Eurachem

A FOCUS FOR ANALYTICAL CHEMISTRY IN EUROPE

Survey on the Accreditation of EQA Scheme Organisers in Laboratory Medicine

Final Report

17 October 2005

Survey on the Accreditation of EQA Scheme Organisers in Laboratory Medicine*

Eurachem/EQALM Report, 17 October 2005

*Organised and compiled by:

[1] Eurachem Proficiency Testing Working Group, c/o Ulf Örnemark, EQUALIS, Box 977, SE-751 09 Uppsala, Sweden, ulf.ornemark@equalis.se

[2] EQALM, c/o Gitte Marie Henriksen, DEKS, 54M1 Herlev University Hospital, Herlev Ringvej 75, DK-2730 Herlev, Denmark, gitte.m.henriksen@deks.dk

Table of contents

Summary

A worldwide survey among organisers of external quality assessment schemes (EQAS) was carried out between May and October 2005. The objectives were to explore the current status of accreditation/certification and to clarify the reasons why EQAS organisers chose to, or plan to, or do not plan to obtain a formal recognition of their services. The survey was triggered by a similar investigation organised by Eurolab in 2004.

Fifty organisers from 32 countries responded to the survey. The results, in absolute numbers, below, indicate a strong tendency towards accreditation/certification of EQA activities.

Type of 3rd party recognition	Yes	Have applied	Will apply	No
EQA accreditation	14	5	11	20
EQA certification	10	1	5	32
Other accreditation	13			35

Only thirteen organisers operate schemes without any support from accreditation or certification, hence a majority have implemented a quality management system and is subject to 3rd party assessment. Most organisers, however, have no general accreditation, e.g. as testing laboratory as in-house support to their EQA activities. The organisers experience from the accreditation/certification process is generally positive and it has, in most cases, not influenced the participation fees.

Introduction

Terms and definitions

Interlaboratory comparisons involve the "organisation, performance and evaluation of measurements/tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions". The detailed objectives of such comparisons vary but are often related to:

1. Determination of laboratory testing performance,
2. Evaluation of the performance of measurement/testing methods,
3. Assignment of values to test/reference materials.

Comparison of a laboratory's routine test results with those of other laboratories play an important role as a means of external quality assurance. Comparisons can be organised by the laboratory itself and involve only a few other laboratories, or by a professional **provider** [1] or **organiser** [2] and then usually involve a number of participants.

Proficiency testing (PT) is the "determination of laboratory testing performance by means of interlaboratory comparisons" [3]. **External quality assessment** (EQA) is similarly defined as "determination of individual and collective laboratory performance, and performance characteristics of examination procedures by means of interlaboratory comparison" [4]. In some technical areas PT/EQA schemes are also referred to as "laboratory performance studies".

In laboratory medicine, the term EQA [2] is frequently used in Europe and South/Central America while PT is more common in North America. It is frequently argued that PT is associated with schemes operated for regulatory purposes. A footnote to the definition of EQA in EN 14136 states that "The primary objectives of EQA are educational...". Most schemes, however, have a high educational value and are therefore often used for continuous education and training of laboratory staff in many sectors.

The term **External quality assurance programme** (EQAP) is more comprehensive [2]. It is used in laboratory medicine for an interlaboratory comparison designed and operated to assure one or more of following aspects:

- Participant performance evaluation, e.g. analytical performance, test interpretation, advice to the clinician on laboratory requests and on diagnosis,
- Method performance evaluation,
- Vigilance of in vitro diagnostic (IVD) medical devices,
- Continuous education, training and help.

Accreditation and regulatory aspects of PT/EQA

The participation in EQA schemes (here from normally abbreviated EQAS) has gained in importance with the publication of the laboratory accreditation standards ISO/IEC 17025 [5] (first edition in 1999) and ISO 15189 [6]. According to ISO/IEC 17025 [5] article 5.9, laboratories are required to ensure the quality of their results, e.g. by interlaboratory comparisons or PT programmes. ISO 15189 states (Section 5.6.4) that "External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures".

Within the accreditation process and during surveillance, accreditation bodies shall take into account the laboratory's participation and performance in PT [7]. In some fields, especially in the legally regulated area of food and water, laboratories are required to participate in certain schemes to be allowed to be active in these fields [8]. During the past years it has been discussed to which extent accreditation bodies should require PT participation within laboratory accreditation. A sentence was introduced into ISO/IEC 17011:2004 [7], asking accreditation bodies to specify the minimum amount of proficiency testing and the frequency of participa-

tion in cooperation with interested parties and appropriate in relation to other surveillance activities (ISO/IEC 17011, 7.15). In the same discussion the question of appropriateness and quality of the schemes was raised.

Accreditation of EQAS organisers

Background

While systems for the accreditation of calibration laboratories have been in existence since the 1970s and for testing laboratories since the end of the 1980s, the accreditation of PT providers (and of reference material producers) has only recently started in Europe. The process was certainly triggered by the development and publication of ILAC Guide 13 [1] and the international standard ISO/IEC 17011 [7], which mention the competence of PT providers and/or the appropriateness of their schemes. Countries exist, e.g. Sweden, where the majority of medical laboratories are accredited and this situation has certainly influenced some EQA organisers' decision to accredit their schemes.

Third-party assessment (through accreditation of certification) of PT/EQA activities is today a reality in many countries. The number of accredited organisers in Europe has grown rapidly the last few years, from around ten in 2001/2002 [9] to some sixty in September 2004 [10].

Current debate

Accreditation of PT providers has been and still is subject to much discussion within organisations such as EQALM* (see page 26), Eurachem† (see page 27), Eurolab,‡ and EA§, and ILAC.** Several international meetings related to quality assurance have covered the topic [11, 12, 13, 14] debating, e.g. whether or not accreditation of PT providers is appropriate.

