[1]. It must also be kept very straightforward so as to be easily understood by all staff and easy to monitor. A quality management system aims at satisfying the laboratory's interests but also the customer's needs and expectations.

All costs arising from laboratory accreditation have to be seen as costs which would otherwise have had to be borne as a result of utilising incorrect testing methods and the ensuing commercial and legal consequences of that practice. Quality improvement programmes should therefore include a cost reduction component arising from making the staff more aware of the need for quality and the desire to resolve problems. Take corrective action and follow through results.

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The implementation of accreditation in a chemical laboratory

L. Cortez
Instituto Português da Qualidade, Rua António Gião 2, 2829-513 Caparica, Portugal

This article describes the current state of the art in the accreditation of chemical laboratories, both in Europe and world-wide, emphasising the most common discussion topics. The results of recent proficiency testing in chemical laboratories are summarised to draw conclusions on the performance of accredited laboratories. ©1999 Elsevier Science B.V. All rights reserved.

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1. Introduction

Although accreditation has only become a familiar word for the scientific community and society in recent years, its beginnings go back to the 1970s (and before that, in Australia). One of the starting points was the problem faced by some National Metrology Institutes (NMIs) with growing requests from industry to continue providing them with reliable calibration services, while the NMIs needed time to devote themselves to scientific investigations. This led to a compromise in which they recognised some laboratories competent enough to perform calibrations on their behalf, through an assessment of their capability to provide reliable and traceable services.

In Europe, the New Approach and the Global Approach Directives were responsible for the generalised development of accreditation systems, based on the EN 45001 standard [1], derived from the existing ISO/IEC Guide 25 [2], which had been used until then.

Laboratory accreditation can be defined [3] as a formal recognition by an authoritative body of the technical competence of a laboratory to perform tests or calibrations. This recognition is given by an accreditation body, which acts as a third party between the

laboratory and its clients, and aims to establish confidence between them. One of the main objectives and reasons for the existence of accreditation systems is the need to remove technical barriers to international trade, i.e., that a product once tested in an accredited laboratory should not need to be retested by the client, since another accredited laboratory in another country would find a similar result. Nevertheless, accreditation is normally granted for a limited scope of activities or tests, which generally do not include all the tests or analyses that the laboratory offers to its clients. It is up to the laboratory to propose to the accreditation body which tests or types of tests they wish to include in the scope of accreditation.

Accreditation has been seen from a number of perspectives since it started: originally it was a voluntary activity, required sometimes for specific tasks. Then it became a competitive factor, seen as a commercial strategy, and nowadays it is a survival requirement in many sectors, since it has become mandatory (by government) or preferred (for the public).

2. State of the art

Today, accreditation is performed by several accreditation bodies throughout the world, generally with a national status or recognition and with a non-profit aim. Accreditation should be distinguished from certification of quality systems, since it concerns the evaluation not only of quality systems but also the technical competence. Accreditation is applied nowadays not only to laboratories, but to all bodies performing conformity assessment functions [4], such as:

- calibration;
- testing;
- certification of quality systems (ISO 9000);
- certification of environmental management systems (ISO 14000);
- certification of products;
- certification of personnel;
- inspection.

Accreditation activities, and related conformity assessments, are harmonised world-wide through several international standards and guides prepared by the ISO/CASCO committee [5].

2.1. Accreditation in Europe

In order to harmonise procedures, and to facilitate the establishment of mutual recognition agreements, the accreditation bodies have organised themselves into co-operating entities of international character. Thus, the accreditation bodies in Europe created the EA (European co-operation for Accreditation), following previous sectorial merging [6].

The first Multilateral Agreement (MLA) in Europe dates from 1989, and was signed under the auspices of WECC, an existing co-operation for accreditation of calibration laboratories. Since then the MLA has been extended to other fields of accreditation, and more signatories have been accepted, including today almost all western European countries. The existence of an MLA implies that the accreditation bodies that are signatories to it recognise between themselves the test reports and calibration certificates issued by a laboratory which has been accredited by one of them. This facilitates not only international trade but also the acceptability of data and circulation of technical information between countries.

