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## ❖ New MLA Signed Worldwide

The first agreement on mutual recognition of accreditations of quality management certification bodies in IAF (International Accreditation Forum, Inc.) was signed on 21 January 1998. During the last years, intensive efforts have been made to conclude similar agreements in the field of accreditation of certification bodies for products and environmental management systems.



Therefore it was necessary to align the IAF interpretation papers on ISO Guide 66 and ISO Guide 65 (identical in wording with EN 45011). Furthermore, based on an extensive evaluation program, peer evaluations were conducted to ensure that all accreditation bodies have implemented the harmonised procedures and therefore the accreditations of IAF MLA signatories for certification bodies for products and environmental management systems (EMS) would also become comparable.

The new MLA for EMS certification bodies was signed on the part of Germany by the TGA GmbH and the new MLA for product certification bodies by DATech e.V. and DAP GmbH.

Altogether the *IAF MLA for environmental management systems* has been signed by:

EA and PAC as regional groups with the following accreditation bodies:

EA: BELCERT/Belgium, BMWA/Austria, CAI/Czech Republic, COFRAC/France, DANAK/Denmark, DAR/TGA/Germany, ENAC/Spain, FINAS/Finland, INAB/Ireland, NA/Norway, RvA/The Netherlands, SAS/Switzerland, SINCERT/Italy, SNAS/Slovakia, SWEDAC/Sweden, UKAS/UK.

PAC: CNAB/China, ema/Mexico, JAB/Japan, JAS-ANZ/Australia & New Zealand, KAB/Korea, KAN/Indonesia, NAC/Thailand, SCC/Canada, TAF/Chinese Taipei

as well as SANAS/South Africa and ANSI-RAB NAP/USA as single accreditation bodies.

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Worldwide agreements on mutual recognition of accreditations are currently existing in the following fields:

- IAF: QMS and EMS, certification bodies for product certification (34 signatories)
- ILAC: testing laboratories, calibration laboratories (51 signatories)

The existing IAF QMS MLA was additionally signed by RENAR/Romania and HKAS/Hong Kong.

The existing MLA in ILAC for the accreditation of laboratories was additionally signed by DSM/Malaysia, KAN/Indonesia, SA/Slovenia, ESYD/Greece and RENAR/Romania.

Furthermore, investigations have been carried out to determine the effectiveness of the MLAs and the state of implementation of the Guidance on Cross-Frontier Accreditation. They serve to find out in which way the MLA affects cross-frontier activities. The aim is to prevent accreditations abroad without any reason.

BAM S.42 - M. Wloka

*Legend (from left to right):  
 IAF Vice Chair Elva Nilsen,  
 Dr. Thomas Facklam (TGA, DATech),  
 Prof. Dr. K. Ziegler (DAP),  
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## ❖ News from the DAR

### Basic Documents

On its meeting in September this year the DAR made necessary changes of basic documents and prolonged their validity or determined that they are valid until a more stable solution (e.g. the law on accreditation) replaced the DAR.

The DAR decided that all necessary action is to be taken for arranging a fully operational accreditation system for the accredited bodies even during the transition period.

The DAR is conscious of its responsibility and will supervise the transition rules from the technical point of view.

### Law on Accreditation

The BMWA (German Federal Ministry of Economics and Labour) informed about the state of development of a law on accreditation. Currently, there is no draft law publicly available, as the agreements in the respective departments of the BMWA are still under consideration.

The law goes along with a study investigating the benefits of accreditation and of a reorganisation of the German accreditation system and its impacts.

### New Technical Documents

The following new documents have been endorsed and may be retrieved from the DAR Homepage:

- DAR-8-EM-01 *IAF Guidance on the Application of ISO/IEC 17024:2003* (for use in accreditation of certification bodies for persons)
- DAR-3-EM-21 *IAF Code of Conduct for Accreditation Body Members of the IAF*. This Code of Conduct and all accreditation bodies having signed it are published on the IAF Homepage ([www.iaf.nu](http://www.iaf.nu)).
- DAR-3-EM-20 *IAF Guidance on Cross Frontier Accreditation*. This Guidance sets out rules and conditions, under which the accreditation bodies, in particular those being members in the international MLA, shall conduct accreditations in other countries or how the cooperation between the accreditation bodies could be arranged.

