

## *ISO/IEC 17025 approved – Transition arrangements for accredited laboratories*

The majority of the national ISO/IEC and CEN representatives has voted for ISO/IEC 17025 „General requirements for the competence of testing and calibration laboratories“. The ISO Secretariat has already issued the ISO/IEC 17025 standard. On its meeting in March 2000 CEN/CENELEC will decide on the publication of the EN ISO/IEC 17025 and the subsequent withdrawal of the EN 45001.

Extensive revision of the international standard for laboratory competence and requirements for quality system and technical preconditions took more than five years to complete. A special edition devoted to main changes and amendments of this standard was given in our 1999 September Issue of DAR-aktuell.

An ILAC Working Group started elaborating a „Guidance for accreditation to ISO/IEC 17025“, which shall be the basis to use this standard in the field of accreditation and to provide arrangements on the transition period, within which both standards (the old and the new one) will be valid.

As the Guidance Paper is still a Draft, which is under voting in ILAC for the next two months, it is not yet available on ILAC's Homepage (<http://www.ilac.org>).

All those who are interested in this Guidance, in particular accredited laboratories, may require this Paper from the DAR Secretariat ([dar@bam.de](mailto:dar@bam.de)),

taking into account that it is still a Draft which has to be endorsed.

The ILAC Guidance contains a table with cross-references, which allow a comparison between the chapters of the new Standard ISO/IEC 17025, the old Guide 25 and the EN 45001. It focuses on some explanations, such as subcontracting, internal audits, uncertainty of measurement, reports of results. Special notes are given in particular for accreditation bodies, so as to ensure a consistent application of the new ISO/IEC 17025, in particular in view of a successful conclusion of a MLA (Multilateral Agreement) within ILAC.

The transition period comprises the following arrangement: It is agreed among the accreditation bodies that preferably two years after publication of the ISO/IEC 17025 accredited laboratories shall comply with the requirements set out in this standard. It is a matter of course that contractual liabilities remain in effect, if no other provisions have been agreed. On its meeting held on 13.12.1999, the DAR-ATF (Committee for Technical Issues) discussed the transition arrangements and submitted them to the DAR to be endorsed on its meeting held on 09.03.2000. On the basis of these arrangements, the accreditation body will assess during the assessment visit following after the transitional period of two years, whether the accredited body meets the requirements of the new ISO/IEC 17025. The accredited laboratories will be informed about the arrangements by their accreditation bodies.

From the date of publication of ISO/IEC 17025 applicant laboratories are accredited according to the new standard.

New checklists are currently elaborated and assessors are trained according to the new requirements.

If you have any questions relating to the implementation of the ISO/IEC 17025, please refer trustfully to your accreditation body or to the DAR Secretariat ([dar@bam.de](mailto:dar@bam.de)). Under its Box NEWS the DAR Homepage (<http://www.dar.bam.de>) provides regular information on seminars and workshops on this topic.

M. Wloka, BAM-S.42

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## *The new ISO 9000:2000 standards under preparation; Communiqué on transition arrangements*

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Currently the Drafts on ISO 9001:2000 and ISO 9004:2000 are being discussed vehemently. Nevertheless, the international organisations EA and IAF are already determining future transition arrangements. This is due to the fact that some bodies could not wait until the publication of the new standards and wanted to certify or being certified according to the new Drafts.

Under the leadership of dr. Facklam, Managing Director of the TGA (Trägergemeinschaft für Akkreditierung GmbH, Association for Accreditation) and IAF Vice Chair, IAF initiated a joint session between ISO TC 176 and ISO CASCO, at which a Communiqué has been agreed upon that subsequently has been endorsed at the IAF General Assembly. This Communiqué can be downloaded from IAF's Homepage (<http://www.iaf.nu>).

The following arrangements that in particular concern accreditation bodies and accredited certification bodies have been reached:

1. Accredited certificates to the new ISO 9001 shall not be granted until the publication of ISO 9001:2000 as an International Standard (IS).
2. Certification/Registration body assessments to the latest draft of the new standard may begin prior to publication of the ISO 9001:2000 International Standard (IS).
3. Certificates issued to the 1994 editions of ISO 9001, ISO 9002 or ISO 9003 shall have a maximum validity of 3 years from the date of publication of ISO 9001:2000.
4. ISO 9001:2000 will require auditors and other relevant Certification/Registration Body personnel to demonstrate new competencies.

IAF member accreditation bodies will advise their accredited certification/registration bodies that

accreditation surveillance in the period following publication by ISO of ISO DIS 9001:2000 will concentrate on how the certification/registration body is managing the change within its certification/registration service. In particular, the surveillance will focus on the competence of the certification/registration body auditors and other relevant personnel with respect to the aspects of ISO DIS 9001:2000 that are different from those necessary to provide certification/registration to ISO 9001/2/3:1994. The accreditation body will assess the certification/registration body's program to ensure that its auditors and other relevant personnel demonstrate knowledge and understanding of:

- the eight Quality Management Principles on which the revised standards are based;
- the requirements of ISO 9001:2000 and;
- the concept and terminology of ISO 9000:2000.

