

The new national accreditation body in Germany started working (see page 2)

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From left to right: Mrs Inga Schlüter (DIN), Mr Hans Meierhofer (KOGB), Mrs Andrea Valbuena (DGA), Mrs Dr. Gabriele Dudek (head of the DAR Secretariat/BAM), Mr Dr. Thomas Facklam (DGA), Mr Dieter Penning (DAR deputy chair/KOGB), Mr Dr. Michael Nitsche (BAM), Mr Dr. Michael Wolf (DKD), Mr Dr. Markus Racke (DAU), Mrs Dr. Monika Wloka (DAR Chair/BAM), Mr Dr. Bernd-Josef Schlothmann (GAZ), Mr Prof. Dr. Erwin Thiemann (GAZ), Mr Reinhard U. Wanzek (GA-A), Mr Andreas Lehmann (KBA), Mr Dr. Jürgen M. Schulz (AKS), Mr Ulrich Böhshagen (DAR deputy chair), Mr Dr. Andreas Steinhorst (DGA), Mr Lipka (BMW), Mr Prof. Dr. Kurt Ziegler (DGA), Mr Ingo Ruthemeier (BAM)

On 9th December 2009, the 50th Meeting of the German Accreditation Council (DAR) took place at the BAM Bundesanstalt für Materialforschung und -prüfung (Federal Institute for Materials Research and Testing), Berlin.

It focused on decisions and transitional arrangements set out until the new national accreditation body in Germany will be established and ready to work. Its goal was to enable the accredited bodies a transition to the new German accreditation system as convenient as possible, even if during the meeting exhaustive information on the future operation of the DAkKS (Deutsche Akkreditierungsstelle GmbH), which started its work on 1st January 2010, could not be given.

Arrangements were made on the validity of the DAR accreditation certificates, the use

of the DAR symbol, and the DAR certificate with the Federal Eagle, the DAR Rules and Procedures, and the remaining tasks to be fulfilled by the DAR Secretariat (see also page 2).

Following the meeting, a ceremony was held in honour of the 50th DAR meeting, pointing out some of the highlights of the DAR. All DAR members and committees, supporting institutions, and ministries, and above all the staff members of the DAR Secretariat were thanked for their extensive and successful work.

The DAR has established a good and solid basis for the German accreditation system and for the international recognition of German accreditations, thus making a significant contribution to improve trade relations.

BAM S.2—M. Wloka

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Germany's accreditation body DAKKS GmbH started working

In the last issue of DAR - aktuell it was reported that the building up the national accreditation body is still in progress. The German accreditation body DAKKS GmbH has been working since 1st January 2010. It was authorised by the German Federal Government to perform accreditations pursuant to the Ordinance on Authorisation of Accreditation Services (AkkStelleG-Bleihungsverordnung of 21st December 2009 (BGBl Part 1 No. 81, 39, 62)).

The German Accreditation Body (DAKKS GmbH) was founded by the Federal Republic of Germany represented by the Federal Ministry of Economics and Technology (BMWi). The former members of the European co-operation for Accreditation (EA) - DGA and DKD - were trans-

ferred to the DAKKS. As a start, the DAKKS fully covers the recent activities of the DGA and the DKD. Basis for the foundation of the DAKKS is Article 4, Para. 1 of the Regulation (EC) No. 765/2008 according to which from 1st January 2010 the Member States shall designate one single national accreditation body with the aim to carry out accreditations under the EC Regulation. With entering into force of the Accreditation Body Act (AkkStelleG) of 7th August 2009, the legal framework was provided for establishing this national accreditation body in Germany. Industry and the German Federal Government are involved in the new accreditation body. A continued participation of the German Federal States is presently under discussion.

Name and location of the DAKKS GmbH

The headquarters of the DAKKS is in Berlin; further locations are in Braun-

schweig and Frankfurt on the Main.

For a transitional period, the headquarters of the DAKKS is located at the BMWi Federal Ministry of Economics and Technology (DAKKS GmbH c/o BMWi, Scharnhorststraße 34 – 37, 10115 Berlin).

Latest news about the DAKKS can be found on its websites at www.dakks.de.

At a central information meeting jointly organised by the BMWi and the BAM Federal Institute for Materials Research and Testing held on 25th January 2010 information was provided about the framework conditions and structures of the DAKKS as well as about results reached by the Specialist Team in the BMWi for establishing this new accreditation body (see page 3).

