Ann. Ist. Super. Sanità, vol. 32, n. 2 (1996), pp. 193-198

First steps toward harmonisation of European EQAS in occupational and environmental laboratory medicine: from Dublin to Rome

Marina PATRIARCA *(a)*, Antonio MENDITTO *(a)* and Andrew TAYLOR *(b)*

(a) Laboratorio di Biochimica Clinica, Istituto Superiore di Sanità, Rome, Italy
(b) Trace Element Laboratory, Robens Institute of Health and Safety, University of Surrey, Guildford, Great Britain

Summary. - Laboratories performing analyses in the field of occupational and environmental medicine (OELM) must provide reliable results for an increasing number of analytes related to exposure to chemicals. Participation in external quality assessment schemes (EQAS) allows laboratories to assess their performance and is regarded as a pre-requisite for accreditation from appropriate national and supranational bodies. Within the framework of the European Union, harmonisation of procedures for evaluation of laboratory performance in EQAS is desirable, in order to achieve a similar degree of excellence within Europe. Collaboration among different countries would also be profitable to compare experiences, develop new schemes, covering a wider range of analytes, and to devise common research on specific problems. We report on initiatives developed to meet this objective, in collaboration with the Standards, Measurements & Testing (SM&T) programme of the European Commission (EC), Directorate General XII. Meetings were held in Dublin and Rome which allowed experience among European EQAS organisers in OELM to be shared. Discussion focused on the identification of common needs and areas where collaborative work could be carried out.

Key words: external quality assessment schemes, European Union, occupational and environmental laboratory medicine.

Riassunto *(Primi passi verso l'armonizzazione degli schemi europei di valutazione esterna di qualità in medicina occupazionale e ambientale: da Dublino a Roma).* - I laboratori che effettuano analisi nel settore della medicina occupazionale ed ambientale (MOA) devono fornire risultati affidabili per un numero crescente di analiti connessi con l'esposizione a sostanze chimiche. La partecipazione a schemi di valutazione esterna di qualità (VEQ) permette ai laboratori di valutare le proprie prestazioni analitiche e viene considerata un requisito essenziale per l'accreditamento da parte delle organizzazioni nazionali ed internazionali. Nell'ambito dell'Unione Europea, sarebbe desiderabile che le procedure per la valutazione delle prestazioni dei laboratori negli schemi di VEQ fossero armonizzate allo scopo di ottenere un livello confrontabile di prestazioni in tutta Europa. La collaborazione tra paesi diversi sarebbe vantaggiosa per il confronto di esperienze, lo sviluppo di nuovi schemi per un numero più vasto di analiti e la promozione della ricerca su problemi specifici. Vengono riportate le iniziative sviluppate per il raggiungimento di questo obiettivo, in collaborazione con il programma "Norme, misure e prove" della Commissione Europea, Divisione generale XII. Sono stati organizzati incontri tra gli organizzatori di schemi europei di VEQ in MOA, tenuti a Dublino e a Roma, nel corso dei quali sono state riportate le varie esperienze. La discussione è stata focalizzata sull'identificazione dei bisogni comuni e delle aree in cui promuovere la collaborazione.

Parole chiave: schemi di valutazione esterna di qualità, Unione Europea, medicina occupazionale ed ambientale, prestazioni analitiche di laboratorio.

Introduction

In the European Union (EU), many efforts are devoted to ensure that fair and equivalent conditions apply to the citizens of all member states. In terms of individuals' needs, this could be described as providing a similar quality of life throughout Europe. Health is a major part in the quality of life and therefore all individuals should have the same opportunities to enjoy a healthy life. In the context of occupational health and safety, this means that the same level of protection from health hazards at the workplace should be provided to all workers, since the same law applies to all member states. Undue exposure to chemicals present in the environment is also a cause of increasing concern and appropriate actions, to be agreed upon at the European level, are required. For these reasons biological monitoring programmes, for both exposed workers and the general population, are increasingly carried out to provide the information necessary for risk assessments.

Achievement of the goal of equivalent conditions of health care for all European citizens requires adequate prevention, prompt diagnosis and effective treatment of health impairing conditions.

Laboratory medicine is an essential component of health care and the results of biochemical tests are often decisive in terms of action required. Reliability and comparability of the results of laboratory tests throughout Europe are therefore essential prerequisites to the provision of equivalent health care.

