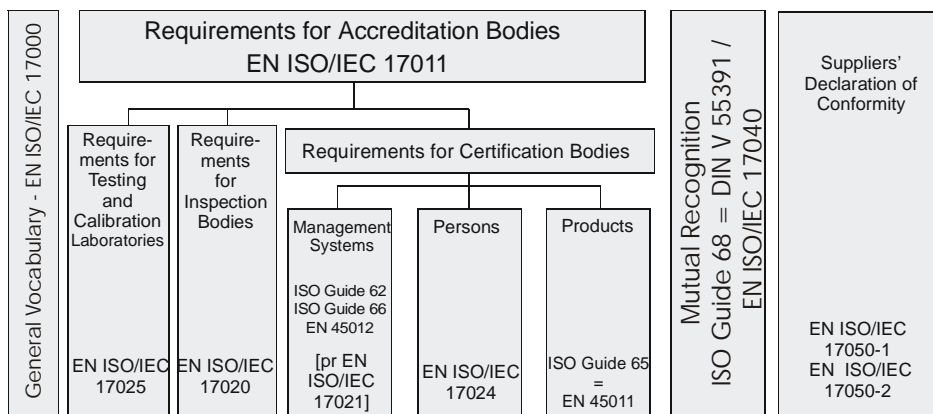


❖ Conformity Assessment Standards The ISO/IEC 17000 has a series of new standards



The EN ISO/IEC 17020 "General criteria for the operation of various types of bodies performing inspection" was published by the DIN in its German version in November 2004. It is identical in wording with the EN 45004 and has only a new front page. The requirements for inspection bodies were therewith harmonized as a worldwide standard.

The EN ISO/IEC 17024 "Conformity assessment - General criteria for certification bodies operating certification of persons" was already published by the DIN in October 2003. It supersedes the previous EN 45013:1990.

A further new standard is the EN ISO/IEC 17040 "Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies".

At the 20th General Assembly of ISO/CASCO (ISO Committee on Conformity Assessment) in Amsterdam in November 2004 it was stated that the main part of the standards on conformity assessment summarized in the standards series 17000 will be soon completed and published. A survey of all standards on conformity assessment is shown in the picture above.

The new standard EN ISO/IEC 17000 "Conformity assessment - Vocabulary and general principles" supersedes the second part of the present ISO/IEC Guide 2:1996 or the EN 45020:1998 that explained the terms and definitions relating to conformity assessment. This standard was published in March 2005 by the German Institute for Standardization (DIN) and does not only contain terms on conformity assessment, but also describes the system of functional approach in which a conformity assessment is divided into different steps.

The EN ISO/IEC 17011 "Conformity assessment - General requirements for bodies providing assessment and accreditation of conformity assessment bodies" supersedes the EN 45003 (identical in wording with ISO Guide 58), the EN 45010 (identical in wording with ISO Guide 61) and the ISO/IEC TR 17010. These three previous standards described the accreditation systems for laboratories, certification bodies and inspection bodies respectively. The EN ISO/IEC 17011 published in German language in February 2005 specifies all requirements for accreditation bodies operating accreditation of any kind of conformity assessment bodies. This standard clearly shows the difference between accreditation and certification and does not allow the accreditation bodies to perform any conformity assessment activities among their accreditation activity.

In the field of mutual recognition there has only been the ISO Guide 68 so far describing fundamental terms for mutual recognition, while the EN ISO/IEC 17040 specifies general requirements for the evaluation of accreditation bodies and the peer assessment of certification bodies and other conformity assessment bodies.

A last new standard in this series is the EN ISO/IEC 17050-1 "Conformity assessment - Suppliers' declaration of conformity", Part 1 "General requirements", and the EN ISO/IEC 17050-2 "Conformity assessment - Suppliers' declaration of conformity", Part 2 "Supporting documentation" dated January 2005. These standards supersede the previous EN 45014:1998 or the ISO Guide 22 respectively.

In this series, the following standards are currently still under discussion: the EN ISO/IEC 17025 is being revised by including the Amendment agreed upon in 2005. This standard is expected to be published in the middle of 2005. Furthermore, a draft standard for an ISO/IEC 17021 "Conformity assessment - General requirements for bodies operating assessment and certification/registration of quality or environmental management systems" is in preparation. This standard will supersede the ISO Guide 62, the ISO Guide 66 and the EN 45012. There are currently intensive discussions in the responsible working groups; the standard is not expected to be published before next year.

To facilitate the revision of the standards in future, the WG 23 is presently working on the so-called Common Elements, i.e. on text modules to be used by the standards bodies to allocate equal facts in standards with the same equal requirements.