BAM S.2—M. Wloka

Information from the DAR

The **50th DAR meeting** was held at the BAM, Berlin, on 9th December 2009 (see page 1). At this meeting which could likely be the last one of the DAR all necessary decisions and arrangements were taken relating to the transfer of the tasks and responsibilities to the new national accreditation body. It was decided that the DAR as a board jointly supported by the Government and industry will not cease its work until the BMWi has given notification of a necessary closing of the DAR. Measures have been taken in order to issue in a proper and reliable way all accreditations granted with a DAR Certificate until 31st December 2009 and remain their validity until they expire.

Period of validity of DAR Certificates and the DAR Logo

Pursuant to Article 39 of the Regulation (EC) No. 765/2008, accreditation certificates issued before 1st January 2010 remain valid until their date of expiration, however no later than 31st December 2014. This also applies to all DAR certificates issued until 31st December 2009. However, it was decided that the DAR accreditation bodies will grant accreditations with reference to the German Accreditation Council only until 31st December 2009 and DAR Certificates bearing the Federal Eagle may be issued only by this time. Starting from 1st January 2010, the EU Regulation and the Accreditation Body Act will apply in Germany. The same period of validity applies to the use of the DAR symbol. Also in future contact partner for all issues in this context will remain the BAM which so far has been holding the DAR Secretariat.

DAR Rules and Procedures

The German translations of below documents have been endorsed and included in the DAR Rules and Procedures:

IAF/ILAC-A5:04/2009 *IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004 as [DAR-3-EM-24](#)*

EA-2/17:2009 rev01 *EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes as [DAR-3-EM-25](#)*

EA-7/05 *EA Guidance on the Application of ISO/IEC 17021:2006 for Combined Audits as [DAR-7-EM-08](#)*

EA-7/04 *Legal Compliance as a part of Accredited ISO 14001:2004 certification as [DAR-7-EM-09](#)*

The following document was withdrawn:

DAR-5-EM-03 *EA Guidance on the Application of ISO/IEC TR 17010 (EA-3/10) "General Requirements for Bodies Operating Accreditation of Inspection Bodies"*

DAR-3-EM-16 *Accreditation of Laboratories and Inspection Bodies with Several Locations is supposed to be applied to medical laboratories in the future (reference to ISO 15189).*

The DAR decided that new regulations of the DAR Rules and Procedures as well as changes with regard to their content will be made only until 31st December 2009. The Rules and Procedures will be available on the DAR homepage as long as accreditations granted on this basis continue to

be valid. Pursuant to the Accreditation Body Act, the DAR Rules and Procedures will be handed over to the responsible new accreditation body with effect from 1st January 2010.

Presentation of the merged body DGA

At the 50th DAR meeting, a presentation was given about the merger of DACH, DAP, and TGA into the Deutsche Gesellschaft für Akkreditierung DGA (German Association for Accreditation). This merger represented an intermediate step in preparation for establishing the national accreditation body DAKKS. All bodies accredited by the DACH, DAP, and TGA were informed that the DGA, and later from January 2010, the DAKKS will be the legal successor of these accreditation bodies and their accreditations.

In order to further provide a contact partner for the accredited bodies and to ensure a consistent transfer of the tasks and responsibilities to the new national accreditation body, the DAR requested and the BMWi instructed the **BAM** to assume any outstanding tasks of the DAR Secretariat, just as maintenance of the DAR Database, provision and security of the information on the DAR homepage, securing the DAR Rules and Procedures until they were handed over to the DAKKS as well as being a contact point for all matters relating to above mentioned tasks.

Enquiring partners may keep on addressing with all issues to the following contact:

office@deutscher-akkreditierungsrat.org

BAM S.2—S. Stobbe

Accreditation and notification in Germany from 2010

Information meeting held on 25th January 2010 and organised by the BAM Federal Institute for Materials Research and Testing in cooperation with the BMWi Federal Ministry of Economics and Technology



Prof Hennecke, President of BAM, giving the welcome speech

On 25th January 2010 an information meeting was held in Berlin in the Hotel Steglitz International and attended by more than 400 participants. As there were far more applications a further meeting will be held on 10th February 2010 to provide information about the same topic.

This information meeting was particularly addressed to the conformity assessment bodies and to all those who are in need of information about the new accreditation body in Germany.