The tests performed in the field of occupational and environmental laboratory medicine (OELM) aim to identify exposure to given chemical(s), evaluate the level of internal exposure and assess any health risk involved. Occupational and environmental health laboratories are concerned with the determination of a large number of analytes, often difficult to measure and often present at low concentrations. They are involved with the assessment of sampling and storage procedures, method development and the exploitation of analytical techniques to achieve adequate level of sensitivity, specificity, accuracy, and reproducibility. Traditionally, measurements of essential trace elements, such as Cu, Se and Zn, and those used as therapeutic agents, such as Li, Pt and Au, have also been carried out at OELM laboratories, due to their expertise in trace metal determinations.

According to international guidelines [1, 2], all testing laboratories should demonstrate the reliability of their results by implementing an appropriate quality assurance system, to include participation in external quality assessment schemes (EQAS). Participation in EQAS is of the utmost importance for analytes for which few or no certified reference materials are available. In most European countries, EQAS in OELM have been promoted by national research organizations and universities for at least some analytes [3-13]. Since the number of participants in each country is limited and commercial control materials are not available for most analytes [14], procedures for the preparation of suitable control materials, the organization of the trials and the evaluation of the results have been developed separately by each scheme and a wide range of analytes is covered according to local needs and legislation.

Within the EU, collaboration and harmonisation of EQAS in OELM should be sought, in order to develop a common approach to the challenging organisational and analytical problems in this field. Collaboration between EQAS organisers is necessary to address new methodological problems, to ensure the reliability of data produced for a growing number of potentially toxic chemicals, and to support the quality of rare analyses by means of initiatives at a European level. Accreditation of occupational and environmental health laboratories by the Western Europe Laboratory Accreditation Conference, for which participation in EQAS is required, could also benefit from harmonised protocols for European EQAS in this field.

The first steps toward harmonisation of EQAS in OELM were supported by the EC, Directorate General XII, Standards, Measurements & Testing (SM&T) programme, which issued a Directory of European EQAS in Laboratory Medicine, including OELM [15]. The SM&T programme also coordinated a multicentre project to compare procedures for evaluating laboratory performances in blood lead analysis used by EQAS operating in different European countries [16], contributed to the organization of two meetings to promote the sharing of information about different EQAS and provided a setting for initial discussions to be carried out. In this paper, the major points raised in these discussions and the proposals for further collaboration are reported.

Meetings of the organisers of European EQAS in OELM

EC Workshop on "Biomedical Measurements in Occupational Health. New trends and reliability of analytical results", Dublin, 1994

The EC, Directorate General XII, Science, Research and Development, organised a workshop on "Biomedical Measurements in Occupational Health. New trends and reliability of analytical results", (Dublin, 24-26 March 1994), "to review current measurements and testing practices in biomedicine, with particular relevance to occupational health...", which is of particular concern to the EC. The organization of this workshop, at a time close to the end of the 3rd framework programme 1990-1994, aimed also to achieve an "improvement in identifying topics and objectives to be incorporated in the Research and Development (R&D) programme "Standards, Measurements and Testing (SM&T)", 4th framework programme (1995-1998)".

The workshop programme focused on the following topics: occupational health and medicine (1st day); metrological requirements for measurements in analytical chemistry/biochemistry and microbiology (2nd day); overview of EQAS activities in the field of occupational health (3rd day). In this section, the main features of the EQAS for blood lead in Belgium (F. Claeys), Denmark (J. Kristiansen), France (A. Pineau), Germany (R. Heinrich-Ramm), Great Britain (A. Taylor), Italy (A. Menditto), The Netherlands (C.W. Weykamp), and Spain (D. Marcuello) were presented [3, 4, 7-12]. Finally, the results of the collaborative study organised between some of the EQAS organisers were presented (J.M. Christensen). This study focused on the comparison of the various methods for evaluation of laboratory performance in the determination of lead in blood adopted by five different EQAS [16].

In the ensuing discussion - with the participation of, among others, J. Angerer (Germany), A. Aitio (Finland) and R. Dybkaer (Denmark) - a first attempt was made to determine the extent to which EQAS in occupational medicine within the EU could be harmonised. It was suggested that a systematic study should be carried out to evaluate the correspondence between existent EQAS and IUPAC/ISO/AOAC recommendations. It was proposed that this should be done individually by each of the EQAS organisers and their conclusions discussed in a later meeting. The general feeling was that it would be desirable to achieve a degree of harmonisation among the different EQAS of the EU, as this would enable the performance of any laboratory in the member countries to be categorised using similar criteria. However, the discussion among participants highlighted large differences in organisational procedures and evaluation of results among different schemes. Reference values were strictly adopted in the German scheme, while other schemes used consensus values or a combination of both. The greatest differences, however, were observed for the methods for evaluation of performance.

