

PREAMBLE

This document is directed to External Quality Assurance Programmes (EQAP) organizers 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 External Quality Assurance Programmes or to improve the quality of the service provided by installing a quality system based on the requirements in this document.

The following sections of this document provide appropriate requirements for competence of EQAP organizers.

These *Guidelines* have been developed with the following major features:

- a) They are a basis for recognising the competence of EQAP organizers. The organisation which is responsible for coordinating and providing of External Quality Assurance Programmes should ensure that all tasks involved in the provision of such schemes have been performed competently, whether they are carried out by the coordinating organisation itself or in combination with collaborators.

[Note: Definition 1.3.2 refers]

Accordingly, it is the organizer (and any sub-contractual arrangements used by the organizer) which should be evaluated for compliance with these *Guidelines*.

- b) The *Guidelines* are based on ISO Guide 43-1:1997 and on the *relevant* elements of ISO EN/ IEC 17025:1999 applicable to the characterisation, homogeneity and stability testing of External Quality Assurance test materials. Additionally, relevant elements of ISO 9000:1994 are included to eliminate the need for separate recognition of an organizer of External Quality Assurance Programmes for compliance with ISO 9000:1994 if wanted. Accordingly, the *Guidelines* have been prepared in two sections covering, respectively:

- (i) Management System Requirements;
- (ii) Technical Requirements

- 3 These Guidelines are also based on the ILAC G13:2000 document: "guidelines for the requirements for the competence of Providers of Proficiency Testing" and take into account the particular aspects of external quality assurance for medical laboratories. [These particular aspects are printed in blue.](#)

- 4 These guidelines include also several requirements from Clinical Pathology Accreditation (CPA) standards used for

accreditation of External Quality Assessment schemes in the UK.

PURPOSE

This document is directed to EQAP organizers 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 External Quality Assurance Programmes or to improve the quality of the service provided by installing a quality system based on the requirements in this document.

Note: Fulfilment of these Guidelines is not the only tool for establishing confidence in External Quality Assurance Programmes.

AUTHORSHIP

This publication was prepared by the International Federation of Clinical Chemistry (IFCC), Education and Management division; Committee of Analytical Quality with following members:

Daniel Maziotta, Argentina

Daniella Harel, Israel

Gerhard Schumann, Germany

Jean-Claude Libeer, Belgium

More information can be found on the website of IFCC: www.IFCC.org

The text of the ILAC G13 has been used as starting point and amended where needed with specific and missing requirements for External Quality Assurance Programmes in medical laboratories.

PREAMBLE.....	1
PURPOSE.....	1
AUTHORSHIP.....	1
SECTION 1 : GENERAL	3
1.1 Scope	3
1.2 References	3
1.3 Definitions.....	3
SECTION 2: MANAGEMENT SYSTEM REQUIREMENTS	5
2.1 Quality Management System	5
2.2 Organisation and Management	5
2.3 Document Control	6
2.4 Request, Tender or Contract Review	7
2.5. Use of Collaborators (Subcontractors)	7
2.6 Procurement of Services and Supplies	7
2.7 Client Feedback	8
2.8 Control of Non-conforming Activities	8
2.9 Corrective Action	8
2.10 Preventive Action	9
2.11 Records	9
2.12 Internal Audits	9
2.13 Management Reviews	10
SECTION 3: TECHNICAL REQUIREMENTS	10
3.0 General	10
3.1 Management, Staffing and Training	10
3.2 Facilities	11
3.3 Collaborators (Subcontractors)	11
3.4 Organisation and Design Logistics	12
3.5 Choice of Method or Procedure	16
3.6 Conduct of EQAP schemes	16
3.7 Data Analysis and Interpretation of Scheme Results	17
3.8 Communication with Participants	20
3.9 Confidentiality	20
3.10 Collusion and Falsification of Results	20
APPENDIX A: COMMONLY-USED STATISTICAL METHODS FOR TREATMENT OF PROFICIENCY TEST/EAQ DATA	21
APPENDIX B: CROSS-REFERENCES TO ISO 9000, ISO GUIDE 43-1 AND ISO/IEC 17025	22
APPENDIX C: BIBLIOGRAPHY	25

Section 1 : GENERAL**1.1 Scope**

These *Guidelines* set out the criteria, which an organizer of External Quality Assurance programmes (and associated collaborators) shall meet in order to demonstrate competence to provide specific types of EQAP.

1.1.1 It is the responsibility of the organizer to ensure that the requirements (i.e. both technical and management systems) are met by the organizer and any associated collaborators.

1.1.2 It is recognised that there may be a number, of alternative methods, used by organizers to comply with these *Guidelines* and throughout the document. *Notes* provide information on possible sources of guidance. Such *Notes* do not form an integral part of the *Guidelines*.

1.1.3 Where clauses of these *Guidelines* are considered to meet the existing requirements of ISO/IEC Guide 43.1:1997 and ISO EN/IEC 17025:1999 or ISO 9000:1994, these are cross-referenced in Annex 2.

1.1.4 Organizers complying with these *Guidelines* are considered to comply also with the relevant requirements of ISO 9000 Series: 1994 as applied to the design and provision of specific types of External Quality Assurance Programmes.

1.2 References

prEN/ISO DIS 15189.2: 2002. *Medical laboratories-Particular requirements for quality and competence*

ISO EN/IEC 17025:1999 *General requirements for the competence of calibration and testing laboratories.*

ISO Guide 35:1989 (under revision), *Certification of reference materials – General and statistical principles.*

ISO/IEC Guide 43.1 (1997) *Proficiency testing by interlaboratory comparisons - Part 1: Development and operation of EQA schemes.*

ISO 9000 Series: 1994 *Quality - management and quality assurance standards.*

European Commission Guideline's for the Production and Certification of Reference Materials: 1997,

Document BCR/01/97 Part A.

The International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical laboratories. *Journal of AOAC International*, 76, No.4, 1993, pp, 926-940.

Evaluation of Matrix Effects: Proposed Guideline, NCCLS Document EP-14R National Committee for Clinical Laboratory Standards, Villanova, PA, 1994.

Eurachem document 1995 (under revision by) Eurachem and CITAC): *Quantifying Uncertainty in Analytical Measurement.*

ILAC-G13:2000 document. *Guidelines for the requirements for the competence of Providers of Proficiency Testing.*

Clinical Pathology Accreditation standards for EQA organisations (UK) see [12] Appendix C

Other publications on educational EQA programmes and ethics for organizers of EQAP (see Appendix C)

1.3 Definitions

For the purpose of *these Guidelines*, a distinction is made between Proficiency testing (PT), External Quality Assessment Schemes (EQAS) and External Quality Assurance Programmes (EQAP).

Some so called existing PT schemes may also include several EQAP aspects.

These guidelines cover the requirements for all above mentioned types of schemes: PT, EQAS and EQAP.

1.3.1. Proficiency testing (PT)

This is the general used term in North America.

In a strict sense, PT focus essentially on laboratory performance evaluations for regulatory purposes.

1.3.2. External Quality Assessment Schemes (EQAS)

This is the general used term in Europe and South America.

EQAS focus essentially also on laboratory performance evaluations but the purpose of the schemes is educational

1.3.3 External Quality Assurance Programmes (EQAP) is an

interlaboratory comparison designed and operated to assure one or more of following aspects:

- Participant performance evaluation

Note: this evaluation is not limited to analytical performance, but can also include test interpretation, advice to the clinician on laboratory requests and on diagnosis

- Method performance evaluation
- Vigilance of IVD's
- Continuous education, training and help

Note: Examples of such schemes: see publications in appendix C

The primary intention of the activities of an EQAP in laboratory medicine shall be to support quality improvements of the services provided by participating laboratories for the benefits of the patients.