For these reasons, the establishment of MLA requires several activities:

- the discussion and preparation of harmonised interpretations of requirements [7];
- the periodic realisation of peer reviews or assessments between signatories [8];
- and the organisation of international comparisons [9] to confirm the technical equivalence of results between accredited laboratories [10,11].

Besides the MLA signed by almost all western European countries, EA has also established bilateral agreements with several accreditation bodies outside Europe. However, since the MLA is an on-going process, actual data (and other information, such as guidance interpretation documents) should be consulted at the EA web site (www.european-accreditation.org).

2.2. The international scene

As in Europe, the American and Asian accreditation bodies also organised themselves into a co-operative structure, APLAC (Asian-Pacific Laboratory Accreditation Co-operation – see the web site: www.ianz.govt.nz/aplac), with similar goals and objectives, having also established an MLA between themselves [12].

An international structure, ILAC (International Laboratory Accreditation Co-operation – see web site: www.ilac.org), was created to facilitate understanding and harmonisation between the European and Asia-Pacific regions (and others).

In the near future world-wide recognition of accredited laboratories will be possible under the umbrella of ILAC.

2.3. Requirements for accreditation

Although different standards and specifications were used at the beginning of accreditation, the ISO/IEC Guide 25 was the first commonly accepted standard, and many accreditation bodies continue to grant accreditation based on its requirements. This standard was adopted in 1989 by CEN/CENELEC into EN 45001, which has been used since then in the European context. However, nowadays both the ISO and EN standards are revised together, in order to produce a common standard which will be known as ISO 17025 [13]. This standard will not only integrate the accumulated experience in accreditation and the many interpretations used, but will also make more explicit and visible the quality system requirements common to the ISO 9000 standards [14].

The requirements can be divided into management and technical requirements, and some of them are described below.

● Ethical requirements, such as legal identity, independence, and impartiality mechanisms: also the keeping of confidentiality of clients' results must be fulfilled.
● Organisation and management procedures should be clearly defined so that everyone knows the tasks they should, and can (or cannot), perform, i.e., the laboratory should work in a disciplined way.
● A quality system, with a quality manager, a quality manual, and document control should be implemented to ensure the continuity and improvement of the quality of the work done.
● In order to correctly accept testing or analysis requests and tenders, a contract review routine should be defined and implemented.
● Any sub-contracting of tests and calibrations should be previously accepted by the client, clearly stated on reports, and give guarantees of the sub-contracted work.
● Purchasing of services and supplies should be done in such a way as to assure that their quality is adequate for their intended use.

● Focus should be given to service to the client, facilitating contacts and requiring continuous feedback before, during, and after the analyses are performed. Laboratories should aim not only at the satisfaction of clients but to exceed their expectations, in a quest for excellence in their work.
● Control of non-conforming work should be implemented so that proper preventive and corrective actions are enforced once detected, to prevent their recurrence.
● Records of important technical and quality information should be kept and archived.
● Internal audits should be made regularly to monitor the implementation of the quality system and drive most of the continuous improvement process.
● Management reviews should be organised periodically to study the need for changes in the quality system.
● Personnel should be qualified and trained for their specific tasks.
● The facilities should be adequate to perform the tests, both in the environmental conditions and in separation of incompatible work.
● Test and calibration methods should be adequately selected, studied, and validated if developed in-house.
● The equipment necessary for the tests and calibrations should be appropriately selected, operated, and subjected to maintenance, calibration and verification as needed.
● Measurement traceability should be guaranteed by proper selection of external calibrations, traceable internal calibrations, and the use of (certified) reference materials where applicable.
● Sampling procedures should be defined and used to allow a representative, and homogeneous if necessary, sample to be taken.
● Handling and transportation of samples inside and outside the laboratory should be done in an adequate and traceable way.
● Assurance of the quality of test and calibration results should be implemented by means of an external and internal quality control system.
● Reporting the results should be done in a clear, accurate and objective way; when relevant, the uncertainties of results should be estimated and reported.

