

How can the comparability of test results be achieved?

Technical activities in DAR and in international organisations

In our last DAR-aktuell 1/95 we reported about the mutual recognition of accreditation systems, that are members of a Multilateral Agreement. In order to support the general acceptance of test reports or certificates of the accredited bodies and to reach a comparability of test results, the particular technical aspects that are relevant for the result must be examined. To handle such topics, the DAR founded the "Committee for Technical Questions" (ATF) in December 1993. Members of the DAR-ATF are representatives of accreditors in the German-speaking area (Germany, Austria, Switzerland), of laboratories, of the industry and of the German Authorities. During the last two years the work of the DAR-ATF and of the European or international Working Groups was concentrated on the following technical topics:

1 Traceability in a calibration sense or traceability in testing

In EN 45 001 the English term traceability is given as the "traceability of measurements to national or international measuring standards", i. e. in the frame of a calibration programme. In March 1995 EAL (European cooperation for Accreditation of Laboratories) issued a relevant Guideline EAL-G12 "Traceability of Measuring and Test Equipment to National Standards", which interprets this requirement of the EN 45 001 for the needs of all interested organisations (laboratories, industry, accreditation bodies). In the international standard ISO Guide 8402 the term traceability is generally defined in the sense of quality assurance (ability to trace the history, application or location of an entity by means of recorded identifications). One realised that traceability in testing needs this further interpretation,

above all for those test results that do not only consists of measurements or that cannot be traced to international or national standards, as these do not exist.

The DAR-Committee for Technical Questions (ATF) elaborated a "Guideline for Traceability in Testing" [1], which gives examples for instruments or procedures of traceability that are based on the practice in German laboratories.

The EAL-EUROLAB-Permanent Liaison Group (PLG) as a joint Working Group of both organisations of the accreditors (EAL) and of the laboratories (EUROLAB) prepared a draft which explains the requirements of the EN 45 001 for *traceability* as a means to realise the reliability and the comparability of test results [2]. A special Workshop on this topic will be organised by EUROLAB-F (France) and EAL (see page 4) on March 1996.

The laboratories for chemical analysis tried to explain the traceability of measurements on several stages, depending on which degree and which level of comparability of the test results is strived for [2].

2 Statement of the scope of accreditation in testing

PLG issued two Guidelines:

EAL-G9 describes the elements of the scope of accreditation (scope parameters). This proposal has also been made by the ILAC-Committee 2 Working Group 7. The national implementation was elaborated in DAR-ATF and endorsed in October 1995. The scope of accreditation is subdivided into the following parameters - not all parameters must be given, but through its combination the field of competence of the testing laboratory is unambiguously determined:

- testing field
- type of test
- test item
- test method and/or technical specifications
- and
- optional: statements on a further characterisation of the test methods (e. g. uncertainty of the test results, limit of detection etc.)

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EAL-G14 describes how the assessment of the test methods should be performed in a classic accreditation procedure or in a flexible scope of accreditation. The last possibility is particularly addressed to testing laboratories that are competent to develop new test methods for certain types of tests. A national implementation of this document is being elaborated in DAR-ATF.

3 Validation in testing

For the first time the topic of validation was comprehensively discussed on the EUROLAB Workshop in Stuttgart in March 1994 (see DAR-aktuell 2/94). The different views made it necessary to draw up Guidelines both for the accreditors and for the laboratories. The concept of validation of test methods is getting important in particular for testing laboratories that - due to their activities (e. g. Research + Development) - strive for a flexible scope of accreditation, i.e. the possibility to develop, to modify or to change test methods within a clearly defined field of activity.

The DAR-ATF is elaborating a Guideline for "Validation in Testing" that gives a new definition of the term "validation" and five definite methods for the determination of characteristics of test methods (e. g. uncertainty of results, testing field, limit of quantification) [3].

PLG is also developing a document that describes two ways leading to validation: the scientific and the

comparative method. In the scientific approach the testing laboratory examines the various constituent elements and characteristics of the test method under the following influence factors: human being, environment and/or equipment. In the comparative approach the test method is validated by comparison with other test methods that have already been validated [4].

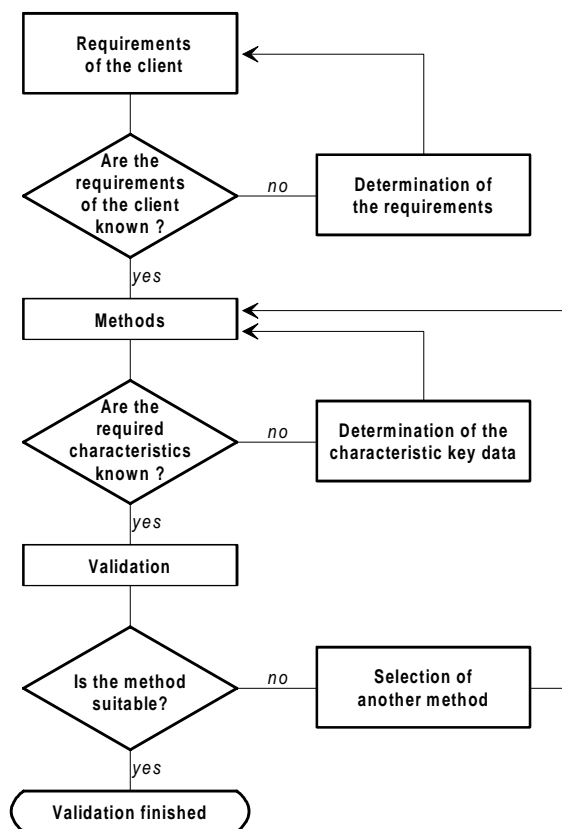
Under German Chairmanship ILAC has briefly listed in its Working Group 6 the main points of the validation of test methods [5].