1.3.4. EQAP **organizer**

A body (organisation or firm, public or private) that undertakes the design and conduct of one or several External Quality Assurance Programmes.

1.3.5. **Collaborator (Subcontractor)**

A body, (organisation or firm (public or private» that undertakes subcontracted activities for an EQA scheme or EQAP organizer.

1.3.6 **Coordinator**

The person with responsibility for coordinating all of the activities involved in the operation of one of several EQA schemes or EQAP.

Section 2: MANAGEMENT SYSTEM REQUIREMENTS

2.1 Quality Management System

2.1.1 The organizer of EQAP's shall establish, implement and maintain a quality management system appropriate to its scope of activities including the type, range and volume of EQAP's that it provides.

2.1.2 The EQAP's organizer shall define and document its policy, objectives and commitment to ensuring and maintaining the quality of all aspects of organizing EQAP's, including test material quality (e.g. homogeneity, stability, viability and appropriateness), characterisation (e.g. equipment calibration and measurement method validation), assignment of property values (e.g. use of appropriate statistical procedures), evaluation of participating laboratories' performance, distribution of test material, storage, safety and transport procedures, statistical treatment of test results, interpretation, and reporting.

The quality policy shall include a commitment to conduct EQAP's, which conform to the technical requirements contained in Section 3 of these *Guidelines*.

2.1.3 The EQAP organizer shall establish and maintain a documented quality management system appropriate to the type, range and volume of EQAP's that it provides to ensure that the schemes conform to specified requirements.

The EQAP organizer shall have a quality system that, in particular, covers the following:

- a) aims, scope, statistical design and format of EQAP's;
- b) operational procedures;
- c) preparation and issuing of reports;
- d) policies on confidential and ethical procedures;
- e) computing and information systems;
- f) collaboration and sub-contracting, where relevant;
- g) fees for participation;
- h) scope of availability of EQAP's;

- i) general policies on participation;
- j) use of scheme results;
- k) procedures for handling complaints.

2.1.4 The documented quality management system shall specify which activities are undertaken by the EQAP organizer and, where relevant, which activities are undertaken by collaborators, and shall include policies and procedures used by the EQAP organizer to ensure that all activities conducted by collaborators comply with the relevant clauses of these *Guidelines*.

2.1.5 The documented quality management system shall define the roles and responsibilities of the technical manager and the quality manager (however named) and the coordinator, including their responsibilities for ensuring compliance with these *Guidelines*.

2.2 Organisation and Management

2.2.1 The EQAP organizer, or the organisation of which it is part, shall be legally identifiable.

2.2.2 The EQAP organizer:

- 5 shall have managerial personnel supported, by technical personnel with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the quality management system or the procedures for providing EQAP's and to initiate actions to prevent or minimise such departures;
- b) shall have arrangements to ensure that its management and personnel are free from any commercial, financial and other internal and external pressures that may adversely affect the quality of their work;
- c) shall have policies and procedures to ensure the protection of confidential information and proprietary rights of participants in EQAP's;
- d) shall have policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgement or operational integrity;

- e) shall define, with the aid of organisational charts, the organisation and management structure of the EQAP organizer, its place in any parent organisation, and the relations between management, technical operations, support services, collaborators and the quality management system;
- f) shall specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the provision of EQAP's ;
- g) shall have technical management, which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of EQAP procedures;
- h) should appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that these *Guidelines* are implemented and followed at all times. The quality manager shall have direct access to the highest level of management at which decisions are taken on the EQAP policy or resources;
- i) should, where possible, appoint deputies for key managerial personnel such as the coordinator, technical manager and quality manager.

Note: Where EQAP organizers have a small number of personnel, individuals may have more than one function and it may be impractical to appoint deputies for all major functions

- j) shall operate on a scientific basis and publish his findings as appropriate. There are in principle no secrets on techniques and scientific approaches.
- k) Is basically non-profit. Any surplus must be counter balanced either in the size of fees or in investment improved services, e.g. new schemes.
- l) Should establish mutual understanding so that resources are used optimally for the benefits of the patient
- m) Must be independent of the interest of manufacturers of in vitro medical devices
- n) Must be prepared to give assistance to colleagues and EQAP organisations in less developed areas in the world.

2.3 Document Control

2.3.1 General

The EQAP organizer shall establish and maintain procedures to control all documents (both internally generated and from external sources) and other information that forms part of its quality documentation.

2.3.2 Document approval and issue

2.3.2.1 All documents (including documented procedures) issued to personnel as part of the quality management system shall be reviewed

and approved for use by authorised personnel prior to issue. A master list or equivalent identifying the current revision status of documents in the quality management system shall be established and be readily available to preclude the use of invalid and/ or obsolete documents.

2.3.2.2 The procedures adopted shall also ensure that:

- a) all documents are uniquely identified;
- b) authorised editions of appropriate documents are available at all locations where operations essential to the effective provision of EQAP's are performed;
- c) documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements;
- d) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
- e) obsolete documents retained for either legal or information preservation purposes are suitably marked.

2.3.3 Document changes

2.3.3.1 Changes to documents (including documented procedures) shall be reviewed and approved by the same personnel who conducted the original review and approval, unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

2.4 Request, Tender or Contract Review

2.4.1 Each request, tender or contract for provision of an EQAP shall be reviewed by the EQAP organizer to ensure that:

- a) the requirements are adequately defined documented and understood;

- b) the EQAP organizer has the capability and resources to meet the requirements;
- c) any differences between the contract or order requirements and those in a tender are resolved.

2.4.2 Records of such reviews, including any changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements, and/or the results of the work during the period of execution of the contract or request.

2.4.3 The review shall include any work that is carried out by collaborators.

2.5. Use of Collaborators (Subcontractors)

2.5.1 The EQAP organizer shall have procedures for evaluating and selecting collaborators on the basis of their ability to meet subcontracted requirements in terms of both their technical competence and any specific quality assurance requirements relevant to their tasks. The technical requirements to be satisfied by collaborators shall be equivalent to the technical requirements defined in Section 3 of these *Guidelines*.

2.5.2 The EQAP organizer shall maintain a register of all collaborators used in the provision of EQAP's and include a record of any assessments made of their abilities to conduct subcontracted tasks.

2.6 Procurement of Services and Supplies

2.6.1 The EQAP organizer shall have procedures for the selection of services and supplies that affect the quality of its EQA schemes.

2.6.2 The EQAP organizer shall use only those services and supplies that are of adequate quality to sustain confidence in its EQAP's.

2.6.3 When no formal approval of the quality of services and supplies is available, the EQAP organizer shall have procedures to ensure that purchased materials and services comply with specified requirements and records of actions taken shall be maintained.

2.6.4. The EQAP organizer shall ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with standard specifications or requirements.

2.6.5 The EQAP organizer shall maintain records of approved suppliers of services and supplies.

2.7 Client Feedback

The EQAP organizer shall have procedures for the effective handling of complaints or other feedback received from participants. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the EQAP organizer.

2.8 Control of Non-conforming Activities

2.8.1 The EQAP organizer shall have a procedure to be implemented when it establishes that any aspect of its activities does not conform with its own procedures or the agreed requirements of a client.

