

## New Requirements for Accreditation Bodies

In this Issue

The EN ISO/IEC 17011 "Conformity Assessment - General Requirements for Bodies Accrediting Conformity Assessment Bodies" was published in Germany in February 2005 and replaces the EN 45003 (Accreditation of Laboratories), the EN 45010 (Accreditation of Certification Bodies) and the ISO/IEC TR 17010 (Accreditation of Inspection Bodies).

This standard lays down the requirements for accreditation bodies subjected to an evaluation process with the purpose of mutual recognition among accreditation bodies. It is the fundamental basis for the MLAs in the organisations EA, ILAC and IAF, also German accreditation bodies belong to.

These international organisations decided that accreditation bodies having signed the MLAs shall demonstrate in a self-declaration the implementation of the ISO/IEC 17011 towards their regional groups until 01 January 2006. For German accreditation bodies this is the Regional Group EA. From the beginning of this year the ISO/IEC 17011 standard has been used as a basis for international evaluations.

At its last meeting the DAR decided to include the EN ISO/IEC 17011 in its list of binding documents. It was decided that the DAR accreditation bodies operating in the voluntary area have to implement this standard by 01 January 2006. Evaluations in the DAR have been carried according to the EN ISO/IEC 17011 already in 2005. However, in line with the international practice, the accreditation bodies need to have eliminated nonconformities according to this standard only by 01 January 2006.

As well in the mandatory area, the implementation of the standard has been prepared. A KOGB ad hoc group elaborated a checklist that will be used for a self-assessment.

### What is new in the 17011?

In particular the requirements for assessment and the performance of the accreditation procedures correspond to the common practice, so that the known accreditation procedure will not be changed for the accredited bodies.

Instead of this, more emphasis as in the previous standards was placed on the requirement for impartiality of the accreditation body, for the organisation and for the quality management system of the accreditation body.

The standard clearly states on impartiality that an accreditation body must not provide any services that are performed by other conformity assessment bodies.

The meaning of this regulation is to clearly distinguish between accreditation and other conformity assessment activities to ensure that the accreditation body is in no way in competition with conformity assessment bodies.

The requirements for the personnel - be it the directly employed personnel of the accreditation body, be it the assessors or experts involved in the accreditation process, or be it the committees of the accreditation body - are much more clearly described.

### Changes in the USA

On international scale, this relatively clear and rigorous regulation on impartiality requires a number of accreditation bodies to revise their activities. In the course of the evaluations performed in the last year by EA, ILAC or IAF these activities have already been analysed.

As a result of this regulation, e.g. the American accreditation body ANSI-RAB NAP operating accreditation of certification bodies for quality and environmental management systems—which in addition to its accreditation activities was also performing certifications of auditors— has re-organised. From the beginning of this year, ANSI-RAB NAP divided into two separate organisations. RAB will continue to provide the certification of auditors as a certification body. ANAB (ANSI-ASQ National Accreditation Board) will in future operate as an accreditation body that will operate independently from RAB.

In this way, this accreditation body located in the USA has fulfilled a requirement resulting from the evaluation, in order to further being a successful signatory of the Multilateral Arrangement of IAF.

BAM S.4 - Dr. M. Wloka

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## News from International Organisations

### Report about the 15th EA General Assembly, Helsinki, 08 to 09 June 2005

1. As the new Chairman Lorenzo Thione (SINCERT, Italy) was elected and Vice-Chairman Graham Talbot (UKAS, Great Britain) respectively. They will take office on 01 January 2006. As Committee Chairs the following persons were elected: Gro Rødland / Norway (Multilateral Agreement Committee MAC), Tom Dempsey / Ireland (Communications and Publications Committee CPC), Hanspeter Ischi / Switzerland (Laboratory Committee LC), Merih Malmqvist / Sweden (Inspection Committee IC), Norbert Müller / Austria (Certification Committee CC). Rosza Ring / Hungary was elected representative of the joining countries in the Executive Committee.
2. The following recognition arrangements (Memorandum of Understanding/MoUs) were signed or are in preparation:
  - An MoU between EA and EUROMET was signed.

