

EN 45 001/ISO Guide 25 and ISO 9000 - Common grounds and differences

Initial basis

In Europe the EN 45 001 ("General criteria for the operation of testing laboratories", German version: 1989) and the ISO Guide 25 ("General requirements for the competence of calibration and testing laboratories", confirmed in 1990) serve as a basis for the accreditation of laboratories, i.e. for confirming the competence of laboratories and for ensuring the comparability of their results.

Slight differences between both standards exist in the more detailed description of the requirements related to the Quality Management in ISO Guide 25. In Germany the DIN EN 45 001 is generally applied in the common accreditation practice. Where necessary or required, the accreditor checks additional items of the quality management system (see below). The revision of the EN 45 001 has begun and shall lead to a complete correspondence of both standards.

The ISO 9001 standard (German version: DIN EN ISO 9001 "Model for quality assurance in design/

development, production, installation and servicing", last version: August 1994) contains general hints for establishing a quality management system, particularly in manufacturing firms. Owing to the high degree of generalisation and validity of these comments - independent from kind and extent of production or service - the certificates according to ISO 9000 have reached a high acceptance as well in Germany as in Europe.

Comparison

What are the common grounds and differences between an accreditation to the EN 45 001 standard/ISO Guide 25 and certificates to the ISO 9000 standards series?

Numerous detailed comparisons have been drawn and discussed, among others, in the DAR and its Committees and have been considered in the accreditation practice on the basis of the given recommendations.

Comparison between certification to ISO 9000 and accreditation to EN 45 000

Accreditation	Certification
<i>Definition:</i> Confirmation of competence for testing laboratories and certification bodies	<i>Definition:</i> Certification of conformity according to ISO 9000
aims at securing the test data, technical credibility, competence to carry out specific tests or tasks	general system for the quality management of an organisation independent of its functions
<i>the following elements are checked:</i> <ul style="list-style-type: none"> - quality management system - special requirements of the technical competence as: <ul style="list-style-type: none"> * personnel (also the manager) * behaviour of the personnel and management * well-defined test methods * validation of test methods * participation in interlaboratory comparisons, proficiency tests * adequate requirements for equipment, traceability 	<i>the following elements are checked:</i> <ul style="list-style-type: none"> - general quality management system - system requirements Assessment of the conformity with certain system standards In ISO 9000 the following elements are described in detail: <ul style="list-style-type: none"> * Valuation of the quality management system by the management * internal quality audits * review of the contract * test condition * corrective measures * statistical procedures

Conclusions

Clients of testing laboratories who are more accustomed to the ISO 9000 than to the EN 45 001 should know whether the laboratory follows also the requirements of the ISO 9000 concerning the quality management system. As the laboratories alone are not the clients of certification bodies and the additional certification of the quality management system of the laboratory is neither useful nor necessary, in some European countries the laboratory is given - if required - a confirmation on the accreditation certificate that it fulfils also the requirements of the DIN ISO 9000. The DAR has comprehensively dealt with this wish of the laboratories and has reached the following conclusion:

1. At the request of the testing laboratories the accreditation body can check the conformance of the relevant requirements of the DIN ISO 9002 and confirm this on the accreditation certificate.
2. The QM elements which are not sufficiently or even not at all contained in the present version of the DIN

EN 45001 have to be checked additionally by the assessor. Therefore it is necessary that the accreditation body has the required qualification and the assessors are appropriately trained.

3. A corresponding statement on the accreditation certificate is only permitted if this is explicitly asked from the laboratory and if the on-site assessment has proved that the requirements of the DIN ISO 9002 are fulfilled. Thus retrospective confirmations without any preliminary examination are not allowed.

