / ILAC

Joint General Assembly (left to right): P. Unger (USA), E. Nilsen (Canada), T. Facklam (Germany), D. Pierre (France), A. Dever (Australia)

From 18th to 20th October 2009, the IAF and ILAC General Assemblies took place in Vancouver, Canada. At the joint meeting of ILAC and IAF it was particularly discussed how a joint cooperation can be arranged more effectively in future. A survey will be conducted among the members about how close this cooperation may be, also considering a joint organisation in the future.

Cooperation with IEC

The cooperation between IAF, ILAC, and IEC will be elevated to a new level. A new Memorandum of Understanding will be

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developed and one single „steering committee“ of IEC/CAB (Conformity Assessment Board) together with IAF and ILAC will be established with the aim to better coordinate future cooperation. Previously, there used to be two separate committees, one each for IAF and ILAC.

A joint communiqué was agreed as for recognising certificates issued by a manufacturer's testing laboratory for the IECEE system and by an independent testing laboratory for the IECQ system. Lists of IEC assessors are provided which can be used by IAF and ILAC accreditation bodies with the aim to use the technical competence for accreditation within IEC.

Results from IAF

In IAF, the structure of the Multilateral Agreement for Mutual Recognition (MLA) is currently being discussed intensively.

The structure adopted at the last General Assembly consisting of main scopes (standards of the 17000 standards series for conformity assessment bodies) and of sub-scopes (technical standards for the requirements for systems, products and other objects of conformity assessment in various technical fields) has been clarified, and evaluation procedures for various MLA levels were a subject under discussion.

As a first step, two new management systems were adopted as sub-scopes for the MLA:

- Accreditation of ISMS (Information Security Management System Certification Bodies) and
- Accreditation of FSMS (Food Safety Management System Certification Bodies).

The ISMS MLA is based upon ISO 27001 as a requirement for certified organisations and upon ISO 27006 as a requirement for certification bodies in addition to the requirements set out in ISO/IEC 17021.

The FSMS MLA is based upon ISO 22000 as a requirement for certified organisations and upon ISO/TS 22003 as a requirement for certification bodies in addition to ISO/IEC 17021. For this MLA, a specific IAF application paper is still a subject of discussions in the Technical Committee.



The MLA Committee will submit a work plan on how to develop this new MLA structure.

Functions in IAF

Randy Dougherty, USA, was elected new Chair of IAF. Xiao Jianhua, China, was elected Vice Chair of IAF. The previous Chair Thomas Facklam, Germany, will act in the Board of Directors as a representative of accreditation bodies of high income economies. Norbert Borzek, Germany, was elected Chair of the Technical Committee.

Results from ILAC

ILAC's financial structure will be changed. In the context of comparisons between IAF and ILAC, the funding of the Secretariat has been much discussed. ILAC-G13, which so far used to be the basis for the accreditation of proficiency testing providers, will be withdrawn after publication of ISO/IEC 17043. It was confirmed that ISO 15189, which has been used for the accreditation of medical laboratories, is covered by the ILAC Arrangement (MRA) for testing.

Andreas Steinhorst, Germany, was elected Chair of the ILAC Accreditation Management Committee (ILAC AMC).

Evaluations of the Regional MLA Groups

The evaluation procedures for regional groups were subject of intensive discussions at the meetings. In 2010, the re-evaluations of the regional groups EA, PAC, APLAC, and IAAC will commence. In future, the evaluation procedures will be carried out more effectively. The aim is to fully evaluate the regional groups within two years and in the meantime to carry out regular verifications to ensure that the regional groups will be monitored continuously and the harmonisation process will be updated constantly.

BAM S.2—M. Wloka

EA

Status of assumption of new responsibilities by EA under the New Legal Framework

Results of the 23rd EA General Assembly held in Luxembourg from 27th to 28th May 2009

The General Assembly approved the network of Directives set up by the Horizontal Harmonisation Committee (HHC). 18 networks will be established for the various EC Directives. German representatives are among others Johann Huber (ZLS), Michael Gierloff (DIBt), Undine Soltau (ZLG), Matthias Gattwinkel (EBA), Ralf Egner (DGA).

To prevent the formation of parallel systems which cannot be controlled, any tendencies of some European accreditation bodies to perform assessments according to general accreditation criteria that would result in no accreditation should be strictly counteracted.

By means of the EA Resolution 2009 (23) 10, the General Assembly gives the mandate to the EA Executive Committee and the EA Chair to sign both the Frame-

work Partnership Agreement (FPA) between EA and the European Commission and the corresponding Annexes for the year 2010. The FPA forms the basis for the EC Commission's financial contribution to carry out the expanded role of EA according to Regulation (EC) No. 765/2008 and to Decision (EC) No. 768/2008.

The General Assembly confirmed the implementation phase for EA-2/17 (rev.01), July 2009, "EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes", starting from January 2010.

The German translation of EA-2/17 will shortly be published on DAR's websites as DAR-3-EM-25 "EA Guidance on horizontal requirements for the accreditation of conformity assessment bodies for notification purposes".

The document EA-2/17 shall be applied by the EA accreditation member bodies from 1st January 2010 when accrediting conformity assessment bodies which are intended to serve for notification. By 1st January 2012, all accredited notified bodies have to be assessed according to EA-2/17. This document has been classified by EA as a mandatory document (Category 2).