Information was given about the foundation of the DAkkS Deutsche Akkreditierungsstelle GmbH (German Accreditation Body), which took up its activities on 1st January 2010, as well as about legislative activities that form the basis for the work of the DAkkS, such as the Regulation (EC) No. 765/2008 of 9th July 2008, the Accreditation Body Act (AkkStelleG) of 7th August 2009, the Ordinance on Authorisation of Accreditation Service of 21st December 2009, the accreditation body's Fee Regulation of 21st December 2009, and the Regulation on the Accreditation Symbol of 25th December 2009.

Presently, the DAkkS GmbH is headed by two managing directors, **Mr Barz and Dr Facklam**. Mr Barz informed about the fact that from January 2010 accreditation will be a public authority task for any determination of competence of conformity assessment bodies.

Mr Penning, BNetzA Federal Network Agency, provided information about the structure of the DAkkS, responsibilities, contact partners, and potential contacts.

Presently, the DAkkS has six Departments: Department 1: Construction/Traffic/Materials; Department 2: Equipment and Plant Safety/Telecommunications/EMC; Department 3: Health/Forensics; Department 4: Health Protection, Agriculture, Chemistry and Environment; Department 5: Metrology; Department 6: Certification Bodies for Management Systems and Persons. Departments 1 to 5 cover the accreditation of laboratories, inspection bodies and product certification bodies.

Structural elements of the DAkkS are the following: Shareholders' Meeting, Board of Directors, Management, Accreditation Committee which—depending on the required decision—is composed of knowledgeable and competent persons and may also involve power-conferring authorities or experts from the Federal Government and the German Federal States.

Mrs Valbuena briefed on the surveillance of existing accreditations. Based on Article 5, Para. 3 of Regulation (EC) No. 765/2008 as well as on ISO/IEC 17011, the DAkkS will perform sufficiently frequent and periodic on-site assessments. Surveillance requirements for accreditations granted before 1st January 2010, even though conducted by other accreditation bodies, have been transferred to the DAkkS pursuant to § 13, Para. 1 of the Accreditation Body Act (AkkStelleG).

At the information meeting details were provided on the regulations valid from 2010 for those bodies which were accredited by other accreditation bodies before 1st January 2010 and whose accreditations are still valid as defined on the accreditation certificate (possible until 31st December 2014 at the most).

Mr Huber, ZLS Zentralstelle der Länder für Sicherheitstechnik (Central Body of the German Federal States for Safety) gave a presentation of the interaction of accreditation and recognition/approval and reported on the distribution of tasks. In future, accreditations will be performed by the DAkkS only. Designations, recognitions, approvals, and notifications will continue to be made by the present competent bodies. In areas where previously the ZLG, the AKS/SAL or the ZLS granted authorisations, in future the DAkkS will authorise these bodies to undertake assessments and surveillances and jointly act in order to be able to perform both accreditation and recognition/notification. It was noted that by pooling procedures synergy effects should be expected and the acceptance of test reports and certificates should be improved in Europe and internationally. It is a precondition that the procedures are described adequately and all persons involved into the flow of information are

well integrated.

Directly thereafter, a report was given on selected project results reached by the **Specialist Team** at the BMWi who prepared the fundamentals for establishing the new German accreditation body.

Among others, presentations were made of the accreditation procedure and the changes to be expected from 2010. Focus was especially held on the composition of the accreditation committee in order to achieve an involvement of the power-conferring authorities or the competent departments in the decision on accreditation.

The basics of the **cost regulation** were introduced and practical examples for calculating costs were demonstrated. The changes presented here particularly refer to the fact that future accreditation must be governed by the Administrative Costs Act. As a result it was noted that in future the costs for accreditation will not increase significantly.

Dr Mahnke informed about the public demonstration of the accreditation symbol pursuant to the Symbol Regulation. The DAkkS will introduce a new mark which can be used in combination with the registration number as a symbol for the accredited bodies. The present accreditation certificates of the DAR will remain their validity until the date given on the certificate, however until 31st December 2014 at the latest. The DAR logo currently used by the accredited bodies in combination with the registration number of the DAR may also be used up to that time (on certificates it can be used in combination with the registration number until 2017).

Mr Egner introduced the quality management system of the DAkkS and the internal processes as well as the operational processes during accreditation. In principle it must be said that the processes continue to conform to ISO/IEC 17011 and will not be changed basically. The application form for accreditation can already be downloaded from the DAkkS homepage. Its design has been slightly modified, since with this application an administrative act is initiated. As a result of accreditation, a notification on the accreditation is given; but at the same time, an accreditation certificate is issued, as the accreditation bodies so far have been used to it.

