

## *Mutual recognition of test results and certificates*

Since January 1st, 1994 we are implementing the common Single Market in Europe, an economic area for 378 millions of customers. Such a common market may be only realised, if all technical barriers to trade are eliminated. As a result testing and certification as confirmation of compliance with the demands of the customers on the products have gained great significance. The non-recognition of tests and certificates may create great barriers to trade. No doubt, this fills the orderbooks of the testing and certification bodies, but equally increases the costs for products without showing a real increase in value.

How can a mutual recognition be obtained?

### The "Global Approach"

In the „Global Approach to Testing and Certification“ the Commission of the European Union (EU) has made proposals how technical barriers to trade can be removed:

1. Putting into force of harmonised **EU-Directives**, which contain fundamental requirements concerning:

- specific products relevant to the safety and protection of persons,
- the performance of their adequate conformity assessment procedures and
- the bodies carrying out those procedures and notified to the Commission of the EU by the Member State.

2. Drawing up **voluntarily applicable standards** to substantiate provisions of the guidelines.

3. **Creation of confidence** in the activities of the testing and certification bodies by confirmation of their competence, i.e. by **accreditation**.

Hence the **requirements of the Global Approach** are:

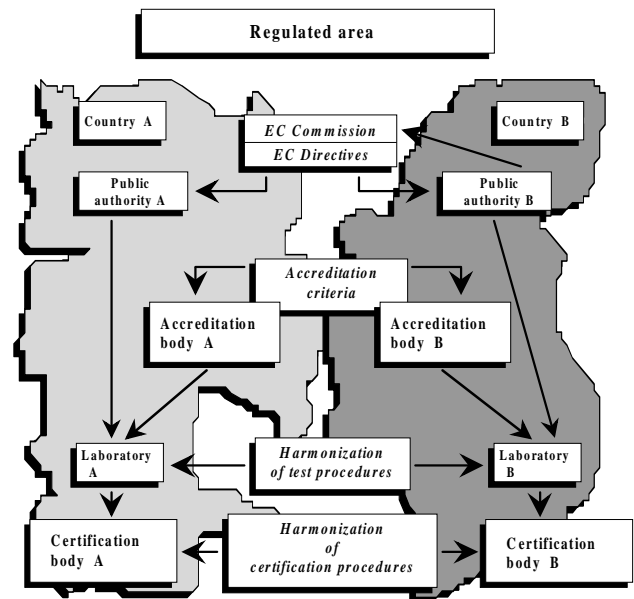
- Establishment of national accreditation structures,
- uniform rules for the operation of testing laboratories and certification bodies and
- uniform rules for the accreditation.

Essential contributions to realise this objective are:

- **Concerning the products:** the application of harmonised European standards,
- **concerning the manufacturer:** the use of techniques of quality assurance according to the international standards series ISO 9000 (meanwhile as European standards part of the national standards in EU and EFTA),
- **concerning the testing, certification and accreditation bodies:** the fulfilment of the European standards of the EN 45000 series.

### Concept for mutual recognition

#### Mandatory area



According to the EU Contract in the mandatory area the authorities of each Member State are compelled to recognise the certificates of conformity given by a notified body. <sup>1</sup>

Hence the Member State takes the political responsibility that the notified bodies are in compliance with the minimum requirements defined in the directives. Under these conditions, the mutual recognition of test and certification results by the authorities of the other

<sup>1</sup> A notified body is a neutral organisation the conformity assessment procedures of which are confirmed by its national government in the meaning of EU harmonisation directives. This body is notified to the Commission of the European Community as well as to all other Member States.

Member States is **obligatory**.  
**Voluntary area**

In the voluntary area the **client** decides which test results and certificates he accepts and whether he demands an accreditation or not. Two ways are possible:

1. Mutual recognition of the certificates by the **Certification bodies** integrated into **Agreement Groups** and having concluded a **Recognition Arrangement**. Examples for agreements in the electrotechnical field are:
  - CENELEC-Certification Agreement (CCA),
  - HAR - for cables and lines,
  - EMEDCA - for electromedical devices.

For the „normal client“ all those agreements rapidly get unclear, as several Agreement Groups in the same field but with different and not always transparent conditions may establish.

Therefore the Commission of the European Union has founded **EOTC** (European Organisation for Testing and Certification) that registers Agreement Groups under the following circumstances:

- At least three countries from EU/EFTA are participating.
- The criteria of the EN 45000 standards series are fulfilled.
- The objective of the group is the mutual recognition of tests or certifications.

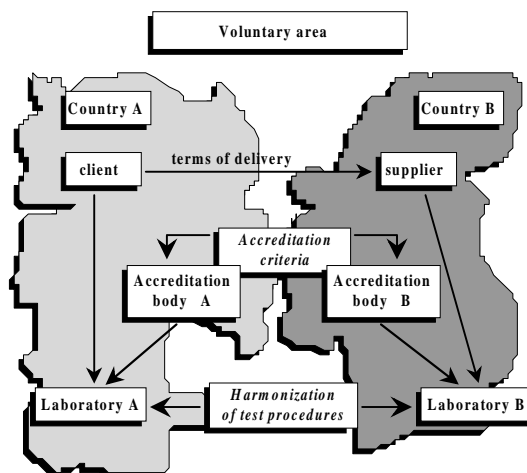
2. Mutual recognitions of **accreditations** which shall ensure the equivalence of the confirmation of competence of the testing laboratories or certification bodies and thereby the respective recognition of test results and certificates.