In particular the developing countries press for the accreditation bodies of the industrialised countries not to increasingly accredit in the developing countries.

### State of Admission of New Members

On the 40th DAR meeting, the BAM Evaluation Committee was introduced for the first time. This Committee was assigned by the DAR Chairman to perform the evaluations of those institutions willing to be admitted to the DAR. Although all parties concerned recognised that the DAR is currently passing through a transition period, two applicants have signed a contract so far and are now under evaluation. It was furthermore reported about the state of preparation of the DAR accreditation bodies for evaluation.

### Technical Issues

The DAR supports the decision of the ATF not to accredit producers of reference materials as producer only on the basis of ISO Guide 34. The ATF had argued for an accreditation of a laboratory - which is a producer of reference materials - according to ISO/IEC 17025 in connection with ISO Guide 34.

The accreditation of providers of proficiency tests was intensively discussed on the 40th DAR meeting. The majority of the ATF members had argued for an accreditation of providers of proficiency tests on the basis of ISO/IEC 17025 or ISO/IEC 17020 in connection with ISO Guide 43.

The DAR will have to continue to discuss this issue, as there are requests from the industry, whether bodies/institutions which are no laboratories or inspection bodies may seek for an accreditation as provider of proficiency tests.

As the currently approved ISO/IEC 17011 - specifying general requirements for accreditation bodies - does not sufficiently describe such rules the ATF was mandated to continue the discussion of this issue and to draw up essential technical requirements and rules for accreditation.

### Letter to the Laboratories for Compliance with the Requirements of ISO 9001:2000

As already defined on the 39th DAR meeting, accreditation bodies may confirm to the accredited laboratories in a covering note on the certificate the fulfilment of the relevant criteria of the ISO 9001:2000, if they have been accredited according to ISO/IEC 17025. The wording agreed in EA may be used by the German accreditation bodies and made available to the accredited bodies, if required, so that the laboratories may inform their customers. Extracts of the German translation of this covering note are given on the DAR Homepage under NEWS.

### Transition Periods for Implementing new Standards

The English edition of the ISO/IEC 17011 was published in September. The German edition is expected to be released at the end of this year. On its 40th meeting the DAR discussed the transition periods. As the accreditation bodies have been dealing with ISO/IEC 17011 over a longer period of time, no problems are to be seen for the accreditation bodies to comply with the requirements after half a year after publication of the standard. Nevertheless, the internationally agreed transition periods will be adhered to (see below).

The Amendment to ISO/IEC 17025 has not yet been published, just as not the entire new ISO/IEC 17025. A publication of this standard is not expected before the first quarter of 2005. The DAR argued for arranging the transition periods for implementing this new ISO/IEC 17025 in such a way that no special surveillance visits of the laboratories would become necessary, but the surveillance visits should be performed in regular intervals. The internationally agreed surveillance times will be followed as well in this case.

BAM S.42 - Dr. M. Wloka

## ❖ News from International Organisations ILAC and IAF

Both organisations held their annual General Meetings in Cape Town/South Africa in October 2004. It was already the 4th joint General Assembly of both organisations at the same place and at the same time, so as to enable the accreditation bodies being members both of ILAC and IAF an effective participation in possibly all events.

**MoU Signed between UNIDO, ILAC and IAF.** The three organisations plan to closer cooperate, in particular in supporting the developing countries, a.o. also in performing pre-peer evaluations. The developing countries shall be enabled to reach a sooner membership in the ILAC and IAF MLAs.

**Inspections:** The new IAF/ILAC Guidance on ISO/IEC 17020 on interpretation and use of the ISO/IEC 17020 has been approved by both organisations and will be used by the accreditation bodies from 1st January 2005.

An international MLA for accreditation of inspection bodies is in preparation. Existing structures in both organisations shall be used for this MLA.

### Joint Procedures for Conducting Evaluations with the Aim to Sign Agreements on Mutual Recognition

The Joint WG on Harmonisation of the MLA Procedure finished its work. ILAC and IAF confirmed the implementation of the new documents (A-Series Documents) ensuring the same performance of evaluation for the purpose of the MLA in both organisations.