The procedure shall ensure that:

- a) responsibilities and authorities for the management of nonconforming work are designated;
- b) the actions to be taken when a nonconformance is identified are defined;
- c) an evaluation of the significance of the nonconforming work is made;
- d) work is halted if necessary
- e) remedial actions are taken promptly;
- f) where necessary, the results of nonconforming test materials or statistical evaluations already issued to participants are recalled;
- g) the responsibility for authorisation of the resumption of work is defined;
- h) complete records are maintained, where practicable, of all nonconforming activities.

Note: Requirement (f) extends to notifying clients when it is discovered that an EQAP sample was inhomogeneous, deficient, or that an error has occurred in the statistical report of the scheme.

2.8.2 Where the evaluation indicates that the supply of nonconforming test materials could recur or that there is doubt about the EQA organizer's or collaborator's compliance with their own policies and procedures, the corrective action procedures in 2.9 shall be promptly followed to identify root causes of the problem and to eliminate these causes.

2.9 Corrective Action

2.9.1 General

The EQAP organizer shall establish a policy and procedures and shall designate appropriate personnel for implementing corrective actions when nonconforming test materials or departures from the policies and procedures in the quality management system or with EQAP activities have been identified.

Any corrective action taken to eliminate the causes of nonconformances or other departures shall be appropriate to the problems and commensurate with the risks encountered.

The EQAP organizer shall document and implement any required changes to the operational procedures resulting from corrective action investigations.

Note: The identification of problems with the quality management system or with EQAP activities can occur at various places within the, quality management system such as: client complaints, - quality control, checking of test materials and statistical evaluations, staff observations or supervision, management reviews and internal or external audits.

2.9.2 Cause analysis

Corrective action procedures shall include an investigation process to determine the root causes of the problem.

2.9.3 Corrective actions

The EQAP organizer shall identify possible causes and potential corrective actions. It shall select the actions most likely to eliminate the problem and to prevent it recurring.

2.9.4 Monitoring of corrective actions

After having implemented the corrective action, the EQAP organizer shall monitor the results to ensure that the actions taken have been effective in overcoming the problems originally identified.

2.10 Preventive Action

2.10.1 All operational procedures shall be systematically reviewed at regular intervals to identify any potential sources of nonconformances and any opportunities for improvement, either technical or within the quality management system. Action plans shall be developed, implemented and monitored, to reduce the likelihood of such nonconformances and to take advantage of the improvement opportunities.

2.10.2 After the implementation of preventive actions, the EQAP organizer shall monitor the results to establish any reduction in nonconformances in this operational area, thereby establishing the effectiveness of the preventive action.

2.11 Records

[see also Clause 3.7.1]

2.11.1 General

2.11.1.1 The EQAP organizer shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records. [See also Clause 3.7.1]

2.11.1.2 All records shall be legible and shall be stored and retained in such away that they are readily retrievable, and in facilities that provide a suitable environment to prevent damage, deterioration or loss. Retention times of records shall be established and recorded. [See also Clause 3.7.1.4]

Note: Records may be in the form of any type of media, such as hard copy or electronic storage media.

2.11.1.3 All records shall be held secure.

2.11.1.4 The EQAP organizer shall have procedures to protect electronically-held data at all times and to prevent unauthorised access to, or amendment of, such data.

2.11.2 Technical records:

The EQAP organizer shall establish and maintain a records system to suit its particular circumstances and to comply with any applicable regulations. The EQAP organizer shall arrange for all individual measurement observations, appropriate calculations and derived data (e.g. statistical treatments and uncertainty budgets), results from participants and scheme reports to

be retained until it is no longer probable that they will need to be referred to.

The results of each measurement (or series of either), or homogeneity or stability tests carried out by the EQAP organizer and its collaborators, where appropriate, shall be reported accurately, legibly, indelibly, unambiguously and objectively, in accordance with any instructions in measurement or test methods. The results shall normally be reported in a measurement report and shall include all information necessary for interpretation of measurement results and a summary of the method employed.

2.12 Internal Audits

2.12.1 The EQAP organizer shall, periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality management system and these *Guidelines*. The internal audit program shall address all elements of the quality management system, including the technical and test item preparation activities leading to the provision of an EQAP. It is the responsibility of the quality manager to plan and organise audits as required by the schedule and requested by management. Such audits shall, wherever resources permit, be carried out by trained and qualified personnel who are independent of the activity to be audited.

Note 1: Personnel should not normally audit their own activities except where it is necessary and it can be demonstrated that an effective audit has been carried out.

2.12.2 When audit findings cast doubt upon the effectiveness of the operations or on the correctness or validity of test materials, procedures, EQAP results, or a scheme's implementation, the EQAP organizer shall take timely corrective action and shall notify, in writing, his participants whose activities may have been affected.

2.12.3 All audit findings and corrective actions that arise from them shall be recorded. The management shall ensure that these actions are discharged within an appropriate and agreed timescale.

Section 3: TECHNICAL REQUIREMENTS**2.13 Management Reviews**

2.13.1 Senior management, shall periodically conduct a review of the EQAP organizer's quality management system and EQAP procedures to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. The review should take account of reports from management and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, feedback from participants and other relevant factors.

2.13.2 Findings from management reviews and the actions that arise from item shall be recorded. The management shall ensure that those actions are discharged within an appropriate and agreed timescale.

3.0 General

This section specifies the requirements that an EQAP organizer and any of its associated collaborators, must meet to demonstrate that they are competent to provide specific types of EQAP's.

3.1 Management, Staffing and Training

3.1.1 The coordination and conduct of EQAP schemes shall only be undertaken by EQAP organizers and associated collaborators having experience with interlaboratory test comparisons and with external quality assurance aspects. EQAP organizers or associated collaborators shall also have competence in the measurement of the properties being determined, e.g. for assignment of values, and homogeneity and stability testing, for statistical evaluations, for sample preparation.

Note 1: In new areas of EQAP's, it is possible that no one would have direct experience with the set-up of EQAP within that area.

Note 2: In evaluating the competence of a EQAP organizer's laboratory; possession of laboratory accreditation to ISO/IEC 17025:1999 for appropriate tests and/or measurements will satisfy the requirement for demonstration of competence. In circumstances where the EQAP organizer's laboratory does not hold accreditation, other factors which should be considered; when evaluating the EQAP organizer's compliance with these Guidelines will include satisfactory performance in appropriate EQAP.

[Refer also to Section 3.2 on Collaborators].

3.1.2 The EQAP organizer and associated collaborators shall have managerial personnel with the necessary authority, resources and technical competence required to discharge their duties.

3.1.3 Measurement of the properties of interest (e.g. in determining the homogeneity, viability and stability of test materials) and statistical treatment of participants' results shall be completed by, or under the supervision of, a technically-competent manager qualified preferably both in terms of suitable academic qualifications and relevant work experience.

3.1.4 The EQAP organizer's management shall define the minimum levels of qualification and experience necessary for the key posts within its organisation.

3.1.5 The EQAP organizer shall have sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions. All new staff are given a comprehensive orientation and induction programme, including health and safety.

3.1.6 The EQAP organizer must have access to advice from a safety officer in the event of there being problems with contamination of infection.

3.1.7 The EQAP organizer shall ensure that staff receive additional training, when necessary, to ensure competent performance of measurements, operation of equipment and any other activities which affect quality. Where possible, objective measures should be used to assess the attainment of competence through training.

Note: The need to periodically retrain staff should be considered. Staff training and retraining policies should take account of technological change and aim at continuous skills upgrading.

3.1.8 There are resources for staff to attend appropriate seminars, meetings and conferences.

3.1.9 There is a continuing education programme for all staff and there is a staff appraisal system.

3.1.10 The EQAP organizer shall maintain an up-to-date record of the training that each staff member has received. These records shall provide evidence that individual staff members have been adequately trained and that their competence to perform their assigned tasks has been assessed.