2.4. Chemical laboratories focus

When accrediting chemical laboratories, some special features must be emphasised. First, chemical lab-

oratories do not have a metrological infrastructure such as found in many physical areas, where an SI unit is defined and realised (normally) by the NMIs, which then pass this metrological information to calibration laboratories, which in turn pass it to the testing laboratories and industry. This metrological chain that transfers the SI unit from where it is realised to the end users is nowadays well established for most physical quantities, allowing for traceable measurements.

In chemistry (and biology) this is not achievable nowadays [15], since the SI unit for the amount of substance (mole) cannot be realised as for physical quantities, and there is no metrological chain of calibration laboratories for chemical properties. However, nature finds its own way, and alternatives such as the use of certified reference materials [16], or the use of mutual consent standards or methods, or participation in proficiency testing schemes [17], may provide sufficient evidence of the comparability of results.

Secondly, to compensate for this lack of SI traceability, chemical (and biological) laboratories have introduced additional control measures for their results, via internal and external quality control schemes [18] which give enough confidence to the quality of the work performed.

Thus, in chemical laboratories it is extremely important to implement appropriate quality control actions, which should be carefully planned and selected to allow an adequate balance between costs and risks. For each analysis or type of analysis, both external checks (via CRMs or proficiency tests, as available) and internal checks (duplicates, blanks, recoveries, control samples and control charts) should be used as appropriate, to control critical points in the analytical path.

A third item now commonly discussed is the estimation of the uncertainty of analytical measurements [19,20]. Originally a topic only for calibration laboratories, the ISO GUM [21] methodology has also been applied to chemical analysis [22], and accreditation bodies are now encouraging laboratories to make continuous progress in the implementation of this topic.

Another subject of debate in chemical laboratories' accreditation is method validation [23], which should give enough evidence that each method is appropriate for its intended use. Although in many cases laboratories use standardised methods, which only require proof of evidence that the laboratory is capable of appropriately implementing and using them, there are other situations where adaptations or modifications must be introduced for particular type of samples.

The need for method validation strategies increases for R&D laboratories, which should also work under quality assurance systems [24]. Accreditation bodies are also adapting themselves to the new needs, and particularly to these non-routine situations, and are introducing flexible scopes of accreditation [25], where the laboratory is given the opportunity to implement new standard methods or develop in-house methods if needed.

EURACHEM, CITAC and EA have co-operated to provide guidance in the interpretation of accreditation requirements for chemical analysis [26,27], and this has been very helpful for achieving harmonisation at the international level.

2.5. Accreditation process

The accreditation process is nowadays more or less harmonised between the different accreditation bodies, since an international standard (ISO/IEC Guide 58) [28] describes the expected functioning of an accreditation body. It is up to the candidate laboratory to contact the accreditation body to find out what the specific requirements are, and the methodology to follow.

Normally, after presenting a request for accreditation, the candidate laboratory is assessed (audited) [29], by a team of qualified assessors [30] who have been trained in the accreditation requirements and methodology [31], and include technical experts in the testing fields proposed for accreditation. After the assessment a report is made, highlighting the aspects that do not comply with the requirements, and which need improvements. This report is sent to the candidate laboratory, which comments and describes the corrective and preventive actions taken to eliminate the non-conformities. If these actions are judged satisfactory, accreditation is granted for a well-defined scope, which is written in the accreditation certificate, and the laboratory is authorised to use the accreditation logo (under certain conditions).

If, following the comments provided by the candidate, doubts still prevail, a follow-up audit is scheduled to verify the efficiency of the corrective actions. Normally, after one year a surveillance audit is performed, aiming at monitoring the continuing compliance with the accreditation requirements, and thereafter at regular intervals (1–2 years).

In a case of serious or repeated non-compliance, the accreditation may be suspended or even terminated. Also, the laboratory may apply for an extension of the scope or, to the contrary, a partial reduction of the

scope. The laboratory may also take the initiative to ask for a suspension (partial or total) or even a cancellation of the accreditation.