4. The additional statement given on the DAR certificate is:

„The laboratory has proved that it fulfils - as a body offering performances and results of ... (testing/calibration) also the requirements of the DIN ISO 9002.“

Further information: Subdepartmental sections 7.13, 7.14

News from the DAR

On the 14th DAR-meeting on 13th June 1994 further members were admitted to the DAR:

- ZLG - Central Body of the Länders for Health Protection with regard to Medical Devices
- DACH - German Accreditation Body Chemistry
- DASET - German Accreditation Body for Steelwork and Power Engineering
- BSI- Federal Office for Safety in Information Technology

The new DAR-composition is shown by the figure on the following page.

Committee for Cooperation between the mandatory and the voluntary area (DAR-AZ)

On its last meeting the Committee could report the following results:

- * Agreements on the cooperation and definite task division of labour in accreditation matters exist between the following bodies:
 - BAPT, DATech and DEKITZ
„Agreement on the cooperation between BAPT, DATech and DEKITZ“
 - TGA/BAPT
„Agreement on the joint accreditation of certification bodies for QMS between BAPT and TGA“
 - BMPT/DEKITZ
„Agreement on the cooperation between the Federal Ministry of Posts and Telecommunications and the German Coordination Body for IT Standards Conformity Testing and Certification“

Committee for Technical Questions (DAR-ATF)

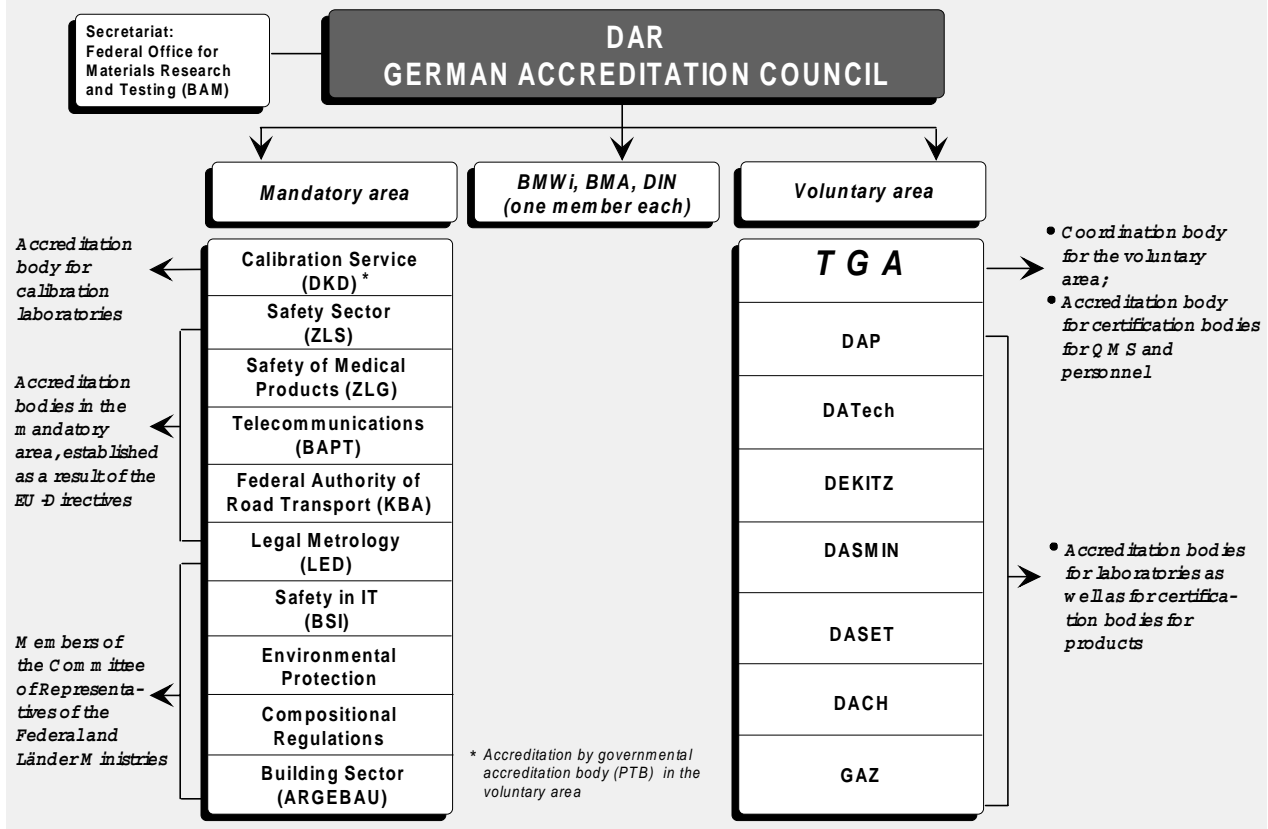
- * Since its foundation the following ad-hoc-working groups have been established:

- (1) Traceability in testing (Definitions and determination of terms; setting up of possible methods for traceability in a testing laboratory; necessary measures in a testing laboratory / For the time being a draft is in discussion)
- (2) Statement of the scope of accreditation (Structure in testing according to descriptors)
- (3) Uncertainty in testing (Definitions and determination of terms; application of the existing international recommendations /e.g. ISO/TAG 4/; methods for estimating the uncertainty / proposals for the statement of the test result; a draft giving examples about the statement of uncertainty in test results is in discussion)
- (4) Proficiency tests (Recommendations for general performance; reasonable requirements of the accreditors for carrying out interlaboratory comparisons; information on possibilities of a participation in interlaboratory comparisons/ as draft a DAR recommendation is at hand)
- (5) Validation in testing (possible validation methods; concepts for the comparability of test results; statements on the reliability and trustworthiness of test results /a draft for a DAR recommendation is being elaborated)

All these works promote a better transparency and comparability of the requirements of the standards (EN 45 001 and ISO Guide 25) for laboratories and certification bodies.

Further information: Subdepartmental section. 7.13

Composition of the DAR



News from standardisation

EN 45001: It is expected that during next year a revised version of the ISO/IEC-Guide 25 will replace the existing version of the EN 45001.

EN 45011/12/13: At the present time the drafts of the Guidelines ISO/CASCO/WG8/55-57 are being revised. After their endorsement it is planned to take them over into the European standards series EN 45 000. Then the ISO/CASCO/WG8/55 will be the

standard giving general criteria for bodies accrediting certification bodies. Both other Guidelines will replace the standards for general criteria for certification bodies certifying QMS and products.

ISO 9000/EN 29 000: The EN 29 000 standard will be deleted.

Further information: Subdepartmental section 7.13

News from international organisations

EAL

Merger of the European accreditation organisations for laboratories

WECC + WELAC = EAL. This is the „formula“ for the new organisation „European cooperation for Accreditation of Laboratories“ with the acronym EAL.

EAL was founded in Paris on 1st June 1994 by merging the existing European organisations Western European Calibration Cooperation (WECC) and Western European Laboratory Accreditation Cooperation (WELAC).

The beginning of this merger was marked by a Memorandum of Understanding (MoU) - signed by the delegates of 17 countries - and by the election of an Executive Committee (Chairman: Mr. Kaarls, NL).

The work of this new organisation, which means also (as a consequence of the merger) one organisation less

on the European level, is oriented first of all in using this advantage: The accreditors can understand each other in a better way and take part in an effective exchange of experience.

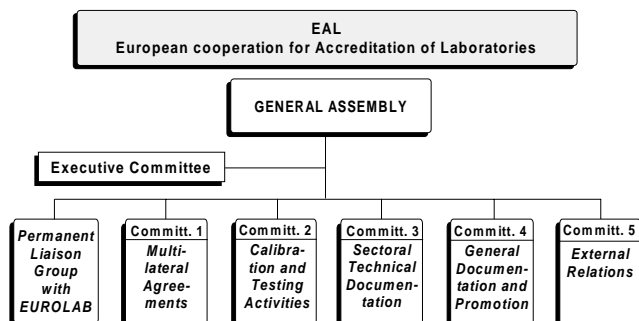
The cooperation between laboratories and accreditors is coordinated by an EAL/EUROLAB-Permanent Liaison Group (PLG).