3.1.11 Regular staff meetings are held to review services

3.2 Facilities

3.2.1 There are appropriate office and laboratory space

3.2.2 There are suitably located staff facilities

3.2.3 There is appropriate space available for

reception of materials and their subsequent handling, storage and despatch

3.2.4 There are appropriate and adequate data storage, retrieval and communication facilities

3.2.5 The laboratory equipment meets the demands of the service and is properly maintained

3.2.6 There is adequate and safe provision of facilities

3.2.7 There are adequate storage facilities for materials, reagents and records

3.2.8 There is a safe working environment in accordance with current legislation

3.2.9 There are written procedures for the decontamination of all items of equipment and working space

3.3 Collaborators (Subcontractors)

3.3.1 The EQAP organizer shall be required to demonstrate that the collaborators' experience and technical competence are sufficient for their assigned tasks and comply with the relevant clauses of these *Guidelines*. [See also Clause 2.5.1]

3.3.2 Where the EQAP organizer subcontracts any part of testing of a test material or test item (e.g. for assessment of homogeneity or stability), this work shall be placed with a competent laboratory. [Refer to Note under 3.1.1.]

3.3.3 In assessing the competence of a collaborator, the EQAP organizer shall require information on the collaborator's knowledge of the subject and, details of past experience in the field,; for example, by providing acceptable results for comparable measurements.

3.3.4 The EQAP organizer shall ensure that all details of the methodology, results and all the outcomes of monitoring of any collaborators are available and that a register or database of all collaborators and their accreditation or other form of competence determination is maintained.

3.4 Organisation and Design Logistics

3.4.1 Planning

3.4.1.1. EQAP must be provided for most possible aspects of relevant laboratory investigations in the field covered e.g. within the particular medical laboratory speciality or sub-speciality, local, national regional, supra-regional or world-wide. High priority should be given to programmes for new types of investigation.

NOTE: Sharing programmes with other organisations may be a way to overcome the demands of programmes of the more exotic investigations with sufficient number of participants in a cost effective way.

3.4.1.2. The EQAP organizer shall provide programmes of high quality, i.e. relevant sample material, well defined interval of satisfactory results on a scientific base to support diagnosis and treatment of patients.

3.4.1.3 In the concept phase of a new programme, the EQAP organizer shall first define the goals of the programme so that the design matches as much as possible the desired outcome, especially if the scheme is addressing other EQAP aspects related to training and help.

Note: The outcome can be clinical relevance, support for IQC, familiarisation with rare parasites, interference studies, provide traceability, standardization and reference interval studies,...

3.4.1.4 The EQAP organizer shall identify and plan those processes which directly affect the quality of the scheme and shall ensure that they are carried out in accordance with prescribed procedures.

A plan should be agreed upon and shall be documented before commencement of the scheme and typically would include the following information:

- a) the name and address of the EQAP organizer;
- b) the name and address of the coordinator and other personnel involved in the design and operation of the scheme;
- c) the nature and purpose of the scheme;
- d) where appropriate, a procedure, for selection of scheme participants; or criteria to be met before participation is

allowed.

- e) the names and addresses of collaborators involved in the provision of the scheme (e.g. patient selection, sampling, sample processing, homogeneity testing and assigning values);
- f) the number and identity of expected participants in the scheme;
- g) a description of the manner in which test items are to be obtained, processed, checked and distributed, which takes account, in its design, of the major sources of errors involved in the area of EQAP's offered;
- h) a description of the information which is to be supplied to participants (pre-notification) and the time schedule for the various phases of the scheme;
- i) the expected initial and target dates or deadlines of the scheme, including, where appropriate, the dates on which testing is to be carried out by participants;
- o) for on-going schemes, the frequency or dates upon which test items are to be distributed to participants;
- k) information on methods and procedures, reconstitution, storage conditions which participants may need to use to perform the tests;
- l) an outline of the statistical analysis to be used, including the determination of target values and any outlier detection techniques;
- m) a description of the data or information to be returned to participants;
- n) the basis of performance evaluation techniques, where appropriate;
- o) a description of the extent to which test results, and the conclusions that will be based on the outcome of the scheme are communicated;

3.4.1.5 The organisational and technical input of the different collaborators involved shall be identified, documented and regularly reviewed. A mechanism (e.g. a management/technical advisory group) shall be established to make recommendations on how to plan the activities involved in the provision of each EQAP.

Note: These could include recommendations for the objectives of the scheme, the production and testing of test materials or test items prior to their distribution to participants, the determinations to be carried out by participants, distribution of test items, and the statistical treatment of test results and expected outcomes and targets.

3.4.1.6 The EQAP organizer shall be assisted by an expert board which shall include specialists with detailed experience in the relevant field of analysis and include, or have access to, a statistician who can give advice on sample validation and data analysis of EQAP results.

3.3.1.7 The responsibilities of an expert board should include, but are not necessarily be limited to, consideration of the following:

- a) design of the scheme (e.g. goals, number of samples, frequency of distribution, reply forms, evaluation of results);
- b) the evaluation of the clinical relevance of the schemes and the involved parameters
- c) agree on the selected parameters in the surveys
- d) sample nature of the test item(s) and test(s) selected, as well as a short description of the considerations underlying these choices, where appropriate;
- e) range of values to be expected for the test items;
- f) where appropriate, the test methods to be used;
- g) help in the search for appropriate patient sample material
- h) any difficulties expected in the preparation and maintenance of homogeneous test items or in providing a stable reference value for a measurement artefact; preliminary sample evaluation studies;
- i) agree on detailed instructions for participants;
- j) agree on any standardised reporting formats to be used by participants;
- k) getting feedback from participants
- l) number of significant figures to which results are to be reported;
- m) comments on any remark raised by participants;
- n) provision of advice for participating laboratories;
- o) establish acceptance limits and criteria for detecting poor performers;
- p) comments on the performance both and on individual participants and on participation as a whole;
- q) commentary on the summary report;
- r) evaluation of the responses of participants performing poorly (if feedback is required).

3.4.2 Preparation of test items

3.4.2.1 The range of test and/or concentrations are adequate and appropriate.

3.4.2.2 The material used in the manufacture of EQAP materials must conform with all relevant safety standards, provisions and legislation

3.4.2.3 Written procedures shall be developed to ensure proper acquisition, collection, handling, storage and disposal of all materials

3.4.2.4 In planning the overall process for preparation, testing and distribution of test materials and test items, the EQA organizer shall provide for, where appropriate, procedures and resources for:

- a) material selection (including donor preparation);
- b) preliminary storage and transport to the EQAP organizers facilities
- c) maintaining suitable environments for preparation and testing of test material;
- d) material preparation;
- e) measuring and testing;
- f) calibration/validation of equipment and measurement methods;
- g) assessing test material homogeneity, viability;
- h) assessing test material stability and integrity also during transport from the EQAP organizer to the participants;
- i) organising interlaboratory test comparisons with collaborators, where necessary; (see Note 1 below)
- j) ensuring adequate storage facilities and conditions;
- k) ensuring adequate packaging and labelling;
- l) ensuring appropriate transport and distribution arrangements;
- m) statistical analysis of test results and assigning values of measurands and associated uncertainties;
- n) ensuring adequate reporting service to participants.

Note 1: Item (i) may apply where the scheme organizer seeks to establish the capability of a potential collaborator to comply with these Guidelines by requesting that it participate in related EQAP before using its services as a collaborator.

Note 2: The EQAP organizer will need to give due consideration to training aids for participants after results have been evaluated and to replace any test items lost or damaged during distribution.