In some countries EQAS are active for only one or two analytes (always including blood lead), whereas in others a wider range of analytes in body fluids is included. The German scheme encompassed the widest range of analytes, at concentrations relevant for both environmental and occupational medicine, and was the only scheme, among those presented, which included organic substances which pose the greatest health risks and analytical difficulties.

The final discussion focused on future needs for: new EQAS, currently operating EQAS and EQAS operating in novel fields.

It was agreed that new EQAS should be activated primarily for substances which are known toxicants and their metabolites and for which there is a recognised need for biological monitoring (e.g. solvents and pesticides). New schemes for these chemicals should be promoted in each country or as a supranational scheme.

Currently operating EQAS will be faced with the need to harmonise existing procedures to guarantee the achievement of similar levels of performance throughout Europe and mutual recognition of analytical results.

The future needs for EQAS operating in novel fields were recognised as the establishment of validated methods for new analytes (e.g. adducts); the assessment and improvement of comparability through intercomparison exercises; and the evaluation of novel procedures for sample preparation and strategies of evaluation of results.

At the end of the workshop, EQAS organisers had gained knowledge of reciprocal schemes and some of the problems underlying the topics of harmonisation had been unveiled, although further work was necessary to progress toward harmonisation and the development of collaborative activities.

Satellite meeting of the European Organisers of EQAS in OELM (Rome, 4 December 1994)

After the Dublin workshop, there was a recognised need for further discussion among EQAS organisers in OELM to allow some common strategies to be developed. In addition, the Dublin meeting had mainly focused on EQAS for blood lead analysis, because of the previous collaborative activity [16]. However, EQAS are operating for many other substances of interest in OELM and some of these schemes were not represented in Dublin.

A meeting of European Organisers of EQAS in OELM was held as a satellite meeting of the International Conference on "Analytical quality control and reference materials in life sciences" (Rome, 4 December 1994), with the partial support of the EC, SM&T programme.

The aims of this second meeting were: to improve the reciprocal knowledge, with extension to schemes for analytes other than blood lead; to identify common needs; to assess differences and establish common ground; to identify common activities where collaboration among schemes could provide improved solutions and comparability of analytical results among countries; to promote harmonisation of EQAS.

The meeting considered the following topics: role of Proficiency Testing/EQA schemes in OELM (A. Menditto); presentation of the document "Minimal requirements for EQAS", as proposed by a working group of European EQAS organisers in Clinical Chemistry [17]; reports by representatives of Proficiency Testing/EQA schemes in OELM on respective national/international responsibilities, legal aspects and implementation (J. Molin Christensen, J. Kristiansen, Denmark; F. Claeys, Belgium; A. Menditto, M. Patriarca, G. Morisi, Italy; R. Heinrich-Ramm, Th. Goen, Germany; A. Pineau, France; A. Taylor, Great Britain; C.W. Weykamp, The Netherlands; A. Aitio, Finland); possibilities of support through the 4th framework programme of the EU, Standards, Measurements & Testing (SM&T) programme (C. Dirscherl); identification of problems to be solved at a European level; proposals for a collaborative project.

The opening presentation reviewed the key objectives of external quality assessment (EQA) and examined the need for further R&D programmes on quality assurance within the EU. A series of questions were proposed for further examination by the group during the meeting, concerning harmonisation of: "medical translation" of ISO and EN standards, methods for evaluation of laboratory performance and programmes for training and continuous education in this field at a European level.

The document "Minimal requirements for external quality assessment schemes for clinical laboratories in Europe" [17] was discussed in detail. This document is a list of requirements suggested by a working group of

the Clinical Chemistry EQAS Organisers Group, convened by the EC, SM&T programme, and was offered for comments by other scheme organisers [17]. A difference of philosophy was quickly identified amongst the OELM scheme organisers between those for whom EQA is perceived as primarily educational, but which may also be used for certification of laboratories, and those for whom this latter activity is the main or only objective. It was noted that where certification is the primary aim of a scheme, legal requirements exist which can make other arrangements difficult to introduce. Other points under discussion included the adoption of reference or consensus values as target values against which the performance of participants is judged and the distinction between "harmonisation" and "standardisation". An agreed revised draft of the document, to meet the objectives of OELM EQA schemes, is given in the Appendix, whereas the above mentioned points were left open to further discussion.