There is concern that this form of accreditation will increase the costs and may lead to fewer providers, especially in specific areas [9]. It is also feared that accreditation bodies may create a demand for providers to become accredited and for accredited laboratories to use only accredited providers [9]. Eurolab refers in its report to a survey revealing that some accreditation bodies recommend/mandate accredited laboratories to participate in accredited/recognised/approved PT schemes in preference to a non-accredited scheme in the same field, or recommend/mandate participation in an accredited/recognised/approved PT scheme outside the country in preference to a non-accredited scheme in the same field in their own country [9]. In October 2004, on the request of ILAC an additional column was inserted in the EPTIS [15] database providing information on the accreditation status of the providers. This measure may create some "ranking" and promotion of accreditation.

The European Commission's position seems to be that "...In the specific case of reference materials producers and proficiency testing providers, accreditation should [therefore] only be performed where producers and providers carry out conformity assessment tasks themselves [16]." This statement seems not to be in line with current practice. Based on the below definition, one can argue that PT/EQA in itself is very much a conformity assessment activity.

> **Conformity assessment:** "demonstration that specified requirements relating to a product, process, system, person or body are fulfilled" [17].

---

* EQALM: European committee for External Quality Assurance programmes in Laboratory Medicine, www.eqalm.org

† Eurachem: A focus for analytical chemistry in Europe, www.eurachem.ul.pt

‡ Eurolab: the European Federation of National Associations of Measurement, Testing and Analytical Laboratories, www.eurolab.org

§ EA: European co-operation for Accreditation, www.european-accreditation.org

** ILAC: International Laboratory Accreditation Cooperation

Documents underpinning PT/EQA accreditation

Accreditation of PT/EQA activities is presently based on various combinations of normative documents, thus illustrating the still not harmonised approaches of the accreditation bodies [9, 10]. In particular one can distinguish two major approaches:

1. The use of documents, which exclusively focus on PT, e.g. ISO/IEC Guide 43 [3] and ILAC-G13 [1]), or
2. ISO/IEC Guide 43 and/or ILAC-G13 in combination with international conformity assessment standards, e.g. ISO/IEC 17025 [5] or ISO/IEC 17020 [18]).

The relevant international document specifying the technical basis for organisers of PT/EQA schemes is ISO/IEC Guide 43 [3]. Its part 1 describes the different types of proficiency testing, their organisation and design, the operation and reporting. Important aspects are test item characterisation (e.g. homogeneity and stability), packaging and transportation, data analysis and evaluation and confidentiality. Examples of statistical methods for data treatment are given in its annex and in the draft standard ISO 13528 [19]. The guide points to specific aspects for PT organisation but does not contain detailed information on the general quality management or the general requirements for technical competence of an organisation. However, in most cases, the organiser will include sample characterisation, homogeneity and stability testing, which should be carried out according to the general requirements for the competence of a laboratory as described in ISO/IEC 17025 [5]. A compendium covering various technical aspects of EQA has been produced by EQALM [20].

Merging relevant aspects of ISO/IEC Guide 43 and ISO/IEC 17025 resulted in the Guide ILAC-G13 [1]. It also provides cross-references between ISO/IEC Guide 43, ISO/IEC 17025 and ISO 9001. The particular aspects of external quality assurance for medical laboratories have been included in the so-called EQAP document [2], which is based on ILAC-G13 and produced by an IFCC working group. Translation of ILAC-G13 and the EQAP document into other languages has been done as support to EQAS organisers and to those performing third party assessment activities [21].

In some cases it may be more practical to treat the general work of the PT provider as an inspection activity, for which the requirements are laid down in ISO/IEC 17020 [18] (EN 45004). Data collected from accreditation bodies show that different options of the above-mentioned normative documents are currently applied when accrediting PT/EQA.

ILAC has established a Consultative Group for PT, which met for the first time in September 2005. This group is expected to take the lead on issues such as accreditation of PT providers, revision of ILAC-G13 and ISO/IEC Guide 43, the need for a multilateral agreement for PT/EQA, and a common standard as basis for accreditation of these activities.

Survey on the accreditation of EQAS organisers

Rationale for the survey

Eurolab's survey [9] reached only a few EQAS organisers since it was based on address information in the Eptis database [15]. Discussions within EQALM [10] had shown that many members are interested to proceed to accredit their services. A complementary survey was therefore proposed and agreed [22].

Objectives

The survey targeted EQAS organisers in laboratory medicine. The objectives were to explore the current status of accreditation/certification, and to clarify the reasons why organisers have chosen to, or plan to, or do not plan to obtain a formal recognition of their services.

Logistics

The questionnaire, reproduced in Annex 1, was in English and based on the one from Eurolab [9]. It consisted of five sections:

A. Current accreditation/certification status
B. Appraisal of accreditation of EQAS organisers
C. Customers'/others demand for accreditation/certification of EQA organisers
D. Contacts with national accreditation/certification bodies
E. Information about organisers and schemes

The questionnaire together with background information was published on EQALM's website www.eqalm.org in April 2005. The material was also distributed with the May issue of EQAnews [23]. The deadline for returning the questionnaire was set to 26 August.

A draft report, based on 41 replies, was circulated 30 August to responding organisers, and among others, to EQALM, Eurachem, and Eurolab for comments. The intention from start was to be able to provide at least a draft report that could be used during working group discussions at a forthcoming Eurachem workshop [13]. This final report takes into account feedback delivered at the meetings of ILAC (Auckland 13 Sept.) and of EQALM (Rome 9-11 Oct.) 2005 [14].

Results and discussion

Response to the survey

Participants

By 12th October 50 questionnaires had been received from EQAS organisers in 32 countries. (Table 1).

Table 1. Overview of EQAS organisers responding to the survey.