3.4.2.5 When selecting sample material, preferences should be given to non-human material where possible. Possible use of e.g. recombinant material for spiking purpose should be considered.

Due regard is paid to ethical considerations in the use of human material.

Where possible, human material should be given with written consent by the patient/donor. Donors should know the purpose of the use of blood.

Blood donations should be given according to ethical considerations, i.e. preferably no payment involved, infrequent donations, medical surveillance to minimise the risk of the donor, where possible use of donated blood in the same geographic area, as where it is collected.

NOTE: EQAP organisations should adhere to the general ethic requirements as included in Annex C of prEN ISO/DIS 15189: medical laboratories – particular requirements for quality and competence.

3.4.2.6 Adequate separation shall be observed during the manufacturing process of raw materials, materials in preparation and EQAP materials ready for issue.

3.4.2.7 The EQAP organizer shall be able to demonstrate that the test material is sufficiently homogeneous for the particular EQAP and is safe for use.

Note: A relatively inhomogeneous material may be the best available, and may there fore still be useful as an EQAP test material provided the uncertainty of the assigned property values takes due account of this.

3.4.2.8 When producing processed EQAP materials, these should, where practicable, be commutable in order to simulate the measurement process in patient material as nearly as possible.

Note: An example of a protocol for establishing such similarity is given in document NCCLS EP-14P; published by the National Committee for Clinical Laboratory Standards, Villanova, PA, 1994.

3.4.3 Homogeneity, viability and stability testing during normal storage conditions and under transport conditions

3.4.3.1 The EQAP organizer or its collaborators, where appropriate, shall use a statistically random selection of a representative number of samples from a batch of test material to assess the homogeneity, viability of the material.

This assessment procedure shall be documented and be conducted in accordance with acceptable statistical designs, for example, analysis of variance on replicate results under repeatability conditions. In the case of measurement artefacts, preliminary stability checks shall be made and periodic checks, of assigned property values should be carried out throughout the course of the scheme.

Note: It is recognised that different experimental designs may be used for evaluation of homogeneity. Some guidance on possible techniques is given in ISO Guide 35 (under revision) and in BCR/01/97 and the International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories. (See Clause 1.2 References.)

For some surveys (blood smears, parasitology smear with a very low presence of abnormalities or parasites, it may be necessary to check every slide in order to guarantee a good sample for every participant

3.4.3.2 The assessment of homogeneity should be performed after the test material has been packaged in its final form and before distribution to participants unless, for example, stability studies indicate that it should be stored in bulk form. In some cases, an intermediate homogeneity check may be necessary, for example, before sealing into ampoules.

Note: Homogeneity testing may on some occasions not be done prior to distribution for practical, technical or logistical reasons, but great caution must be exercised if it is not done or if it is done after test result have been collated. In all cases, the EQAP organizer is required to document the procedure by which it is ensured, that homogeneity is adequate.

3.4.3.3 Test items shall be demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the survey.

Note: If the material is to be used for EQAP's extending over a lengthy period of time, then depending on the nature of the sample material;

it may also be necessary to carry out homogeneity checks during the period of its use.

3.4.4 Statistical design

3.4.4.1 The EQAP organizer shall document the statistical model and data analysis techniques to be used, together with a description of the reasons for their selection, and shall ensure that they are carried out in accordance with prescribed procedures.

Note: Details of commonly used statistical procedures for the treatment of proficiency testing data are given in -Annex A of ISO/IEC Guide 43-1 (1997).

3.4.4.2 Appropriate statistical design of a EQAP is essential. In designing a scheme the EQAP organizer shall give careful consideration to the following:

- a) Acceptance limits for every measurand
- b) the number of participants in the scheme are sufficient to ensure meaningful evaluations of performance;
- c) the number of samples to be tested and the number of repeat tests or measurements to be conducted on each sample or for each determination;
- d) the procedures to be used to estimate the assigned value of each measurand if no reference method value is used as target value;
- e) procedures to be used to identify statistical outliers when using parametric statistics;
- f) where appropriate, the homogeneity viability, and stability of test materials.
- g) where appropriate statistical procedures for the evaluation of censored values
- h) the acceptable result(s) for discrete variables, results on nominal or ordinary scale.

3.5 Choice of Method or Procedure

3.5.1 General

Scheme participants shall normally be permitted to use the test method or measurement procedure of their choice, which is consistent with routine, procedures used in their laboratories. In certain circumstances the scheme coordinator may instruct participants to use a specified method or to use a specific number of determinations per day/per run.

3.5.2 Where participants are permitted to use a method of their choice, the EQAP organizer shall, where appropriate, request details of the method, calibrator, measurement equipment, kit used to permit comparison and comment on the results obtained by different test methods and kits.

3.6 Conduct of EQAP schemes

3.6.1 Introductions to participants [See also Clause 3.8.1]

3.6.1.1 The EQAP organizer shall give participants early warning of the intention to conduct a scheme to ensure that they are aware of the aims of the scheme and that their staff are available at the required time.

3.6.1.2 The EQAP organizer shall give detailed document instructions to all participants. Such instructions may, for example, be included as an integral part of the scheme protocol.

3.6.1.3 Instructions to participants shall include details of factors which could influence the testing of the test materials, for example, conditions of storage, the nature of the materials or test items, the test procedure employed, and the timing of the testing.

3.6.1.4 Specific instructions on the manner of recording and reporting test results shall include, but are not necessarily limited to, the units of measurement, the number of significant figures, reporting basis, the latest date for receipt of test results and clinical data allowing an interpretation of data.

Note: For consistent in the presentation of test results, and for ease of statistical treatment, standardised report sheets are often prepared and distributed to participants. They are sometimes supplemented by asking participants to also submit a test report in their usual format.

3.6.1.5 Scheme participants shall be required to treat EQAP samples in the same manner as routine samples (unless there are particular requirements of an EQAP which require departure from this principle).

3.6.1.6 The target value(s) shall not be disclosed to participants until after the results have been collated.

Note: In some cases it may be appropriate to advise target ranges prior to testing.

3.6.2 Materials handling and storage

3.6.2.1 In order to avoid contamination of the test material, the EQAP organizer and any associated collaborators shall identify, preserve and segregate all test materials and test items, for example, from all chemicals and other materials from the time of preparation through to their distribution to scheme participants.

3.6.2.2 The EQAP organizer and any associated collaborators shall ensure adequate packaging of all test materials and shall provide secure storage areas and/or stock rooms which prevent damage or deterioration of any item or material between preparation and distribution. Appropriate methods, for authorising despatch to, and receipt from, such areas shall be defined.

3.6.2.3 When appropriate, the condition of all stored or stocked items and materials shall be assessed at specified intervals during their storage life in order to detect possible deterioration.

3.6.3 Packaging, labelling and distribution

3.6.3.1 The EQAP organizer shall control packaging and marking processes to the extent necessary to ensure conformity with relevant regional, national and/or international safety and transport requirements.

Note 1: Adequate steps should be taken to make sure that samples are presented in such a manner to ensure that the integrity of the samples is maintained; for example, those which require uninterrupted storage in cold conditions

3.6.3.2 The EQAP organizer shall ensure that material labels are securely attached; to the product packaging of individual units and are designed to remain legible and intact within the period of use in an EQAP survey.

3.6.3.3. The EQAP organizer shall apply all needed precautions to avoid exposure of people to dangerous materials, whether they work in own EQAP organisations, in the participating laboratories or point of care sites or are serving the scheme, e.g. during transport and mail.

