

Accreditation of inspection bodies

Since March 1995 the European Standard EN 45004 "General criteria for the operation of various types of bodies performing inspection" is in force. According to this standard *inspection* is defined as follows:

"Examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements, or, on the basis of professional judgement, general requirements."

Note 1:

Inspection of processes includes personnel, facilities, technology and methodology.

Note 2:

The results of inspection may be used to support certification.

This standard differentiates **among** three types of inspection bodies:

Type A: Inspection body that provides "third party" services.

Type B: Inspection body that forms a separate and identifiable part of an organisation involved in the design, manufacture, supply, use or maintenance of the items it inspects.

Type C: Inspection body which is involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects or of similar competitive items and may supply inspection services to other parties not being its parent organisation.

The requirements for the independence of these three types of inspection bodies are different.

How do inspection bodies differ from laboratories or from product certification bodies ?

For a long time the reply to this question has not been clear. Various European and non-European countries answered this question in a different way. An EAL/EAC Working Group has reached agreement on the following differences:



	<i>Product certification</i>	<i>Inspection</i>
<i>Type of activity</i>	Certification of product series, always by Third-Party bodies (indirect assessment of conformity) No certification of products, installations in operation	Inspection of individual products, not only by Third-Party bodies (direct assessment of conformity) Inspection of products, installations in operation
<i>Licensing</i>	Certificate or licence can be withdrawn	No licensing
<i>Products marking</i>	Certification mark can be affixed on all products and on products manufactured under licence	The mark is affixed only on the product accepted during inspection
<i>Surveillance</i>	Surveillance usually not necessary	Surveillance usually not necessary
<i>Subcontracting</i>	Normal regulation	Special regulation

Who now had thought, everything **would** be all right and he might have understood the differences, will meet with conflicts when reading the new ISO Guide 2 (1996) or the revised EN 45020 Para. 14.2, where inspection - similar to Para. 13.3.1 in EN 45020 (1993) - is defined as follows: "Conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging".

Although Para. 1.4 of EN 45004 says that this standard does not cover testing laboratories, certification bodies or the suppliers' declaration of conformity, in practice a clear distinction between inspection bodies, testing laboratories and certification bodies is not easy.

The definitions given in the EN 45000 standards series are not consistent and their application creates difficulties.

<u>In this issue</u>	<u>Page</u>
● Accreditation of inspection bodies.....	1
● News from international organisations	
◦ First General Assembly of ILAC after its re-constitution.....	2
◦ Worldwide IAF MLA under preparation.....	3
● News from the DAR	
◦ Exchange of experience between DAP and accredited laboratories.....	3
◦ 20 years DKD - 140th PTB Seminar.....	3
◦ News from the DAR-Committee "Cooperation" (DAR-AZ).....	3
◦ Regulation on the disposal of used cars.....	4
● 2nd AMOS Information Days in Berlin.....	4

A former German proposal aimed at restricting the EN 45004 standard only to products in use. This would allow an applicable differentiation.

German approach:

The national foreword to EN 45004 says: "The German state accreditation bodies declared that they do not make the DIN EN 45004 standard a principle of their accreditation decisions, but they will take the DIN EN 45011 standard as a basis, in connection with the DIN EN 45001 standard, if appropriate. The accreditation of testing bodies, as far as they are covered by EC Directives, is performed in line with these standards. In the voluntary area the DIN EN 45004 standard is intended to be used for those accreditation of bodies, which can neither be accredited as testing laboratories to the DIN EN 45004 standard nor as certification bodies to the DIN EN 45011 standard."

DAR proposal:

As the accreditation of inspection bodies is being more and more applied in Europe and an increasing demand will be expected in Germany too, the DAR agreed on a pragmatic approach, the aim of which is:

- * to produce as little additional expenditure for accreditation bodies, assessors and applicants as possible,
- * to cause as little confusion for differentiating among testing laboratories, inspection and certification bodies as possible, and
- * to avoid that horizontal fields in the EN 45001 and EN 45011 standards are subject to different requirements, if possible.