To realise this, concepts have been developed by:

WECC - Western European Calibration Cooperation (accreditor of calibration laboratories),

WELAC - Western European Laboratory Accreditation Cooperation (accreditor of testing laboratories),

EAC - European Accreditation of Certification (accreditor of certification bodies).



In the case that a client from country A buys a product tested for a quite low price in a laboratory of another country B, this client should have confidence in this laboratory B, if it has been accredited by the accredita-

tion body B to the same conditions that are known in country A.

If the testing procedures are additionally harmonised, the accreditation bodies A and B have mutually recognised each other and are probably applying the same accreditation criteria, then the customer should have confidence and the cost-saving variant should be acceptable by him.

To be able to realise this concept, the following steps are necessary:

- Exchange of experience in the respective expert groups or organisations (e.g. WELAC, WECC, EAC),
- consultation and harmonisation of the accreditation criteria and of the testing and certification procedures,
- development of a procedure for joining into the „Multilateral Agreement“ (MLA),
- mutual evaluation for review and establishment of confidence as well as for preparation of the joining into the MLA.

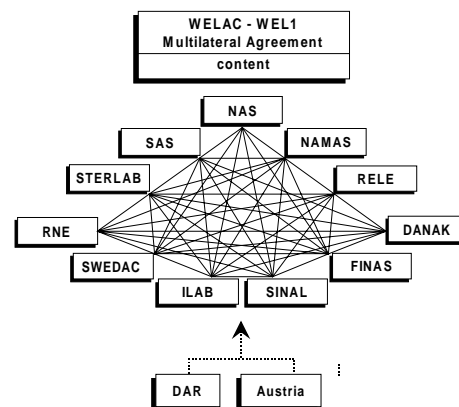
## State of mutual recognition of accreditations

### WECC

For the time being the WECC-MLA has been signed by eleven accreditation bodies: BNM (F), DANAK (DK), DKD (D), FINAS (SF), ILAB (IRL), NAMAS (UK), NKO (NL), NKT (N), SCS (CH), SIT (I), and SWEDAC (S).

It includes the recognition of the calibration results.

### WELAC



For the time being the WELAC-MLA has been signed by eleven national accreditation bodies: DANAK (DK), FINAS (SF), ILAB (IRL), NA (N), NAMAS (UK), RELE (E), RNE (F), SAS (CH), SINAL (I), STERLAB (NL), and SWEDAC (S). The German accreditation system will presumably finish its evaluation procedure in 1994.

### EAC

The first MLA will probably be signed in May 1994. At present the following countries participate in the evaluation: Germany, Great Britain, Italy, Norway, Sweden, Switzerland, and The Netherlands.

## News from the DAR

### Committee „Technical Questions“

The Committee „Technical Questions“ (ATF) was founded as a result of the discussion about the ensurance of the technical competence. Its objective is to make accreditations more comparable and transparent by adequate and technically justified requirements and thereby to promote the comparability of test results and certificates.

The ATF shall support the DAR in elaborating technical requirements on horizontal technical questions and shall represent these requirements in WELAC, WECC, EAC, EOTC and other organisations.

A first result are provisions on the handling of measuring instruments in the accreditation of test laboratories and on the assessment of measuring and test equipment in view of calibration and traceability.

### Subcontracting

A discussion on this topic within the DAR led to the following result:

1. The subcontractor of a laboratory to be accredited should, but do not need to be accredited.
2. The accredited laboratory keeps its responsibility and proves its competence by ensuring that the subcontractor duly operates according to DIN EN 45001.
3. During the accreditation the accreditor makes sure that the testing laboratory to be accredited is complying with the requirements of the standard in view of subcontracting. Testing services, but also tasks of traceability and calibration may be placed as subcontracts.

### DIN EN 45 000, and GLP

For the time being the DAR deals with several comparisons between the requirements on the quality management systems in the above mentioned standards. Starting point was the revision of the ISO Guide 25, in which in particular the requirements of the ISO 9000 shall be brought in, as well as the practice of several European accreditation bodies, which confirm the accredited laboratories by the accreditation that they fulfil the requirements of the ISO 9000 (especially of the ISO 9002). An actual result of the comparison is shown by the following table:

<i>Accreditation to EN 45 000</i>	<i>Certification of the QMS</i>
Confirmation of competence for testing laboratories and certification bodies	Conformity with ISO 9000 EN 29000
aiming at security of test data, technical reliability	general system for the Quality Management of an organisation regardless of its function

The accreditation bodies are preparing themselves for the fulfilment of the requirements of the new ISO Guide 25. If it is the wish of the laboratory, the assessors may additionally check the QS elements which at present are not contained in the EN 45001, and confirm the fulfilment on the accreditation certificate. As far as the revision of the ISO Guide 25 is not yet finished, it was proposed within the DAR to refer only to the compliance with the requirements of the DIN ISO 9002 in case of a positive check-up of the additional QS-requirements given above.

