

The new ISO/IEC 17025 comes to the vote

The ISO/CASCO Secretariat has now prepared the Final Draft on ISO/IEC 17025 for voting by the national standardisation organisations. Analogously, the European standard EN ISO/IEC 17025 - which is identical in wording (hereinafter called ISO 17025) – comes to the vote in Europe.

EA and ILAC are preparing a document, which demonstrates the differences between the former ISO Guide 25 and the new ISO 17025. This document should give help to accreditation bodies and laboratories during the transitional period to facilitate the adjustment to the requirements set out in the new standard. After a transitional period of two years (starting with the issue of this standard), the accredited laboratories should fulfil the requirements of the new standard.

Although the result of the voting will be known not until the end of this year, let us assume that the present Final Draft will substantially reflect the internationally harmonised requirements for a competent laboratory.

In the following we will shortly present essential modifications in comparison to the requirements set out in the ISO Guide 25 and the EN 45001.

1. Aims of revising ISO Guide 25 and EN 45001

The new ISO 17025 shall include all (relevant) criteria of the ISO 9000 series. The aim of this is to achieve in future that laboratories fulfilling this standard have a

quality system that meets the present requirements. However, the requirements set out in the Draft are formulated in such a way that they will be understood and can easily be applied by the laboratories. The ISO 17025 is predominantly intended for use by laboratories. Nevertheless, when revising this standard, the use by accreditation bodies had been considered.

The ISO 17025 shall be applied by routine and non-routine laboratories, but not by research laboratories which are only engaged in basic research.

When revising the standard all interpretation papers on the currently available ISO Guide 25 or on the EN 45001 were considered.

2. Scope of ISO 17025

The standard will be applicable to the following laboratories:

- testing laboratories, calibration laboratories;
- sampling laboratories;
- routine laboratories (using standard methods);
- non-routine laboratories (using non-standard or laboratory-developed methods);
- first-party-laboratories, second-party-laboratories, third-party-laboratories;
- laboratories that contribute to the work of inspection or certification bodies;
- laboratories that are part of an organisation;
- laboratories with permanent or mobile facilities.

The question of **one-man-laboratories** is explained as follows: This standard is applicable to all laboratories regardless of the number of personnel and of the scope of testing and/or calibration activities.

However, required are:

- managerial and technical personnel;
- a quality manager;
- a deputy for chief executives, such as the quality manager;

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(The one-man-laboratory would have to create a temporary measure, e.g. taking over deputy functions by adjoining or associated laboratories.)

- internal audits by persons who are independent of the activities being audited (exceptions are tolerated).

3. General requirements

For **legal identification** purposes, the text has been changed, but not the content of the requirements.

It is important that the laboratory can be held legally responsible. I.e. it shall have such a legal form (single laboratory or part of an organisation) and exist under such conditions that the client receives the possibility to hold the laboratory responsible, if problems occur.

The requirement for **impartiality, independence and integrity** has been maintained, even if the text of the draft has been changed in comparison with the EN 45001.

To demonstrate its impartiality, independence and integrity towards the client, the laboratory has to obey the following steps:

- Disclosure of all other activities;
- Conflicts of interest shall be made transparent to the client;
- Management and personnel shall be free from any commercial, financial or other pressures;
- Confidential information and proprietary rights of the client shall be protected;
- Activities that could diminish the confidence in competence, impartiality, professional judgement and operational integrity of the laboratory should be avoided.

4. Quality system requirements

The fundamental requirements for a quality system of a laboratory laid down in ISO 17025 are directly comparable to those set out in ISO 9001 or ISO 9002. This concerns in particular:

- requirements for the responsibility of the management;
- arrangements on competence/authority and responsibilities of all persons belonging to the staff;
- representative appointed by the management to take over the responsibilities of a quality manager;
- quality policy and drawing up a quality handbook;
- document control;
- control of nonconforming testing and calibration activities;

- corrective and preventive actions;
- management review;
- purchasing services and supplies;
- contract review.

In order to fulfil the requirements set out in ISO 9001 or ISO 9002 respectively, from this follows a set of additional requirements in comparison with the EN 45001 which is still in force.

For **purchasing services and supplies** this means for example:

- A list of authorised suppliers shall be established.
- Procedures for reviewing contracts shall be introduced. Suitable testing or calibration methods that have to fulfil the requirements of the clients shall be selected.

When a laboratory subcontracts **testings or calibrations**, special issues that go beyond the general requirements for a quality system shall be obeyed. This is understandable insofar, as decisive results of the laboratory are concerned.