On its meeting held on 15.04.1997 the DAR took the following decisions based on the knowledge at that time:

1. Testing laboratories seeking to receive a confirmation of being capable to give estimations, are assessed according to EN 45001 and EN 45004. On request they receive both accreditation certificates.
2. Bodies mainly using external testing institutions for performing the necessary tests, are assessed according to the EN 45001 and EN 45004 standards. However, they receive only one certificate as inspection body.
3. Certification bodies which need the accreditation as inspection body for formal reasons for their "direct"

confirmation of conformity, receive it on request without an additional assessment, provided that the necessary tests are performed in the main by their staff and the testing equipment is assessed according to the EN 45001 standard. The additional assessment of accredited testing laboratories or certification bodies according to the EN 45004 standard is generally a mere document review, as far as the abovementioned principles are fulfilled. However, in particular the extent of independence (type A, B, C) is to be ascertained.

The terms therefor are shown in Para. 4 of the EAL/EAC recommendation EAL-G24 "Accreditation of Inspection Bodies". They are harmonised in Europe.

Is a special standard to be applied by accreditation bodies for inspection bodies a matter of necessity ?

The tendencies to be observed at some European accreditation bodies - to establish special accreditation bodies or sections for the accreditation of inspection bodies and to elaborate a special European standard - are not supported in Germany. A comparison between the EN 45010 and EN 45003 standards made by an EAL-EAC Working Group shows that the requirements for accreditation bodies for laboratories and for certification bodies do not differ very much compared with those for the accreditation of inspection bodies, so that a separate standard for the accreditation of inspection bodies would be justified. Nevertheless, it is to be feared that the international "urge to draw up standards" will lead to a third standard to be applied by accreditation bodies instead of combining the EN 45010 and EN 45003 standards.

ISO/CASCO decided to adopt the EN 45004 as an international standard, and is preparing the so-called Fast Track Procedure for voting. The German accreditation bodies for laboratories and for product certification bodies have already included in their scopes the accreditation of inspection bodies. They are practising a pragmatic approach according to the abovementioned procedure. In Germany one inspection body has been accredited to date by the German accreditation body DATech. Several inspection bodies have applied for accreditation. The partly unclear definitions given in the respective standards shall not bring disadvantages to laboratories and inspection bodies.

M. Wloka, BAM-S.42

News from international organisations

First General Assembly of ILAC after its re-constitution

In issue no. 2/96 of DAR-aktuell we reported about the re-organisation from ILAC as International Laboratory Accreditation Conference to the International Laboratory Accreditation Co-operation with the aim to tighten up the organisation and to become more effective.

For the first time after its re-constitution the ILAC General Assembly met in Gaithersburg/USA from 14 to

15 October 1997, after the Committees had finished their meetings the days before.

As a result of the first General Assembly one can realise that ILAC begins to reorganise. The membership of Stakeholders and laboratories has been determined.

ILAC's information policy must be improved considerably. Therefor a new INTERNET page has been prepared, which is retrievable under <http://www.netorder.com.au/jwebster/ilac>. In future ILAC will clarify the problems of the Secretariat, will

check, whether ILAC can become a "legal entity" and whether an international accreditation logo shall be applied by ILAC.

The mutual recognition of accreditations granted within the organisation ILAC shall be organised through regional MLAs, if possible. In the near future preparatory work will be done therefor within the Committee for Accreditation Policy.

During the Meeting of the General Assembly several members called for a closer cooperation with IAF with the aim to merge these two organisations in future into one international organisation for accreditation bodies as well for laboratories as for certification bodies, which will coordinate all essential international tasks at one hand.

In future views and opinions on matters of interest to the accreditation community may be presented in the ILAC-Newsletter "ILAC-News". This possibility will be offered also to German accreditation bodies and

accredited laboratories. If readers of DAR-aktuell wish to contribute to ILAC-News, they are invited to submit their information to the DAR Secretariat at any time.