At the margins of the General Assemblies of ILAC and IAF, a meeting of EA members took place in Vancouver on 18th October 2009 to provide guidance on next steps. Emphasis was placed on the EA work plan 2010, the Framework Partnership Agreement between EA and the European Commission (EC), the financial contribution of the EC to the work of EA, and the expected increase of the EA membership fees by 1,5% in 2010.

Results of the 24th EA General Assembly held in Bruges, Belgium from 25th to 26th November 2009



The 24th EA General Assembly took the following decision:

EA Resolution 2009 (24) 05

"The General Assembly agrees to the transfer of the EA full membership status jointly from German accreditation bodies DKD and DGA to the legal entity named DAkkS (German Accreditation Body). The date of transfer is to be determined by the Federal Ministry of Economics and Technology (BMWi) and notified to EA in advance."

BAM S.2 – J. Thiele

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Next EA GA:

- 20 to 21 May 2010, Zurich/
Switzerland
- 24 to 25 November 2010,
Budva, Montenegro
- May/June 2011 Berlin,
Germany

Miscellaneous:

- 9 December 2009—2nd
International Production
Management Systems,
Effective Strategies &
Applicable Models Summit,
Istanbul, Turkey
- 25 January 2010—Information
session „Accreditation and
Notification in Germany 2010“,
(BAM on behalf of the BMWI),
Berlin, Germany
- 16 April 2010 Colloquium
EuroLab-D, BAM, Berlin,
Germany
- 19 to 23 April 2010—
CAFMET—3rd International
Metrology Conference, Cairo,
Egypt
- 27 to 28 April 2010—New
training course „Use of
reference materials and the
estimation of measurement
uncertainty“, IRMM, Geel,
Belgium
- 6 to 8 September 2010—
9th MS-Symposium and 22nd
ICPMS meeting of users,
(EuroLab-D), WISTA, Germany

News from Standardisation

Information from CEN/CENELEC TC1

At the CEN/CENELEC TC1 meeting held on 1st October 2009, the mandate M417 of the European Commission for confirmation of harmonised standards in the field of the New Approach was reviewed. It was noted that it is necessary to establish task forces on further draft standards currently being developed in the field of conformity assessment at ISO/CASCO to check whether the requirements of the European Commission, in particular the requirements for notified bodies set out in the Decision (EC) No. 765/2008, find themselves in the draft standard.

It was decided to establish a task force both for the current revision of ISO/IEC 17020 (requirements for inspection bodies) and for the draft standard ISO/IEC 17021-2.

The first Task Force on revision of the draft standard ISO/IEC 17065 (requirements for product certification bodies) also met in early October. Some improvements were discussed to be made in ISO/IEC 17065 and were given to the relevant ISO/CASCO Working Group WG 29. However, no significant discrepancies were found which could prevent the draft standard ISO/IEC 17065 from leading to a harmonised standard with its current wording.

State of development of conformity assessment standards

The following standards/guides are currently under revision: ISO/IEC 17020, ISO/IEC 17024, and ISO Guide 65. The stages of their developments are different.

While the revision of the standards ISO/IEC 17020 and ISO/IEC 17024 is still in its infancy, a Draft International Standard (DIS) ISO/IEC 17065 exists already; it is currently under discussion in the national standards bodies.

The draft on ISO/IEC 17021-2 (requirements for third party certification audits of management systems) has been translated into German and is supported by the German Institute for Standardisation (DIN). It is expected that the new ISO/IEC 17021-2 includes all requirements of the current 17021. In future, only one standard would be needed to describe the requirements for certification bodies for management systems as well as the requirements for conducting audits and the requirements for the auditors.

There is a new ISO/CASCO project: A standard ISO/IEC 17067 – Conformity Assessment – Fundamentals of Products Certification – will be developed which will supersede ISO/IEC Guide 67. Initially, Germany opposed the development of this standard. However, there will possibly be the attempt to include requirements that arise for product certification bodies in the EU.

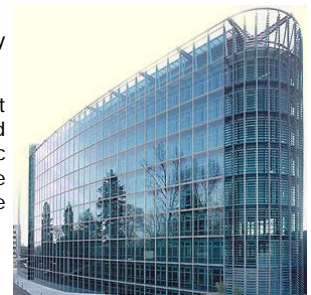
State of development of ISO/IEC 17043

The drafting of the standard ISO/IEC 17043 „Requirements for proficiency testing“ will be finalised in the near future. The standard will soon be put to a vote and it is expected that this standard will be published in early 2010.

ISO/CASCO General Assembly

From 12th to 13th November 2009, the ISO/CASCO Plenary meeting was held in Geneva, Switzerland.

At the Plenary meeting, the ISO strategy 2011-2-15 that comprehensively deals with management systems and conformity assessments was discussed. Under the rubric „CASCO interpretations“, the ISO/CASCO homepage www.iso.org/iso/conformity_assessment.htm will provide answers on specific questions to ISO/CASCO in the future.



ISO/CASCO workshop 2009 Role of International Standards in managing the global supply chain and traceability

Prior to the Plenary meeting, a workshop dealt with the „Role of international standards in managing the global supply chain

and traceability“. The contribution of international standards in support of the global market was also discussed.

BAM S.2—M. Wloka



We wish all our readers a Merry Christmas and a Happy and Prosperous New Year 2010.

Also in 2010, you will be kept informed about developments in accreditation.