5. Certification/Registration Bodies will need to take particular care in defining the scope of certificates issued to ISO 9001:2000, and the permissible exclusions to the requirements of that standard.

Replacement of the 1994 editions of ISO 9001, ISO 9002 and ISO 9003 with a single requirement standard (ISO 9001:2000) will necessitate the use of a very clear and concise description of the activities of an organisation that are included in the certification/registration process. Attention should be given to the requirement in the standard, which states that the organisation may only exclude quality system requirements that neither affect the organisation's ability, nor absolve it from its responsibility to provide product that meets both the customer requirements and applicable regulatory requirements.

The accreditation bodies inform their accredited quality system certification bodies through an agreed standard letter about the transitional arrangements.

*M. Wloka, BAM-S.42*

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## *News from international organisations*

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### **1. From IAF**

From 27.9. to 1.10.1999 the **13th IAF Plenary** took place in Vienna/Austria. Since 1999 IAF has been a legal entity registered in the US Federal State Delaware as IAF International Accreditation Forum, Inc.

A lot of documents dedicated to the future operation of IAF were discussed and afterwards sent with Letter Ballots for voting to the IAF Members. The documents included such topics as provisions on criteria for membership, complaints procedures, MLA Policies and Procedures, Terms of Reference and operation of

various Working Groups. New members were affiliated to the Multilateral Arrangement on Mutual Recognition (hereinafter called MLA): INMETRO (Brazil), PAC as well as member bodies both from the regional groups EA – BELCERT (Belgium), CAI (Czech Republic), and from PAC - CNAB (China), KAB (Korea), DSM (Malaysia) as well as SAC (Singapore).

To gain more experience, it has been agreed upon to test in practice the IAF Guidance on Application of ISO/IEC Guide 65 for another year. A recently established Task Force will deal with the current major

problem of alternative methods for accrediting certification bodies according to ISO 9001/2/3 (IAF/ISO TC 176 – ISO/CASCO - Communiqué on transition planning for ISO 9000:2000, see above article). Further Task Groups have been established with the aim to develop proposals how to state the IAF Guidance on ISO Guide 62 more precisely and to make it applicable to specific cases as well as to draw up a document for applying the ISO Guide 61 to regional groups. New MLAs are initiated only subject to the demands of the market.

An ad hoc-group will jointly discuss with ILAC representatives main features of a future common policy of both international organisations, in particular with regard to the future MLA (especially among regional groups).

## 2 | From ILAC

Proposals made at the 3<sup>rd</sup> ILAC Conference held in Rio de Janeiro/Brazil give evidence for the efforts to search for common solutions on technical issues. New full members were taken on board of the ILAC MLA: NAT (Hungarian Accreditation Board), National Accreditation Board for Testing and Calibration Laboratories (India) as well as ICBO Evaluation Service Inc. (USA). The Croatia Metrology Society is now a stakeholder of ILAC. The ILAC ExeCom will investigate the feasibility to transform ILAC into a *legal entity*.

For the time being ILAC has not yet concluded a Multilateral Arrangement, but elaborates numerous documents which make up future preconditions for concluding MLAs.

Dr. Mittmann (BAM/Germany) has been elected new Chairman of the Accreditation Policy Committee (APC).

The following Guidelines developed within ILAC-TAI (Committee for Technical Issues) have been endorsed:

- Guidelines for the use of accreditation body logos

and for claims of accreditation status

- Identifying and correcting abuses of accreditation status
- ILAC Guidelines for the requirements for the competence of Reference Materials Producers (provided that it will be revised after the approval of ISO-REMCO 34)
- ILAC Guidelines for the requirements of the competence of providers of proficiency testing schemes.

Further information can be found either on ILAC's Homepage at <http://www.ilac.org> or general information on ILAC in our Supplement to this Issue.

## 3 | From EA

At the EA General Assembly held in Athens from 23. to 25.11.1999 the following Guidelines have been endorsed:

- technical recommendations for calibration (Guidelines on the Calibration of Temperature Indicators and Simulators by Electrical Simulation and Measurement; Guidelines on the Calibration of Temperature Block Calibrators)
- Guidelines on the Application of EN 45012 for accreditation of Information Security Management Systems Certification Bodies
- Guidelines on Accreditation for EN 729 Welding
- Guidelines on transition arrangements for the accreditation of EMS certification bodies to ISO/IEC Guide 66.

New full members were affiliated: SMIS-SA (Slovenia) and RENAR (Romania). DZNM-NSO (Croatia) became associated member of EA.

Under its button *DATABASE* the EA Homepage provides a new service: links established to the databases or Directories of accredited bodies of the EA member states. This new service contributes to enlarge the information about EA's member countries and will hopefully find a broad practical application.

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## News from DAR


### Exploring DAR's accreditation Websites

The German Accreditation Council (DAR) hosts an informative Website at <http://www.dar.bam.de>, which is worth visiting at any case.