Region	Country	No. of replies
Europe	Austria	1
	Belgium	1
	Bulgaria	1
	Croatia	1
	Czechia	1
	Denmark	1
	Finland	1
	France	2
	Germany	2
	Hungary	1
	Italy	4
	Ireland	1
	Netherlands	2
	Norway	2
	Portugal	1
	Serbia and Montenegro	1
	Slovakia	1
	Slovenia	1
	Spain	2
	Sweden	1
	Switzerland	3
	United Kingdom	5
Asia-Pacific	Australia	2
	China	1
Africa	South Africa	2
North America	Canada	2
South and Central America	Argentina	2
	Bolivia	1
	Costa Rica	1
	Guatemala	1
	Paraguay	1
	Uruguay	1
Σ	**32**	**50**

Information about EQAS and organisations

There is no similar inventory such as the Eptis database [15] for EQA resources. The most comprehensive compilation is probably that available from the Centers for Disease Control and Prevention (CDC) in USA [24]. The latest version from June 2003 includes around 150 organisers/programmes.*

Many countries have one, perhaps two organisations that operate on a national basis. In addition, schemes may also be arranged on a regional basis within a country, e.g. as in Italy. A few organisers offer their services worldwide.

* Attempts to contact >20 organisers listed in the inventory mid September failed in many cases, due to wrong address information.

For some sectors in some countries, e.g. general clinical chemistry in Israel and Norway, individual experts coordinate participation in foreign international schemes. The decision to accredit/certify EQA activities locally may, therefore, depend on the situation pertaining at the coordinating organiser. Schemes are also organised by the diagnostic industry.

The EQAS linked to this survey cover most "clinical laboratory sciences". A few hundred measurands are typically included in schemes from larger organisations. The questionnaire indicated ten disciplines but there is a substantial overlap between some of them. The most frequent services are provided in general clinical chemistry, haematology, immunology/transfusion medicine, and microbiology (Table 2). The average organiser offers schemes in 4 disciplines.

Table 2. Major disciplines covered by the EQAS organisers in the survey.

Clinical discipline	Description*	No. of organisers covering the field(s)
(Morphological) Pathology	Branch dealing with the basis of diseases, especially structural and functional changes in organs and tissues causing or caused by disease.	8
Cytology	Science dealing with structure, function and life-history of cells.	7
Pharmacology	Science dealing with the characteristics, effects, and uses of drugs and their interactions with living organisms.†	19
Toxicology	Discipline dealing with hazardous substances, their nature, metabolism and effect on living organisms.	
Microbiology	Discipline dealing with the properties of micro-organisms, including bacteria, fungi, parasites and virus, and their effects on the host and on the environment.	29
Physiology	Part of biology dealing with functions and activities of organisms.	2
Haematology	Discipline dealing with the properties of cells and related components in blood-forming tissues and blood in health and disease including the laboratory aspects of transfusable blood products.	31
Molecular biology/(DNA)	Study of biological phenomena at the molecular level.	14
Immunology	Discipline dealing with the immune system and immune responses in health and disease.	25
Transfusion medicine	Branch of medicine concerned with the transfusion of blood and blood components‡	
Genetics	Study of the nature, transfer and expression of heritable information that controls the development of living organisms, and the distribution of this information during reproduction and growth.	7
General clinical chemistry		38

Apart from the disciplines in Table 2, the organisers referred to EQAS for individual components, e.g. haemoglobin A_{1c} (3) and Hb screening, ESR, TDM, specific proteins, for groups of

* Extracts from IUPAC, IFCC (Recommendations 1995) Compendium of Terminology and Nomenclature in Clinical Laboratory Sciences. Rigg J. C. et al. (editors), Blackwell Science.

† Example of description from the Internet 2005-07-21.

‡ Example of description from the Internet 2005-08-24.

components, e.g. tumour markers (2), lipids, and cardiac markers. Sub-groups of disciplines, e.g. virology (2), parasitology (3) and mycology were mentioned, as well as coagulation/haemostasis (2), endocrinology/hormones (2), instrumental control (3), HIV diagnosis and monitoring, neonatal diagnosis/newborn screening (3), trace element analysis (2), synovial fluid, serology including nucleic acid testing, allergy, urine analysis (5), urinalysis (images), urology, urine sediment, biological monitoring, organic solvent, mycobacteria, flow cytometry, immunoassays (2), biochemical markers of myocardial disease, forensics, occupational and environmental laboratory medicine, and industrial applications.

Part A – Current accreditation/certification status

Accreditation status for EQA activities

Twenty-eight percent of the organisers are currently accredited but another 32% have applied for accreditation, or state that they will do so. There is little difference between European organisers (Figure 1) compared to the whole group (Figure 2). This is a confirmation of previous surveys [9, 10]. Five of the fourteen accredited organisers received their accreditation already during the 1990s. Organisers from South and Central America mentioned that their national accreditation body is not yet ready, or has only recently achieved ILAC recognition for this activity.

Accredited organisers exist in Australia, Belgium, Italy, South Africa, Sweden, Switzerland and United Kingdom. Other countries, where organisers have applied for accreditation are Italy, Spain, Portugal, Germany and Czechia.

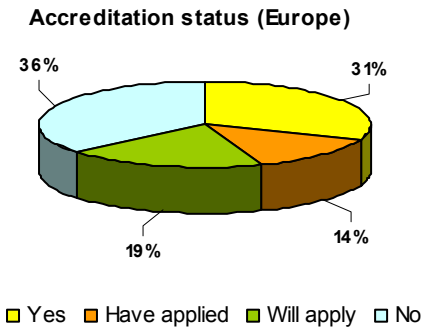

Figure 1

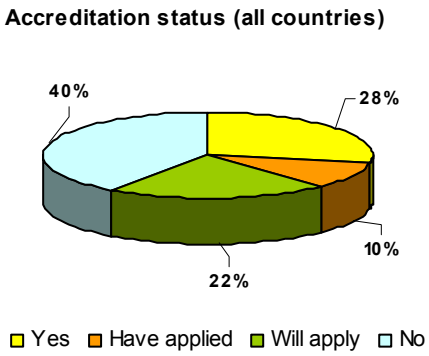

Figure 2

Certification status for EQA activities

About 30% of the organisers also state that their EQA activities are/will be covered by an ISO 9001, or similar, certification (Figure 3 and Figure 4). Certified organisers already exist in Argentina, Australia, Canada, Hungary, Italy, Serbia Montenegro, Switzerland and United Kingdom.