BAM S.4 - Dr. M. Wloka

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New DAR Members

The DIAS Deutsches Institut für Akkreditierungssysteme GmbH (German Institute for Accreditation Systems) located in Stuttgart has successfully passed the evaluation procedure and has been accepted as a member of the DAR effective from 15 January 2005.

The DIAS GmbH (www.dias-acc.de/) will perform accreditations of inspection bodies and is currently active in the voluntary area.

Evaluation of present DAR Members

The evaluation contract between the BAM and the accreditation bodies operating in the voluntary area has been signed since by all private accreditation bodies (DACH, DASMIN, DAP, DATech, TGA, GAZ). Presently an evaluation schedule to be submitted at the BMI (German Federal Ministry of the Interior) is in preparation.

Law on Accreditation

On its 40th Meeting, the DAR informed about the current state of legislative projects. There are still discussions in the respective departments. Common accreditation rules are required that are accepted both by the mandatory and voluntary areas. According to an actual time schedule, the bill will be discussed in the cabinet in 2005 and enter into force as from 2006.

The following issues are particularly in discussion: the scope, the rules for approval and the obligatory recognition of accreditation required by the law and granted by the private bodies.

Survey of Accreditation

A survey going along with the law has been worked out. The survey consists of 4 modules:

- Module 1: "Definitions" (worked out by the BMWA following the ISO/IEC 17000)
- Module 2: "Advantage of recognition and accreditation" (worked out by Prof. Ernstthaler, Kaiserslautern)
- Module 3: "Recognition and Accreditation in Germany; Examples of other countries" (worked out by the BAM as a survey and comparison of accreditation systems of Germany, Europe and worldwide)
- Module 4: "Advantage of the reorganisation of the German recognition and accreditation system" (worked out by Prof. Blum, Halle)

Results from the SOGS

The last EU Commission and SOGS documents show in which direction the EU Commission plans to go in respect of conformity assessment and accreditation. The DG Enterprise and the DG Competition have agreed upon to let the Member States decide whether they prefer to establish an accreditation system free of competition or allowing competition. This means that the German legislative project is compatible with the European one. The most European representatives prefer an accreditation system free of competition. This is the reason why objections and concerns are expressed against the German proposal. However, the interests and initial points in the individual European states are different. In Germany in principle we have to follow the right for freedom of exercise of profession and we need to allow competition even in accreditation. However, there is still a need to discuss to what extent this right is applicable to the mandatory area and whether accreditation is a service of public interest.

ILAC/IAF-MLA Logo

The accreditation bodies being signatories to the MLAs of ILAC and/or IAF have the possibility to refer to its membership in the MLAs by using the logos of ILAC and IAF in connection with the logo of the accreditation bodies.



The bodies accredited by an MLA accreditation member body can also use the ILAC or IAF logo in connection with their own accreditation mark and the registration number.

There is not yet consensus within the DAR about a consistent use of the logos in combination with the MLA logo of ILAC or IAF.

Information from Standardisation

The DAR accreditation bodies will implement the EN ISO/IEC 17011:2005 until 01 January 2006. Evaluations based on this standard have already been conducted in the DAR in 2005. The accreditation bodies are bound to correct nonconformities according to this standard by 01 January 2006.

12th Tutors' Exchange of Experience, 16 March 2005

Information from the 12th Tutors' Exchange of Experience may be requested at the DAR Secretariat.

BAM S.4 - S. Stobbe

❖ News from the Coordination Committee Environment

With the „Agreement on the Cooperation of the Federal States with the participating accreditation bodies in the field of environment“ - in the meantime signed by all Federal States and the accreditation bodies concerned - the precondition was established to avoid in future double assessments for demonstrating competence for testing laboratories and measuring points in this area. With the so-called technical modules, the Federal States and the accreditation bodies have established consistent requirements for demonstrating competence of these bodies. I.e. accreditations as well as respective recognitions for accreditations have to be used for recognitions (notifications) in the legally regulated environmental area.

To support this Agreement in practice, a Coordination Committee has been established having the function to give advice and decide on occurring issues related to the technical content and procedures. It is composed of representatives from the Federal States as well as from the accreditation bodies, whereby the Federal States representatives are authorised by the "Bund-Länder-Ausschüsse/-Arbeitsgemeinschaften" (committees/Working Groups of the Federal Government and the Federal States) for Waste Material, Soil/Waste Deposits, Immission Control, Chemicals and Water.

The first task of the Coordination Committee was to lay down requirements for the assessors employed for accreditations and recognitions to demonstrate competence. Assessors fulfilling these requirements are listed in a Pool of Assessors. Precondition to consider a demonstration of competence for a recognition or accreditation is to employ assessors from this Pool in assessments. Meanwhile, this Pool already comprises 75 assessors primarily authorized by the accreditation bodies. Assessors from the Federal States Authorities are expected to be nominated during the next time.