3.7 Data Analysis and Interpretation of Scheme Results

3.7.1 Data analysis and records (see also Clause 2.11]

3.7.1.1 Data processing equipment shall be adequate for all data entry and statistical analysis requirements and shall be capable of providing timely and valid results. The EQAP organizer shall also establish and maintain a description of all data processing equipment.

3.7.1.2 The EQAP organizer shall define the role and responsibility and designate a person to be responsible for the effective operation of the data processing system.

3.7.1.3 All data processing equipment and system software shall be properly maintained and validated in accordance with documented procedures before being brought into use. The results of such maintenance and operational checks shall be recorded. Software maintenance shall include a back-up regime and system recovery plan.

3.7.1.4 There is a written procedure for the reception of results. Results received from participants shall be promptly recorded and analysed by appropriate documented statistical procedures. Documented procedures shall be established and implemented to check the validity of data entry data transfer and statistical analysis, Data sheets, computer back up files, printouts and graphs shall be retained for a specified period.

3.7.1.5 Data analysis shall generate summary measurement and performance statistics and associated information consistent with the EQAP statistical model and objectives.

3.7.1.6 The influence of extreme results on summary statistics shall be minimised by the use of appropriate tests to detect statistical outliers, or by the use of robust statistics.

The EQAP organizer shall have documented criteria and procedures for dealing with test

results that may be inappropriate for statistical evaluation, for example, gross errors, blunders, miscalculations and transpositions.

Note: Annex A of ISO/IEC Guide 43-1 (1997) contains examples of statistical methods for treatment. Extreme results can provide important information and should not be disregarded in treatment of results of EQAP without due consideration.

3.7.1.7 The EQAP organizer shall have documented criteria for determining whether test items are not suitable for evaluation, for example, because of undetected inhomogeneity, instability or contamination. (Refer also to Section 3.4.2.2)

3.7.2 Evaluation of performance

3.7.2.1 There shall be written definitions of unacceptable performance and the procedures to be followed when such performance is detected

3.7.2.2. Results from participating laboratories shall be evaluated on the same way for all participants

Results originating from different in-vitro diagnostics or manufacturers shall be evaluated on the same way

3.7.2.3 Where an evaluation of performance is required the EQAP organizer shall be responsible for ensuring that the method of evaluation is appropriate for maintenance of the credibility of the scheme. Such a method shall be documented and shall include a description of the basis upon which the evaluation is made.

3.7.2.4 The EQAP organizer shall, where appropriate, enlist the assistance of technical advisers, which may include a statistician to provide expert commentary on the performance of participants with regard to the following:

- a) overall performance against prior expectations, taking measurement uncertainties into account;
- b) variation within (intra) and between (inter) laboratories, and comparisons with any similar previous schemes or published precision data;
- c) variation between methods or procedures, if applicable;
- d) possible sources of error (with reference to extreme results) and suggestions for improving performance;
- e) any other suggestions, recommendations or general comments;
- f) conclusions

Note 1: It may be useful to provide individual summary sheets for participants periodically

during or after completion of a particular scheme. These may include updated summaries of performance for individual laboratories over successive rounds of an on-going scheme. Such summaries can be further analysed and trends highlighted if required.

Note 2: There are a number of alternative procedures for assessing the performance of participants; (See Reference in Annex A of procedures for assessing the performance of ISO/IEC Guide 43-1 (1997).

Note 3: A scheme organizer must sometimes assess that unpredicted factors were involved in a survey so that no conclusions can be made on participants performance

3.7.3 EQAP reports

3.7.3.1 General

The content of EQAP reports will depend on the purpose of a particular scheme, but each report shall be clear and comprehensive and include data on the distribution of results from all participants, participants groups together with an indication of the performance of individual participants.

3.7.3.2 The following information shall normally be included in reports of an EQAP:

- a) name and address of the EQAP organizer;
- b) names and affiliations of persons involved in the design and conduct of the scheme, including expert board members;
- c) date of issue of the report;
- d) report number and clear identification of the scheme.
- e) clear description of the items or materials used, including, where appropriate, details of sample preparation and homogeneity testing; ,
- f) laboratory participation codes and test results;
- g) statistical data and summaries, including target values and range of acceptable results and graphical displays;
- h) [page numbering and confidentiality closure](#)

- i) procedures used to establish any assigned value or [Reference Measurement Value \(RMV\)](#);
- j) details of the traceability and uncertainty of any assigned values or [RMV](#), where applicable;
- k) assigned values and summary statistics for test methods/procedures used by other participants (if different methods are used by different participants);
- l) comments on participants performance by the EQAP organizer [and expert board](#);
- m) procedures used to design and implement the Scheme (which may include reference to a scheme protocol);
- n) procedures used to statistically analyse the data, where applicable. (see Annex 1 for guidance);
- o) advice, where appropriate, on the , interpretation of the statistical analysis.
- p) [comments, recommendations](#)

Note: For schemes operated on a regular basis, it may be sufficient to have simpler reports such that many of the recommended elements in 3.7.3.2 could be excluded from routine reports, but included in scheme protocols or in periodic summary reports and provided upon request to participants.

3.7.3.3 Reports shall be made available to participants within specified timetables. In schemes such as long term measurement comparison schemes, interim reports shall be issued to individual participants.

Note: Although, ideally, all original data supplied should be reported to all participants, it may not be possible to achieve this in some very extensive schemes. Participants should receive at least the results from all participants in summary (e.g. graphical) form

3.7.3.4 [The EQAP organisation shall hold copyrights of their reports so that it is possible to assure that the data are referred and correctly used, if they appear in publications. The EQAP organizer will stimulate utilisation of relevant results in publications.](#)

3.8 Communication with Participants

3.8.1 The EQAP organizer shall provide prospective participants with detailed information, for example, in the form of a scheme protocol, on how to apply to participate in the program. This should include details of the scope of the scheme, any fees for participation, and policies about which laboratories may participate.

Note: Subsequent: communication with participants may be by means of a letter; newsletter and/or reports, together with periodic open meetings.

3.8.2 Schemes may also be open for manufacturers of relevant reagents and other specialist laboratories

3.8.3 Participants shall be advised promptly in writing by the EQAP organizer of any changes in scheme design or operation.

3.8.4 There shall be documented procedures for enabling participants to refer to the EQAP organizer if they disagree with the assessment of their performance in an EQAP.

3.8.5 Feedback from participants should be encouraged so they may actively contribute to the development of a scheme.

3.8.6 All communications between participants and the scheme organizer are recorded and filed accessibly, but with due regard for confidentiality.

3.8.7. When possible, regular meetings with participants shall be organized to discuss results of surveys and services provided by the EQAP.

3.9 Confidentiality

3.9.1 The identity of participants in an EQAP shall usually be confidential and known only to the minimum number of persons involved in the provision and evaluation of the scheme.
The EQAP organization shall have a procedure to guarantee the confidentiality of his participants.

3.9.2 All information supplied by a participant to the EQAP organizer shall be treated as confidential.

Note: Participants may elect to waive confidentiality within the group for the purposes of discussion and mutual assistance, for example, to improve performance.

3.9.3 The EQAP organizer shall not allow the use of reports in marketing of in-vitro diagnostic products.

3.10 Collusion and Falsification of Results

EQAP's shall, where practicable, be designed to ensure that there is as little opportunity as possible for collusion and falsification of results.

Note: Although all reasonable measures should be taken by the EQAP organizer to prevent collusion, it should be appreciated that it is the responsibility of the participants to avoid it.