We would like to give you a deeper insight into all our information and services we provide and continually update for you. Please follow our excursion.

The main page contains our contact details and general information as well as *buttons*, via which you get more information on all aspects of interest.

**HOME** always leads you back to our main page.

Our Websites are available in German and English languages. The German version can be obtained by clicking on the German flag .

**NEWS** provides you with information on important seminars, conferences, workshops planned to be held on accreditation, certification, standardisation matters in Germany and other countries. If you wish to be placed at this site with information on general interest, we expect your comments.

Via **DAR-STRUCTURE** you reach the DAR organisational chart with the feasibility to directly contact the accreditation Websites of the accreditation bodies operating under the aegis of the DAR. Moreover, you

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can send from this point e-mail messages to the DAR Secretariat as well as to the DAR Governing Board.

**ACCR-BODIES** provides a survey of the accreditation bodies operating under the umbrella of the DAR. This site is subdivided into three categories: *Foreword*; *Addresses, Links and Brief Descriptions*; *Subjects*. *Foreword* presents an insight into historical aspects of accreditation in Germany as well as on tasks and objectives of the German accreditation system. *Description* allows to download PDF files describing all accreditation bodies currently existing. All details on the respective accreditation body you wish to contact or simply to be informed about are given here, such as contact point, date of establishment, accreditation program provided, fields of accreditation, cooperation aspects (e.g. on membership in other accreditation organisations or MLAs), organisational chart. *Subjects* leads to a detailed information on the accreditation program and the fields of accreditation of each individual accreditation body. For a more convenient searching, this site is categorised in "Accreditation bodies operating in the mandatory area", "Accreditation bodies operating in the voluntary area" and "Other accreditation bodies".

**DAR-AKTUELL** leads to the DAR Newsletter, available in German and English languages. DAR-aktuell reports about recent news and developments in accreditation, certification, standardisation in Germany, Europe and world-wide. All editions issued to date are listed here together with a table of contents for each edition. The Newsletter itself can be directly accessed/downloaded and is also given in PDF format. The Acrobat Reader is provided at the top of this site for those not having this program. Our readers who are on a distribution list are automatically informed about new editions to be downloaded from this site. For those not having Internet access the Newsletter is either sent attached to an e-mail message or per mail. If you wish to be informed regularly, you are invited to join our large group of readers.

**DATABASE** lists all databases currently run and updated at the DAR Secretariat, such as:

- database of accredited bodies (with the feasibility to perform full-text search, i.e. including the annexes to the certificate); Here you find links to the accredited bodies. To complete this survey, we very are grateful to be informed about missing links at any time.
- Lists of accredited bodies (partial search without annex to the certificate), listing according to subjects (technical fields / scope);
- Database of notified bodies (provided by the CEC), currently under preparation;
- EPTIS – a European Information System on Proficiency Testing Schemes (information on proficiency tests offered for testing laboratories in European countries) currently under preparation;

- List of EMAS environmental verifiers accredited in Germany (according to approval by the DAU GmbH).

All these databases can be accessed directly from this site.

If difficulties arise when performing a database search, please turn to our IT specialist and Webmaster Mr. Michael Franke (michael.franke@bam.de) who is pleased to offer support to you on any query. The DAR Secretariat also provides online help on all questions and problems not only related to the database searches, but to any kind of information given in our Websites.

**TRAINING** gives a survey of training courses for assessors planned to be held in future.

Via **STATISTICS** you receive a graphic survey of the number of bodies accredited to date. This site is generated automatically on the basis of the information given in the database of accredited bodies.

**HANDBOOK** is our most comprehensive site. It contains the description of the DAR system (HTML sites) as well as all parts of our Handbook, i.e. all documents elaborated within and endorsed by the DAR, downloadable as PDF files. This site is categorised in chapters identical with those given in the DAR Handbook.

**DOCUMENTS** also lists all documents endorsed by the DAR and/or elaborated by the DAR Secretariat. However, this site additionally provides the feasibility to search for specific documents. If you do not know the exact title, you simply insert a specific keyword, e.g. "validation", click on SEARCH and you get all documents listed dealing with the topic "Validation" or simply containing this term.

**STANDARDS** presents a survey of all standards applied within the German accreditation system. Furthermore, information is given on future planning of revisions and development of standards.

**MLA** informs in general about Multilateral Recognition Arrangements both in Europe and internationally, and provides insight into all MLAs the DAR has already signed and entered.

**LINKS** accommodates a comprehensive link-book, which contains more than 700 entries. Apart from acronyms and their meanings, you find the corresponding website and/or e-mail addresses, if available. We are very busy with keeping this site updated. However, despite of all our efforts, we are not able to constantly check the entries for their correctness. Therefore we cannot assure that every information given here is really up-to-date. So, we would be pleased to be advised of any incorrectness occurring at this site. Please, have a look at it and check your organisation's entries. Your comments to our central address dar@bam.de will be highly appreciated. If your organisation is not listed here, please communicate to the DAR Secretariat.

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