

8.2.2000

**COOPERATION BETWEEN LABORATORIES AND ACCREDITATION BODIES
- THE PERMANENT LIAISON GROUP (PLG)**

Contents

- Summary and conclusions
- Presentations
- Mandates, objectives, work programmes and rules of procedures

SUMMARY AND CONCLUSIONS

Programme

Lars Ettarp, Chairman of EA opened the workshop and wished the participants welcomed. He stressed that there is a continuous need for accreditors and laboratory practitioners to meet and discuss matters of mutual interest. He also expressed the appreciation for the work done in the Permanent Liaison Group (PLG) established jointly by EA, Eurolab and Eurachem.

The workshop programme included the following presentations:

G.B. Thomas, UKAS: Developing the accreditation process for laboratories - Application of ISO/IEC 17025.

D. Holcombe, LGC: Multiple assessment of laboratory competence. Straightening out the process.

D. Pierre, COFRAC: Multiple assessment of laboratory competence.

B. Steffen, DAR/BAM: Validation of test methods - relation to scope of accreditation and method of assessment.

J. Forstén, VTT: The work programme of the permanent liaison group (PLG).

A. Zschunke, BAM: Selection and use of reference materials.

L. Cortez, IPQ: Proficiency testing in accreditation procedures.

N. Müller, Arsenal: Uncertainty in testing.

The presentations (overheads) have been reproduced in Annex 1. The mandates, objectives, work programmes and rules of procedures for PLG and the joint EA, Eurolab and Eurachem working groups are given in Annex 2.

At the end of the meeting the chairmen Lars Ettarp, Veikko Komppa and Horst Czichos of EA, Eurachem and Eurolab, respectively, expressed the stakeholders' views on PLG and its future work. The work in the PLG has been appreciated in all three organisations. The discussions have been on a policy level and PLG should not enter into detailed technical discussions. The previous dialogue between EA and Eurolab has now developed into a "trialogue" after Eurachem has joined.

Finally Horst Czichos thanked the speakers and the participants in the workshop. It was a useful meeting with a good technical discussion. Special thanks were addressed to the Greek organisers for their excellent arrangements, friendly atmosphere and kind hospitality.

In the following there are the technical highlights of the workshop. They have been formulated more or less as suggestions and recommendations to be observed in the future work of PLG and consequently in EA, Eurolab and Eurachem.

SUGGESTIONS AND RECOMMENDATIONS

1.

The acceptance of the new ISO/IEC 17025 standard was considered to be a crucial step forward. A single international standard creates a level playing field and facilitates the acceptance of results worldwide. The proliferation of new standards should not be accepted. All three parties were dissatisfied with the development of a sectorial ISO standard for medical application and they should voice that dissatisfaction to ISO.

2.

The implementation of the new standard is being addressed so that a harmonised approach can be achieved. A certain transition period needs to be defined both with respect to new accreditations as well as reassessments. For practical reasons the accreditors cannot handle a large peak in (re)accreditation requests if that occurs during a short time period. Therefore the assessment of accredited laboratories against the new standard should be done in the course of regular surveillance and/or reassessment visits after the end of the transition period or on request by the laboratory during this period. The decision to reanalyse the need of existing EA guidelines was appreciated especially as it seems that many issues have been defined to sufficient details in the new ISO/IEC 17025 and some EA guidelines may now be superfluous.

3.

Opinions and interpretations have been covered in the new ISO/IEC 17025. However, opinions as such cannot be accredited; it is mainly the process leading to opinions and interpretations, which can be covered in the accreditation process. It was recommended to proceed cautiously in order not to be in conflict with the inspection and product certification activities.

4.

ISO/IEC 17025 contains references to ISO 9000 (1994). When a revised ISO 9000 is accepted there will be a need to analyse what effects that will have. The original ISO/CASCO working group could meet again and propose measures to be taken or amendments to the ISO/IEC 17025 standard.

5.

Laboratories often have a diverse range of "products" and "services" in addition to the testing and calibration activities covered by ISO/IEC 17025. Consequently they have to apply other rules and are assessed by other parties. Such organisations definitely want to use only one quality system or standard and want to avoid multiple assessments. The accreditation bodies must strive to get an agreement on i) mutual acceptance or ii) joint performance of assessments with other organisations or authorities working in the same field. An integrated assessment service should be the ultimate goal. The problem is especially pronounced for multifunction, multidiscipline and multisite organisations. EA, Eurolab and Eurachem should continuously try to get the OECD Good Laboratory Practice (GLP) and Good Manufacturing Practise (GMP) in line with a common assessment

procedure. There is a need to define in more detail the way multisite, multidiscipline and/or multifunctional organisations should be assessed.