APPENDIX A: COMMONLY USED STATISTICAL METHODS FOR TREATMENT OF PROFICIENCY TEST/EAQ DATA

(Information for Guidance only)

To assist EQA organizers, guidance on the selection and use of statistical procedures for the treatment of proficiency test data is given in Annex A of ISO/IEC Guide 43: 1.

The subjects covered in this Annex include:

Determination of the assigned value and its uncertainty

A description of the various procedures which can be used to establish assigned values. The determination of uncertainty of assigned values. The use of a nominal ordinal scale when dealing with qualitative values. The use of a mean, median, mode or other robust measure when dealing with quantitative values. Methods of treating extreme results.

Calculation of performance statistics

Including consideration of performance on single test items, and combined performance scores. Examples of variability measures for calculation of performance statistics. Use of z scores and E_n numbers.

Evaluation of performance

Including consideration of initial performance and monitoring of performance over time. Fitness for purpose. Graphical techniques (error bars, histograms, Shewhart charts, Youden plots).

Preliminary determination of test item homogeneity

In addition, Annex C of ISO/IEC Guide 43: 1 contains an extensive bibliography of publications covering:

Terms and definitions

Criteria in proficiency testing for accreditation

Interlaboratory comparisons

Statistical techniques for collaborative tests

Robust statistics

Proficiency testing and pathology laboratories

APPENDIX B: CROSS-REFERENCES TO ISO 9000, ISO GUIDE 43-1 AND ISO/IEC 17025

Cross-references between elements of the *IFCC, C-AQ Requirements for the Competence of EQAP organizers* and, where relevant, ISO 9001:1994, ISO Guide 43-1:1997 and ISO/IEC 17025:1999

A-QC Requirements		ISO 9001:1994	ISO Guide 43-1:1997	ISO/IEC 17025:1999
2.1.1	Quality management system	4.2.1	-	4.2.1
2.1.2	QM policy objectives	4.1.1	-	4.2.2
2.1.3	Documented quality system	4.2.1 & 4.2.2	-	4.2.1
2.1.4	Activities specified	4.1.2.1 & 4.6.2	-	-
2.1.5	Roles/responsibility	4.1.2	-	4.1.4
2.2.1	Legal identity	-	-	4.1.1
2.2.2	EQAP organizer requirements	4.1.2	-	-
2.3.1	Document control procedures	4.5.1	-	4.3
2.3.2	Document approval and issue	4.5.2	-	4.3.2
2.3.3	Document changes	4.5.3	-	4.3.3
2.4.1	Contract review	4.3.2	-	4.4.1
2.4.2	Records of contract reviews	4.3.3	-	4.4.2
2.4.3	Record includes subcontractors	4.6.2	-	4.4.3
2.5.1	Selection of subcontractors	4.6.2	-	4.5.1
2.5.2	Register of collaborators	4.6.2	-	4.5.4
2.6.1	Supply selection policies	4.6.1 & 4.7	-	4.6.1
2.6.2	Use of adequate services/supplies	4.6.1, 4.6.2 & 4.7	-	4.6.2
2.6.3	Compliance with requirements	4.6.4 & 4.7	-	4.6.3
2.6.4	Inspection & approval	4.6.4 & 4.7	-	4.6.4
2.6.5	Records of approved suppliers	4.6.4 & 4.7	-	4.6.4
2.7	Client feedback	4.14.2	6.7	4.7 & 4.8
2.8.1	Nonconformance with procedures	4.13	-	4.9.1
2.8.2	Corrective actions (Cas)	4.14.2 & 4.14.3	-	4.9.2
2.9.1	Policy for Cas	4.14.1	-	4.9.2 & 4.10
2.9.2	Cause analysis	1.14.2	-	4.10.2
2.9.3	Selection of Cas	4.14.2	-	4.10.3
2.9.4	Monitoring of Cas	4.14.2	-	4.10.4
2.10.1	Preventive action' review	4.14.3	-	4.11.1
2.10.2	Monitoring results of PAs	4.14.3	-	4.11.2
2.11.1.1	Identification etc of records	4.16	-	4.12.1.1
2.11.1.2	Storage of records	4.16	-	4.12.1.2
2.11.1.3	Security of records	4.16	-	4.12.1.3
2.11.1.4	Security of data	4.16	-	4.12.1.3
2.11.2	Technical records	4.16	-	4.12.2.1-3
2.12.1	Internal audits	4.17	-	4.13.1
2.12.2	Corrective action for NCRs	4.17	-	4.13.2
2.12.3	Management review of audit records	4.17	-	4.14.1
2.13.1	Periodic management reviews	4.1.3	-	4.14.1
2.13.2	Record of findings of mgt reviews	4.4.3	-	4.14.2
3.1.1	Staff experience etc requirements	4.1.2.2 & 4.18	-	5.2.1
3.1.2	Managerial staff and resources	4.1.2.2	5.2.1	5.2.5
3.1.3	Measurement staff and resources	4.1.2.2 & 4.18	5.2.2	5.2.5
3.1.4	Min. levels of qualifications & experience	4.1.2.2 & 4.18	-	5.2.2 & 5.2.4
3.1.5	Adequate personnel	4.1.2.2	-	5.2.1
3.1.6	Safety officer	-	-	-
3.1.7	Training	4.18	-	5.2.1 & 5.2.2
3.1.8	Resources for training	-	-	-
3.1.9	Continuing education programme	-	-	-
3.1.10	Records of training	4.18	-	5.2.1
3.1.11	Staff meetings	-	-	-