- An MoU with IRMM is still under revision and will soon be signed. The IRMM plans to organise interlaboratory comparisons and provide free of charge training for EA members and national accreditation bodies in the field of "Metrology in Chemistry".
  - An MoU shall be signed between EA and EUREPGAP. An electronic voting will be performed after 30 June 2005.
  - An MoU between OMCL/EDQM and EA will be signed. It is planned to use OMCL documents and those of its assessors.
3. After publication of the revised ISO/IEC 17025 its date of implementation will be fixed for May 2007. The fulfilment of the new requirements will be confirmed within the frame of due surveillance visits or re-accreditations. In urgent cases, the conformity by a document can be confirmed to a laboratory.

4. The General Assembly decided to extend its Cross Frontier Policy regarding accreditation of certification bodies also to EMS and product certification. IAF will be asked to adopt this decision.
5. EA supports the resolutions of the General Assemblies of ILAC and IAF to establish a joint ILAC-IAF Arrangement Management Committee.
6. The proposal to establish a joint ILAC-IAF Publication Committee essentially based on the regional Publication Committees will be supported by the EA General Assembly.
7. A new EA Financial Oversight Committee comprising of three members (Jiri Ruzicka, Jan van der Poel, John Mat-sas) will be founded.
8. The joint ILAC-IAF Committee for Inspections shall align the different positions of APLAC and EA with regard to the number of witness audits in inspections.

BAM S.4 - S. Stobbe

### Joint Workshop of Euro-lab-D and DAR on "Measurement Uncertainty - What for and How?" held at BAM, Berlin, on 29th June 2005

On 29 June 2005 a Workshop on the topic "Measurement Uncertainty - What for and How?" jointly initiated by Euro-lab-D and DAR took place at the BAM. The aim of this Workshop was to establish working groups on measurement uncertainty in some selected technical fields. They should provide possibilities to enable a continuous exchange of experience on the topic measurement uncertainty that provides method solutions and support in trouble shooting. The working groups may also be developed into an effective tool for maintenance of exchange of experience, if required. The high number of 120 participants in this Workshop coming both from industry and smaller testing laboratories as well as universities, authorities and other scientific institutions demonstrates that this idea encountered lively interest.

As the beginning of the event, Mr. Koch (Institut für Siedlungswasserbau, Wassergüte- und Abfallwirtschaft at the University of Stuttgart) pointed out that the basic benefit of measurement uncertainty—to establish more confidence and to increase the capacity of the results of measurements—can best be met, if the measurement is properly interpreted and not misused for purposes of competition. He furthermore revealed that the evaluation of measurement uncertainty in keeping limits is always associated with a risk evaluation.

The legislator often did not sufficiently regulated how to handle the measurement uncertainty in evaluating the compliance with limits.

Considering the example of steel wire fabric, Dr. Hinrichs (Materialprüfungsanstalt für das Bauwesen / Technical University of Braunschweig) made clear that sometimes intensive efforts are necessary to identify and quantify the main sources of measurement uncertainty and therewith to estimate risk components.

The main part of the event was characterised by the work of seven different working groups from the following technical fields:

1. General issues of determination of measurement uncertainty
2. Chemical analysis
3. Mechanical-technological testing / Physical measurement
4. Building physics
5. Microbiology
6. Electrical engineering
7. Food chemistry

The work in the different working groups proceeded in different ways depending on the technical field—from solving precise problems up to discussing horizontal issues on measurement uncertainty and the legislator's regulations. The results achieved in the working groups were manifold - depending upon the field and the state of knowledge. In some fields, such as microbiology and food chemistry, the work of the working groups was directly taken up and a further specific approach was coordinated.



Numerous participants interested in the Workshop

Other fields (e.g. chemical analysis) showed less need for continuous working groups' activities. Last but not least a noticeable need for events for newcomers dealing with these issues became apparent.

After discussing the future working groups' work, Dr. Sommer (LMET Thuringia) reported about latest developments on the determination of measurement uncertainty and in particular addressed the enhancement of the GUM (Guide on the Expression of Uncertainty in Measurement).