Furthermore, a resolution was passed in both organisations: The Executive Committees of both organisations will prepare a proposal for a common structure of the management of the

MLA and will be submitted at the next General Assembly in 2005.

The peer evaluations to be held in 2005 by the regional groups will already be performed on the basis of ISO/IEC 17011, whereby the respective bodies will be given time until the end of 2005 to eliminate the non-conformities considering the new standard.

### Determinations for Implementing ISO/IEC 17011 in ILAC and IAF

It was decided to draw up a joint ILAC-IAF Guidance on implementation of ISO/IEC 17011. The accreditation body members of the MLAs in ILAC and IAF shall demonstrate the implementation of the 17011 by their regional groups or to ILAC and IAF by self declaration.

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## ❖ News from ILAC

(International Laboratory Accreditation Cooperation)

ILAC adopted version 16 of the Strategic and Business Plan establishing the basis for the organisation's objectives and structure as well as the Committees' tasks.

Parallel to the General Assembly a Workshop was held on special issues of proficiency testing. As a result of this Workshop, a Resolution was passed in ILAC stating that the Executive Committee will be asked to establish a Subcommittee, a consultation group or a Forum for proficiency tests, in which open questions may be discussed, in particular to which extent providers of proficiency tests may be accredited, even if they are neither a laboratory nor an inspection body.

ILAC recommends to perform the accreditation of producers of reference materials based on a combination of ISO Guide 34 and ISO/IEC 17025.

Daniel Pierre has been elected new Chair of ILAC (COFRAC/France) and Peter Unger (A2LA/USA) Vice Chair.

The resolutions of the ILAC General Assembly may be requested at the DAR Secretariat (see also <http://www.compad.com.au/cms/ilac/articles/272.php>)

## ❖ News from IAF

(International Accreditation Forum, Inc.)

Currently, IAF has 64 members, among them 23 accreditation bodies (34 MLA members, 15 associate members, 4 regional groups, 1 partner member and 1 observer).

New documents:

In the course of the year 2004, the following documents were endorsed:

- IAF GD 24 Guidance on the Application of ISO/IEC 17024
- IAF PL 3 Policy and Procedure for Industries Specific Programs
- and the revised versions of the Guidances on the Application of ISO Guide 61, 62 and 66.

All these documents may be retrieved from IAF's websites at [www.iaf.nu](http://www.iaf.nu)

For ISO 14001, IAF confirmed a transition period of 18 months after publication. A review shall take place during the certification interval.

The procedure for handling complaints has been approved in IAF and will be published. IAF will continue to investigate the cooperation with the regional groups, the feedback from the accredited bodies, but also from the clients of the accredited bodies.

BAM S.42 - M. Wloka

## ❖ Which Changes will be Brought About by the New ISO/IEC 17025 ?

### Procedure and Time Limits

As already reported in the last issue of DAR-aktuell, there will be a new ISO/IEC 17025. The voting on the Final Draft of the Amendment to ISO/IEC 17025 has been passed with a positive result. The text of the Amendment to the existing ISO/IEC 17025 - formulated to reach an alignment with ISO 9001:2000 - has been fixed. Currently, there is a parallel voting in ISO and CEN. The ISO/CASCO Secretariat informed that the new ISO/IEC 17025 with the supplements to its Amendment may be published in 2005.

At the ISO/CASCO General Assembly it was proposed to tackle a new revision of ISO/IEC 17025 only after 5 years of being operative and to align with the time limits regarding the revision of ISO 9001.

### Purpose of the Amendments

The aim of the amendments and supplements is to align the new ISO/IEC 17025:2005 with ISO 9001:2000, so as to align the requirements for the quality management system of a laboratory with the requirements of ISO 9001. The laboratory shall consider the state of the art in establishing and implementing a quality management system.

It was the aim of the Working Group of ISO/CASCO and of the majority of the ISO members not to change any technical requirements for the laboratories.

### Essential Amendments

1. In the English issue of the text the term "client" will be replaced by the term "customer". As the German translation provides for both terms "Kunde", the German translation will not be changed.

2. At any place, where the entire management system of the laboratory is referred to, i.e. the quality management system, the administrative system and the technical management system, quality management system will be replaced by management system.