The ISO/CASCO Working Group 10 has discussed over and over again a case, where a laboratory only coordinates testing tasks without having qualified personnel and suitable test equipment. In future, more and more laboratories will use equipment and apply know-how that is used only from time to time. This requires expensive and cost-intensive test methods. However, among the accreditation bodies international consensus has been reached that in principle a laboratory may apply and master those methods for which it wants to be regarded as being competent or for which it has been accredited. Hence, in future the laboratory manager cannot be only a coordinator.

- Thus subcontracting of testings and calibrations is only feasible, if unforeseen circumstances occur (workload, large contracts or some extra technical expertise) or on a continuing basis (e.g. through agreements).
- According to this standard, only competent subcontractors should be chosen. Records should be kept, how the competence has been verified, e.g. by assessments.
- The laboratory shall advise the client in writing and when appropriate gain the approval of the client for subcontracting testings and calibrations.
- A register of the subcontractors shall be maintained.

It can thus be concluded that the requirements for a quality system laid down in this draft of the international standard correspond to the requirements set out in ISO 9001, if the laboratory deals with the development of new methods or corresponds to the requirements of ISO 9002 when exclusively applying standard methods. Thus the requirements of ISO 17025 are to be treated as equivalent to those set out in ISO 9001 or

ISO 9002 for testing and calibration activities performed by the laboratory.

When considering the international standard discussed in this article, one should refer to the fact that the certification of a laboratory's quality system differs from the accreditation of a laboratory. If a laboratory has a certified quality system, it is then recommended to the accreditation bodies to take this factor into account in accreditation. If the laboratory's client attaches great importance to the reliability and accuracy of the testing results, the fulfilment of the requirements according to ISO 17025 should have priority.

5. Technical requirements

The technical requirements laid down in this standard predominantly aim at reliable and accurate results of the laboratory.

5.1 Requirements for personnel

The laboratory's **personnel** is of prime importance for its competence. A new feature of the requirements for personnel is above all that the required qualification, education, skills and experiences the personnel should have are to be formulated, i.e. job specifications must

exist. Training schedules/programmes shall also be established.

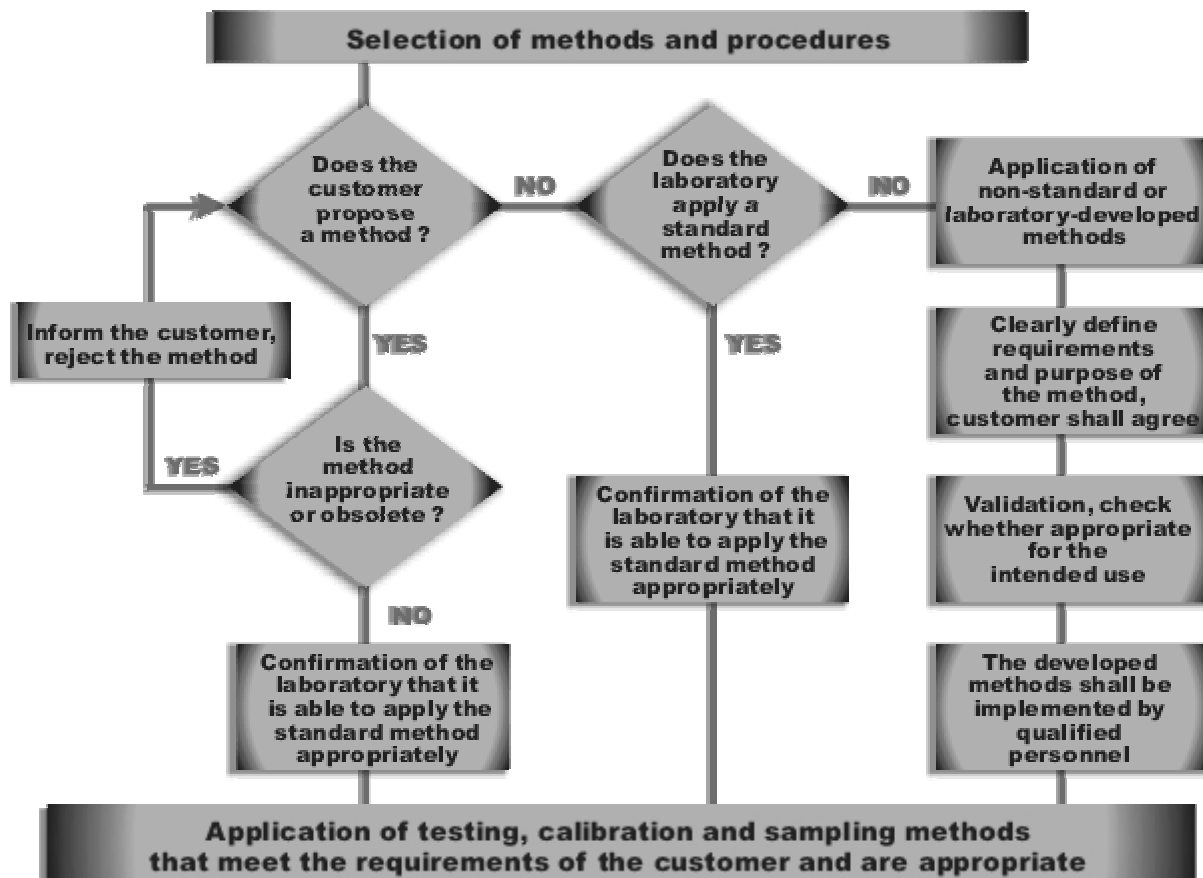
Not only the staff who shall be authorised to operate the equipment, to perform sampling, to undertake tests or calibrations and to sign the reports, must be competent. The same applies to the personnel who evaluates the results. In a note special conditions and requirements are given for the personnel who is authorised to give opinions and interpretations.