The participants' feedback regarding the Workshop was positive, even though not all questions could be clarified exhaustively and not all expectations were satisfactorily met. The aim of the Workshop—to determine the need for working groups and, where required, the establishment of platforms—was reached. The starting signal to commence with the working groups' activities was initiated. It is to be hoped that this work will prove to be successful and provide practical assistance in estimating the measurement uncertainty. Euro-lab-D will actively support the working groups' activities.

BAM S.4 - Dr. G. Wermann

# Developments in Accreditation in the EU Commission

The enhancement of accreditation as well as stronger implementation in different spheres of European Legislation has been described in detail in the series of latest SOGS documents, among others in N514, N515 and N516. The main issues of these documents are as follows:

## **SOGS N514 - Role of Accreditation in Recognition of Notified Bodies**

The purpose of this document is to define the role of accreditation in designating the notified bodies and proposes steps and measures that enable the approximation of notification procedures. At the same time, acceptance by the authorities of certificates and test reports covered by the EA MLAs (Multilateral Agreements on Recognition) shall be supported. The considerations and proposals of the European Commission on the role of accreditation in the recognition process are presented. The following key topics are decisive:

### **Definition/Scope of European Legislative:**

In addition to the corresponding standards of the standards series EN 45000 / EN ISO/IEC 17000 with the general requirements specified therein, the accreditation should also include evaluation of the technical competence in terms of the guidelines/regulations.

### **Supposed effects of the standards series EN 45000/ EN ISO/IEC 17000:**

To legally protect the conformity presumption, the European Committee intends to issue a standards mandate with which the European standards organisations are requested to provide a series of standards for the assessment of notified bodies with a direct relation to the standards series EN 45000 / EN ISO/IEC 17000.

### **Transparency / Consistency:**

Signing the EA MLA Arrangements does not only guarantee the consistent use of the standards series EN 45000/ EN ISO/IEC 17000 by accreditation bodies, but also the mutual evaluation with regard to the continuity of the preconditions for signing the arrangements.

### **Importance of Accreditation / Equivalence:**

Within the frame of the recognition procedures, the national authorities need not necessarily revert to accreditation. If the competence is evaluated in another way, the equivalence of these methods with accreditation needs to be demonstrated and made known appropriately.

### **Strengthening the Role of Accreditation:**

Independence and technical knowledge of the accreditation bodies with regard to their operational activities shall be more expressed in future (e.g. technical experiences of experts/assessors, sufficient professional training, competence in evaluating the PT results or similar comparisons between laboratories, witness audits, etc.).

The general requirements laid down in the standards series EN 45000 / EN ISO/IEC 17000 should not be amended by documents interpreting guidelines.

## **SOGS N515 - European Infrastructure for Accreditation**

Accreditation as a tool of services was developed in the member states in the seventies to enable deliberating about the competence of various conformity assessment bodies. This document outlines the necessity of strengthening the role of accreditation in the context of the revised New Approach and therefore proposes to establish a clear legal frame for a European infrastructure for accreditation, in particular in the following items:

### **I. New Position of EA**

EA should be awarded a clear position in Europe similar to that of an authority.

#### **Legal basis:**

It is proposed both to the national accreditation bodies and the EA to establish and publish a legal basis which regulates:

- that the national authorities are responsible for the accreditation bodies to ensure that they will act in case of a possible malpractice of the accreditation bodies,
- that the accreditation bodies have the necessary freedom of action to implement the corrective action,
- that EA is entitled to derive obliging results from the peer assessments.

If necessary, EA would then report to the Group of Senior Officials for Standardisation and Conformity Assessment (SOGS) about its work and in particular about the functioning of the system of peer assessment.

## **II. Structural Enhancements in the EA**

It is proposed to establish within the EA structure a "Committee of Authorities" that comprises of representatives of national authorities and examines necessities for implementing guidelines.

In general matters relating to accreditation and conformity assessment the EA should be given the opportunity to actively participate in the SOGS meetings.

The Commission could develop a general agreement with the EA which forms the legal basis to mandate the EA to be enabled to execute certain services and activities supporting the implantation of EU policy instruments and promoting the role of accreditation in Europe.