This shall reveal that it is not sufficient for a laboratory to develop a quality management system to reach the main objective of a laboratory, to provide reliable results to the customer.

The development of a comprehensive management system also covering the technical part is equally important. The responsible ISO/CASCO Working Group discussed with representatives of the TC 176 in charge of the ISO 9000 standards series who is the customer for the laboratory and in general for conformity assessment bodies in connection with the circle of continual improvement of the quality management system described in ISO 9000.

While in a supplier relationship the customer is clearly defined, for the laboratory the customer is not only the direct client. For tests and other conformity assessments the requirements of authorities or legal provisions are to be considered and an independent, only technically reasonable result is to be taken in consideration which at a first examination does not always result in a satisfaction of the direct customer.

This peculiarity of the conformity assessment has to be considered and may lead in extreme cases to the loss of the customer order. A conformity assessment body or a laboratory is therefore be bound to a particular code of conduct and not only to the satisfaction of the direct client. The ISO/IEC 17025 tries to fulfil this peculiarity and in spite of all this to reach the alignment with the ISO 9001:2000.

3. For compliance with ISO 9001 the introduction of the new version states the following: "Test and calibration laboratories that are in compliance with this International Standard will also operate in accordance with ISO 9001."

To point out that the introduction of a quality management system according to ISO 9001 does not suffice for a laboratory, however, on the other hand the confirmation of the introduction of ISO/IEC 17025 is not a certification of a quality management system to ISO 9001, the Introduction to the standard states: "Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results. Nor does demonstrated conformity to this International Standard imply conformity of the quality management system within which the laboratory operates to all requirements of ISO 9001."

4. Furthermore, there is a new subclause 1.4: "1.4 This International Standard is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. This International Standard is not intended to be used for the purpose of certification."

Note: The term 'management system' in this International Standard means the quality, administrative and technical systems that govern the operations of a laboratory." It is referred to the fact that the standard is not intended to be used for a certification according to ISO/IEC 17025.

5. Requirements for the management system: New is the explicit requirement for a continual improvement of the management system, e.g. by an amendment in 4.1.4, by an additional requirement in 4.2 and by a new subclause 4.10 "Improvement"

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This shall reveal that it is not sufficient for a laboratory to develop a quality management system to reach the main objective of a laboratory, to provide reliable results to the customer.

The development of a comprehensive management system also covering the technical part is equally important. The responsible ISO/CASCO Working Group discussed with representatives of the TC 176 in charge of the ISO 9000 standards series who is the customer for the laboratory and in general for conformity assessment bodies in connection with the circle of continual improvement of the quality management system described in ISO 9000.

While in a supplier relationship the customer is clearly defined, for the laboratory the customer is not only the direct client. For tests and other conformity assessments the requirements of authorities or legal provisions are to be considered and an independent, only technically reasonable result is to be taken in consideration which at a first examination does not always result in a satisfaction of the direct customer.

This peculiarity of the conformity assessment has to be considered and may lead in extreme cases to the loss of the customer order. A conformity assessment body or a laboratory is therefore be bound to a particular code of conduct and not only to the satisfaction of the direct client. The ISO/IEC 17025 tries to fulfil this peculiarity and in spite of all this to reach the alignment with the ISO 9001:2000.

3. For compliance with ISO 9001 the introduction of the new version states the following: "Test and calibration laboratories that are in compliance with this International Standard will also operate in accordance with ISO 9001."

To point out that the introduction of a quality management system according to ISO 9001 does not suffice for a laboratory, however, on the other hand the confirmation of the introduction of ISO/IEC 17025 is not a certification of a quality management system to ISO 9001, the Introduction to the standard states: "Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results. Nor does demonstrated conformity to this International Standard imply conformity of the quality management system within which the laboratory operates to all requirements of ISO 9001."

4. Furthermore, there is a new subclause 1.4: "1.4 This International Standard is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. This International Standard is not intended to be used for the purpose of certification."

Note: The term 'management system' in this International Standard means the quality, administrative and technical systems that govern the operations of a laboratory." It is referred to the fact that the standard is not intended to be used for a certification according to ISO/IEC 17025.