5.2 Requirements for equipment, accommodation and environmental conditions

The requirements are comparable to those set out in the EN 45001 which is valid up to date. However, they are described more comprehensive.

5.3 Selection between standard and non-standard methods and validation

In ISO 17025 much importance is attached to the selection of methods and procedures. A clear distinction is made between standard and laboratory-designed methods (methods developed by the laboratory). The following flowchart shows the approach how to select methods and procedures:



If a method is proposed by the client, the laboratory has to check whether the method is appropriate and meets the requirements of the task. If the proposed method is considered to be inapplicable, then the request should be rejected.

If the client leaves the decision on the method to be applied to the laboratory, then a distinction is made between the use of standard and non-standard methods.

Standard methods

When selecting standard methods and procedures, the following facts should be considered:

- Standard methods should be preferably used (on the basis of the latest edition of a standard), if the client does not specify the method.
- The laboratory should confirm to the client (whatever the form may be) that it is competent to apply the standard method appropriately.
- The client shall be informed about the method used.

If a standard method that meets the requirements of the client is not available, then standard methods shall be modified, non-standard methods shall be selected or laboratory methods shall be developed.

Non-standard methods

- Requirements and purpose of the method shall be clearly defined and be subject to agreement with the client.
- Laboratory-developed methods shall be implemented systematically and by qualified personnel.
- The method intended to be used shall have been validated appropriately, i.e. objective evidence shall be given by tests that the method is appropriate for the intended use.

The validation as a means for selecting an appropriate method is described in detail.

Validation of methods

In ISO 17025 the term validation is defined in accordance with the ISO 8402:1994 as follows:

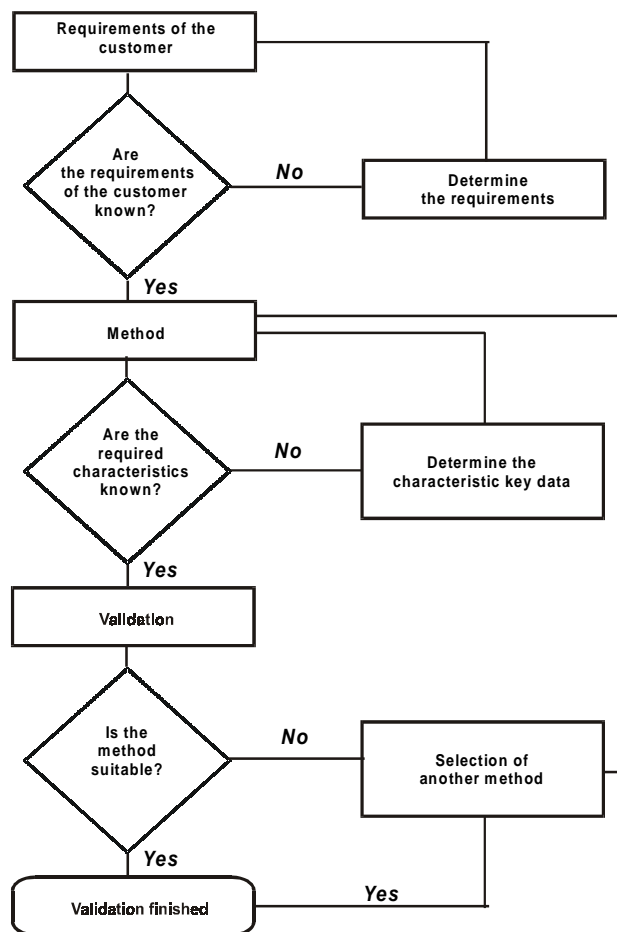
Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