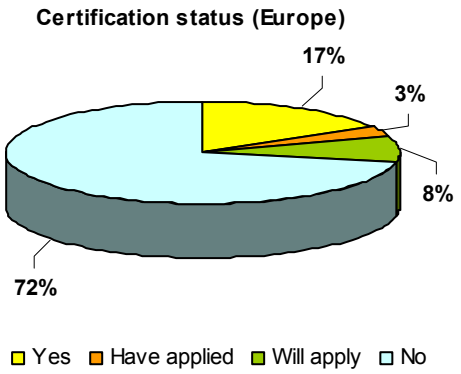

Figure 3

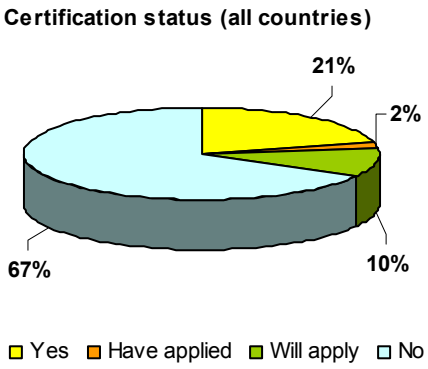

Figure 4

The specific comments related to certification issues were:

- "Our certification covers the benchmarking in pathology quality assurance programmes and the enrolment office of our organisation'.
- "Our mother organisation will be certified (ISO 9001) and the EQA schemes will be accredited'.
- "ISO 9001 requirements will be included in the new standard for EQA by CPA (UK) [25]".

Other accreditation/certifications

A majority of the organisers in this survey has no general accreditation (Figure 5). About 20% are accredited as testing laboratories based on ISO/IEC 17025 or equivalents such as ISO 15189 for medical laboratories [6]. Accreditations as calibration laboratories exist with reference to ISO/IEC 17025, but also to ISO 15193 [26] and ISO 15195 [27].

In-house laboratory resources are advantageous for the organiser but not a necessity. Test material characterisation can be sub-contracted to competent laboratories.

Only thirteen of the 50 organisers have no form of accreditation/certification at this moment. In this group are small as well as large organisers, from countries in Europe and South/Central America. Hence, a majority have implemented a quality management system and is subject to a third-party assessment.

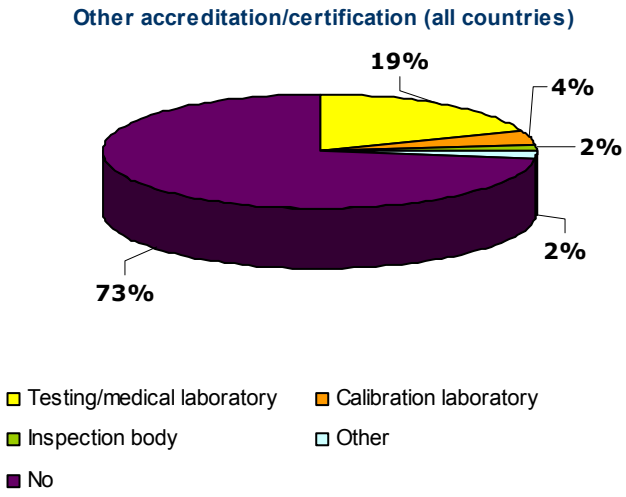

Figure 5

Documents underpinning EQA accreditation/certification

The organisers were asked which standards/guides underpinned/will underpin their accreditation of EQA activities.

Most of them referred to ISO/IEC Guide 43 and to ILAC-G13 Figure 6. As discussed in the introduction, and confirmed in Eurolab's survey [9], these documents are combined differently (Table 3).

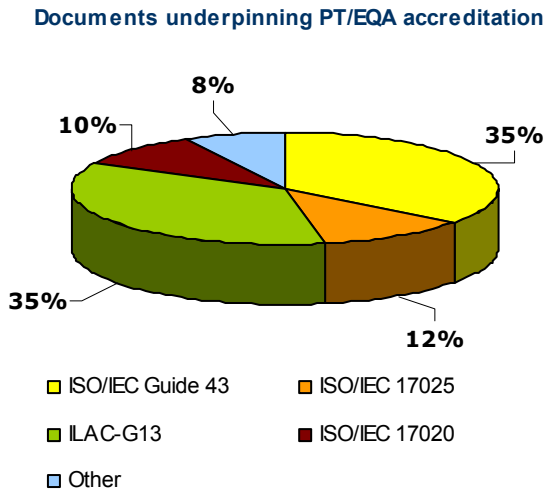

Figure 6

Table 3. Document combinations underpinning existing/on-going EQA accreditations.

Document combination	No. of organisers
ILAC-G13 + ISO/IEC Guide 43	7
ILAC-G13 + ISO/IEC Guide 43 + ISO/IEC 17025	4
ILAC-G13 + ISO/IEC Guide 43 + ISO/IEC 17020	4
CPA EQAS (UK) [25]	2
ILAC-G13	1
ISO/IEC Guide 43 + ISO/IEC 17025 + ISO/IEC 17020	1

References were also given to EN 14136 [4], EN/ISO 13485 [28], ISO 15190 [29] and ISO 9001 [30].

Part B – Appraisal of accreditation of EQA schemes

Effect on quality

A clear majority (84%) of the organisers expect or experience an improvement of their EQA services from accreditation/certification. The specific comments were:

- "Yes, better procedures and better homogeneity testing".
- "Yes, since we started to document improvements continuously in our quality management system, the number of errors has been reduced in our programs and the efficiency has increased. Our annual customer satisfaction surveys are at 85% or higher".
- "Yes, in terms of customer satisfaction".
- "Yes, an annual improvement plan has been developed".
- "Depends on the quality of the accreditation scheme".
- "No, the quality of the service has always been of high standard and was recognised by the accreditation body at the first inspection. Carrying the accreditation logo is important"

Effect on participation fees

Most organisers (67%) expect or experience no change on participation fees from accreditation/certification. The actual stated increases mentioned by fourteen organisers range from 2% to 250% (Table 4). The estimates in the range 10-250% were given by organisers currently lacking third party recognition. The three highest estimates are not unrealistic if the organiser lacks a quality management system, or if the system is not optimised as confirmed by one organiser.