The accreditation bodies also normally have a complementary way of collecting information on the competence of laboratories, by their participation in proficiency testing schemes or interlaboratory comparisons [32,33]. It is important to note that while totally satisfactory results should be the goal for accredited (or candidate) laboratories, these schemes should be considered an improvement tool, not a punishing tool. Thus, a small number of unsatisfactory results can be accepted, provided that the laboratory makes proper investigations and identifies their causes, and implements corrective and preventive actions, so that the same mistake should not be repeated in the future.

3. A proficiency testing case study – 'Are accredited laboratories performing better?'

As part of our monitoring programme for accreditation, IPQ runs a proficiency testing scheme for environmental laboratories. The last one was organised in October 1998, in co-operation with EUROLAB Portugal (RELACRE), and the Instituto Geológico e Mineiro (IGM), which acts as a regulating body for geological resources, including aquifers and springs.

A mineral water was selected, and the participants were given the choice to perform sampling themselves, or to receive a sample collected by IGM: about 50% decided to take the samples themselves. The sample was continuously pumped from an aquifer at 100 m depth, and synthetic solutions with nutrients and metals were given to be diluted in the sample and analysed. Homogeneity and stability tests were performed before and during the exercise, to monitor any abnormality or inhomogeneity.

A request was made for the determination of 33 parameters: pH, conductivity, alkalinity, bicarbonate, hardness, Ca^{2+}, Mg^{2+}, Na^+, K^+, Cl^-, SO_4^{2-}, F^-, SiO_2, NO_3^-, NO_2^-, NH_4^+, PO_4^{3-}, Fe, Mn, Cu, Zn, Al,

Ba, Sr, Cd, Cr, Ni, As, Sb, Se, Hg, Ag, and Pb. These last three metals were not added, and were used to test the limits of quantification and control of contamination. Nitrate, iron, manganese and arsenic were present in both the natural water and the synthetic solutions, allowing one to control that the laboratories did perform the analysis on the diluted sample and not directly on the (concentrated) synthetic solutions.

Each participant was free to select the method of analysis to be used, according to the availability and suitability for the concentration range. The reference values were established using the consensus obtained between an expert laboratory (IGM), the robust average from the participants, and the target values (for the synthetic solutions). Deviations of 5–20% (according to the concentration range) were considered acceptable, and an evaluation was done, using codes to identify the participants.

The 76 participating laboratories represented all types of laboratories, from governmental and regulatory bodies, to public, private, industrial, and university laboratories; 28 laboratories held accreditation for some (or all) of the analysis they performed. A technical discussion was held to close the exercise and to help the participants locate the major causes of unsatisfactory results. A statistical evaluation provided the results presented in Table 1, which leads to the conclusion that the results of accredited analysis are significantly better than non-accredited, since:

● accredited results have a significantly higher percentage of satisfactory results (almost 90%);
● naturally, the percentage of accredited unsatisfactory results (13%) is lower than the non-accredited one (41%). However, even more significantly, a lower percentage of major faults (deviations greater than 100% from the reference value, i.e., more than double, or less than half the reference value) was obtained for the accredited results.

It is important to state that this percentage concerns only the accredited tests and not all the tests done by accredited laboratories, since some of them may not be

Table 1
Comparison of accredited and non-accredited results

	Total results	Satisfactory	Unsatisfactory	Major faults
Accredited results	377 (27% of total)	328 (87% Accred.)	49 (13% Accred.)	27 (7% Accred.)
Non-accredited results	1006 (73% of total)	696 (69% Non-acc.)	310 (31% Non-acc.)	202 (20% Non-acc.)
Total	1383 (total)	1024 (74% of total)	359 (26% of total)	229 (17% of total)

included within the scope of accreditation. A report (in Portuguese) is available with the complete data set and all the conclusions of this exercise [34].

Similar inferences could be drawn from previous exercises, leading to the conclusion that accredited laboratories do tend to perform better.

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TrAC/Internet column

In order to inform analytical chemists about the Internet and the role it could play in their lives, Dr. Michael Guilhaus was invited to become a Contributing Editor of TrAC. The Internet Column has now become a feature of the journal. The column can also be found on the World Wide Web.

Anyone interested in contributing to this column is invited to contact Michael Guilhaus at:

Mike_Guilhaus@gmq.chem.unsw.au

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