

The „New Approach“ celebrates its 20th birthday

On the occasion of this event, a conference will be held in the Charlemagne Conference Centre in Brussels on 30 November 2005 dedicated to the topic: „A case of better regulation at the service of the European Competitiveness“. For full particulars, please visit http://europa.eu.int/comm/enterprise/newapproach/index_en.htm

The issue to be agreed upon will be how free trade in Europe could be improved from different point of views.

As discussed in the last issue of DAR-aktuell, there are currently intensive discussions on the revision of the New Approach in the EU Commission and in the Senior Officials Group of Standards and Conformity Assessment (SOGS).

There are a lot of approaches under consideration, in particular discussions about new developments in accreditation in Europe. A new SOGS document [N524](#) outlines the accreditation policy in the European Community and the responsibilities and commitments of the European accreditation systems.

Pursuant to this paper, accreditation shall not only be understood as an activity of general economic interest, but rather as an action by order of the authorities. However, this does not mean that accreditations inevitably need to be conducted by an authority. Private bodies rather need to be enabled to conduct these activities on behalf of and supervised by the government.

Therefore the accreditation bodies' responsibility for the proper and competent operation is at any case left to the member state.

This paper furthermore states that no commercial competitiveness should develop among the accreditation bodies. From the point of view of the European Commission, these principles should also apply to all accreditation bodies operating in the voluntary area.

As already stated in previous papers, it is proposed to assign a central role to the EA (European Cooperation of Accreditation) by the EU Commission or the SOGS respectively.

Special importance shall be attached to the Peer Evaluation System and the EA MLA. All accreditation systems and notified bodies shall demonstrate their competence by Peer Evaluation — an equivalent approach in Europe.

The various documents in connection with the revision of the New Approach are currently under intensive discussion by all parties concerned in Germany. The BMWa (German Federal Ministry of Economics and Labour) has established a group of consultants having three working groups:

1. Modules
2. Notified bodies, nomination, accreditation and infrastructure of the European accreditation
3. Market surveillance, CE marking, declaration of conformity and hedge clause procedure

The DAR supports the necessity to establish consistent requirements for notified and notifying bodies in Europe. A Commission Committee shall determine whether the relevant ISO standards meet the specifications. In case of a positive decision, the standards shall receive the status of mandated standards.

An appropriate decision of the Council is expected to be prepared by June 2006. The Commission wants to accentuate the accreditation as the preferential way of confirmation of competence. However, it allows for alternative ways, whereas the proof of equality has to be supplied by the respective bodies.

In Germany, a proposal for requirements for notified bodies that could be a possible draft for a normative document is currently being developed.

Hopefully, the whole discussion in the EU Commission will simplify the scene of conformity assessment and accreditation and will make sure that conformity assessment in Europe will become comparable and executed competently.

BAM S.4 - M. Wloka

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News from the DAR

Information from the 42nd DAR meeting, 07th September 2005

- 1. Study on accreditation:** The German Federal Ministry for Economics and Labour (BMWA) has finished the compilation of all modules composing the study „Consequences of reorganizing the German accreditation and recognition system“. The overall summary (<http://www.dar.bam.de/pdf/gesamtzusammenfassung.pdf>) may be retrieved from the DAR homepage. It is, however, available only in German language.
- 2. Developments on accreditation in the EU Commission:**

A detailed report was provided on the developments in the EU Commission and the current discussion in the SOGS. The DAR strictly appreciated the considerations of the EU Commission and will actively take part in advancements through cooperation in the consultants circles in the BMWA and in influencing further developments in the EA.
- 3. Law on accreditation:** The draft law on accreditation has been revised after discussing it in the federal departments; it is currently being harmonized in the BMWA and the subordinated authorities. Due to the present forming of the German government, the original time schedule is currently suspending.
- 4. Renaming of RegTP:** Since 13 July 2005 the RegTP (Regulatory Authority for Telecommunications and Posts) bears a new name (basis: Law on reorganization of the law on energy industry, Federal Law Gazette 2005 Part I N°. 42, p. 1970 ff.) - „Federal Network Agency for Electricity, Gas, Telecommunications, Posts and Railways“ (short term:

Bundesnetzagentur). The tasks of this Authority were extended accordingly.