A-QC Requirements		ISO 9001:1994	ISO Guide 43-1:1997	ISO/IEC 17025: 1999
3.2.1	Office and laboratory space	-	-	5.3.1
3.2.2	Staff facilities	-	-	-
3.2.3	Reception of materials	-	-	-
3.2.4	Data storage	-	-	-
3.2.5	Laboratory equipment	-	-	5.5.1
3.2.6	Provision of facilities	-	-	-
3.2.7	Storage facilities	-	-	-
3.2.8	Safe working environment	-	-	-
3.2.9	Decontamination procedures	-	-	-
3.3.1	Appropriate collab experience	4.6.2	-	4.5 & 5.2
3.3.2	Compliance with ISO/IEC Guide 25	-	-	4.5.1 & 4.5.2
3.3.3	Technical competence	-	-	4.5.1 & 4.5.2
3.3.4	Details of collaborators methodology	4.6.2	-	-
3.4.1.1	Relevancy	-	-	-
3.4.1.2	Quality of programmes	-	-	-
3.4.1.3	Goals	-	-	-
3.4.1.4	Program planning	4.4 & 4.9	5.1.2	4.4 & 4.5.3
3.4.1.5	Identification/ review of collaborators' input	4.6.2 & 4.9	-	-
3.4.1.6	Expert board	-	5.1.1	-
3.4.1.7	Responsibilities expert board	-	?	-
3.4.2.1	Range	-	-	-
3.4.2.2	Safety	-	-	-
3.4.2.3	Acquisition, handing, storage and disposal	-	-	5.8.1
3.4.2.4	Preparation of test items	4.9 & 4.10	5.5.1 & 5.6.2	-
3.4.2.5	Ethical considerations	-	-	-
3.4.2.6	Separation of materials	-	-	5.3.8
3.4.2.7	Homogeneity test	4.9,4.10,4.12 & 4.4	5.5.2 & 5.6.2	-
3.4.2.8	Matrix matching .	4.9,4.10 & 4.12	5.5.3	-
3.4.3.1	Selection of items for homogeneity test	4.9 & 4.10	5.6.2	-
3.4.3.2	Testing after packaging	4.9, 4.10 & 4.12	5.6.2	-
3.4.3.3	Stability checking of properties	4.9 & 4.10	5.6.3	-
3.4.4.1	Statistical model and data analysis	4.20.1	5.4.1	-
3.4.4.2	Appropriate stat design of program	4.20.2	5.4.2	-
3.5.1	Participants' choice of method	-	5.7.1, 5.7.2	-
3.5.2	Requested details of methods	-	5.7.3	-
3.6.1.1	Early advice to participants	-	6.2.1 & 6.7.1	-
3.6.1.2	Detailed instruction with samples	-	6.2.1	-
3.6.1.3	Details of factors affecting testing	-	6.2.2	-
3.6.1.4	Recording and reporting results	-	6.2.3	-
3.6.1.5	Treat samples as normal samples	-	6.2.4	-
3.6.1.6	Disclosure of assigned values	-	5.5.5	-
3.6.2.1	Identification/preservation of test items	4.8 & 4.15	5.6.1	-
3.6.2.2	Adequate packaging and storing	4.15	-	5.8.2 & 5.8.3
3.6.2.3	Reassessment of sample condition	4.15	5.6.3 & 5.6.4	5.8.1
3.6.3.1	Packaging & labelling regulations	4.8 & 4.15	6.3	-
3.6.3.2	Labels	4.8 & 4.15	6.3	-
3.6.3.3	Safety	-	-	-
3.7.1.1	Adequacy and documentation of data processing equipment	4.11.1	5.3, 6.4	5.5.11
3.7.1.2	Role/responsibility of data system mgr	4.1.2	-	-
3.7.1.3	Maint and valid of equipt and software	4.11.1	-	-
3.7.1.4	Recording & processing of data	4.1.6	6.4.1	4.12.2
3.7.1.5	Summary stats	4.20	6.4.2	5.10
3.7.1.6	Tests for oudliers	4.20	6.4.2	-
3.7.1.7	Criteria for non-conforming data	4.20	6.4.3	-
3.7.2.1	Unacceptable performance	-	-	-
3.7.2.2	Evaluation of lab performance	-	6.6.1 & 6.6.4	-
3.7.2.3	Evaluation method	-	6.6.1 & 6.6.4	-
3.7.2.4	Expert commentary	-	6.6.2 & 6.6.5	5.10.5
3.7.3.1	Program reports	4.16	6.5.1 & 6.5.3	5.10

A-QC Requirements		ISO 9001:1994	ISO Guide 43-1:1997	ISO/IEC 17025: 1999
3.7.3.2	Information in program in reports	-	6.5.2 & 6.6.3	5.10
3.7.3.3	Promptness of reporting	-	6.5.4	-
3.7.3.4	Copyrights	-	-	-
3.8.1	Information on participation	-	6.7.1	-
3.8.2	Participation of manufacturers	-	-	-
3.8.3	Changes in program design	4.4	6.7.1	-
3.8.4	Procedures for participant feedback	4.14.2	6.7.2	-
3.8.5	Encouragement of participant feedback	-	6.7.3	-
3.8.6	Records of communications	-	-	-
3.8.7	User's meetings	-	-	-
3.9.1.	Confidentiality of participant identity	-	7.1	-
3.9.2.	Confidentiality of test data, etc	-	7.1	-
3.9.3.	Use of data	-	-	-
3.10.	Falsification of data	-	7.2	-

APPENDIX C: BIBLIOGRAPHY

- (1) ISO/IEC Guide 2:1996, Standardisation and related activities – General vocabulary.
- (2) ISO/IEC Guide 43-2: 1997 *Proficiency testing by interlaboratory comparisons - Part 2: Selection and use of EQA schemes by laboratory accreditation bodies.*
- (3) ASTM E1301-95 *Standard Guide for Proficiency Testing by Interlaboratory Comparisons.*
- (4) ISO 3534-1: 1993, *Statistics - Vocabulary and symbols - Part 1: Probability and general statistical terms.*
- (5) ISO 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results - Part 1: General principles and definitions.*
- (6) ISO 5725-2: 1994. *Accuracy (trueness and precision) of measurement methods and results - Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method.*
- (7) ISO 5725-4:1994 *Accuracy (trueness and precision) of measurement methods and results - Part 4: Basic methods for the determination of the trueness of a standard measurement method*
- (8) ISO 8402:1994, *Quality management and quality assurance – Vocabulary*
- (9) *ISO Guide to the expression of uncertainty of measurement (1995)*
- (10) VIM:1993, International vocabulary of basic and general terms in metrology (under revision)
- (11) ISO/DIS 13528: 2000. *Statistical methods for use in proficiency testing by interlaboratory comparison*
- (12) [CPA EQA scheme accreditation handbook 1996](#)
- (13) [J.C. Libeer. External quality assurance programmes in medical laboratories. Accred Qual Assur \(2001\) 6: 151-153](#)
- (14) [J.C. Libeer. Role of External Quality Assurance Programmes in assessing and improving quality in medical laboratories. Clin Chem Acta \(2001\) 309: 173-177](#)
- (15) [Hill P, Uldall A and Wildng P. Fundamentals external quality assessment \(EQA\). Guidelines for improving analytical quality by establishing and managing EQA schemes. Examples from basic clinical chemistry using limited resources. IFCC 1996.](#)
- (16) [Olafsdottir E, Hellsing K, Steensland H, Tenhunen R, Uldall A. Adding new scopes to traditional EQA schemes emphasizing quality improvement..In: Hyltoft Petersen P, Blaabjerg O, Irjala K, editors. Assessing quality in measurements of plasma proteins. The Nordic Protein Project and Related Projects. Nordkem Clinical Chemistry Project, Helsinki, Finland, 1994: 187-193](#)
- (17) [Libeer JC, Baadenhuijsen H, Fraser CG, Hyltoft Petersen P, Ricos C, Stöckl D and Thienpont L. Characterization and Classification of External Quality Assessment Schemes \(EQA\) according to objectives such as evaluation of method and participant bias and standard deviation. Eur. J. Clin. Chem. Clin. Biochem 199; 34: 665-678](#)
- (18) [Sandberg S and Thue G.. External quality assurance of test requesting and test interpretation. Accred Qual Assur 1999; 4: 414-415](#)

(19) Neumaier M, Braun A, Gessner R and Funke H. Experiences with external quality assessment in molecular diagnostics in clinical laboratories in Germany. Clin Chem Lab Med 2000; 38: 161-163

(20) Stöckl D, Libeer JC, Reinauer H, Thienpont LM, De Leenheer A. Accuracy-based assessment of proficiency testing results with serum from single donations: possibilities and limitations. Clin Chem 1996; 42: 469-470

(21) N. Hamers, J. Smits, A. L'Hoir and JC LIBEER. Interest of the external quality assessment in the evaluation of the performance of commercial kits highlighted by a sample of the Belgian EQA's in immunoassays. Immunoanal BioL Spéc 2001: 16, 419-422.

(22) Steensland H., Eintrei J., Nordin G., Uldall A., Keinänen M., Loikkanen M., Olafsdottir E. A Nordic study on the robustness of clinical chemistry analyzers of today. Proceedings Eurachem/EQALM Workshop on PT, Borås 24-26 Sept 2000, (Abstract)

(23) Compendium on advanced external quality assurance in clinical biochemistry. EQAnews 2000 vol 11; 1-150

(24) A. Uldall. Ethics for organizers of external quality assurance programmes (EQAP). EQAnews 2001 vol12(2); 28-31

(25) ISO/DIS 15189.2 (2002). Medical laboratories – Particular requirements for quality and competence

(26) prEN 14136 (2001): Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic products