
DACH - Report on the accreditation for types of testing

At the beginning of the accreditation of testing laboratories in the end of the eighties only the accreditation of single test methods generally based on standards procedures were possible. The founders of the DACH Deutsche Akkreditierungsstelle Chemie (German Accreditation Body for Chemistry) recognised at the beginning of the nineties that in many fields such an approach is not feasible. That concerned in particular those laboratories which performed non-routine tests.

When founding in 1992, the DACH therefore introduced a new model, which allows more flexibility to the scope of accreditation. Therewith the necessary flexibility of a laboratory during accreditation should also be ensured.

More flexibility of the scope of accreditation seems to be of special importance, if a considerable number of similar standard test methods or in-house test methods and/or non-routine tests shall be accredited. The central tool for more flexibility is the accreditation for types of testing.

After having performed the accreditation for a type of testing, the laboratories are entitled to include into the scope of accreditation further test methods within the granted type of test, without having to give an immediate note to the accreditation body. This note is made within the frame of the determined surveillance intervals.

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First of all the respective technical committees (sectoral committees) had to specify the types of tests for each individual field of testing.

The types of tests were defined both in relation to technology and to their application. Altogether hundreds of types of tests had been defined by the respective sectoral committees. If required, further types of tests can be included at any time. In some fields of testing the flexibility provided by the accreditation for types of testing does not include the flexible scope of accreditation relating to the test object, e.g. in analytics. I.e. the accreditation of the type of testing e.g. *gas chromatography* relates to the test object e.g. *water* and is specified in the annex to the certificate.

Furthermore, the responsible committees laid down minimum requirements having to be fulfilled by the laboratories for the accreditation of one type of testing. One of the priorities is that the laboratories have to provide special instructions on validation or verification of test methods. For the competent approach in validation or verification documentary proof must be given for a minimum of test methods.

In more than 90 accreditation procedures the DACH has successfully applied the accreditation for types of testing. During the surveillance only a few cases showed an incorrect practice with the flexibility and the trust connected therewith. New test methods having included in the scope of accreditation by the laboratory, had not been validated and verified respectively. For this reason the accreditation of the respective types of tests had to be withdrawn from the laboratories.

The model of the accreditation for types of testing as a means for more flexibility in the scope of testing has repeatedly been presented both nationally and internationally. It has been published a.o. in the Journal "Accreditation and Quality Assurance (7/98)" and is an annexed part of the EURACHEM/CITAC Guide 2 "QA Best Practice for Research and Development and Non-routine Analysis".

The procedure proposed by the DACH is implemented in an EA Guideline (EA-2/05 "The Scope of Accreditation and Considerations of Methods and Criteria for the Scope in Testing"), endorsed by the DAR as DAR-EM27 and retrievable from the Internet. The DAR documents DAR-EM7 and DAR-EM8 valid so far as well as the document for flexible accreditation (to be tested in practice) have been therefore withdrawn.

During the DACH evaluation procedure for obtaining the European recognition, the accreditation for types of testing has been recognised by EA (European cooperation for Accreditation). Several accreditation bodies, both national and international, have also introduced the flexible approach for the accreditation of testing laboratories.

Dr. A. Steinhorst, DACH

News from the DAR

6th Tutors' Exchange of Experience within the DAR

On 4th and 5th March of this year, the DAR Secretariat carried out at BAM the 6th Exchange of Experience of the Tutors from the D-A-CH countries on behalf of the DAR-ABT.

All tutors work on the basis of the common D-A-CH training concepts. This **framework training programme for assessors in the German-speaking area** has already been elaborated in 1993 as well as coordinated and tested in an intensive cooperation between the three German-speaking countries and is part of their accreditation systems.

The tutors impart basic knowledge on accreditation to the assessors. During the special training courses (advanced training, exchange of experience) the assessors receive all essential information and documents required for updating their state of knowledge. All the more important for the tutors is the flow and exchange of information on their regular meetings. All these meetings aim at completing the knowledge of the tutors with up-to-date information about European and international accreditations and to provide the tutors with the recommendations elaborated in the relevant

international and DAR Committees. Thus the tutors can both impart their personal experiences and gain new knowledge. International guests and representatives of other accreditation systems (Estonia, Latvia, Jordan, Slovakia, Peru) were also invited to take part in the 6th Tutors' Exchange of Experience. Their participation should contribute to increase the mutual confidence in the qualification and training of the assessors.