4 Uncertainty in testing

There exist already several Guidelines [see references], how the uncertainty of measuring results can be given. In order

to enable an appropriate application to testing and a treatment of qualitative test results, considerations in different testing fields and an examination of various examples are needed. These considerations are being elaborated in an Ad-hoc-Working Group of the DAR-ATF by means of the support of qualified employees from testing laboratories.

Within the 4th framework programme of the EU the EUROLAB-Technical Committee (TC) „Uncertainty in Testing“ is also dealing with the drawing up of such examples from practice.



General flow chart for the validation of test methods

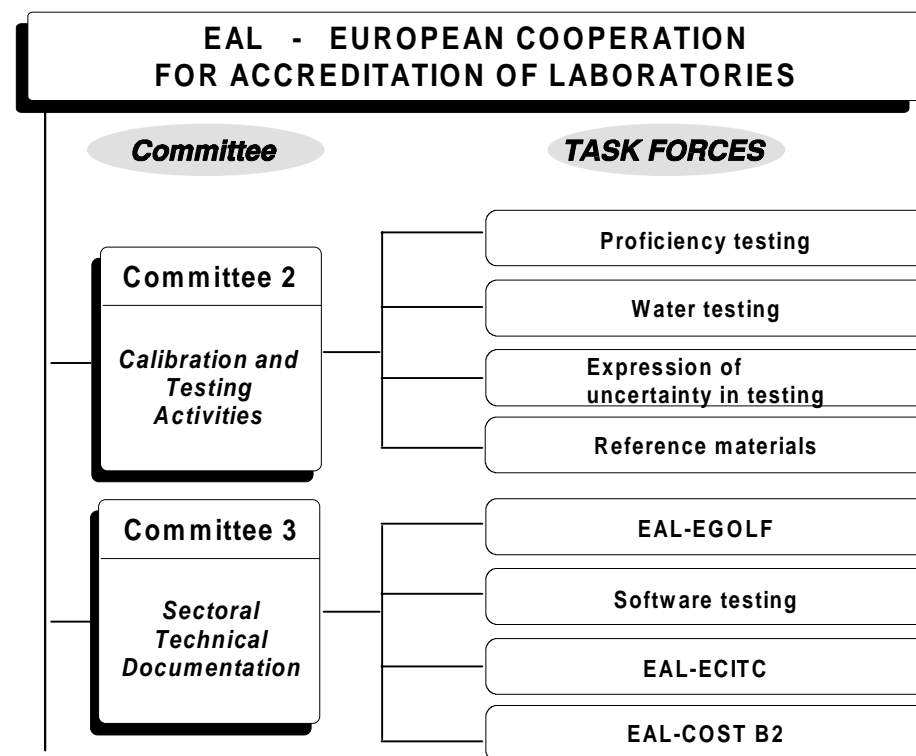
The following Guidelines are available through the DAR-Secretariat:

- EAL-G3* Internal Quality Audits and Review
 - EAL-G4* Accreditation for Chemical Laboratories
 - EAL-G5 Interpretation and Accreditation Requirements in ISO/IEC Guide 25 and EN 45 001
 - EAL-G6 WELAC Criteria for Proficiency Testing in Accreditation
 - EAL-G7 Guidelines for Training Courses for Assessors used by Laboratory Accreditation Schemes
 - EAL-G8 Guidelines for Selection of Participants to Courses for the Training of Assessors Involved in Assessments of Laboratories Applying for Accreditation
 - EAL-G9* Interpreting and Applying the Requirements of Section 4 of EN 45 002 (Scope of Accreditation)
 - EAL-G10 Programme for Course for Tutors for Assessor Training
 - EAL-G12 Traceability of Measuring and Test Equipment to National Standards
 - EAL-G14* Consideration of Methods and Criteria for the Assessment of the Scope of Accreditation
 - EAL-G15 Accreditation for Non-Destructive Testing Laboratories
 - EAL-G16 Accreditation for Sensory Testing Laboratories
 - EAL-G17 Coordinate Measuring Machine Calibration
 - ILAC-Guide Accreditation requirements and operating criteria for horseracing laboratories
- (* German translation available)

5 Activities in EAL-Committee 2 "Calibration and Testing Activities"

5.1 Reference materials

Concerning the requirement for traceability of test results the topic of reference materials takes a particular place in chemical testing, in microbiological



testing, in mechanical-technological testing and in non-destructive materials testing. In a small circle, built up by representatives of the organisations EAL, EUROLAB and EURACHEM, necessary terms of references are being formulated and written down, which are resulting from the treatment, development and production of reference materials in connection with the comparability of test results and the accreditation of laboratories.