- 5. Checklist on ISO/IEC 17011:** An ad hoc Group of the KOGB (Coordination Group of the Mandatory Area) has developed a Checklist with the requirements of the ISO/IEC 17011, which was submitted to and endorsed by the DAR. It may be retrieved from the DAR Homepage (see DOCUMENTS) as DAR-3-EM-22 (available only in German language). This Checklist will be used for the self-assessment of the accreditation bodies or during the evaluation by the accreditation bodies of the DAR for checking compliance of the binding DAR rules.
- 6. Evaluation of the DAR accreditation bodies operating in the voluntary area:** The DAR decided that until 31 March 2006 all evaluations of the DAR accreditation bodies operating in the voluntary area have to be finished. Bodies evaluated until that date without any positive result will be excluded from the DAR.
- 7. Implementation of the ISO/IEC 17025 in the laboratories:** On proposal of the ATF (Committee on Technical Issues) the DAR decided that laboratories accredited under the umbrella of the DAR need to comply with all requirements of the ISO/IEC 17025:2005 until 15 May 2007.
- 8. Revision of DAR documents:** The revised documents DAR-3-EM-06 (Qualification requirements for assessors) and DAR-3-EM-07 (Framework program for training of assessors) have been revised considering the revised standards. DAR-3-EM-09 (Procedure for selection and appointment of assessors) has been withdrawn.

DAR-4-INF-08 (Requirements for testing laboratories and accreditation bodies in terms of estimation of measurement uncertainty according to ISO/IEC 17025) has been revised and endorsed by the DAR.

- 9. DAR Policy on accreditation of providers of proficiency tests (PT) and producers of reference materials (RM):** The conditions under which PT providers and RM producers may be accredited are currently under intensive discussion in the DAR.

The DAR Committee ATF submitted a proposal to the DAR: As discussed with the international organisations EA and ILAC, RM producers will only be accredited, if they are laboratories having the required competence. They will be accredited according to ISO/IEC 17025 in combination with ISO Guide 34.

It is furthermore proposed to accredit PT providers only if they are either a testing laboratory (accreditation according to ISO/IEC 17025 including ISO Guide 43-1 and ILAC G13:2000) or an inspection body (accreditation to ISO/IEC 17020 also including ISO Guide 43-1 and ILAC G13:2000).

It shall be established that accreditation bodies accrediting PT providers do not perform proficiency tests. The discussion on this issue has not been finalized.

- 10. The standard EN ISO/IEC 17025:2005** will be included in the list of binding DAR documents.

BAM S.4 - S. Stobbe

Information from Standardization

NQSZ-3

On its 30th meeting held at 27th October 2005, the NQSZ-3 prepared the ISO/CASCO General Assembly (in November 2005).

It was decided to refuse the draft prISO/IEC 17021 „General requirements for bodies operating assessment and certification/registration of quality or environmental management systems“, as the 2nd option on designing the quality management system (obligatory requirements for complying with ISO 9001) are currently not supported, as it is — similar to other standards of conformity assessment — more focused on describing the management system and ISO 9001 should only be mentioned in a note (as required in the approved ANSI Appeal). Furthermore, it is planned to adapt the standard to the new developments in the EU Commission to enable them to be mandated.

The international harmonization in ISO

resulted in an acceptance of the Draft 17021.

NQSZ-3 did not agree to develop a second part of the 17021 in which requirements for „third party“ auditors would be laid down. In contrast, DIN will propose also to revise ISO 19011, if necessary. In this ISO/CASCO General Assembly it was decided to prepare a New Item Proposal on this 2nd part.