6.

For multisite laboratories the quality system should be evaluated at the central level. At the sites, it should be verified that the quality system is applied in the intended way and that the site personnel is technically competent to perform the designated tasks. For multidiscipline or multifunctional laboratories the accreditation body has to assess the technical competence for the whole scope of activities. In this case the evaluation can be made lighter so that the common part of the quality system and the technical operations are assessed in one shot.

7.

In certain fields peer evaluations are performed. One should discuss if the laboratory in the accreditation process could benefit from a satisfactory outcome in the peer evaluations.

8.

In the new ISO/IEC 17025 validation of test methods is described in such a detail that at the moment no new general guidelines for test method validation need to be developed. EA, Eurolab and Eurachem stressed that it is the responsibility of the standardisation bodies to ensure that the international testing standards are validated to an adequate level. The three organisations should again write to ISO and CEN and ask them to develop a procedure to be followed when validating test methods, all of which must also define the uncertainty of the results. Eurachem has a few years ago published a document on the validation of methods to be used in the chemical and biotechnical field.

9.

The EA-Eurolab-Eurachem (EEE) working group on reference materials (RM) consists mainly of chemists. The workshop noticed that RMs are used also in other sectors than chemistry and consequently the EEE-RM must tackle these reference materials, too. The EEE-RM shall investigate the general needs for using reference materials and give its advice on their use. There could be a need for third party assessment of reference materials producers. The EEE-RM should give its advice/recommendation on

- procedure to be followed (testing, calibration or product certification)
- applicable documents (ISO Guide 34, ILAC)
- establishing traceability of RMs in chemistry.

10.

The interest in proficiency testing (PT) is increasing. The workshop recommended to keep the size of EEE-PT as originally decided (each organisation represented by 5 persons). The EEE-PT can regularly (e.g. once a year) arrange an open meeting. The EEE-PT should not itself manage PTs but identify good providers and/or provide laboratories with information on existing PTs. Although some countries accredit providers of proficiency testing schemes, there was no consensus that this should be the case. It was recommended to carefully analyse the situation before making any decision on a European level. The EEE-PT should mainly discuss policy issues related to the use PTs and their results in order to outline the development on a general level.

11.

Uncertainty of test result is a very complex issue and it is related to i) the measurement system, ii) the characteristics of the test objects and iii) sampling including preparation of the samples. Furthermore, the uncertainty must be put in relation to the uncertainty of the requirement level (e.g. legislative requirements or thresholds, probabilistic distribution of properties, critical values or levels). The uncertainty of basic metrological units is determined by a clearly defined and accepted procedure. For many tests a statistical analysis is not possible in order to determine the uncertainty of the results. Interpretation of the results needs professional judgement. It was also pointed out that uncertainties can in certain cases be used for evaluating and validating test methods. It may be difficult to explain for customers what the uncertainty of test results really means as for example the measurement uncertainty is generally smaller than the uncertainty of test results. This is due to the fact that in the latter case for example the influence of sampling has to be included. Standard test methods must in future include information on the uncertainty of the test results achieved by following the test procedure. It was proposed that the work on uncertainties should proceed test sector by test sector in order to find a reasonable and pragmatic solution.

12.

PLG should develop an informative document explaining what measurement uncertainty means, how to interpret and use the uncertainty. The target group for such an information is industry, service sector and public organisations.

13.

An information leaflet (paper) on the values of accreditation for industry and other users should be prepared. This promotional material should be widely disseminated.

14.

EA, Eurolab and Eurachem and consequently PLG should in future pay more attention to the global development and volunteer to work with other international organisations.

15.

The chairmen Lars Ettarp, EA, Veikko Komppa, Eurachem and Horst Czichos, Eurolab thanked the PLG and the Greek organisers for an interesting, open and useful workshop. The biannual schedule has proven to be a good one. Also in the future the PLG should stay on a technical and strategic level and elaborate different concepts. PLG should not enter into detailed technical discussions but leave them to expert groups.

Jarl Forstén

Hanspeter Ischi

Bernd Steffen