5.2 Proficiency testing in accreditation procedures

EURACHEM organised a Workshop "European Cooperation in Interlaboratory Studies" in the Netherlands from 5th to 6th September, 1995. This Workshop deepened the comprehension and the application of interlaboratory comparisons as well as proficiency testing of the interested circles from the chemical-analytical scope of testing, that were attending the Workshop (laboratories, industry, Authorities and accreditors).

The tasks of a joint EAL-EUROLAB-EURACHEM Working Group „Proficiency Testing for use in Accreditation Procedures“ - to be founded - were drawn up in October 1995. These tasks are still to be endorsed by the respective General Assemblies.

5.3 Water testing

A Task Force of the EAL-Committee 2 was founded for the field water testing in order to submit a project to the European Commission the topic of which is the harmonisation of proficiency testing in the fields of water, sewage and surface water testing.

6 Activities in EAL-Committee 3 "Sectoral Technical Documentation"

6.1 Microbiological testing

In March 1995 EAL endorsed a new Guideline EAL-G18 on the interpretation of the EN 45 000 standards series and of the ISO Guide 25 for the accreditation of testing laboratories for microbiological testing, which is now being published.

6.2 EMC testing

An EAL-Guideline (EAL-G19) on the application of the EN 45 001 for the testing of electromagnetic compatibility (EMC) is now being elaborated.

6.3 Fire testing

In August 1995 a joint EAL-EGOLF-Working Group has first drawn up a general interpretation of the EN 45 001 for fire testing and distributed for discussion in EAL-Committee 3.

6.4 Software testing; Nuclear medicine

A joint EAL-ECITC-Working Group was founded in order to discuss the testing of software in accreditation procedures. Within the frame of the application of software in nuclear medicine discussions on the same topic are running parallel in an EAL-COST B2-Group.

References

- [1] „Leitfaden zur Rückverfolgbarkeit im Prüfwesen“, ATF/25/95, 10.1995
- [2] „Traceability of Measurements to SI: How does it lead to Traceability of Quantitative Chemical Measurements?, P. de Bièvre, to be edited in the English Edition of „Akkreditierung und Qualitätssicherung in der Analytischen Chemie“, H. Günzler, Springer Verlag (1995)

[3] „Validierung im Prüfwesen“, ATF/28/95, 08.1995
[4] „Validation of test methods“, Forstèn (VTT), 08.95
[5] „Report on the Validation and Verification of Test Methods“, International Laboratory Accreditation

Conference (ILAC), Committee Papers, S. 375, 17-21st October, 1994

[6] „The Expression of Uncertainty in Quantitative Testing“, EAL/TFeut (95) 9, Draft 4, 08.95

News from international organisations

eurolab

Third eurolab Symposium for 1996 in preparation

The third Symposium will be held in Berlin from the 5th to 6th June, 1996. It has the subject "Testing and analysis for industrial competitiveness and sustainable development". Among others there will be four topics:

- Services to the industry in the year 2000
- Need for technical valuation and research in the service of the society and of standardisation
- Technical development and new technologies
- Appropriate requirements for the mutual recognition of test results

These topics rise questions e. g. cooperation in determining limit values, environmental management/environmental audit and quality management in research and development.

After the completed handing over of lecture topics, the programme for the plenary, discussion and poster events is now being compiled. This programme is scheduled to carry out 10 parallel meetings on the mentioned four topics as well as an afternoon for the poster presentation and discussion (about 30 registrations). The programme is framed by the celebrations and the scientific events on the occasion of the 125 anniversary of the Federal Institute for Materials Re-

search and Testing (BAM) on the 4th and 8th June, 1996. Furthermore, on Friday 7th June, 1996, as an additional event an EU-Workshop on the topic "Laboratory services and applied research in support of SME" will be taken place, which will be organised by the BAM. Beyond the circle of participants, the Symposium shall address to small and medium-sized enterprises that are directly involved in the development of test methods and technologies, in the production of reference materials within the frame of quality assurance and of reliability tests as well as in the development of standards.

Further information: Subdepartmental Section. S.43 (Dr. Golze, Secretariat eurolab-D, (0049-30-8104-1943), Subdepartmental Section Public Relations of BAM (Dr. Lexow, (0049-30-8104-1003) as well as via the Wirtschaftsverlag NW, Bremerhaven (Fax: 0049-471-42765).

eurolab-Workshop on traceability - in 1996 in Paris

A Workshop "Traceability of measuring equipment and standards in testing and calibration laboratories" will be held in Paris on the 15th and 16th February, 1996. This Workshop will be performed in a plenum (lectures) as well as in various discussion rounds. The exchange of experience shall be in the centre of attention of this event. Registrations are possible in the eurolab Secretariat in France ((0033-1-4095 6028, Fax: 0033-1-4095 6050).

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