The programme of the Tutors' Exchange of Experience of this year comprised the following issues:

- Experience gained in evaluating assessors (monitoring of assessors)
- Up-to-date information in the field of accreditation, e.g. standardisation, information from EA, IAF, ILAC and the DAR
- Technical issues on accreditation, such as proficiency testing, reference materials, flexible scope of accreditation and traceability
- Practical experience on:
 - Cooperation between the mandatory and the voluntary area
 - Accreditation of inspection bodies and for certification bodies for products

N. Bendix, BAM-S.42

DAR Homepage

The DAR Homepage which is certainly known to many of our Readers, has been revised by the DAR Secretariat and designed more user-friendly.

Our Website continues to be accessible at the familiar address <http://www.dar.bam.de>

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 TRAINING STATISTICS HANDBOOK DOCUMENTS STANDARDS MLA LINKS

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Deutscher Akkreditierungsrat

The German Accreditation Council (DAR) is a working group established by the Federal Government, the Laender Ministries and the German industry. The DAR has been founded in 1991. It has the following [tasks](#)

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Information from the EA General Assembly (Venice, 1st to 3rd June, 1999)

- At the EA General Assembly held in Venice from 1st to 3rd June, 1999, the constitution of EA as legal entity with formal seat in Great Britain had been discussed. Due to the complexity of the procedure in Great Britain and e.g. unclear questions with regard to the joining of state accreditation bodies integrated into ministries, the seat of EA shall be rethought again. One agreed on that the transformation of EA into a legal entity should not have consequences both for the MoU and the MLA. The accreditation systems currently operating in the countries shall continue to be existing. Costs and taxes for the foundation and operation of EA as legal entity should kept as low as possible.
- The accreditation bodies of Latvia (LATAK), Lithuania (LA) and Hungary (OMH) are taken on board as EA full members. Estonia (EVS) and Slovenia (SMIS) retain their status as associate members for another one year according to the old rules.
- The paper on the cooperation with sector-specific accreditation systems as well as the Annex to the Document EA-4/02 "Expression of Uncertainty of Measurements in Calibration" have been endorsed.
- Daniel Pierre (COFRAC, France) has been elected new Chairman of EA with the beginning of January 2000.
- The Memorandum of Understanding (MoU) on the cooperation between EA and the European Commission has been signed officially. The EFTA announced an analogous step.
- At its next meeting to be held on 5th November this year, the EA Advisory Board (EAAB) will deal with the following main issues: "Recognition and Acceptance", "Accreditation and Notification" and the "Added Value" of accreditation in the context with mutual recognition agreements.
- A MLA for inspection bodies shall be drawn up after the evaluation of six inspection bodies at the earliest.

Dr. J. Thiele, BAM-S.42

Cooperation between EA and APLAC (Asia Pacific Laboratory Accreditation Cooperation)

On 14th April 1999 the first common meeting of the two MLA Committees took place in Paris. A bilateral agreement on the cooperation and mutual recognition shall be prepared between the two regional accreditation organisations EA and APLAC. To increase confidence, as much mixed teams (between EA and APLAC) as possible shall execute future evaluations.

This method proved very worthwhile during the evaluations of NATA (Australia) and IANZ (New Zealand). The re-evaluations of DAP, DATech and DEKITZ will be accompanied by an APLAC representative as a member of the evaluation team.

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EC-Organic Production Regulation

In the EA Sectoral Committee C5 a Working Group WG8 "Organic Farming" has been set up. Aim of this Working Group is the EU-wide harmonisation of the approach in accrediting inspection bodies for organic farming operating within the EU and in third countries including textually coordinated Checklists, in order to achieve a uniform product certification according to EN 45011 in the field of organic farming in Europe. Basis is the Council Regulation (EEC) No. 2092/91 of 24th June 1991 *on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs* with requirements for inspection bodies in Europe and in third countries. All these inspection bodies, also those with official authorisation, "must fulfil the requirements set out in the EN 45011 standard".

In Germany the "Länderarbeitsgemeinschaft" (LÖK) has drawn up "Coordinating regulations of the federal states". These Regulations imply that there is no pressure of time with regard to the activities of the inspection bodies, which are officially authorised in Germany for several years, as the aspect of the EN 45011 standard has been considered in accordance with Article 9 (11) of the EC Council Regulation. After the fixed-term approvals have been expired, accreditations are also included in the inspections of the admission requirements. The situation with regard to inspection bodies in third countries appears to be more critical. There the examination of each inspection body operating in a third country must be successfully finished with regard to the requirements set out in the EN 45011 standard until 30th June 1999 at the latest. The following approach has been predetermined in the Regulations: "Private inspection bodies must undergo a regular supervision with regard to their activities in a respective third country. The supervision can be carried out a.o. by an accreditation body." Appropriate documentary evidence for approvals granted by inspection bodies is an accreditation carried out according to the EN 45011/ISO 65 standards in combination with the EC-Organic Production Regulation valid for that third country from which the products are imported. The accreditation body must be a member of the EA MLA or of the IAF MLA. The first accreditations are currently performed by the German Accreditation System for Testing (DAP).