Thus the realisation of an important aim of the accreditors comes closer: to improve the quality of the laboratories' work and to enable a better comparability of test results.

For Germany and its representation in EAL it is of great importance to be actively involved in the structuring of an effective, i.e. also cost-saving, operation of the organisation and also thereby to bring in EAL the opinions agreed upon German accreditors in Committees, among others, in the DAR.

EAL Committees are the General Assembly, the Executive Committee, five further Committees as well as the PLG (see figure).

The approved terms of reference of the organisation are first of all to promote the international acceptance of the Multilateral Agreements (MLA) and the European infrastructure in testing/calibration as well as to support the cooperation with other organisations as EAC, EOTC, ILAC, EUROLAB, EURACHEM etc.



Further information: Subdepartmental section 7.13

EUROLAB

EUROLAB-Workshop „Validation of testing and analytical procedures“

The EUROLAB-Workshop took place in Germany for the first time (in Barcelona in 1992 on measurement uncertainties; in Espoo in 1993 on the competence of

the personnel; in Stuttgart in September 1994, 120 participants from 19 countries;).

The discussion was characterised by two aspects: the clarification of the term „validation“ and examples of definite validation methods from practice. The discussion was supplemented by poster session. The Proceedings of this conference are available.

3. EUROLAB-Symposium in Berlin

The 3rd Symposium will take place in Berlin during 5. -7. June 1996 under the topic „Testing and analysis for Industrial Competitiveness and Sustainable Development“. A first announcement with a „Call for papers“ is in preparation.

EUROLAB-Directory and Handbook 1994

The present Directory with about 800 European testing laboratories and their testing fields as well as with the most important European and international organisations in the field of accreditation and certification is available for a price of DM 374,-- (EUROLAB members: DM 182,--), additionally with a diskette (for an extra charge) via: Beuth-Verlag GmbH, Burggrafenstr. 6, D-10787 Berlin (Tel./Fax: (+30) 2601-2260/1231) or via: EUROLAB-Deutschland, Unter den Eichen 87, D-12205 Berlin (Tel./Fax: (+30) 8104-3769/1717).

Further information: Subdepartmental section 7.14

Cooperation between Western and Eastern Europe in building up accreditation structures

In Berlin, September 1993, a first joint East-West-Symposium organised by the Deutsche Gesellschaft für Zerstörungsfreie Prüfung (DGZfP, German Society for Non-Destructive Testing) took place under the title „different history - common future“ with the topics accreditation, standardisation and certification. Numerous representatives from national and European organisations as well as Eastern European partners, as e.g. from institutes and organisations from Russia, Belorussia and Hungary took part in this Symposium. Special questions of accreditation, certification of products and personnel in the field of NDT in these countries as well as the validation of NDT test procedures were in the centre of interests.

As a result of the Symposium and on an initiative of the DGZfP - in cooperation with the TGA, the DAP and the BAM - an information seminar supported by means of the BMWi¹ was carried out in Minsk (Belorussia), in which more than 130 interested persons from industrial firms and institutes from the GUS² took part. In the centre of interest was the present experience in the European technical harmonisation from the German point of view and the seeking of effective possibilities to realise the relevant processes for the systems in the GUS now developing under complex conditions.

Therefore in December 1994 a second training course for assessors, this year in Piztany/Slovakia, took place in which the VdTÜV³ and the BAM took part.

Apart from fundamental questions on sense, benefit as well as content and detailed procedure of an accreditation, also problems of the selection and training of assessors played an important part in the lectures and discussions and afterwards in the round table discussion.

First successes of those contacts, which should not be limited to the mutual information and exchange of experience, are the accreditations - carried out by the TGA - of the engineer's centre „Certico“ in Minsk and of the testing and training centre of the MGU „Bauman“ in Moscow as certification bodies for personnel in the field of NDT.

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¹ German Federal Ministry of Economy

² Commonwealth of Independent States

³ Association of Technical Inspection Agencies