Table 4. Expected/experienced increase in participation fees (%) and accreditation/certification status.

Increase (%)	Provider's status	Increase (%)	Provider's status
2	• Certified • EQA accreditation and general accreditation • EQA accreditation, certification and inspection body	20	• No accreditation/certification
4	• EQA accreditation	50	• No accreditation/certification • No accreditation/certification
5	• Will apply for accreditation and certification • Will apply for accreditation • No accreditation/certification	100	• No accreditation/certification
10	• No accreditation/certification • No accreditation/certification	250	• No accreditation/certification

Suitability of standards and guidance document

Sixty-nine percent of the organisers find existing standards and guidelines sufficient. EQALM has argued for inclusion of the specific clinical aspects of PT/EQA that are present in the EQAP document [2] if and when documents are revised. Specific comments from the organisers in the survey were:

- "It would be better to have just one complete guide".
- "Harmonisation of ISO 17020, ISO Guide 43-1 and ILAC-G13 is required rapidly".
- "Issues associated with EQA of medical labs to include homogeneity and stability of biological material, assessment of qualitative surveys, alternative models when small numbers of labs exist".
- "We are developing standards based on EQAP document and ISO Guide 43 in the MERCOSUR region (Argentina, Brazil, Uruguay, Paraguay)."
- "The EQAP document is our basis".
- "Yes, these document are included in the CPA standard [25]".

Need for interest organisation

The survey inquired whether the organisers saw a need for an organisation that represents their interests, e.g. against accreditation/certification bodies. The question, although not so well put (see comment below), is relevant. EQA is a new accreditation area and with that

follows need for education and training of assessors [11, 12]. Some national accreditation bodies provide PT/EQA services and this fact has also been debated. Among the answers in this survey, one is known to come from such an organisation.

Almost two thirds (62%) of the organisers indicated a need for somebody or some organisation representing their interests. Those who commented on this matter referred to their own staff, or to EQALM, IFCC, to existing networks of organisers, e.g. that in occupational and environmental laboratory medicine (OELM) and other scientific associations. All of them can probably give advice for harmonisation and procedures, e.g. developing of a standard for accreditation of EQAS organisers.

One organiser said that EQA schemes have issues that need addressing beyond those that involve accreditation bodies, e.g. education, and research and development issues. Another comment reflected upon the positive experience (see below) that many organisers have from their contacts with accreditation/certification bodies. This organiser saw a need for an organisation that guarded the interest “not ”against” but ”moderating” accreditation/certification bodies and ”exchanging priorities” with these bodies”.

Part C – Customers’/others demand for accreditation of EQA organisers

Customers’ interest

Almost 80% of the organisers feel that their customers are either interested in their accreditation or that this will be the case in the future (Figure 7). One international organiser noted most interest from outside his country.

The customers seem to prefer a specific accreditation as EQAS organiser compared to a general accreditation (Figure 8). Eurolab’s survey resulted in a different conclusion [9].

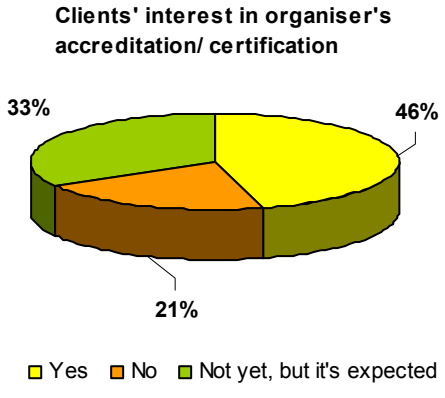

Figure 7

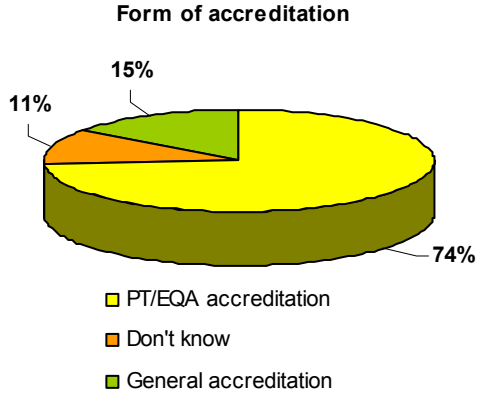

Figure 8

Main reasons for decision to accredit/certify EQA activities

The reasons why organisers decide to obtain a third party recognition of EQA services are rather well divided between the four options given in the questionnaire This is further supported by the specific comments (below) given by fourteen organisers.

- "The decision was made within the organisation to seek accreditation for the QA programmes. In 2004, the national regulatory requirements in Australia (NPAAC) stated that laboratories should choose an accredited PT provider for external QA".
- CPA (UK accreditation body) demands that laboratories participate in accredited EQA schemes".

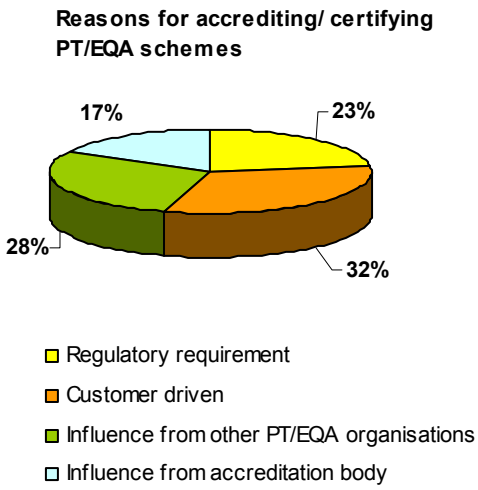

Figure 9

- "It was a demonstration project. As an academic-based program, it was essential that we be seen to strongly support quality audits, not only for others but also for ourselves".
- "Accreditation helps one to find things more easily", "It was our own commitment".
- "To improve the quality of our EQA schemes", "Internal needs for improving our EQA programmes", "Needs for improvement of our organisation". "Expected improvement of our quality management system".
- "Accredited laboratories use our services to obtain information about the analytical quality. It seems therefore, sensible that we are also accredited. Our customers do not point to this, it is more our own opinion within the organisation. The majority of our customers belong to primary healthcare and <1% of them being accredited".
- "It's helpful if you have to argue with local authorities".
- "Proof of excellence to various parties, ensuring proof of conformity, ensuring reliability of the organisation's activities".
- "It made commercial sense to be accredited before participant laboratories".
- "It was a mix of pressure from the accreditation body and our wish to be a national recognised EQA organisation. Now accreditation is mandatory".