DIN Notes 10-2005

The DIN Notes (DIN-Mitteilungen) 10-2005 contain a series of contributions on standards on conformity assessment:

- Standards of the series EN ISO/IEC 17000 (general presentation of the series), p. 16-19
- EN ISO/IEC 17000 Conformity assessment — Vocabulary and general principles, p. 21-22
- EN ISO/IEC 17011 Conformity assessment — General requirements for

bodies accrediting conformity assessment bodies, p. 23-25

- Inspection bodies to EN ISO/IEC 17020 Requirements, tasks and activities, p. 26-29
- EN ISO/IEC 17021 The certification of management systems — Requirements for certification bodies, p. 30-31
- EN ISO/IEC 17024 Certification of persons — a module in global trade, p. 32-35
- EN ISO/IEC 17025 Requirements for the competence of testing and calibration laboratories, p. 37-40
- EN ISO/IEC 17040 Peer Assessment, p. 41-42
- EN ISO/IEC 17050, Part 1 and 2, Conformity assessment of suppliers, p. 43-45

BAM S.4 — M. Wloka

Joint ILAC-IAF General Assembly (GA), Committee Meetings, Auckland, New Zealand, September 2005

Joint ILAC/IAF General Assembly, 18th September 2005

Results:

1. One main result of the Joint ILAC/IAF General Assembly was to discuss and deal in future with joint resolutions in the Joint GA in order to prevent the organisations from drifting apart. The Joint Committee on Closer Cooperation (JCCC) and the ExeComs of ILAC and IAF will prepare the necessary steps for the next General Assembly.
2. International organisations cooperating with ILAC and IAF were presented and their results of cooperation introduced. The IEC/CAB (Conformity Assessment Board) has established three Schemes: **IECEE**—IEC System for Conformity Testing and Certification of Electrical Equipment, **IECEX**—IEC Scheme for Certification to Standards relating to Equipment for Use in Explosive Atmospheres, **IECQ**—IEC Quality Assessment System for Electrical Components. An MoU with ILAC was signed on 05 February 2005. Numerous joint assessments have already been conducted by these organisations and ILAC and further are planned to be performed in future.
3. The WTO (World Trade Organization) published at its Website the Annual Report that also reflects the views of the WTO on conformity assessment and accreditation (see http://www.wto.org/english/res_e/reser_e/annual_report_e.htm).
4. New Terms of Reference for the Joint Committee on Closer Cooperation (JCCC) as well as an Agreement for Closer Cooperation between ILAC and IAF were elaborated.
5. The Joint Working Group on Inspection has completed its work on the joint guidance on application of ISO/IEC 17020 that was published as a joint document A4 which was implemented on 01 January 2005. After clarifying some open technical issues, an MRA/MLA for the accreditation of inspection bodies will be initiated.
6. The Joint Developing Support Committee has realized the special needs of the developing countries. They need proficiency tests and for this reason more and more use EPTIS. They are interested to implement the Cross Frontier Policy as well as to have special training courses performed.
7. The documents A1, A2 and A3 developed by the Joint Working Group on Maintenance of A-Series Documents describe the requirements for the evaluation procedure in ILAC and IAF. The work in this Group led to successful joint evaluations (two regional groups, four accreditation bodies).

8. In future, training activities for evaluators will be jointly organized. New Terms of Reference were adopted.

9. The Joint WG on Guidance on 17011 prepared a Draft which is currently under revision.

ILAC General Assembly, 18th and 19th September 2005

Results:

The results of the ILAC GA are reflected in the resolutions adopted at the GA. In the following a few extracts:

1. The A-Series Documents A1, A2, A3 have to be revised in terms of ISO/IEC 17011 and to be implemented on 01 January 2006.
2. In terms of accreditation of providers of proficiency tests, a soon revision of ISO/IEC Guide 43 (Parts 1 and 2) and its transformation in a standard are requested. A consensus among the European providers of proficiency tests in terms of accreditation should be reached.
3. The rules on application of the ILAC MRA mark should be modified in order to allow the sublicensees to use the combined MRA mark on calibration certificates and test reports, on letterheads, in vacancies, advertisements, on websites and in other documents. There is no need to change existing sublicense contracts of the accreditation bodies.
4. To simplify the decision-making process, the work of the MLA Management Groups (IAF MLA MC and ILAC AMC as well as IAF MLA Group and ILAC Arrangement Council) shall be arranged in future in close cooperation.
5. An MLA text for inspection is in preparation. It is planned to conclude an MLA only after EA and APLAC have agreed upon the witnessing.
6. The accreditation of producers of reference materials according to ISO Guide 34 in combination with ISO/IEC 17025 shall be included in the existing ILAC MLA as soon as appropriate rules have been developed and agreed in ILAC.
7. The contents of the documents ILAC P9 (Policy for Participation in National and International Proficiency Testing Activities) and ILAC G21 (Cross Frontier Accreditation Policy) shall be incorporated into the QM documentation of an accreditation body until 31st March 2006.
8. The EA GA confirmed a transition period of 2 years (1st June 2007) for implementing the ISO/IEC 17025:2005.

IAF General Assembly and Meetings of the MLA Committees and their Subgroups 11th to 19th September 2005

Results:

1. New accreditation bodies as members of IAF are the following: INN/Chile and OLAS/Luxembourg), new associated member became IPC (former IATCA) as well as two observers (WFSO World Food Safety Organization and EASC Euro-Asian Council for Standardization, Metrology and Certification). ITIC (Information Technology Industry Council) has finished its membership.
2. The following bodies joined the IAF MLA as new members: OAA/Argentina and PCA/Poland (both for QMS, EMS and product certification).
3. A joint evaluator workshop was successfully launched. The IAF Subcommittee on Evaluator Training will be closed and the members will partly transferred to the IAF ILAC Joint WG on Evaluator Training.
4. The A-Series documents A1, A2 and A3 have been a basis for the evaluation of accreditation bodies and regional groups for one year now. The existing P&P document was thoroughly shortened.
5. The IAF logo for the MLA was extended to the MLA for Products and EMS. A Task Group will clarify all open questions.
6. A survey on implementation of the Cross Frontier Policy was conducted among the MLA Signatories. The date until which all Critical Locations need to be assessed shall be fixed.
7. The Technical Committee (IAF TC) will continue to revise the guidances on application of ISO Guides 65 and 66.
8. A new guidance on application of ISO/IEC 17011, of ISO 19011 and a Guide on application of prISO/IEC 17021 are in preparation.
9. It was stated that Training Course Providers are no conformity assessment bodies and thus their recognition is no object of accreditation.
10. IAF will regularly publish a Newsletter.

Developing Countries Seminar, 21st September 2005

Results:

The main content of the Seminar was to discuss how accreditation bodies from developing countries may join the arrangements on mutual recognition of accreditations of ILAC and IAF.

UNIDO wants to clarify whether a Pre-Peer Evaluation would be possible for further accreditation bodies.

BAM S.4—M. Wloka

Imprint: Editor:
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November 2005

ISSN-1436-2082

Last-minute news:

News from the EA GA:

In connection with the revision of the New Approach, McMillan (EU COM) informed that the decision of the Council should be submitted as a draft in summer 2006 and approved in 2007 by the Council. A special resolution on accreditation is not planned to be taken. Accreditation is conducted under the aspect „Public Authority“, i.e. the national state takes the responsibility for accreditation and implementation of the corrective measures. Whether accreditation is characterized as „service in public interest“, „service in general economic interest“ or otherwise, competition within a member state among the accreditation bodies or the accreditation bodies and the customers must not take place. McMillan considers accreditation the precondition for a notification of the bodies. If a body should be notified without accreditation the EU COM will require in future the single demonstration of competence. The market surveillance is to be strengthened considerably. The ISO 17000 standards series shall be mandated as a package. The service for the conformity assessment bodies should be clearly improved by establishing sectors. This could also lead to a use of accreditation by industrial sectors which so far did not use this service.