The laboratory shall validate:

- non-standard methods;
- laboratory-designed/developed methods;
- standard methods used outside their intended scope and
- amplifications and modifications of standard methods.

The scope of validation should correspond to the requirements. The results shall be recorded.

The following flowchart shows the procedure of a validation.



Validation of a test method

5.4 Uncertainty of measurement

General starting point of the ISO 17025 is that competent laboratories are able to estimate the uncertainty of measurement for all calibrations affecting the testing or calibration results. Orientation is given to a method described in more detail in the GUM¹ that is commonly accepted and should be used in support of a better comparability.

GUM procedure

When applying this method, one often forgets that reasonable estimations can be performed on the basis of experience. A calculation made on the basis of comprehensive statistics is not always required.

Over the intervening years, numerous examples that can serve as an aid for laboratories have been collected and compiled.

¹ *Guide to Expression of Uncertainty in Measurement, Issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML, revised in 1995*

The requirements set out in ISO 17025 differentiate between calibration and testing laboratories, as for

calibration laboratories the statement of the uncertainty of measurement is a decisive factor for estimating their efficiency:

Calibration laboratory	Testing laboratory
For all calibrations and types of calibrations a method for the determination of the uncertainty of measurement must exist.	For all internal calibrations a method for the determination of the uncertainty of measurement must exist.
	A reasonable estimation of the uncertainty of measurement shall be made, if the methods do not allow a calculation or statistical estimation.
Application of well-established estimation methods (<i>GUM</i>)	Application of well-established estimation methods (<i>GUM</i>)
Consideration of all components that are of importance	Consideration of all components that are of importance
The uncertainty of measurement shall be stated in the calibration certificate.	The test report shall not allow an exaggerated impression with regard to the uncertainty of measurement; Statement of the uncertainty of measurement only, if it is relevant to the validity, application and the compliance with limits or submitted by the client.

5.5 Measurement traceability

All laboratories shall have an established program and procedures for the **calibration** of their measurement and test equipment significantly affecting accuracy and validity of the results. For testing laboratories the requirements given above apply for measuring and test equipment with measuring functions used (as only measurements are traceable to SI units).

General requirements for all calibrations performed are as follows:

- It shall be ensured that calibrations are traced to SI units.
- If calibrations are performed by external laboratories, then only competent laboratories fulfilling the requirements of the ISO 17025 shall receive the request. It is not explicitly required to engage an accredited laboratory, i.e. the laboratory may also convince itself of the competence.
- A documentary evidence shall be available that there is a link to a primary standard or to a natural constant realising the SI unit by an unbroken chain of calibrations.

For testing laboratories these requirements are only applicable, if the influence of the calibrations on the result has to be considered.

Where traceability to SI units of measurement is not possible and/or not relevant, other means for providing confidence in the results shall be applied such as:

- the use of suitable certified reference materials;
- mutual-consent standards or methods which are

clearly specified and agreed upon by all parties concerned;

- participation in a suitable programme of interlaboratory comparisons;
- participation in proficiency testing programmes.

There is a clear distinction between **reference standards** and **reference materials**.

- According to VIM² *reference standards* are standards, generally having the highest metrological quality available at a given location or in a given organisation, from which measurements made there are derived.
- *Reference materials* are materials or substances, one or more whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

The ISO 17025 requires for both:

- The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration.
- Reference standards and reference materials are used for intermediate checks to maintain confidence in the calibration status and reference materials shall be carried out according to defined procedures and schedules.

The laboratory shall have a programme and procedure for the calibration of its *reference standards*. Calibrations shall be carried out only by those bodies meeting the requirements set out in ISO 17025.

² *International Vocabulary of Basic and General Terms in Metrology:1993*

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

5.6 Sampling

Sampling laboratories can be accredited on the basis of this standard.

