

What may we expect after 1st January 2010?

Which changes will be caused to the accredited bodies in Germany after the EU Regulation on Accreditation and Market Surveillance has come into force?

In the last issue 2/2008 of DAR-aktuell we covered the approval of the EU Regulation N°. 765/2008 of the European Parliament and of the Council Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products.

In this Regulation reference was also made to the essential elements relating to the changes of the requirements for accreditation and the consequences for Germany.

What does this mean for the accredited bodies in Germany?

We were hoping that we would be able to present to our readers a concrete draft of a Law on Accreditation for Germany. At present, intensive work on this Law is yet being done in the Federal Government to find a solution acceptable to all parties concerned.

However, Germany also aims to comply with the EU Regulation and to establish a single national accreditation body in the future that would be operative from 2010.

At its 48th meeting held on 8th December 2008, the German Accreditation Council intensively dealt with potential consequences of a legal regulation with respect to the further work of the DAR and to the bodies accredited within the DAR system as to the new developments.

The DAR members agreed that the introduction of the new Law shall not lead to any changes relating to the technical assessment of the accredited bodies in Germany.

The political intention is to avoid any additional efforts by the accredited bodies in maintaining their accreditation or in gaining new accreditation caused by this new Law.

At its 48th meeting, the DAR discussed a list of tasks of the DAR and of the DAR Sekretariat to be transferred to the new system;

this list will be permanently updated and adapted to the recent developments.

As to ensure the regular surveillance visits, all accreditations granted prior to 1st January 2010 shall be assumed by the new national accreditation body.

During the discussions on how to shape the transition, emphasis was placed on the continuance of the international recognition of the German accreditations, and that safeguarding this would be one of the first tasks of the new national accreditation body.

The accreditations with DAR certificate will remain in circulation at least until their validity expired. For this reason, the DAR deliberated on how to guarantee these certificates. The DAR will continue to ensure the surveillance of the DAR accreditation bodies.

All in all it can be stated that the persons involved watch the work of the German Government and await the draft of the Law on the national accreditation body.

A critical point which is still being discussed controversially and the parties concerned cannot agree on is the basic constitution of the future national accreditation body. Will a private body out of a merger from those accreditation bodies currently operating in the DAR be established and entrusted by the German Government? Or will a governmental body be founded, e. g. a new Federal Authority for Accreditation?

At any case, in compliance with the requirements of the EU Regulation the Government will ensure a high influence on the accreditation in Germany.

For the time being we have to await the issue and continue securing the accreditation as before.

BAM S.2—M. Wloka

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News from the DAR

1. Future Work of the DAR

The DAR is presently preparing the transition to the new national accreditation body which will be operative from 1st January 2010 at the latest in accordance with the EU Regulation. The interim arrangements required for this transition period are presently being coordinated. At its 48th meeting held on 8th December 2008, the DAR decided to update the list of those tasks of the DAR which have to be transferred to the new system as well as to adapt this list accordingly.

2. Amendments to the DAR Rules of Procedures

The DAR document DAR-3-EM-03 "Instructions for Use of the Accreditation Certificate of the German Accreditation Council" was updated and amended by the terms "Wound assistant and wound therapist" as well as "Call Centre Personnel" relevant for the area of certification of persons. The IAF MD documents MD1 to MD4 binding on all IAF MLA signatories will be translated into German language and will be included in the DAR Rules of Procedures as documents of recommending nature.

The German translation of EA-2/13 ("EA Cross Frontier Policy for Cooperation between EA Members") will be provided as information document (DAR-3-INF-02).

3. Surveillance / Evaluation of private DAR accreditation bodies

Pursuant to the DAR Rules, surveillance visits at the accreditation bodies operating under the DAR in the voluntary (private) area need to be performed within the surveillance period expiring in 2009. The DAR surveillance visits within the frame of the BAM Evaluation Procedure are now being prepared accordingly to take place in the second half of 2009. Any possible mergers are to be considered.

4. Technical Issues of Accreditation

The regulations on "Accreditation of Conformity Assessment Bodies with Several Locations" in DAR-3-EM-16 will not be changed until different valid decisions have been made by EA.

An ILAC Survey on the need for the revision of ILAC G3:1994 *Guidelines for Training Courses for Assessors* was distributed among the ILAC member accreditation bodies.

Information was provided that the DAR Tutors' Exchange of Experience is scheduled for 12th March 2009 at the BAM, Berlin.

A meeting of the ABT (DAR Committee for Training of Assessors) has been appointed for 13th March 2009 in order to initiate the revision of the DAR Modules of

the Framework Programme for Assessors in accordance with the EU Regulation N°. 765/2008; the meeting is to be held jointly with the accreditation bodies of Austria and Switzerland.

5. Information from Standardization and Standards Committees

Within the European standards organizations, the authorization of those standards being of significance for the new legal framework is being promoted. The conformity with the respective authorized standards shall cause a presumption of conformity with regard to the EU Regulation N°. 765/2008, however not with regard to the respective EU Directive itself. This is not to be mixed up with the requirements for products and services or for the manufacturers. A Task Force drawing up ISO/IEC 17065 was founded at CEN/CLC TC1; it shall elaborate the essential requirements to be included in order to authorize this standard in the future. A member of CEN/CLC TC1 will be sent to the respective ISO/CASCO standards committee.

Finally, it was pointed out that an inquiry about the need for revision of the standards ISO/IEC 17020 and ISO/IEC 17024 is to be expected in 2009.

BAM S.2 – F. Behrens

News from Standardization

The 24th Plenary Meeting of the ISO Council Committee on Conformity Assessment (ISO/CASCO) was held in Geneva, Switzerland, from 30th to 31st October 2008.

Standards Activities in the Field of Market Surveillance

In order to investigate the need and interest in international standards activities on market surveillance, a workshop on "Conformity assessment standards in support of market surveillance" took place prior to the CASCO Plenary Meeting. In the course of the workshop it became obvious that different countries and regions use very diverse approaches to market surveillance. In consideration of numerous existing regulations and documents, the majority of the participants spoke out against direct standards activities on market surveillance. However, it was noticed that interpretation documents on market surveillance could be quite helpful.

The ISO/CASCO Secretariat had drawn up a discussion paper that leaves open the standardization of a governmental market surveillance and market monitoring or provides for the preparation of a horizontal guideline containing general elements on market surveillance. This subject is expected to lead to further discussions in the respective ISO/CASCO Committees.

Liaison Organization

During the Plenary Meeting much attention was given to the discussion on the joint activities of ISO, IAF, and ILAC. An action plan on the review and improvement of the effectiveness of accredited management systems was developed but not yet exhaustively discussed. However, voices critical of ISO/CASCO dealing too much with the liaison of the organizations and that this would adversely affect the cooperation with the national standards organizations could also be heard.

The inclusion of the liaisons in the respective Committee shall therefore be discussed again at ISO/CASCO.

CASCO Technical Interface Group (TIG)

The TIG shall ensure the compatibility of ISO standards with the CASCO Toolbox. This also includes the exchange with ISO TCs and their support in matters of conformity assessment issues.

At first those projects dealing with conformity assessment were identified and surveyed. A summary of the respective projects shall be submitted at the next CASCO Plenary Meeting.

Information on the Status of Revision of Standards

WG 21 Certification of Management Systems (ISO/IEC CD 17021-2)

This Working Group debates whether to directly include Part 2 of ISO/IEC 17021 in the revision of this standard and not to finalize Part 2 as a separate standard.

WG 23 Common Elements

In 2008, the ISO PAS 17005 Management Systems was published, and the Working Group 23 was closed accordingly.

WG 27 ISO/IEC Guide 7 (ISO/IEC 17007)

The future ISO/IEC 17007 follows the principle fixed in the ISO/IEC Directives to clearly separate the requirements on the object of conformity assessment from the specifications of conformity assessment. The standard is expected to be published at the end of 2009.

WG 29 Product Certification

The drawing up of the future ISO/IEC 17065 is strongly focussed on the principles laid down in ISO/IEC 17021. Present discussions cover the impartiality of the certification body to be ensured by a special committee, another respective structure or suitable mechanisms.

The problem that the future standard may also cover the certification of processes which gives rise to the concerns of a possible mixture of processes and systems is still under discussion.

BAM S.2 – M. Wloka

News from EA

The 22nd EA General Assembly took place in Lisbon/Estoril, Portugal, from 18th to 19th November 2008.

Against the background of the new EU Regulations, the *EA Articles of Association* and the *EA Rules of Procedures* were scheduled to be adapted. Aims are among others the strengthening of the EA Executive Committee and the professionalization of EA. Both the EA members and the observers as well as Stakeholders were requested to provide their comments on the submitted changes of the „*Articles of Association*“ by the end of 2008. The changes were then included by the EA ExeCom in a revised draft which was re-distributed to the members after the meeting of the EA ExeCom in January 2009 for another commenting phase. The revised papers shall be adopted at the 23rd EA General Assembly in May 2009 - in due time prior to the commencement of the EU Regulation.