The approach of mutual advantage of competence evaluation has successfully been initiated in the meantime. However, like in many new systems, this or that question or need for discussion arise. In order not to have the discussions only in the Coordination Committee it is planned to conduct in autumn this year an exchange of experience among the responsible Federal States Authorities and the accreditation bodies concerned for each of the environmental areas.

The enquiry system ReSyMeSa for measuring points and technical experts is ready to operate and can be used to make enquiries about which testing laboratories, measuring points and technical experts have a recognition in the individual German Federal States in the legally regulated area of environment (www.luis-bb.de/resymesa). Establishment and maintenance of the above system are under the auspices of the Landesumweltamt Brandenburg (Environmental Agency of the German Federal State Brandenburg).

However, we do not only want to inform about technical activities. At the end of March this year, the Chair of the Coordination Committee Mr. Dr. Thormann, Hess Ministry for Environment, Agriculture and Consumer Protection, retired. Mr. Thormann did not only hold the Chair of the Coordination Committee, but also provided from the very beginning for making possible the current approach in the field of environment. We thank him so much for his commitment in this field. As his successor to be the Chair of the Coordination Committee Mr. Dr. Assmann, Ministry for Environment, Agriculture and Consumer Protection of North-Rhine Westphalia, could be engaged.

BAM P.2 - Dr. A. Recknagel

❖ News from the Committee for Technical Issues (ATF)

The spring meeting of the DAR Committee "Technical Issues" took place in Frankfurt on 02 March 2005. A main point of discussion during this meeting was the updating of the technical DAR documentation, in particular documents on measurement uncertainty. The German translation of the EA Guidance on Measurement Uncertainty (EA-4/16) has been tackled. An update of the DAR documentation on the uncertainty of qualitative test results has also been initiated. During the next meetings, the ATF members plan to exchange their experience about the practical implementation of the ISO/IEC 17011:2004. Furthermore, in future the rules for accreditation bodies covering

the accreditation of providers of proficiency testing will be harmonised.

The proposals for a new ATF working program were intensively discussed. It was decided to much more consider the accreditation of inspection bodies in the future work of the ATF. Comments to be submitted at the international organisations (EA, ILAC and IAF) will be further prepared and agreed upon in the ATF, so that a consistent representation of the German accreditation system abroad will be ensured. The DAR endorsed the new Working Program of the ATF DAR-2-GL-07 at its 41st meeting on 11 March 2005.

BAM S.4 - Dr. G. Wermann

❖ News from Standardisation

❖ Supplementing Standards on ISO 9000 Standards Family and Start for Revision of 9000 Standards Series

In addition to the ISO 9000 standards series, a group of standards on customer satisfaction is in preparation, among others ISO 10018 "QM- Customer Satisfaction - Guide for Handling Complaints" - already available in German language (draft).

ISO Committee Drafts

- for ISO 10001 "Management - Customer satisfaction - Guidelines for Codes of Conduct for organizations" and
- for ISO 10003 "Management - Customer satisfaction - Guidelines for Dispute resolution external to organizations"

are available.

These drafts provide guidance on the conduct/behaviour of companies in case of complaints and have primarily been initiated and promoted on the initiative of consumer councils.

The following standards are under revision or have recently been drawn up - still as drafts - the ISO 9000, first as FDAM (Amendment to ISO 9000: 2000) as well as with further prospective results as a later new standard ISO 9000, however not before 2007.

The German standard DIN 55350 is also under revision with supplementing concepts in the fields of testing in quality management.

- Part 11: "Concepts of the Quality Management
- Part 11: Concepts of Quality Management, Supplement to DIN EN ISO 9000:2000-12"

BAM S.4 - Dr. R. Schmidt

❖ 2005 IECEE Re-Accreditation Programme

MoU signed between IECEE (IEC System for Conformity Testing and Certification of Electrical Equipment) and ILAC



ILAC Chair Daniel Pierre and IECEE Executive Secretary Pierre de Ruvo agreed to continue developing the relationship and working even more closely in the future on joint assessments and common and consistent application of ISO/IEC 17025.

The IECEE and ILAC have formalised and signed a Memorandum of Understanding (MoU) that aims to improve efficiency and reduce assessment costs for testing laboratories.

The Agreement makes official a working relationship that had been operating informally since December 2003.

For detailed information, please visit <http://www.iecee.org/html/whatsnew.htm> or http://www.compad.com.au/cms/ilac/workstation/upFiles/934745.MOU_ILAC_IEC_CAB_2005_FINAL.pdf

BAM S.4 - S. Stobbe

❖ From Japan via the Pacific to Germany

On 24 January 2005, a delegation from Japan visited the Offices of the German Accreditation Council DAR. The guests wished to be informed about the experience in founding the DAR and about the operation of a national umbrella organisation.