Sampling is a defined procedure whereby a part of a substance, matrix, material or product is taken to provide for testing or calibration a representative sample of the whole.

Essential requirements for the laboratory carrying out these tasks are as follows:

- The laboratory shall have a sampling plan that should describe the allocation, withdrawal and preparation of one or more samples.
- The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions and the diagrams or other equivalent means to identify the sampling location as necessary, and if appropriate, the statistics the sampling procedures are based upon.
- Where the client requires deviations, additions or exclusions from the documented sampling procedure, these shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

5.7 Reporting the results

It is provided that the results of testing laboratories are *test reports* and of calibration laboratories are *calibration certificates*.

Test reports and calibration certificates

The following requirements are applicable to both:

- They shall include all information requested by the client, i.e. all information necessary for the interpretation of the test or calibration results and all information required by the method used.
- In the case of tests or calibrations performed for internal clients, and in the case of written agreement with the client, the results may be reported in a simplified way.
- In the case the required data are not contained in the report, they shall be readily available in the laboratory.

- Electronic data transfer is possible, i.e. original signatures need not to be available.

Test reports

The following requirements are applied to test reports:

- Where relevant, a statement of compliance/non-compliance with requirements and/or specifications can be made. However, these statements need not to be mixed up with a product certification, which has to be performed not only according to other standards, but exclusively by other independent Third Parties.
- When relevant to the validity or application of the test results, when a client's instruction so requires, or when uncertainty affects compliance to a specification limit, a statement on the estimated uncertainty of measurement of the test result shall be included in the test report.
- Where appropriate and needed opinions and interpretations, which shall be clearly indicated, can be included in the test report. However, the principles upon which these opinions and interpretations have been made shall be documented in writing. Any confusion with inspections and product certifications shall be avoided.

Examples for opinions and interpretations are:

- opinion on the statement of conformity/nonconformity of results with requirements;
- fulfilment of contractual requirements;
- recommendations on how to use the results;
- guidance to be used for improvements.

Calibration certificates

The data given on calibration certificates are formulated more stringent.

- They relate only to metrological quantities and to results of functional tests.
- They shall specifically state which clauses of the specification are met or not met.
- When a statement of compliance with a specification is made omitting the measurement result and associated uncertainties, the laboratory shall take them into consideration and record and maintain them for possible future references.
- A calibration certificate shall not contain any recommendation on the recalibration interval except where this has been agreed with the client.

6 Prospects

The voting result on this standard will be available probably at the beginning of the year 2000. We will keep you informed on further developments.

Dr. M. Wloka, BAM-S.42

Several information events and seminars are presently offered:

- Seminar '99 - Introduction into DIN EN ISO/IEC 17025 „*General Requirements for the Competence of Testing and Calibration Laboratories*“, 27th September 1999, Darmstadt/Germany, 3rd November 1999 Berlin
Time: 8:30 - 16:45
- Workshop „*Quality Assurance of Computer Systems in Laboratories*“, BAM Federal Institute for Materials Research and Testing, Berlin/Germany, 30th September and 1st October 1999
- Workshop „*Materials Testing 1999*“, Technical discussion „*What's new in the DIN EN ISO/IEC 17025*“, Kurhaus Bad Nauheim/Germany, 02.12.1999, Time: 17.20 - 18.50, Conference phone: (+49) - 6032 303 419

Further information can be obtained from DAR's Website clicking on the box **NEWS** or can be requested at the DAR Secretariat.

News from standardisation

Functional approach to a potential re-structuring of the standards series EN 45000

Case history and problems facing us

In 1995 the European Commission mandated the European standardisation organisations CEN and CENELEC to consider a re-structuring of the standards series EN 45000. The currently valid standards of this series are focused on the different types of conformity assessment bodies, such as testing laboratories, inspection, certification and accreditation bodies. From the point of view of the European Commission the disadvantage is that there is no definite relation between these standards and the modules for conformity assessment that are applied on the basis of the Global Approach and in the sense of the Guidelines. For the bodies concerned, in particular those with testing, inspection and certification activities, this structure means the existence and validity of different standards with specific requirements for different services and therewith increased efforts regarding their application and implementation. CEN/CLC TC1 as competent standardisation committee should therefore examine, whether it is possible to re-structure the standards series based on different functions of conformity assessment.

As a first step towards this direction the European Commission ordered a study, which was made by Dr. Reuter (formerly employed at VDTÜV³). As neither the European Commission nor CEN/CLC TC1 regarded the outcome of this study as a sufficient solution of the problem, a Working Group should continue to work on this task.