5. Requirements for the management system: New is the explicit requirement for a continual improvement of the management system, e.g. by an amendment in 4.1.4, by an additional requirement in 4.2 and by a new subclause 4.10 "Improvement"

"4.10 Improvement: The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review."

and consideration of improvement proposals in 4.14.1 (management review).

Furthermore, the internal communication and the communication with the customer is especially explained. E.g. there is a supplement in 4.1.5.: "4.1.5...k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system."

and a new subclause 4.1.6.: "4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system."

Furthermore, 4.2 requires that the top management shall demonstrate its responsibility regarding the continual improvement of the management system and that it shall impart to the organisation the relevance of the fulfilment of the customer requirements and of the legal and regulatory requirements.

In addition, it is required that the top management shall ensure that "the effectiveness of the management system is maintained, if changes in the management system are planned and implemented."

6. As a result of the compliance sub-clause 1.6 therefore states "1.6 If testing and calibration laboratories comply with the requirements of this International Standard they will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001.

An Annex provides cross-references between this International Standard and ISO 9001. ISO/IEC 17025 covers technical competence requirements that are not covered by ISO 9001."

#### Changes in the Technical Requirements

In the entire clause 5 only 2 items regarding the continual improvement are changed. A supplement to 5.2.2 was introduced so that "the effectiveness of the training actions taken shall be evaluated."

and in 5.9 Assuring the quality of test and calibration results is supplemented by "Quality control data shall be analysed, and where they are found to be outside predefined criteria planned action shall be taken to correct the problem and to prevent incorrect results from being reported."

#### Use of the New ISO/IEC 17025 by Accreditation Bodies

Due to the currently invalid ISO 9001 dated 1994, the accreditation bodies presently do not confirm to the laboratories on the accredited certificates that they comply with the requirements of ISO 9001.

The valid standard ISO/IEC 17025 provides only one sentence relating to the invalid 9001.

The current practice is therefore - as already informed in the last issue of DAR-aktuell - that the accreditation bodies provide to the accredited bodies a letter for their customers, in which the current situation regarding the ISO/IEC 17025 in relation to the ISO 9001 is described. After ISO/IEC 17025:2005 has become effective, the accreditation bodies will have to discuss this issue again. The accreditation bodies are currently including these requirements and changes in their assessment practice for future assessments.

#### Conclusions for Laboratories

There are no essential changes in the technical requirements. New is the explicit requirement for a continual improvement of the management system. Also the internal communication and the communication with the customer in particular is described and the new terminology will be adapted. Moreover, the laboratories find a new Cross Reference List for ISO 9001:2000.

It can be concluded that laboratories which have already described and controlled their processes in the laboratory - as already required in the valid 17025 - needn't to make any fundamental changes, neither in the quality manual nor in the practice of the management system.

BAM S.42 - M. Wloka

## ❖ ILAC and IAF MLA Mark on German Certificates for Signatories of the Mutual Recognition Arrangements

ILAC and IAF approved a mark to indicate the membership in the mutual recognition arrangements for accreditations on certificates and documents of the accreditation bodies as well as on documents of the accredited laboratories and certification bodies. On 22 September 2004, both Secretariats informed about a "Joint ILAC & IAF Communiqué on ILAC-MRA Mark & IAF-MLA Mark".

The accreditation bodies need to conclude licence agreements with ILAC or IAF, before they pass on the marks to their accredited bodies. No fees are incurred for these licence agreements. Only membership fees in the respective organisations (ILAC, IAF) are incurred. For the DAR members having signed the MLA - DAP, TGA, DATech, DACH, DASMIN, DKD - a uniform design of the ILAC-, IAF-MLA-logos in connection with the DAR-logo and the logo of the accreditation bodies needs to be developed.

The form of circulation of the combined mark to the accredited bodies is currently discussed by each accreditation body.

It is intended to create a uniform design using the DAR-logo in the combined mark. The combined mark will include for IAF or ILAC the protected symbols given below. Instead of the new symbols or combined marks, a text reference on the certificates - as already used - may point to the MLA membership.



Logos to be used for the accreditation of certification bodies (left) or for laboratories (right)

BAM S.42 - Dr. J. Thiele



We wish all our readers a Merry Christmas in peace and harmony and an untroubled and successful New Year 2005.  
Your Editorial Staff

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