Further information: Departmental Section 7.13

### Comparison between ISO 9000,

## News from International Organisations

### eurolab

° General Assembly: 05.01.94 in London; Election of the Executive Board - new member: Prof. Czichos; Invitations from ISO and CEN to EUROLAB to revise ISO Guide 25 respectively the standards series EN 45000; Intensification of the cooperation with EURACHEM - joint declaration in preparation.

° Announcement of Workshop and Symposium: topic „Validation“ in Stuttgart on 15./16.09.1994; topic "Testing for the Year 2000" in Florence from 25. to 27.04.1994.

° EUROLAB Directory 1994: published in the beginning of 1994 as the first European Directory of this kind with approximately 700 testing laboratories; current information on market trends, possibilities of par-

ticipation in round robin and proficiency tests, on European organisations and EU-Directories; order and delivery via the EUROLAB-D Secretariat.

° EUROLAB-Germany: since 01.01.1994 Secretariat and newsletter "EUROLAB-D AKTUELL".

Further information: Departmental Section 7.14

### EAL

The merger of WECC and WELAC to EAL (European Laboratory Accreditation) is getting ahead. On the Meeting of WELAC/WECC Joint Assembly in Lisboa the draft of the MoU (Memorandum of Understanding) was discussed with the aim to submit a revised version

till the end of February 1994. This new MoU shall be signed at the foundation of EAL at the end of May. A possible incorporation of the WELAC/EUROLAB-Liaison Group into EAL is under discussion. In the focus of EAL should be the exchange of experience, the mutual approach, and the establishment of confidence.

*Further information: Departmental Section 7.13*

## **EURACHEM**

is intensively dealing with questions of comparability and traceability of amount of substance in the analytical chemistry. Workshops in Belgium in 1992 and in the Netherlands in 1993 dealt with this topic. EURACHEM/D as the national mirror organisation supports these efforts in view of the quality assurance to be promoted in analytical chemistry, e.g. by recommendations on participation in future projects as IMEP (International Measurement Evaluation Programme).

A EURACHEM Workshop "Evaluation of Measurement Uncertainty in Chemical Analysis" will take

place in Graz, Austria, from 5.-6. September 1994.  
*Further information: Departmental Section. 7.12*

## **NORDTEST**

### 1993 publications from the Technical Group for Quality Assurance

- ° Änkö, S., Job descriptions in testing laboratories, NT Technical Report 196
- ° Törrönen, K., Sillänpää, J., Häyrynen, J., Integration of quality assurance into project and quality management, NT Technical Report 197
- ° Salmi, T., Methods for testing laboratories to evaluate customer satisfaction and enhance the service quality, NT Technical Report 216
- ° Kjell, G., Larsson, P.-O., Larsson, E., Svensson, T., Torstensson, H., Guidelines for in-house calibration, NT Technical Report 217

*Further information: Departmental Section. 7.14*

## **GLP-experience in comparison**

GLP (Good Laboratory Practice) is a special system for quality assurance in the mandatory area. It lays down principles for tests which are applied for the estimation of materials in view of its risk for man and environment. The OECD principles of GLP win worldwide recognition and are part of the German Chemical Law. The respective „GLP certificate“, which authorises to perform tests, is granted as a result of an inspection by a respective authority.

A special colloquium at BAM, Adlershof, in autumn of 1993 showed that GLP focuses aspects of surveillance and documentation. A peculiarity of GLP is that the staff responsible for quality assurance must be technically qualified on the one hand, but is not allowed to take part directly in the tests on the other hand.

The difficulties with GLP testing lie in the fact that such a test is accompanied by a long chain of „bureaucratic“ operations, whereas its „skilful“ performance seems to recede into the background: set-up of a testing plan before each testing, justification and allowance of necessary later deviations from the testing plan, review (audit) by QA personnel during critical phases of testing, information of the Head of laboratory and the person in charge for testing in case of not allowed deviations from the testing plan or from standard operation procedures, statement of the person in charge for testing on the test report about the test performance meeting GLP (GLP declaration), statement of the QA unit about audits carried out and reports on possible deviations (QA declaration) and at least the complete recording of all documents connected with the test, including raw data, test report and QA recordings.

The following example of a medium-sized firm illustrates the expenditure for recording: 145 pages of documents to be recorded for a simple identity testing, which have to be stored for a period of 30 years. The person in charge for testing is allowed to examine these records only in the presence of the person in charge for recording.

Although this example may not be motivating at first sight, so the report clearly expressed that this system of quality assurance measures had led to a grown quality consciousness of the staff.

For the BAM the following two conclusions may be drawn:

1. Tests that meet the GLP should be limited to the field prescribed by law. Otherwise preference should be given to the quality system according to DIN EN 45001 which focuses much stronger the technical competence of the laboratory.
2. The BAM in its double function as „estimation authority“ and test laboratory has the advantage to slip reasonably its own practical experience from its testing activity in its „authority role“. This should be considered in assessing testing laboratories.

*Further information: Departmental Section 7.14,  
Dr. Golze*