Scheme organisers provided summaries of their EQA work [3-5, 7-11] and also described the legal requirements for monitoring laboratories' performances in their own countries, mechanisms for assessing performance of participants and thoughts for future collaboration.

Suggestions included the possibility for EQAS organisers to collaborate as a group of reference laboratories at a European level, also selecting national laboratories with optimal performances to be included in the group, to establish target values for some of the control materials used in national schemes and/or to produce reference materials for rare analytes.

Opportunities to work together within the guidelines of the EU SM&T programme were discussed. The areas of the programme more closely related to the subject of EQAS were identified under theme II, as "Support for the accreditation and quality assurance of laboratories" and under theme III, as "Health and safety".

The main points of a rationale to move forward were agreed as follows:

a) to establish a core group who would coordinate and disseminate information to interested groups throughout the EU, identify suitable projects for submission to SM&T programmes, liaise with experts for preparation of project proposals and identify partners for participation in projects;

b) to set-up a "thematic network" of laboratories for EQAS special projects and for other appropriate activities;

c) to work together on projects within the remit of the SM&T programme (e.g. Improvement of Measuring Procedures);

d) to work together for training.

A further discussion was concerned with the implications of "Amended proposal for a Council Directive on the protection of the health and safety of workers from the risks related to chemical agents at work" [18], which, in article 11 and its associated annex, refers to "minimum safety and health requirements" for activities, both existing and new, involving chemical agents. Within the context of "Special health surveillance measures" mention is made of "biological monitoring" for workers exposed to: chemicals known to cause sensitisation; arsenic and its compounds; beryllium; cadmium and its compounds; carbon disulphide; chromates; cobalt; lead and its compounds; mercury and its compounds; organophosphoric esters and tetrachloroethane. In this context, it is established that "biological limit values and related requirements have to be observed as part of health surveillance". If the same measures of biological monitoring have to be implemented, also involving reference to biological limit values, it is necessary that a similar level of reliability of analytical results is achieved throughout Europe and warranted by participation in harmonised EQAS. Therefore, the compounds mentioned above should be considered as a priority in establishing new EQAS in OELM.

An EQA programme functioning at a European level would support national and Community biological monitoring programmes, identify and reduce analytical errors and/or poor methods, provide comparability of results among countries for the benefit of workers and exposed populations, and promote the transfer of knowledge and expertise throughout the EU. Such a programme could provide support for all European laboratories performing such analyses, whereas local EQAS may not reach a sufficient number of participants, and also achieve financial and organisational economies, and harmonisation of national schemes.

It was agreed to discuss further initiatives, including establishment of standards of laboratory performances, education and training and the development of new pilot schemes according to a harmonised protocol (to be agreed) as a network of European EQAS, coordinated by Dr. Andrew Taylor (UK). Since national experts/representatives have been already involved in the drafting of the proposed Directive, their advice/collaboration could be helpful to the proposed activities of the network.

As a basis for further collaboration, it would be useful to maintain up-to-date information on EQAS in OELM operating in the EU. It was agreed to prepare a comprehensive report on the state of the art of currently operating EQAS and the discussions carried out among EQAS organisers in Dublin and Rome, for further reference and documentation.

Conclusions

The first steps to achieve harmonisation of EQAS in OELM have encompassed a survey of existing schemes and discussions of key-issues of EQA in meetings of EQAS organisers. In these occasions, EQAS organisers have gained reciprocal knowledge and created a positive

basis for further collaboration as a network of European EQAS organisers. The proposed activity of the network should focus on development of standards of laboratory performance, implementation of new harmonised EQAS, with priority given to substances of major concern according to the present European legislation, and common initiatives for education and training.

Submitted on invitation.
Accepted on 1 February 1996.

REFERENCES

1. THOMPSON, M. & WOOD, R. 1993. The international harmonized protocol for the proficiency testing of chemical analytical laboratories. *Pure Appl. Chem.* **65**: 2123-2144.

2. DYBKAER, R., JORDAL, R., JORGENSEN, P.J., HANSSON, P., HJELM, M., KAIHOLA, H.-L., KALLNER, A., RUSTAD, P., ULDALL, A. & DE VERDIER, C.-H. 1993. A quality manual for the clinical laboratory including the elements of a quality system. *Scand. J. Clin. Lab. Invest.* **53** (Suppl. 212): 60-84.