## **III. Mission of the EA**

The mandate to the EA has been outlined in this document as follows: First priority task of the EA is to promote with its work as a European organisation transparent and quality oriented services in the field of conformity assessment in the entire European Union and the EFTA member states.

To foster this, the EU

- organises a stringent, transparent system of peer assessment to ensure an equivalent level of competence of its member states and to strengthen the acceptance of the results of conformity assessments reached by its accredited bodies;
- promotes consistent and coherent interpretation and implementation of accreditation-related standards and develops, if necessary, additional guidance papers, in case a need based on the policy on sectoral schemes was formally established.

The EA member states inform the EA and the Commission which sectoral schemes they perform and which they intend to implement.

The EA is mandated by the Commission to support the implementation of EU policy instruments.

Moreover, the Commission provides to the EA the possibility to actively participate in the various sectoral working groups responsible for the development and implementation of guidelines, as far as accreditation related issues are concerned.

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Editor: Dr. M. Wloka  
DAR  
German Accreditation  
Council  
c/o BAM, S.4  
Unter den Eichen 87  
DE-12205 Berlin  
GERMANY

Phone: ++49-30-8104 1942  
Fax: ++49-30-8104 1947  
E-Mail: [office@deutscher-akkreditierungsrat.org](mailto:office@deutscher-akkreditierungsrat.org)

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A participation of the EA in the various coordination meetings of the notified bodies should be envisaged, if issues on transparency and preconditions for accreditation in terms of the guidelines/directives are dealt with. On request of the Commission, the EA could handle technical issues or provide required experience, if decisions in the field of accreditation or notification give reason to discrepancies. This would also include cases associated with a hedge clause procedure.

On international level the EA should prepare for making a reliable and concerted European contribution to the international work in accreditation related matters, namely in international accreditation organisations such as ILAC or IAF, but also in ISO and IEC, if international standardisation in the field of accreditation is undertaken.

Furthermore, the Commission will check to what extent it can use the services of EA at international level for discussion with third countries or with international organisations or in implementing trade agreements with third countries, if questions related to quality and competence of conformity assessment bodies are in discussion.

### **SOGS N516 - Revision of the New Approach - Market Surveillance**

The document in its draft version defines the common frame for the market surveillance according to Chapter 9 of the SOGS N492 document (revision of the New Approach and of the overall concept). This frame includes three levels, namely:

- A) - "Essential elements" of a market surveillance systems,
- B) - Monitoring of the Community,
- C) - Cooperation of the Community (Administrative Authorities).

The Annex to this Document contains:

- A predraft of a guideline (Part 1) describing the planned market surveillance system in an interpreting description and
- Proposals for implementation (Part 2).

To realise an efficient market surveillance system, the Commission proposes (in Part 2 of the Annex) the following:

To A)

The Directives need to contain regulations binding the member states to establish a "System of Sanctions" with deterrent character. It is to be ensured that legal means are made available to the manufacturer against each measure taken. The Commission will examine the coherence and the equivalence of the national systems.

To B)

Simplification of data transfer regarding the national regulations on implementation by providing a standard file/record along with a standard form. This would allow to make available harmonised data on the national systems.

To C)

- The cooperation with the administrative authorities (General activities; Exchange of information: Database with several functions and sectors / CIRCA and RAPEX / Fraud; Consideration of casualties; Controls at the external frontiers; Role of the customs authorities / The VO 339/93 on the Control of Compliance of products imported from third countries with applicable regulations on product safety),
- Joint projects (Information campaign, programme for joint mutual visits, programme for common actions),
- Special consideration of the field of e-commerce.

The proposed documents are currently being discussed and will in future be included in corresponding binding EU documents.

*BAM S.4 - N. Bendix*

### **Miscellaneous:**

The EA Homepage has a new design and may be accessed via the known address [www.european-accrreditation.org](http://www.european-accrreditation.org)

### **DIARY:**

#### **EA GA**

17—18 November 2005, Rome

07—08 June 2006, Riga

18— 19 October 2006, Istanbul

June 2007, Sofia

#### **ILAC/IAF Conference, General Assemblies and Committee Meetings**

11—21 September 2005,  
Auckland / New Zealand