

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

10. EVALUATION OF THE QUALITY SYSTEM

10.1. INTERNAL AUDIT

AUTHOR	VERSION	APPROVED BY	DATE	

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1. INTRODUCTION (1)

There should be a system of planned internal audits. (2-4)

Results of internal audits should be documented and responsible staff should be informed. (4)

Action taken in response to the results of internal audits should be documented. (2-4)

There should be procedures for corrective actions and assessment of their effectiveness.

All procedures should be checked at least once a year. (5)

There should be a checklist of all items and aims described in the handbook and this should be checked once a year.

1.1 SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 98000: 2000	ISO 17025
4.6. Control of non-conformities. (4.6.1. to 4.6.2.) 4.8. Preventive actions. (4.8.1. to 4.8.3.) 4.9. Corrective actions (4.9.1. to 4.9.6.) 4.10. Quality and technical records 4.10.1. 4.11. Internal audits. 4.11.1. to 4.11.3. 4.12. Management review. 4.12.1. to 4.12.3. 5.8. Reporting results. 5.8.6.	8.2. Measurement and monitoring. 8.2.2. Internal audit.	4.10. Corrective action. 4.13. Internal audits

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

- Jansen RTP, Blaton V, Burnett D, Huisman W, Queraltó JM, Zérah S, Allman B. European Communities Confederation of Clinical Chemistry: Essential criteria for quality systems of medical laboratories. Eur J Clin Chem Clin Biochem 1997; 35(2): 123-132.
- ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998; 4.10., 4.13.
- ISO. DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000; 8.2.2.
- ISO/TC 212/WG 1. Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality management in the medical laboratory (December 1998), 4.6.1., 4.6.2., 4.8.1., 4.8.2., 4.8.3., 4.9.1., 4.9.2., 4.9.3., 4.9.4., 4.9.5., 4.9.6., 4.10.1., 4.11.1., 4.11.2., 4.11.3., 4.12.1., 4.12.2., 4.12.3., 5.8.6.
- Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.
- Burnett D. Understanding accreditation in laboratory medicine. London: Association of Clinical Biochemists, 1996, 130-170-178.
- Plebani M. Sistema qualità de accreditamento nel laboratorio clinico (II). Aspetti applicativi. Milano: Biomedica, 1999.

1.5. RELATED DOCUMENTS

3.2. Organization and Management. Internal organizational structure

4.1. Personnel. Job descriptions, duties and responsibilities

4.4. Personnel. Staff appraisal system

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- 6.3. Equipment, material and reagents. Calibration
- 7.4. Pre-analytical phase. Request procedures
- 8.1. Analytical phase. Validation
- 8.4. Analytical phase. Quality assurance and assessment
- 9.6. Post-analytical phase. Archiving
- 10.1.1. Evaluation of the Quality System. Internal audit. Quality audit program
- 10.1.2. Evaluation of the Quality System. Internal audit. Quality audit form
- 10.2. Evaluation of the quality system. Internal and external complains
- Safety Manual of the Clinical Chemistry Department
- Environmental (Waste) Management Manual

1.6. ABBREVIATIONS

CV: Curriculum Vitae

EAP: Environmental Action Plan

1.7. RELATED DEFINITIONS

document: a piece of written or printed matter that provides a record or evidence of events.

laboratory director: the person who governs the policy of a laboratory. NOTE A specific person may be director of a number of similar or dissimilar institutions (See: **laboratory management**).

laboratory management: collective body of those persons who manage the activities of the laboratory headed by the laboratory director.

laboratory manager: a person who carries out the administration of a laboratory in accordance with a policy. NOTE The policy is usually prepared by the laboratory director in consultation with the laboratory manager.

laboratory supervisor: head of technicians, whose has responsibility in planning the day to day work.

non-conformity: non-fulfilment of a specified requiremen.

quality officer: the member of the staff in charge to establish and maintain the quality system on behalf of the laboratory management. The quality officer has the highest range in the laboratory, directly under the laboratory director.

safety officer: the member of the staff who has the responsibility to establish and maintain the health, safety and environment program.

section manager: Clinical Chemist in charge of a section of the Clinical Chemistry Department.

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2. ORGANISATION AND MANAGEMENT

Internal audits of all matters covered by the Quality Manual are conducted at a predetermined date decided by the Laboratory Manager, the Laboratory Supervisor and the Quality Officer at least once a year.

A checklist is kept, and used to conduct the internal quality audit, as detailed in the document *10.1.1. Evaluation of the Quality System. Internal audit. Quality audit program.*

The audit is planned and co-ordinated by the Quality Officer, who draws up a report, which is discussed with all those concerned. The audit are conducted by the Laboratory Manager, following a formal agenda agreed with the Quality Officer and the laboratory Supervisor.

The following year's Action list is adjusted on the basis of the audit report.

The Quality Officer is responsible for ensuring that detailed records of all reviews are kept, including clear indications as to any actions to be taken, by whom and in what timescale. He has also responsibility that any corrective actions required as a result of audits are satisfactorily discharged in the specified timescales

The document *10.1.1. Evaluation of the Quality System. Internal audit. Quality audit program* provides information regarding the proposed schedule for audits and reviews, identifying names of audit officers, frequency of auditing and check lists of questions to be addressed for each aspect to be audited. Records of audits and reviews are held by the Quality Manager.

A sample Audit Report Form used by the Clinical Chemistry Department is included in the document *10.1.2. Evaluation of the Quality System. Internal audit. Quality audit form.*

3. DOCUMENT PREPARATION AND CONTROL

The following items should be audited

3.1. QUALITY MANUAL

Complete and fully up-to-date copies of the Quality Manual are retained by the laboratory Director and the Quality Officer.

3.2. PROCEDURES

The standard operating procedures kept in areas where the activities prescribed are regularly undertaken. The Quality Officer ensures that all copies of each procedure are identical and up-to-date.

Laboratory Technicians are notified of any procedural revisions by the Clinical Chemists at the weekly work discussion meetings (see the document *4.1. Personnel. Job descriptions, duties and responsibilities*).

Changes (and familiarity of the staff) recorded in the document *3.2. Organization and Management. Internal organizational structure.*

3.3. QUALITY ASSURANCE DATA

Quality assurance data, retained and checked at the workstations is audited periodically.

4. PERSONNEL MANAGEMENT

The personnel file, kept on each member of staff, containing the individual's CV and recording his or her annual appraisal.

The Laboratory Supervisor is responsible for updating the CVs, according the document *4.4. Personnel. Staff appraisal system.*

5. PREMISES AND ENVIRONMENTAL. HEALTH AND SAFETY

5.1 PREMISES

The Quality Officer periodically checks that access doors and escape routes are clear and that fire extinguishers and emergency facilities are in working order.

5.2. SAFETY EQUIPMENT

The Quality Officer periodically checks are made on all other safety equipment: fume cupboards are checked to see that they are working properly, the presence of safety goggles and other protective gear is checked, chemicals cupboards are inspected and so on, as it is stated in the *Safety Manual of the Clinical Chemistry Department.*

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5.3. WASTE

As part of the waste and environmental management arrangements, the Safety Officer performs periodic checks and records his or her findings in the logbook. The checks cover separated collection, storage, rebelling and disposal of waste in accordance with the instructions set out in the documents *Environmental (Waste) Management Manual* and *Safety Manual of the Clinical Chemistry Department*.

On the basis of these quality checks and records of waste volumes, a waste report is compiled.

The Quality Officer's findings are recorded in a logbook.

5.4. REPORTS AND LOGBOOK

This report is in its turn used as the basis for the annual audit, leading finally to production of the Environmental Action Plan (EAP), which sets out the new activities to be undertaken, environmental objectives and modifications to the environmental management system. Interim changes can also be made on the basis of the quality checks, periodic registration and testing of waste or the periodic work discussion meetings.

6. LABORATORY EQUIPMENT MANAGEMENT

The logbook of each automated piece of equipment, where faults affecting the equipment are recorded, along with the corrective action.

Calibration data and periodic preventive maintenance is checked in accordance with the standard operating procedures. (See documents 6.3. *Equipment, material and reagents. Calibration*).

7. PRE ANALYTICAL PHASE

All service requests are recorded in the laboratory's computer system. The system allocates the service requests to and generates work lists for the various workstations (see document 7.4. *Pre-analytical phase. Request procedures*).

The frequency with which tests are done is specified in the standard operating procedures. The Section Managers are responsible for initiating tests on time. The Biochemistry Section Manager has to ensure that urgent requests are properly processed. Also, the Section Managers are responsible for the prompt authorization of results, so that they can be reported in good time.

The Clinical Chemists ensure that the service users receive any interpretation advice which may be necessary.

8. ANALYTICAL PHASE

Every type of test undertaken is regularly checked by analysing control material, according document 8.4. *Analytical phase. Quality assurance and assessment*.

The control material to be used, the timing of control tests and the criteria which results must meet for authorization are all specified in the relevant standard operating procedure.

Quantitative control test results are plotted on graphs together with the target values and warning and/or action levels.

The Quality Officer compiles monthly summaries of control test results and the derived statistical parameters. With various types of test, the average of a sequence of results from specimens under investigation is checked to see that it remains within the prescribed range.

Before authorizing the results of a test, the Section Managers check the control material results. Control material is tested in the same way as the corresponding specimens under investigation and the results are acted upon in accordance with the standard operating procedures. The results of the internal control tests are considered by the Clinical Chemists and Departmental Manager at their work discussion meetings

New test methods are validated before adoption. Validation at least involves the study of reproducibility within and between runs, accuracy, linearity, sensitivity (detection limits), matrix sensitivity, liability to failure and practicality. See document 8.1. *Validation*.

9. POST ANALYTICAL PHASE

The reporting and archiving arrangements, described in document 9.6. *Post-analytical phase. Archiving*, is checked periodically.

10. NON CONFORMITIES AND THE HANDLING OF COMPLAINTS

Complaints and non conformities are recorded and dealt with as described in the document 10.2. *Evaluation of the quality system. Internal and external complains*.

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Organizational improvements may be suggested at any of the work discussion meetings.

The Laboratory Supervisor also maintains a Suggestions and Comments file in which suggestions and complaints regarding organizational matters can be entered by any member of staff at any time (if they wish, anonymously).

Entries are considered at work discussion meetings by the Laboratory Supervisor and Laboratory Technicians and by the Clinical Chemists and Section Managers.

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