3. DE PLAEN, P., CLAEYS-THOREAU, F. & DE BOECK, R. 1996. External quality assessment scheme in Belgium. Heavy metal analysis. *Ann. Ist. Super. Sanità* **32**(2): 215-220.

4. CHRISTENSEN, J.M. & KRISTIANSEN, J. 1996. The Danish external quality assessment scheme. *Ann. Ist. Super. Sanità* **32**(2): 221-224.

5. VALKONEN, S., ENGSTRÖM, K., AHONEN, I., MUTANEN, P. & AITIO, A. 1996. FIOH external quality assurance scheme for organic solvent metabolites. *Ann. Ist. Super. Sanità* **32**(2) 225-231.

6. BARUTHIO, F., ARNAUD, J. & PIERRE, F. 1996. The French interlaboratory quality assessment programme for copper, zinc and selenium in blood serum. *Ann. Ist. Super. Sanità* **32**(2): 233-239.

7. GUILLARD, O., PIRIOU, A. & PINEAU, A. 1996. French external quality assessment schemes for lead in blood and aluminium in plasma and dialysis water. *Ann. Ist. Super. Sanità* **32**(2): 241-245.

8. HEINRICH-RAMM, R., LEHNERT, G. & ANGERER, J. 1996. The German external quality assessment scheme in occupational and environmental medicine. *Ann. Ist. Super. Sanità* **32**(2): 247-251.

9. TAYLOR, A. & BRIGGS, R.J. 1996. The Guildford trace element external quality assessment scheme. *Ann. Ist. Super. Sanità* **32**(2): 253-259.

10. MENDITTO, A., PATRIARCA, M., CHIODO, F. & MORISI, G. 1996. The Italian external quality assurance scheme for trace element analysis in body fluids. *Ann. Ist. Super. Sanità* **32**(2): 261-270.

11. WEYKAMP, C.W. & PENDERS. T.J. 1996. Trace elements in body fluids: external quality assessment scheme in The Netherlands. *Ann. Ist. Super. Sanità* **32**(2): 271-275 .

12. MARCUELLO, D. 1996. The Spanish external quality assessment scheme for lead in blood. *Ann. Ist. Super. Sanità* **32**(2): 277-280.

13. QUINTANA, M.J. & MAZARRASA, O. 1996. The Spanish external quality assessment scheme for mercury in urine. *Ann. Ist. Super. Sanità* **32**(2): 281-284.

14. MENDITTO, A., PATRIARCA, M. & MORISI, G. 1992. Organization of interlaboratorial quality assurance programmes for the analysis of trace elements in blood: evaluation of procedures and analysis of data. *Microchem. J.* **46**: 137-46

15. EUROPEAN COMMISSION - DIRECTORATE GENERAL XII. 1994. EQAS for health care related analysis. Organization and functioning of external quality assessment schemes (EQAS) in EC member states together with Finland, Switzerland and Norway. C. Dirscherl (Ed.). Brussels (EUR Report no. 15645 EN, EC).

16. CHRISTENSEN, J. M. & OLSEN, E. 1996. Comparison of some European external quality assessment schemes in the field of occupational and environmental medicine. *Ann. Ist. Super. Sanità* **32**(2): 285-294.

17. BULLOCK, D. G., LIBEER, J.C. & ZENDER, R. 1994. Minimal requirements for external quality assessment schemes for clinical laboratories in Europe. *EQA News* **5**: 1-2.

18. EUROPEAN ECONOMIC COMMUNITIES. 1994. Amended proposal for a Council Directive on the protection of the health and safety of workers from the risks related to chemical agents at work. *Off. J. Eur. Comm.* (C 191 of 14/7/94, p. 7-29) .

Appendix. - Minimal requirements for EQAS in OELM in Europe [*]
Draft, 1 February 1996 open for comments

External quality assessment (EQA) is a vital component of quality assurance (QA) in clinical laboratories, which fulfil an essential and increasingly important role in the prevention of occupational and/or environmental ill-health by the monitoring of uptake and in the assessment of body burden exposure to chemicals in the workplace and /or environment.

EQA assesses laboratory performance, identifying problems, stimulating improvement, and monitoring progress; it also provides information on analytical procedure (method principle, instrument, reagent, calibrant) performance, which is useful in post marketing monitoring of *in vitro* medical devices (IVDs).

For an EQA scheme to be effective, it must fulfil the following minimal requirements, within which factors such as the number and type of participant laboratories, the investigation(s) surveyed, and logistic constraints will lead to variations in scheme design from country to country and from scheme to scheme according to the investigation, i.e. the quantity(ies) or property(ies), assessed.