Part D – Contacts with national accreditation/certification body

Organisers' experiences

Thirty-two organisers commented on their experience from interactions with accreditation/certification bodies before during and after the process. The experience is generally very good. Interactions are, e.g. described as:

- "Positive, with good outcome for the programmes. There has been some concern regarding individual assessors' interpretations of the requirements. They do not have a clear understanding of EQA but that can be an advantage because they are totally objective".
- "Basically positive and useful", "positive", "very positive", "excellent contact", "positive and motivating", "absolutely satisfying", "positive contacts exist", "neutral".

- "Active contacts (as a participant in the accreditation body's group for PT/EQAS accreditation)".
- "We invested a lot of time".
- "All recommendations from the accreditation body to improve our programs have been followed".
- "Our expert and the people from the accreditation body were very professional and did quite a good job", "A mutually agreed requirement carried out with good humans".
- "Experiences were good. There were some improvements", "OK, good", "No problems", "limited acquaintances."
- "The accreditation organisation provided good documentation and the process was straightforward".
- "Positive. Apart from the control that our routine procedures follow requirements in the standard, we also get many good pieces of advice about handling different situations that are not described in the standard."
- "Our organisation is certified according to ISO 9001:2000. This standard is not sufficient for an EQAS organiser, and this caused some difficulties in the process of certification. On the other hand the national accreditation body is not yet ready for accreditation of a PT/EQAS organiser".
- "We have many contacts and they know that our process is running. In the Internet page of our Accreditation body we are recognised as PT provider in our country for clinical laboratories", "We have no problems in communication with national accreditation body".

Creating a demand for accreditation of EQA activities

The concern that various parties express about accreditation of PT/EQA must be taken seriously. Eurolab's report [9] discussed this in detail, why it was relevant to explore the matter also among the organisers in laboratory medicine.

Surely the accreditation bodies are interested in promoting accreditation of PT/EQA. ILAC-G13 [1] is directed to providers of PT/EQA schemes who wish, on a voluntary basis, to demonstrate their competence, for the purposes of accreditation or other recognition, by formal compliance with a set of internationally acceptable requirements for the planning and implementation of such schemes. It is said in the preamble of ILAC-G13 that "assessors and laboratory accreditation bodies will be better placed to use the results of PT/EQA schemes as an aid in the accreditation process if they are confident that such schemes are operated competently and in harmony with appropriate requirements. Other users of the schemes may also have additional confidence if the schemes have been independently accredited."

In this survey, 42% of the organisers sensed that the conformity assessment bodies (CABs) attempt to create a demand for accreditation/certification of PT/EQA for some reason [Figure 10]. This is a smaller fraction compared to Eurolab's survey [9]. The specific comments from the organisers on this matter are rather neutral:

- "This is a requirement now but not at the time the organisation made the decision to seek accreditation for the QA programs".
- "I think they encouraged accreditation by making it available and advertising it, but I have no objection to this".

- "The national accreditation body does not relate to most provincial laboratory accreditation bodies or to most PT/EQA organisers".
- "No, not for the moment".
- "We expect a future interest".
- "In this field there is no market for our accreditation body".
- "They know that this is very important for laboratories. Best service, best quality".
- "NABs have expressed an interest in accredited PT/EQA".

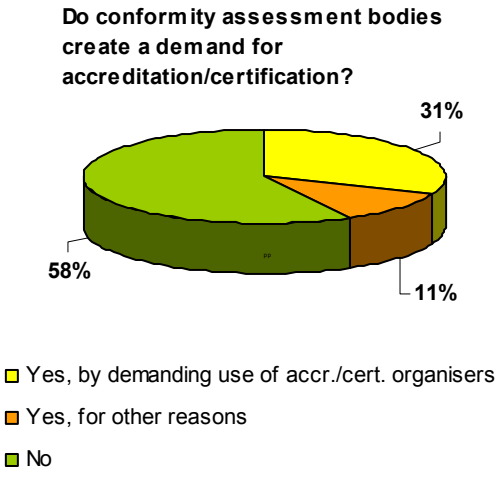

Figure 10

Organisers' overall experience from accreditation/certification process

Twenty organisers concluded that it was worthwhile the effort and that they would recommend other organisations to go through an accreditation/certification process. No organiser was of the opposite opinion. The specific comments on this matter were:

- "The accreditation body offers programs for medical testing laboratories who are accredited to ISO/IEC 17025. It is only appropriate that the QA programs are also accredited. It is essential that our organisation demonstrate its competence to the participants".
- "We have improved some of our practices, gained the confidence of third party assessment, and gained general external recognition. We also now have more contact with other PT providers".
- "I believe that every enterprise should as a minimum be certified to ISO 9001:2000".
- "The ISO certification was worthwhile and useful for us".
- "We hope to be accredited at the end of 2005".
- "We are not accredited [yet] but we think it's very important."
- "Building a quality management system is very important. A process with external audits helps improving this. Which way you choose (e.g. ISO 9000, accreditation or what else) depends on the local situation. In our country, it was very helpful to have an accreditation".
- "The most important is to have implemented a quality management system based on a standard and to follow that standard. You can do that without an accreditation but the contact with the accreditation body is valuable too".

How representative is the survey?

The lack of information about available EQA resources makes it difficult to conclude on how well the answers reflect the current situation. Large, multidisciplinary, accredited organisers that operate internationally are perhaps more likely to respond to the survey than others. An attempt is made here to judge the outcome against the size of the EQA organisers' activities.