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News from standardisation

ISO 9000

After the Committee Drafts 1 (CD 1) on the revised standard series ISO 9000:2000 have been published in Autumn 1998, the Committee Drafts 2 (CD 2) have been available for public discussion since May this year. This will lead to repeated revision proposals within the NQSZ-1 in the Middle of May.

These proposals will then be considered in the international discussion and voting in ISO TC 176. The next steps then will be ISO/DIS and ISO/Final DIS, so that according to the time schedule the passed standards ISO 9000 (substitute for 9000-1 and 8402), ISO 9001 (substitute for 9001, 9002, 9003) and ISO 9004 (substitute for 9004-1) are expected to be issued at the end of 2000.

A little later a fourth standard (the previous ISO 10011, parts 1-3) will be expected, which is to be replaced by a new standard, the ISO 19011 - for the Auditing of Quality and Environmental Management Systems. Up to now the Draft of a Guideline exists, which is still under discussion in the respective committees (a.o. in NQSZ-1.3 and NAGUS).

Even now companies (which have already been certified) as well as certification bodies are just determining so-called "Deltas", i.e. additional requirements, in order to prepare for a practical change-over.

As the new ISO 9001 does not explicitly lay down a management manual structure, the manuals structured on the basis of the old ISO 9001 can be retained unchanged.

Those who have orientated anyway with their management system in their companies by the most significant processes, are quite correct with the new ISO 9000, because it is process-oriented (see Fig.).

Besides the reduction to four core standards, further essential advantages of the new standards can even now be foreseen:

- A better compatibility between quality management and other management systems (a.o. EMS)
- Through process orientation: Better applicability by service providers as well as other branches and in different sizes of companies

- Clear orientation by customer demands/expectations, following from that the feasibility of a "Tailoring", i.e. bringing the management systems into line with these expectations

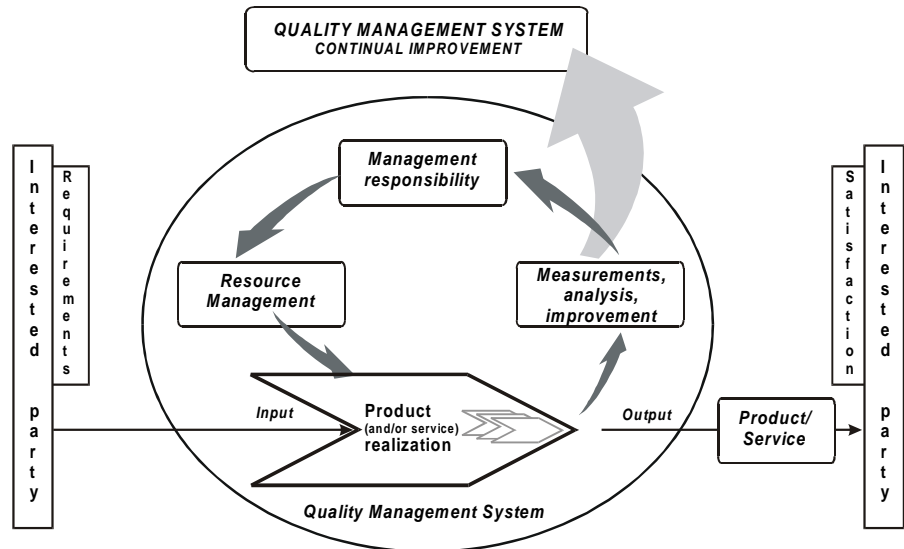


Fig.: Quality Management Process model of the new ISO 9001/9004

- A more intensive inclusion of the "Self-Assessment" for verifying the system's efficiency
- Orientation and compatibility with "Excellence"-systems (Awards).

Some additional requirements of the new ISO 9002 relate to:

- Objectives relating to quality management review
- Consistent improvement processes
- Evidence, not only for the performance, but also for the effectiveness of training courses
- Orientation towards customer demands

According to present interpretations of the drafts, the new ISO 17025, which is structurally based on the previous ISO 9000 standards series, reflects very well also the new ISO 9000, so that after the publication of the new ISO 9000 a modification of the ISO 17025 will not be immediately necessary.

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Preview DAR-aktuell 3/99

In few weeks the next Issue of our Newsletters DAR-aktuell will be published and mostly dedicated to the topic of "standardisation" (EN 45000, 17025).

Imprint: Editor: Bundesanstalt für Materialforschung und -prüfung (BAM), DAR Sekretariat, Unter den Eichen 87 D-12205 Berlin, GERMANY, (++49-30-8104-1942, Responsible for redaction: Dr. Monika Wloka, BAM-S.42 July 1999, ISSN 1436-2082