M. Wloka, BAM-S.42

Worldwide IAF MLA under preparation

In October 1997 the MLA Committee of IAF (International Accreditation Forum) held its first meeting dedicated to the evaluation reports of the five accreditation bodies for quality system certification having been evaluated by an evaluation team with regard to the fulfilment of the requirements set out in the international standards and IAF Guidelines. The aim is to reach the mutual recognition of QS certificates.

Three other accreditation bodies applied for entering into the IAF MLA. The results gained at this MLA Committee meeting point out that the first international IAF MLA could be signed in January 1998.

M. Wloka, BAM-S.42

News from the DAR

Exchange of experience between DAP and accredited laboratories

The DAP (German Accreditation Body for Testing) organised an exchange of information and experience among accredited laboratories held in Berlin on 26 September 1997. Even representative of non-accredited laboratories took part to inform about latest trends/developments and chances. About 150 participants discussed about fundamental experience gained through the accreditations conducted by the DAP to date and the latest development of standards (EN 45001 and ISO Guide 25), in particular considering the aspects of uncertainty or results, validation, professional judgement. EUROLAB-D (Germany) seized the opportunity of presenting its activities at national and European level.

Topics of special interest were recent developments in accreditation practice, as eg the flexible scope in accreditation and the cooperation with accreditation bodies from the mandatory area. These topics are also reflected by first results gained in the DAR Committee DAR-AZ "Committee for Cooperation between voluntary and mandatory area". At the same time it became apparent that current problems related to the international recognition of test results and certificates (as well the recognition of the respective accreditation bodies granting the certificates) can be solved only through appropriate ways of cooperation.

C. Peters-Tanneberger (DAP), R. Schmidt, BAM-S.41

20 years DKD - 140th PTB seminar

On 2nd September 1997 the DKD (German Calibration Service) celebrated its 20th day of foundation. We congratulate the DKD on this event and wish many further

successful years in providing necessary services for a highly developed infrastructure in metrology. The DKD is one of the most active accreditation bodies within the DAR, in particular in view of its activities within the DAR Committee ATF (Technical Issues). This is also reflected by the 140th PTB Seminar held on 3rd September 1997 and dedicated to the 20th DKD Anniversary. The following topics were under discussion: the DKD as an element of the infrastructure in metrology from the industry's point of view, specific problems of traceability to SI units in chemistry and laboratory medicine, electric measurement technology and micro- and nano-technologies in process measurement technology as well as the accreditation in the chemical industry and the role of accreditation in international trade relations.

R. Schmidt, BAM-S.41

News from the DAR Committee "Cooperation" (DAR-AZ)

In 1997 the DAR-AZ held three meetings, which were focussed on the following topics of interest:

- * Elaboration of a uniform specimen of a quality manual to be used by DAR accreditation bodies considering their specific branch-related problems
- * DAR Procedure for complaints
- * The EN 45004 standard in the German accreditation practice
- * Handling of subcontracting in accreditation
- * Surveillance of food manufacturers by the Authorities (a. o. application of the EN 45000 standards series in implementing the EC Directive 93/99/EEC)
- * Accreditation in the field of medical devices
- * Comparison of requirements set out in GLP, GCP, ISO Guide 25/EN 45001, ISO 9000 and ISO 14000
- * Performance of inspections on the basis of the "Altauto-Verordnung" (Regulation on the disposal of used cars) by experts (coordination of demands to be made on experts

with the BMU - German Federal Ministry for Environment, Nature Conservancy and Reactor Safety)

Further information was given about various activities with regard to the individual scopes of accreditation and about the DAR.

