

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

2. QUALITY POLICY AND STRATEGY

2.3. QUALITY STRATEGY OF THE LABORATORY

AUTHOR	VERSION	APPROVED BY	DATE	

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1. INTRODUCTION (1)

The quality system of the laboratory should be described in a quality manual. (2, 3, 5)

There should be a list of specific quality goals of the laboratory. (5)

The general structure of documents should be defined.

The general format of procedures should include:

1. Subject
2. Purpose and scope
3. Responsibility
4. Definitions
5. Action and methods
6. References
7. Documentation

There should be a system for document control defining the responsibilities for writing, evaluation, authorization and distribution of quality system documents. (6)

Information appearing on each page of any document should include title, version number, page number of total number of pages, and document identification code.

Only valid versions of procedures should be used, dated and signed by the responsible staff officer.

The quality manual should be accessible for all personnel. (2,4)

Personnel should be actively involved in writing and changing of procedures and they should take notice of such changes.

All procedures should be evaluated at least once a year. (2)

1.1. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
4.2. Quality management system. 4.2.5. and 4.2.6.	4. Quality management system. 4.1. General requirements.	4.2. Quality system. 4.2.1. to 4.2.4.
4.3. Document control. 4.3.1. to 4.3.3.	4. Quality management system 4.2. General requirements of documentation	4.3. Document control. 4.3.1. General.
5.1. Personnel. 5.1.3.	5. Management responsibility. 5.1. Management commitment	4.3. Document control. 4.3.2. Document approval and issue.
5.1. Personnel. 5.1.4.(e).	5. Management responsibility 5.4. Planning. 5.4.1. Quality objectives.; 5.4.2. Quality planning. 5. Management responsibility 5.5. Management. 5.5.5. Quality manual; 5.5.6. Document control 5. Management responsibility. 5.6. Management review. 7. Product production. 7.1. Planning the production process.	

1.3. PUBLICATION CREDITS

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1.4. REFERENCES

1. 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.
2. ISO/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality Management in the Medical Laboratory (December 1998), 4.2.5., 4.2.6., 4.3.1., 4.3.2., 4.3.3., 5.1.3., 5.1.4.(e).
3. ISO/DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000; 4.1., 4.2., 5.1., 5.4.1., 5.4.2., 5.6., 7.1.
4. ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998; 4.2.1., 4.2.2., 4.2.3., 4.2.4., 4.3.1., 4.3.2.
5. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.
6. Burnett D. Understanding accreditation in laboratory medicine. London: Association of Clinical Biochemists, 1996, 255-258.

1.5. RELATED DOCUMENTS

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

quality manual: set of documents describing the quality system of the Clinical Chemistry Department.

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.

quality system: organisational structure, procedures, processes, and resources needed to implement quality management.

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2. QUALITY MANAGEMENT

2.1. THE QUALITY OFFICER

The Quality officer shall have responsibility for ensuring that the requirements of the National requirements are met on a day-to-day-basis.

In his (her) absence, the Deputy Quality officer shall fulfil this role.

The Quality officer is directly responsible to the Director of the Laboratory.

The Quality officer has overall responsibility for the control of quality and will advise on and monitor all aspects of quality in the Laboratory.

The Quality officer shall be responsible for:

- (a) arranging for the documentation control and maintenance
- (b) maintaining records of documentation amendments
- (c) planning and organising audits and reviews
- (d) ensuring that the details of reviews are recorded
- (e) ensuring the completion and discharge in the appropriate timescale of corrective actions resulting from audits

2.2. THE LABORATORY SUPERVISOR

The Laboratory supervisor shall have overall responsibility for:

- (a) the technical operation of the Laboratory
- (b) ensuring that the accreditation requirements are met
- (c) implementing the quality policy for the Laboratory.

2.3. STAFF

Staff are required to adhere to the Laboratory's quality policies and procedures at all times.

Departures are only permitted when it can be shown that there are valid technical reasons for doing so and that it can be shown that the quality of the Laboratory's tests is not thereby jeopardised. The Quality officer must first approve any such departures. The justification for the departure, together with the endorsement of the respective member of staff, shall be recorded.

If it is found that staff have in any way departed from the Clinical Chemistry Department policies and procedures and that any such departures may affect the quality of services being provided, work is stopped immediately. The senior member of staff responsible for the area concerned is informed and the matter is thoroughly investigated. Any service items identified as being at risk is, where appropriate and possible, repeated. In this case, the physician who has ordered is notified and a repeat sample requested.

The member of staff responsible of such departure is alerted to the seriousness of their actions and measures are taken to prevent recurrence.

2.4. DOCUMENTATION

All methods and procedures necessary for the proper performance of tests and consultation are readily available to the staff concerned.

All such documentation (including the Quality Manual) is subject to strict management control. The Quality Officer has this responsibility.

Requests for amendments to existing documents and for new procedures shall be brought to the attention of the Quality Officer.

Staff is not permitted to make amendments to documentation without the prior consent of the Quality Officer

The Quality Officer approves amendments to existing documents.

All laboratory manuals are reviewed on an annual basis. The responsibility for the annual review lies with the appropriate Section Head.

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The Quality officer co-ordinate the process of distribution of new documentation, retrieval of old documentation and maintenance of records of amendments.

The Quality Manual shall be reviewed every year as part of the audit programme.

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