At the General Assembly it was decided to establish a new Horizontal Harmonization Committee (HHC) which shall address the following tasks:

- Harmonization and implementation of the new legal EU Regulations and of the ISO/IEC 17011 standard by the individual accreditation bodies. The ISO/IEC 17011 standard sets out the requirements for the competence of the accreditation bodies;

- Harmonization of general assessment practices in the field of the New Approach;
- Supervising and governing the network of “Persons in charge of Directives” who shall ensure within EA the know-how and the coordination for assigned directives, as well with the Commission.

Decision was taken on the preliminary Terms of Reference of the HHC, and Merih Malmqvist Nilson, SWEDAC, was elected chairwoman. The EA members are currently requested to nominate their representatives for the HHC.

The status quo of the work carried out in the Project Groups which had been founded to implement the EU Regulation on accreditation was presented. The document “*EA Guidance on the horizontal requirements for the assessment of Notified Bodies*” drawn up by **Project Group 1** (PG 1: “Harmonization of assessment practices”) was distributed to the members for comments by 12th December 2008. The paper afterwards consolidated by PG 1 will be submitted for comments to all parties concerned, such as the EA members, the Commission, SOGS, and others. Subsequently, this paper will be subject to the common EA voting procedure.

The proposal to establish a Network of Persons in charge of Directives made at the 21st EA GA by the **Project Group 2** (PG 2:

“Network for directives”) was implemented. The results of the query carried out among the member states and a proposal on how to proceed were introduced at the 22nd EA GA.

A recently completed benchmarking on the document developed by the **Project Group 3** (PG 3: “Communications with the national regulators”) is currently being analyzed by the EA Secretariat and the PG 3.

The **Project Group 4** (PG 4: “Communication processes of EA members with the bodies of the EC”) did not submit any updated report.

The document “Draft paper to EAAB on Peer Evaluation” drawn up by the **Project Group 5** (PG 5: “Enhancing the peer evaluation process”) on the basis of proposals made by the German representatives and others and introduced to the EAAB was accepted. The statements in this document shall also be included in the next revision of the EA document EA-2/02.

At the EA General Assembly there was discussion on the need for further involvement of the stakeholders, in particular in the technical work of EA, and for developing a tool to better serve the stakeholders’ interests. To this end, a discussion papers was submitted.

The merger of DATech and TGA was officially approved by the 22nd EA GA.

BAM S.2 – F. Behrens

News from ILAC and IAF

From 10th to 21st October 2008 the IAF and ILAC Committee meetings as well as the single and the joint General Assemblies of ILAC and IAF took place in Stockholm, Sweden.

Results from IAF

Acceptance of new members in IAF: **DA** Albania, **INDECOPI-TCRP** Peru, **ANSI** USA and **BoA** Vietnam.

IAF MLA members: At present there are 42 MLA signatories and 3 regions. Recently accepted members are **BoA** Vietnam (QMS), **TURKAK** Turkey (EMS and Product), **ANSI** America, and **CNAS** China (Product).

End User Advisory Group

As a result of the three Industry Days that took place in 2004, 2007, and 2008, the End User Advisory Group was founded; it will deal with the following topics:

- What users expect from accreditation;
- Credibility of accredited certificates;
- Expected outcome for accredited certificates of ISO 9001 and ISO 14001.

Technical Committee

The following projects were concluded:

- Multisite certification and sampling;
- Transfer of accredited certification;

- Advanced Surveillance and Re-assessment Procedure (ASRP);
- Validation of DIS ISO 9001;
- Workshop on Assessor Competence.

Currently, work is being carried out on two new projects:

- Task Force on the Application document on ISO/IEC 20000 (IT Service Management Standard);
- Task Force on the Development of a statement on ISO 9001:2008.

Two new Working Groups were established:

- Food Safety Management System;
- Greenhouse Gases.

Joint General Assemblies of ILAC and IAF

As to the joint future of both organizations, four options were suggested and discussed. A more effective cooperation is supported, and more effective forms are required. To this end, a Group was established that will explore possibilities of joint activities.