1. Scheme management and operation

1.1 The scheme seeks to improve the quality of analytical results produced in OELM. The activities of the scheme range from purely educational to compulsory accreditation of laboratories, according to local legislation.

1.2 The scheme is independent of any manufacturing or marketing interests in equipment, reagent in its field of operation. Specific tasks (e.g. specimen preparation) may, however, be subcontracted to commercial organizations.

1.3 The schemes are fully coasted and supported exclusively from participants' subscriptions and/or public funding, on a not-for-profit basis with reinvestment of any operating surplus in the schemes. Scientific work to support scheme development may be accepted without charge.

1.4 Management arrangements ensure that the scheme can operate continuously without major breaks in service.

1.5 The scheme is open to any laboratory offering relevant analyses for the investigation(s), and preferably also to others (e.g. diagnostics manufacturers).

1.6 Organizations offering EQA services aim to include a wide range of investigations, with an ideal of covering all those of clinical importance for which a scheme is practicable.

1.7 The senior staff responsible for the scheme are appropriately qualified members of the appropriate profession(s).

1.8 The scheme has scientific and clinical input from practicing professional advisors, and have appropriate links with relevant national and/or international professional societies.

1.9 Specimens conform to relevant health and safety regulations, and transport arrangements conform to postal regulations. The properties of human components in specimens should be tested appropriately to minimise infective hazard.

1.10 The organising center has, or aims to have by 1999, a documented quality system and manual.

1.11 The scheme preferably uses SI units, in particular the litre and mole in preference to deciliter and submultiples of the gram, and complies with other relevant recommendations on nomenclature and symbols.

2. Scheme design

2.1 Harmonisation of scheme design is desirable, and provides a basis for mutual recognition. Rigid rules, however, are counterproductive as they prevent progress and response to scientific and technological advances. The recommendations of WHO EURO and ISO-IUPAC/AOAC provide a useful starting point [1, 2].

2.2 Performance assessment is based on sufficient recent data, achieved through:

2.2.1 an appropriate and sufficiently large number of participants. This may indicate the need for supranational schemes for some investigations;

2.2.2 sufficiently frequent surveys ("distribution") comprising appropriate numbers of specimens;

2.2.3 rapid feedback of performance information after analysis. This may comprise a rapid preliminary report and a later comprehensive report.

2.3 There is effective feedback of performance data, through:

2.3.1 well-structured, informative and intelligible reports, using graphical presentations where appropriate;

2.3.2 a performance assessment system. Ideally this is based on a sufficient number of observations, a scoring or classification system based on cumulative data from several surveys;

2.3.3 assessment of interpretation as well as analysis wherever this is beneficial.

2.4 The basis for assessment is appropriate including:

2.4.1 stable, homogeneous specimens with behavior as close as possible to test specimens. "Authentic matrix" materials are preferred to "synthetic" or "artificial" materials wherever availability, homogeneity and stability permit;

2.4.2 target values which are reliable and validated. Target values traceable to reference methods and materials are preferred, but method-dependent targets may be necessary to avoid incorrect performance assessment due to matrix and other effects attributable to interaction between the EQA specimens and method used.

3. Communication

3.1 All communications between the scheme and participants (and vice versa) are clear and unequivocal.

3.2 Participants are provided with clear information on the scheme's design and operation, including scoring systems, and on interpretation of reports and performance data.

3.3 Confidentiality is desirable. The extent of confidentiality, and to whom data may be provided, is clear to participants and in conformity with national legislation.

3.4 There are appropriate mechanisms for providing impartial professional advice and assistance.

3.5 Any mechanisms for reporting laboratories with poor performance in the scheme to a third party are reliable and in accordance with the conditions of participation.

3.6 Any mechanisms for reporting procedures (instruments, reagents, calibrants) showing performance problems in the scheme are reliable and in accordance with relevant regulations.

4. Bibliography

1. *External quality assessment of health laboratories*. WHO EURO, Copenhagen, 1981.

2. ISO/IUPAC/AOAC. International harmonised protocol for proficiency testing of (chemical) analytical laboratories. *J. AOAC Int.* **76**: 926-940, 1993. *Pure Appl. Chem.* **65**: 2123-2144, 1993.

[*] this draft is developed from a text prepared for comments by David G. Bullock, Jean Claude Libeer, Robert Zender on behalf of the Clinical Chemistry EQAS Organisers group convened by the EC Measurement & Testing programme [17]