Dr Dudek reported on the international representation and the processes how to determine rules and regulations, which in the future will be developed by the new accreditation body DAkkS. Pursuant to §5 AkkStelleG, an Accreditation Advisory Board (AKB) will be set up to advise the Federal Ministry of Economics and Technology (BMW) and the DAkkS on accreditation related issues. The Secretariat of this AKB will be located at the BAM. Its task is to identify general and sectoral rules for specifying accreditation and conformity assessment activities, in particular those from legislation.

The AKB will promote accreditation as a confidence building element of conformity assessment as well as coordinate the German representation at EA.

The DAkKS will be granted the status of an EA MLA signatory. The first evaluation of the DAkKS will be completed by EA

in summer 2010. An initial evaluation visit took place already in January 2010.

The **discussions** showed clearly that in future lots of questions need to be clarified in detail. However, the fundamental rules for on-site assessment and accreditation will not change substantially. The accredited bodies will continue

to come across well-known accreditation procedures. Significant synergies are expected from a good cooperation between the DAkKS and the power-conferring authorities and departments, so that in future accreditations granted by the DAkKS may be recognised and accepted by all authorities.

BAM S.2—M. Wloka

DIARY:

Next EA GA:

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

Miscellaneous:

- 19—23 April 2010—CAFMET—3rd International Metrology Conference, Cairo, Egypt
- 27—28 April 2010—New training course „Use of reference materials and the estimation of measurement uncertainty“, IRMM
- 6—8 September 2010, 9th MS-Symposium and 22nd ICPMS meeting of users, (Eurolab-D)
- 16 April 2010 Colloquium Eurolab-D, BAM, Berlin, Germany

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The new standards ISO/IEC 17021 and ISO/IEC 17065 and foreseeable impacts on EC conformity assessment procedures

In 2009, the international standards ISO/IEC 17021:2006 (Conformity assessment - Requirements for bodies providing auditing and certification of management systems), ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories), and ISO/IEC 17020 (General criteria for the operation of various types of bodies performing inspection) were adopted and published as European harmonised standards.

The ISO/IEC 17021: 2006 standard is currently being revised and completed by adding Part 2. The ISO/IEC 17065 standard, which is a revision of EN 45011 (General requirements for bodies operating product certification systems), is still available as CD1: 2009; a final version is expected to be issued in 2010/2011.

After the first experiences with the application of ISO/IEC 17025, ISO/IEC 17021 and ISO/IEC 17020 in the mandatory (regulated) area, there are presently active discussions on which extent to apply these standards in practice to individual modules in the EC conformity assessment procedures.

Currently, the following picture emerges that is supported by the work of and relevant decisions taken by notified bodies, e.g. in explosion protection (Directive 94/9/EC, ATEX).

For product testing in the context of the EC conformity assessment procedures (Modules B, G, partly also Modules C and F), the ISO/IEC 17025 standard is applied.

According to experience, for Module H, the ISO/IEC 17021 is still intended to be used in the whole extent of its requirements.

For assessing quality management systems or parts thereof in the context of Modules D and E it may be expected that ISO/IEC 17021 is applied appropriately. Existing complete ISO 9001 certifications as well as procedures related to further directives should be considered. It would be preferable if notified bodies will be given the opportunity to take a decision on their own authority, whether or not after the initial certification and the first surveillance in the following year also flexible surveillance periods might be considered for the respective companies depending on their depth of production and manufacturing scale and on the scope of additional certifications. Provided of course that during the first surveillance no serious nonconformities were found.

Flexibility in this case can also mean: tightened, in case reason therefor is given.

Even now in explosion protection it is practised for notified bodies that Type A-Manufacturers (with a certified ISO 9001 system) are subject to surveillance every 18 months and Type B-Manufacturers (without any certified ISO 9001 system) every 12 months. This is substantiated by Guidelines and so-called Clarification Sheets adopted by all European notified bodies and applied in the context of a unified European approach.

In testing, inspection or QM related surveillance visits complementing product certification, the new draft CD ISO/IEC 17065 points out that the standards ISO/IEC 17025, ISO/IEC 17020 or ISO/IEC 17021 may be applied to an appropriate extent under the responsibility of the executing bodies.

In the future, both for the mandatory (regulated) and the voluntary (private) areas a consistent approach is expected to be applied which also accommodates the interest of the market.

BAM S.1-R.Schmidt / BAM S.2-N.Bendix