The delegation consists of the following persons:

Keiichi Iwase

Ministry of Economy, Trade and Industry (METI), Tokyo

Yoshinobu Uematsu

International Accreditation Japan (IAJapan), Tokyo

Toshio Shino

The Japan Accreditation Board for Conformity Assessment (JAB), Tokyo,

Shimpei Wada

Japanese Standards Organization (JSA), Tokyo,

Koichi Noda

Japan External Trade Organization (JETRO), Geneva.



Such as the German system, the Japanese conformity assessment system has traditionally been developed over a long period of time.

Now it is planned to be reorganized and optimized, so as to better meet the challenges of the rapidly growing globalization and the international exchange of goods.

As in Germany, in Japan there are state and private accreditation bodies with partly parallel scopes. Now the attempt is made to harmonize the five accreditation bodies and possibly to establish an umbrella organisation in Japan similar to that of the DAR.

The aim is to simplify the system, to make cooperation more effective and to establish an overall platform for providing discussions on technical issues.

The Japanese government aims at establishing only one accreditation body per subject area. The German experience shall be used to find an ideal solution in Japan that simultaneously meets the international requirements.

During the vivid discussion, it turned out that Japanese laws refer to international standards and guidelines which is rather an exception conformity assessment in Germany.

The ISO/IEC Guide 65 (EN 45011:1998 General requirements for bodies operating product certification systems) e.g. was implemented in several Japanese laws, such as the law on industry standards, law on product safety, electrical devices and materials safety, law on safety and handling of liquefied gas, law on pharmaceutical concerns.

The industrial standards law and the measurement law refer to the international standard ISO/IEC 17025 (EN ISO/IEC 17025:2000 General requirements for the competence of testing and calibration laboratories).

The Japanese accreditation bodies are signatories to the regional recognition arrangements of the Asia-Pacific Laboratory Accreditation Cooperation (APLAC) for accreditors of laboratories and of the Pacific Accreditation Cooperation (PAC) for accreditors of certification bodies as well as to the international mutual recognition arrangements of ILAC and IAF.

The Japanese guests devoted special interest to the DAR experience gained in joint assessments in the mandatory and voluntary areas and to the procedure how to make decisions on accreditation.

IAJapan considers the accreditation of providers of proficiency tests critical as it holds conflicts of interest. The participation in proficiency tests is a useful tool in accreditation, but not subject of accreditation.

In a short discussion successes that may be reached in a system developed during a long term and based on consensus such as the DAR were pointed out, but also the problems such a system is faced with became apparent, as well as issues that might be reasonable and worth including in the law on accreditation. So far the DAR has been fulfilled essential functions and its model may serve as a positive example in establishing national umbrella organisations.

BAM S.4 - Dr. J. Thiele

❖ Workshop "Measurement Uncertainty", 29 June 2005

On 29 June 2005 a Workshop on Measurement Uncertainty jointly organized by EUROLAB-Deutschland and the DAR will take place at the Federal Institute for Materials Research and Testing (BAM), Berlin, from 9:30 to 17:30.

Objectives

Since the implementation of the international standard EN ISO/IEC 17025 there has been an increasing necessity for the accredited testing laboratories to determine the measurement uncertainty associated with the testing and analysing procedures applied and, if necessary, to include it in the test reports. This task turns out to be pretty difficult for many laboratories, as their employers so far do not have enough experience in this field. Furthermore, experience shows that such a gap might not be sufficiently filled by one- or two-day seminars or workshops, because in addition to knowledge of (statistical) basics, own exercises with practical examples are necessary.

To take this fact into account it is suggested to establish working groups for individual fields of work in which staff members of different laboratories may jointly evaluate the measurement uncertainty for problems they proposed from their own laboratory practice.

To facilitate the establishment of such working groups, EUROLAB-Deutschland jointly with the DAR are organizing this Workshop which will invite all laboratories to participate. Alongside the imparting of knowledge in basics of evaluation of measurement uncertainty, some working groups deal with practical examples from different technical fields, such as

- chemical analytics
- mechanical-technological testing, physical measurement
- building physics
- microbiology
- electrotechnics, electronics, information technology (EEI)

The Workshop furthermore serves to determine the need for working groups. When submitting the application form, there is the possibility to identify problems and issues of laboratories in evaluating the measurement uncertainty. They are compiled by the Secretariat of EUROLAB-Deutschland and may be passed on to the working groups.

The practical approach in establishing working groups as well as their operation will be a point of discussion at the Workshop.

Another aim of the Workshop is to provide possibility for constitutions of first working groups.

Programme and more information may be downloaded from DAR's homepage (www.dar.bam.de/newse.html)

BAM S.4 - S. Stobbe