N. Bendix, BAM-S.42

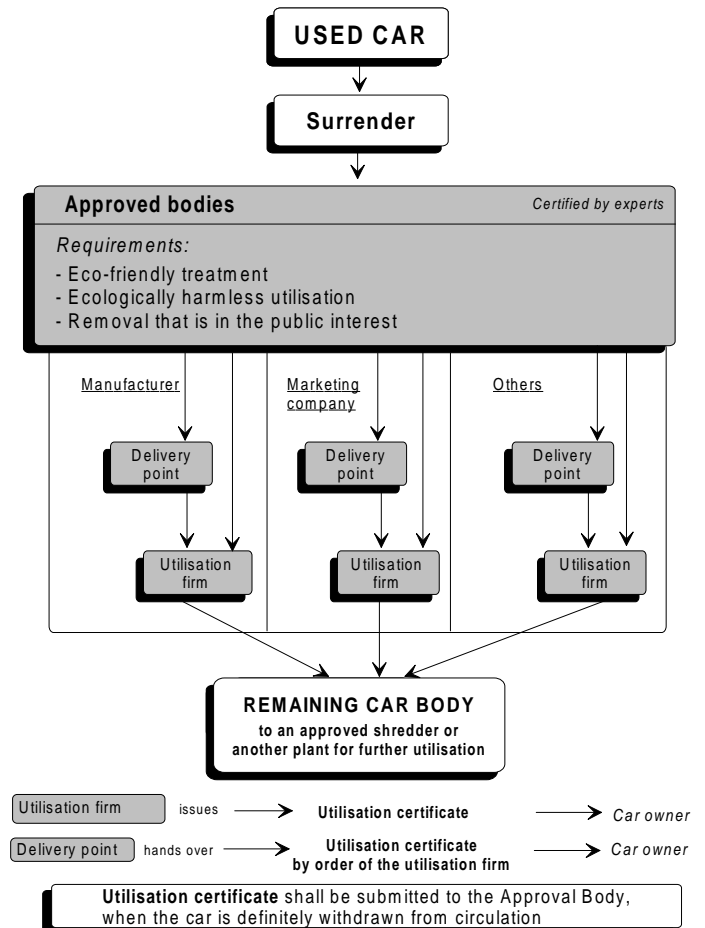
Regulation on the disposal of used cars

§5 of the "Regulation on the surrender and eco-friendly disposal of used cars" (Altauto-Verordnung, published on 04.07.1997 in the Federal Law Gazette I p. 1666) says: "Certificates according to §4 Para. 2 Cl. 1 may be issued by those persons, who are officially authorised according to §36 of the Trade Regulation Act (Gewerbeordnung) or whose qualifications are established by a member of the German Accreditation Council in a commonly recognised procedure."

This means, firms utilising used cars and delivery points have the following feasibilities to have the necessary requirements checked and confirmed:

Regulation on the surrender and eco-friendly disposal of used cars

4th July 1997 (Federal Law Gazette I p. 1666)



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2nd AMOS Information Days in Berlin

Within the frame of the AMOS project ("Accreditation and Certification in Middle and Eastern European States") organised by the Federal Institute for Materials Research and Testing (Bundesanstalt für Materialforschung und -prüfung, BAM) and initiated by the German Federal Ministry for Economic Affairs (Bundesministerium für Wirtschaft, BMWi), several state and private institutions in Middle and Eastern Europe (in particular national accreditation and certification bodies as well as testing laboratories) are supported in bringing the structure and operation of their systems in line with the requirements valid in Western Europe. The aim is to harmonise the West and East European systems and thereby to eliminate the technical barriers to trade - the mutual non-acceptance of test results and certificates -, which still exist between Western and Eastern Europe.

The 2nd AMOS Information Days held in Berlin from 23 to 25 April 1997 made it possible to the fourteen partners from Middle and Eastern Europe (incl. Russia, Ukraine and Belorussia) to inform about latest developments in Europe in the field of accreditation, certification and testing. Focal point of the reports given by lecturers from France, The Netherlands, Switzerland, Sweden and Germany was not only the representation, but above all the implementation of recent developments in the Western European countries. At the beginning representatives from the European Commission and the BMWi presented European and German strategies and aid programmes to support the restructuring processes of the accreditation systems in the Middle and Eastern European countries. On the last day the representatives of the Middle and Eastern European countries introduced their accreditation systems, which were intensively discussed by all participants.

On balance the result of these Information Days was that many partners in the Middle and Eastern European countries have established national structures that are very similar to those of Western Europe and support the mutual trade. The AMOS Project was appreciated by all participants from Western and Eastern Europe. It contributes significantly to the elimination of barriers to trade. All participants expressed their desire to continue the AMOS Project in future.

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