No organiser indicated more than nine disciplines including 'Other' on the questionnaire. Of the fourteen organisers with EQA accreditation, eight offer schemes in 1-4 disciplines and six in 5-9 disciplines (Table 5). Comparing organisers with a general accreditation or a certifica-

tion results gives similar patterns. It seems as size is no matter here. Smaller organisers are, however, more represented among those having no 3rd party recognition.

Table 5. Comparison of the size of organisers' activities (number of disciplines with EQA schemes) against organisers' type(s) of 3rd party recognition.

Disciplines	EQA accreditation	General accreditation	Certification	No 3rd party recognition
1-4	8	6	6	9
5-9	6	7	4	4

Conclusions

The report is based on the views of 50 EQAS organisers from 32 countries. If used together with the 110 results from other sectors previously compiled by Eurolab [9], a good picture of the current situation with regard to accreditation/certification is obtained.

The survey reveals a strong tendency towards accreditation/certification of EQA organisers. This is reflected in that 28% of the responding organisers are already accredited and that this number can increase to 60% if those who have applied or will apply terminate the process successfully. In addition, 33% of the organisers are/will be certified for EQA activities.

The organisers are convinced that the quality of their EQA services benefit from accreditation/certification. A majority says that participation fees are/will be unaffected by the process, or increase by only a few percent.

This survey confirms that customers are interested in the accreditation of the organisers and that they preferably see them acquiring accreditation for EQA services.

There are organisers (42%) whom feel that the conformity assessment bodies themselves create the demand for third-party recognition. Judging by the organisers' comments, this seems, however, not to be very controversial. Most organisers experience good collaboration with these bodies. A dozen European accreditation bodies were known to offer PT/EQA accreditation at the end of 2004 [10] and this survey indicates that the number is growing.

Acknowledgements

The authors thank the organisers who contributed to the survey. The kind provision of templates by Anita Schmidt (Eurolab Technical Secretariat) enabled this report to be compiled in a short time.

References

1. ILAC-G13:2000, Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes“, http://www.ilac.org
2. IFCC/EMD/C-AQ Guidelines for the Requirements for the Competence of EQAP organizers, version 3/2002, www.ifcc.org
3. ISO/IEC Guide 43:1997, Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes. Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies, ISO Geneva
4. EN 14136:2004, Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures, CEN Brussels
5. ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories, ISO Geneva
6. ISO 15189:2003, Medical laboratories - Particular requirements for quality and competence, ISO Geneva
7. ISO/IEC 17011:2004, General requirements for accreditation bodies accrediting conformity assessment bodies, ISO Geneva
8. Koch M. Regulatory aspects of proficiency testing: experience from the water sector, Accred Qual Assur 2004, **11**, 684-687
9. Eurolab Technical report No. 1/2005. Survey on the accreditation of proficiency test providers, Eurolab Technical Secretariat, Feb. 2005, www.eurolab.org
10. Örnemark U. Report on the open discussion on accreditation of EQAP organisations, EQAnews 2004, **15**(4), 57-58
11. Örnemark U et al., proceedings from Eurachem/EQALM workshop on proficiency testing in analytical chemistry, microbiology and laboratory medicine, Borås (SE), 24-26 Sept. 2000. Accred Qual Assur, 2001, **6**(4-5), 140-146
12. Brookman B et al., Proceedings from Eurachem/EQALM/CITAC workshop on proficiency testing in analytical chemistry, microbiology and laboratory medicine, Bracknell (UK) 16-18 Feb. 2003. Accred Qual Assur, 2004, **9**, 635-641
13. Eurachem/EQALM/CITAC workshop on proficiency testing in analytical chemistry, microbiology and laboratory medicine, Portorož (SI) 25-27 Sept. 2005. www.eurachem.ul.pt
14. Noble M. Accreditation of EQA scheme providers: current situation. EQALM symposium, Rome 9-11 Oct. 2005
15. EPTIS, the European Proficiency Testing Information System, www.eptis.bam.de
16. McMillan J to Pierre D, Accreditation of reference materials producers and proficiency testing providers - Commission viewpoints. Letter ENTR/G1/MS/D(2004), Brussels 8 Sept. 2004
17. ISO/IEC FDIS 17000:2004, Conformity assessment - Vocabulary and general principles, ISO Geneva
18. ISO/IEC 17020:1998, General criteria for the operation of various types of bodies performing inspection“, ISO Geneva
19. ISO 13528:2005, Statistical methods for use in proficiency testing by interlaboratory comparisons”, ISO Geneva, 2005 (draft)
20. Uldall A (editor), Compendium on advanced external quality assurance in clinical biochemistry, EQAnews 2000, **11**(1), 1-150

21. SWEDAC DOC 04:10, Riktlinjer för kompetenskrav för arrangörer av kvalifikationsprövningsprogram och program för extern kvalitetsbedömning, SWEDAC, Borås (2004), www.swedac.se (under revision)
22. Personal communication: 1) Örnemark U to Libeer J-C (EQALM) 9 March 2005. 2) Örnemark U to Brookman B et al. (Eurachem PT WG) 9 March 2005. 3) Örnemark U to Golze M (Eurolab) 17 March 2005
23. Örnemark U, Survey on accreditation of PT/EQAS organisers, EQAnews, 2005, **16**(2) 18
24. Inventory of external quality assessement programs, www.phppo.cdc.gov/mlp/pdf/EQA/eqa_list.pdf, CDC, 30 June 2003
25. Clinical Pathology Accreditation Standards for EQA Schemes in Laboratory Medicine, www.cpa-uk.co.uk
26. ISO 15193:2002, In vitro diagnostic systems - Measurement of quantities in samples of biological origin - Presentation of reference measurement procedures, ISO Geneva
27. ISO 15195:2003, Laboratory medicine - Requirements for reference measurement laboratories, ISO Geneva
28. EN ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes, ISO Geneva
29. ISO 15190:2003, Medical laboratories - Requirements for safety, ISO Geneva
30. ISO 9000:2000, Quality management systems - Fundamentals and vocabulary, ISO Geneva