DIARY:

Next EA GA:

June 2006, Riga, Latvia

June 2007, Sofia, Bulgaria

Next ILAC/IAF GAs:

November 2006, ema, Mexico

2007, NATA/JAS-ANZ, Australia

Further events:

Brussels, 30 November 2005,
20 Years New Approach

5th Eurachem Workshop "Proficiency Testing in Analytical Chemistry, Microbiology and Laboratory Medicine", Portorož, Slovenia, 25th to 27th September 2005

At the end of September 2005, 129 participants from 28 countries met in the resort Portorož at the Slovenian Adriatic Sea to discuss current developments with reference to proficiency testing or external quality assurance measures. The Workshop was organized by the Eurachem PT Working Group in cooperation with CITAC and EQALM. The participants came from all areas involved: organizers of proficiency tests, accreditation bodies, ministries and authorities as well as laboratories.



A half day training course on the practical implementation of measurement uncertainty in proficiency testing marked the beginning of the Workshop. After imparting theoretical principles as well as some practical exercises, the course participants could give themselves a trial in estimating the measurement uncertainty and learn how the appraisal of the own performance changes when considering the measurement uncertainty.

The actual Workshop took place on the two following days and was characterized by lecture, posters and syndicate work. The most technical aspects on the current practice were addressed and recent approaches introduced, such as the possibility of online handling of proficiency testing schemes. Cas Weykamp reported about experiences gained in the ERNDIM project - a European Network - which carries out external quality assurance measures in the field of medical diagnostics online (<http://www.erndimqa.nl>). Within two weeks already, the customer will be provided with the proficiency test results.

Steve Ellison introduced the recently revised IUPAC Protocol for proficiency testing in analytical chemistry ("International Harmonized Protocol for the Proficiency Testing of Analytical Chemistry Laboratories"). While the existing Protocol was more designed for organizing proficiency testing schemes, the new Protocol provides additional guidance on the interpretation of the results, both by the participant and the participant's customer. The fundamental ideas and principles of the previous Protocol have not been changed substantially.

The accreditation of PT scheme providers was a repeated object of discussion. Katherine Monnery reported about the experience of UKAS gained within the frame of a pilot study on accreditation of PT providers. As a result of this study, the guidance "Accreditation of Providers of Proficiency Testing Schemes for Laboratory Testing" was developed. Further six applicants are currently being examined.

Accreditation from the point of view of EQUALIS ("External Quality Assurance in Laboratory Medicine in Sweden") was explained more closely by Ulf Örnemark. EQUALIS organizes programmes on external quality assurance in cooperation with various institutions, in particular in Northern Europe. More than 50 of these programmes have been accredited in the meantime, since 2002 partly as flexible accreditation, whereby simplifying modifications between the surveillance visits may be made. In his lecture, he referred to a joint survey conducted by Eurachem and EQALM on accreditation in the field of laboratory medicine. The survey indicated that in the field of laboratory medicine there is a strong tendency to accredit the laboratories. 29% of the organisations having responded to the survey have been accredited. The majority of them has been accredited as testing or calibration laboratory (ISO/IEC 17025; ISO 15189). For the future, a considerable increase is expected.

The experiences from the COEPT Project finished in July 2005 on the comparability of proficiency testing schemes were introduced by Nick Boley. Based on the investigations in the fields of potable water, contaminated soil, milk powder and filter samples it could be demonstrated that there is a high consistency in the calculation and analysis of the programmes within the mentioned fields. As different criteria for passing the interlaboratory test were assumed, the participants' performance resulting from this was often not been assessed consistently.

The discussions in the working groups provided the opportunity to consider the topics raised in the lectures more exhaustively and thoroughly. Under the direction of a responsible person, special issues on proficiency tests were discussed. The organizers in particular paid attention to a balanced allocation of the groups. While at the first day much attention was paid to the accreditation of PT providers, the second day was rather dedicated to future prospects and challenges to PT schemes. The results reached by the syndicate work were presented to the whole auditorium. The event went along with a presentation of numerous posters which were followed up by various discussions during the breaks. Altogether, a high-level, sophisticated and successful event worthwhile for all parties concerned.

BAM S.4 - G. Wermann



**We wish all our readers
a Merry Christmas
and a
Peaceful New Year 2006**