Numerous joint Committees and Working Groups are already in full operation, such as:

- Joint Arrangement Management Committee
- Joint Inspection Group
- Joint Marketing and Communication Committee
- Joint Working Group on A-Series (on evaluation procedure documents)
- Joint Working Group on Training
- Joint Working Group on ISO/IEC 17011.

BAM S.2—S. Stobbe

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DIARY:

Next EA GA:

- 27-28 May 2009, Luxembourg
- 25-26 November 2009, Belgium
- May/June 2010, Bern/Switzerland
- Autumn 2010, still to be fixed
- May/June 2011, Berlin/Germany

Next EA MAC meetings:

- 25-26 March 2009, Tirana, Albania

Next ILAC/IAF GAs:

- October 2009 Vancouver, Canada

Miscellaneous:

- 14th International Congress of Metrology; Added value through better measurement; 22-25 June 2009
- The Second International Proficiency Testing Conference, Sibiu, Romania, 16.-18. September 2009
- CAFMET—Metrology Forum, Benin, 26-30 October 2009

ISO/IEC 17043 Draft International Standard „Conformity Assessment - General Requirements for Proficiency Testing“ has been put to the vote

The evaluation of performance by means of participation in comparison tests is increasingly gaining importance particularly in the field of testing and calibration, as it represents an efficient tool to check and demonstrate quality of services in practice. The number of providers of such laboratory comparisons referred to as proficiency tests has been increased for years. As those evaluations need to be reliable it has become indispensable to formulate general quality criteria for providing proficiency testing schemes. Until now, various documents have been used for evaluating the providers' competence: ISO/IEC Guide 43-1, ISO/IEC 17025, and ISO/IEC 17020 as well as ILAC Guide 13. ISO/IEC 17043 "Conformity Assessment - General Requirements for Proficiency Testing" has now been drawn up as a new standard that extensively defines the requirements for proficiency testing schemes.

At the end of 2008, the revised ISO/IEC 17043 Draft International Standard (DIS) was sent to the ISO/IEC members for comments. At the same time, the German Institute for Standardization (DIN) has put the Draft to the vote, along with a first draft of the German version to be discussed in the Standards Committee NA 147-00-03 AA "Certification principles (principles of conformity assessment") during the next weeks.

The technical part of this Draft is based upon the principles of ISO/IEC Guide 43-1 and of ILAC Guide 13; furthermore, the organizational part takes the essential management requirements of ISO/IEC 17025 into consideration. The underlying documents were combined into one comprehensive requirement document which for the first time resembles a standard that covers both technical aspects for conducting proficiency testing schemes and requirements for an associated management system. This standard may be applied across sectors and accounts for various types of programme designs having particularly evolved in one sector or another. In the three informative Annexes, on the one hand various types of proficiency tests are introduced and on the other hand, prevalent statistical procedures for evaluating the performance of the participants and different ways of using the results from proficiency tests by third parties are explained.

Unlike ISO/IEC Guide 43-1 being a guideline, ISO/IEC 17043 now contains specific requirements for providers of proficiency testing schemes, such as for specifying procedures and for defining principles. The requirements are to be documented and may therefore be checked by third parties. Basically, this standard does not only defines requirements for providing proficiency testing schemes; it also provides essential instructions on how to design proficiency testing schemes. The personnel involved and the planning of programmes, the manufacturing of suitable test items as well as the acquisition and analysis of data received are addressed in this standard.

With this standard, the accreditation bodies are provided with an internationally valid normative basis that may be used for evaluating the general competence of proficiency test providers. To which extent the accreditation of bodies providing proficiency tests may be consistent with the requirement standard for accreditation bodies is currently being examined by ILAC on international level. The objective of this analysis necessary for preparing an international recognition is to avoid conflicts of interest that may arise if accreditation bodies provide proficiency tests as arranged for in ISO/IEC 17011 and at the same time accredit the providers of other proficiency tests.

BAM S.2 – G. Dudek

The Joint IAF-ILAC-ISO Communiqué on the requirements set out in ISO/IEC 17025:2005 in relation to management systems was adapted to ISO 9000:2008 and was re-signed in January 2009

A laboratory's fulfilment of the requirements of ISO/IEC 17025:2005 means the laboratory meets both the technical competence requirements and **management system requirements** that are necessary for it to consistently deliver technically valid test results and calibrations. The **management system requirements** in ISO/IEC 17025:2005 (Section 4) are written in language relevant to laboratory operations and meet the principles of ISO 9001:2008 **Quality Management Systems—Requirements** and are aligned with its pertinent requirements.