Annex 1 – Questionnaire

A	**Current accreditation/certification status**
1	Is your organisation accredited as a PT/EQA scheme organiser? ☐ Yes, since) ☐ We have applied for accreditation ☐ We will apply for accreditation ☐ No
2	If your organisation is accredited as PT/EQAS organiser, which standard(s)/guide(s) underpin this accreditation (tick one or more boxes to illustrate document combinations)? ☐ ISO/IEC Guide 43-1 ☐ ILAC Guide 13 ☐ ISO/IEC 17025 ☐ ISO/IEC 17020 ☐ Other, please specify:
3	Does your organisation hold another accreditation, e.g.? ☐ As a testing laboratory according to ISO/IEC 17025)? ☐ As a calibration laboratory according to ISO/IEC 17025)? ☐ As an inspection body according to ISO/IEC 17020 ☐ As... ☐ No
4	Does your organisation hold a certification, e.g. based on the ISO 9000 series that involves organisation of PT/EQA schemes? ☐ Yes, since) ☐ We have applied for certification ☐ We will apply for certification ☐ No

B	**Appraisal of accreditation of PT/EQA scheme organisers**
5	Do you experience or expect an improvement in the quality of your PT/EQAS services through accreditation/certification? ☐ Yes ☐ No Comments:
6	Do you expect or experience an impact of your accreditation/certification on participation fees? ☐ Increase, approximately) % ☐ Decrease, approximately) % ☐ No change
7	Do you feel that existing standards with requirements for competence of conformity assessment bodies in general (e.g. ISO/IEC 17000 series) and on PT/EQA scheme organisers (e.g. ISO Guide 43-1, ILAC-G13, EQAP-document) are sufficient for your needs? ☐ Yes ☐ No, additional guides would be welcome Comments:
8	Do you see a need for an organisation representing the interests of PT/EQA scheme providers, e.g. against accreditation/certification bodies? ☐ Yes ☐ No ☐ Comments: Our interests are represented by:

C	**Customers'/others demand for accreditation of PT/EQAS organisers**
9	Do/did your customers express interest in an accreditation/certification of your organisation? Yes ☐ No ☐ No not yet, but it is expected ☐
10	If "Yes" to question 9, which form of accreditation do your customers ask for? ☐ Accreditation as a PT/EQAS provider ☐ A general accreditation, e.g. as a testing laboratory ☐ I don't know
11	Which are/were the main reasons for your organisation's decision to accredit/certify PT/EQAS activities? ☐ Regulatory requirements ☐ Customer driven ☐ Influence from other PT/EQA organisations ☐ Influence from the national accreditation body Comments:

D	**Contacts with national accreditation/certification body**	
12	What is your experience from the contacts/interactions with the national accreditation body before, during and after the accreditation/certification process? Comments:	
13	Do you feel that the national accreditation body/certification body attempt to create a demand for accreditation/certification of PT/EQAS organisers? ☐ Yes, by demanding use of accredited/certified PT providers ☐ Yes, for other reasons ☐ No Comments:	
14	If you are an accredited PT/EQA scheme organiser, do you think it was worthwhile the effort and would you recommend other organisations to go through the accreditation/certification process? ☐ Yes ☐ No Comments:	
E	**Information about your PT/EQA schemes and organisation**	
15	Technical field(s) in which you offer PT/EQA schemes ☐ Microbiology ☐ Physiology ☐ Morphological pathology ☐ Cytology ☐ Haematology ☐ Molecular biology/DNA	☐ Clinical immunology/Transfusion medicine ☐ General clinical chemistry ☐ Pharmacology/drugs of abuse/toxicology ☐ Genetics ☐ Other: ☐ Other:
16	Name of organisation: (not mandatory) Country: Contact person: (not mandatory) Email: (not mandatory)	

Annex 2 – Resolution adopted by EQALM

EQALM symposium in Vienna

6-8 September 2004

Resolution

1. According to the vigilance role, given to EQA organisations in Europe according to the IVD directive EC 98/79, there is a strong need to harmonise the accreditation procedures of EQA providers.
2. EQALM welcomes the initiative of ILAC to review the ILAC Document G13
3. The European EQA organizers in medical laboratories strongly support the IFCC so-called EQAP document as this document covers better all aspects from external quality assurance programmes
4. EQALM does not insist to have a separated revised G13 guidance document but wants that the additional items from the IFCC EQAP document are taken over in the revision.
5. EQALM wants to be involved into this revision.

Moreover, we feel a strong need for a real PT/EQA standard.

The revised guide could be the basics of a real PT/EQA standard.

NB; the IFCC–EQAP document is already adapted in Argentina and circulates in Sweden (as draft SWEDAC DOC 04/10) as basic document for the accreditation of EQA providers in the medical field.

Prof. Dr. J.C. Libeer

EQALM chairman

9-9-2004

Annex 3 – Draft Eurachem position paper

Viewpoints on the accreditation of providers of proficiency testing schemes

The Eurachem Executive Committee has tasked the Eurachem Proficiency Testing Working Group to consider and propose viewpoints on the issue of accreditation of providers of proficiency testing schemes. The PT WG proposes the following views:

Considering that the accreditation of PT providers can contribute to an improvement of the quality of analytical measurements, that many PT providers recognise an improvement in quality through the accreditation process and that many laboratories favour a mechanism to identify competent providers, EURACHEM therefore takes the position that:

1. Accreditation of PT providers should be available for those who wish to seek accreditation.
2. Accreditation of PT providers should not be mandatory and neither should it be mandatory for accredited laboratories to use accredited PT schemes.
3. Accreditation should not be prohibited to those providers not undertaking any laboratory activity, since the provision of a laboratory performance assessment by the PT provider, following data analysis etc, could be considered as a conformity assessment.
4. A standard based on ISO/IEC Guide 43 and ILAC-G13 would be welcome.

Brian Brookman

Chair, EURACHEM PT Working Group

28 September 2005

***