³ Verband der Technischen Überwachungs-Vereine e.V. (Association of Technical Inspection Agencies)

The Joint Working Group ISO/CASCO and CEN/CENELEC

A broad consensus was reached within CEN/CLC TC1 to re-structure the standard series world-wide and not only in Europe. In recent years an uncoordinated approach of the international standardisation organisation ISO and of the European standardisation organisations caused a leapfrogging, i.e. guidelines or standards relevant for conformity assessment were reviewed and amended at different times and thus “overtook each other” again and again. In the meantime the problem could be solved by an improved cooperation, so that the relevant normative documents are now practically identical in wording at international and European level. This advancement should not be abandoned by a re-structuring of the European standards.

Hence CEN/CLC TC1 submitted a proposal to the responsible ISO Committee ISO CASCO to discuss in a concerted action a re-structuring of the conformity assessment standards. As a result a Joint Working Group has been established with representatives from Europe and overseas standing for all types of bodies concerned.

The Working Group met thrice so far. The first meeting was a brainstorming, which illuminated the problem from different points of view. At its second meeting several models for a new structure were discussed. Two of these models, namely those of Mr. Eberhard and Mr. Schaub/Mr. Beer, have been published in the EUROLAB Newsletter (see EUROLAB Newsletter No. 16, p.10 and No. 17, pp. 11ff). According to the opinion of the Joint Working Group, a first step towards a simplified structure could be to merge the existing normative documents on requirements for accreditation bodies EN 45003, EN 45010 and ISO TR 17010 into one standard. This standard should describe both the requirements for accreditation bodies and for accreditation procedures irrespective of the type of the body to be accredited.

Meanwhile ISO/CASCO as well as CEN/CLC TC1 agreed to this proposal. An ISO/CASCO Working Group will draw up a draft standard.

At the third meeting, which was held in Geneva on 20 May 1999, the following functions of conformity assessment had been discussed in detail.

Functions of conformity assessment

Starting from a model of activities of a product certification body - as there are especially complex and comprehensive conformity assessments - one could identify the following functions:

A General

- Development of certification systems

This is a basic function, which covers the determination of rules and specifications, on the basis of which the certification procedure and related surveillance measures are performed, if necessary.

B Related to individual certification procedures

- Sampling

Sampling means the selection of representative products to be tested with regard to their conformity with predetermined specifications and requirements.

- Design review

Design review covers the review of product-related documents as provided in Module H of the Global Approach.

- Determination of facts, properties and parameters of products

This function covers such activities as testing, calibration, investigation (as part of inspection) and auditing.

- Assessment

Assessment includes whether and to which extent a product corresponds to predetermined specifications.

- Decision

The certification body shall decide on the issue of a certificate.

- Licensing

This function covers the granting of the certification body's marks and can possibly be included in the decision on the certification.

- Surveillance

These are all measures taken by the certification body to supervise the permanent conformity of the products with the required specifications.

The above mentioned term "product" has to be understood in a very broad sense and includes also processes and services.

Further approach

Until the next meeting of the Joint Working Group to be held in Vienna on 4th October 1999 an agreement on the functions of conformity assessment shall be reached in an internal discussion. Statements and comments from interested parties can also be sent to the EUROLAB Secretariat (Fax: ++49-30-81043717, Email: manfred.golze@bam.de).

As a result of this discussion a model shall be developed at this meeting for an international standard for conformity assessment bodies, which shall be submitted to ISO/CASCO and CEN/CLC TC1 for voting. The aim is to enable conformity assessment bodies to establish a consistent quality system and to undergo only a single accreditation procedure irrespective of the number of functions they perform.

Dr. M. Golze, EUROLAB

News from the DAR

Revision of DAR documents

The below mentioned document has been revised and endorsed by the DAR.

It will be replaced in the DAR Handbook and can be downloaded from DAR's Website directly at <http://www.dar.bam.de/doc/documents.html>:

- DAR-EM10 „Guideline for the Assessment of Measuring and Testing Equipment in Testing Laborato-

ries in View of Calibration and Measurement Traceability to SI Units“

Implementation of IAF/EA documents

The document IAF/EA Guidance on the Application of ISO/IEC Guide 65:1996 „General Requirements for Bodies Operating Product Certification Systems“ has been endorsed by the DAR and will be taken up into the DAR Handbook. *S. Stobbe, BAM-S.42*

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