

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

3. ORGANIZATION AND MANAGEMENT

3.2. INTERNAL ORGANISATION STRUCTURE

AUTHOR	VERSION	APPROVED BY	DATE	

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1. INTRODUCTION

There should be a description of the organizational structure of the laboratory illustrated by a management diagram.

There should be a list of all functions and their tasks, responsibilities and competencies.

1.1. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
5.1. Personnel. 5.1.2., 5.1.4.(b)., 5.1.7.	5.5. Management. 5.5.2. Responsibility and authority. 6.2. Human resources. 6.2.1. Personnel allocation	4.1. Organisation and management. 4.1.4.(e), (f)

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

- Jansen RTP, Blaton V, Burnett D, Huismann 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/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality Management in the Medical Laboratory (December 1998), 5.1.2., 5.1.4.(b)., 5.1.7.
- ISO.DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000; 5.5.2., 6.2.1.
- ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998; 4.1.4.(e), (f).
- Jansen RTP, Bank CMC, Huisman W, Penders T.J. NVKC Model quality manual. 2nd rev. ed. Utrecht: NVKC 1996.
- Burnett D. Understanding accreditation in laboratory medicine. London: Association of Clinical Biochemists, 1996, 96-101.

1.5. RELATED DOCUMENTS

3.2.1. *Procedure for the organization and management of pathology*

5.3.2. *Job Description.*

1.6. ABBREVIATIONS

HHS&EM Hygiene, Health, Safety and Environmental Management

1.7. RELATED DEFINITIONS

clinical laboratory (medical laboratory): a room or building (space) fitted out for scientific examinations (testing) of materials taken from patients for the purposes of diagnosis and treatment

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.

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.

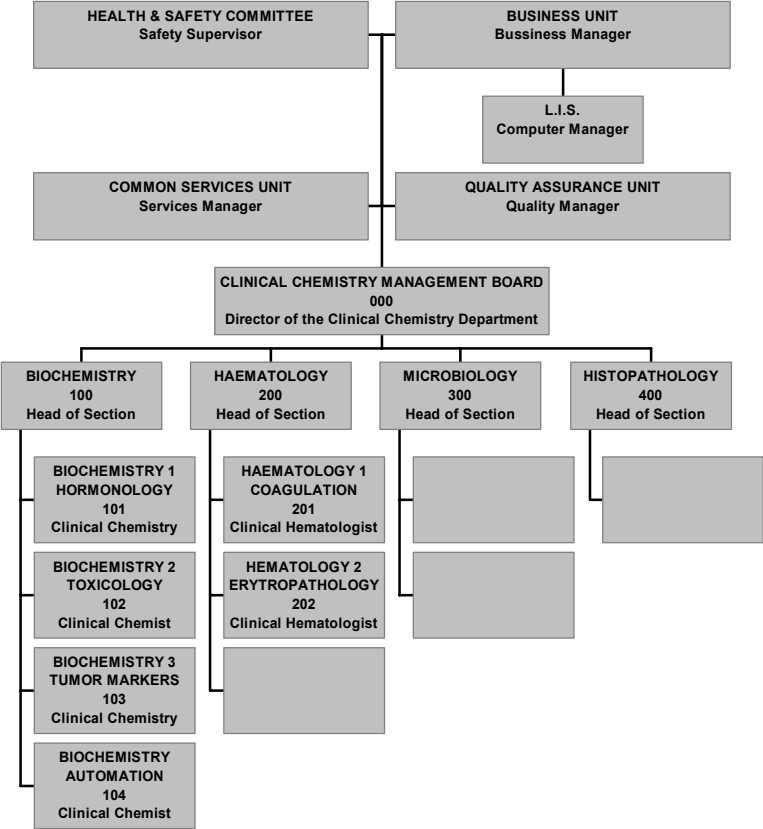
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quality officer: the member of the staff in charge to establish and maintain the quality system on behalf of the laboratory management. The quality officer has the highest range in the laboratory, directly under the laboratory director.

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2. DESCRIPTION OF THE ORGANIZATIONAL STRUCTURE OF THE LABORATORY



3. FUNCTIONS AND TASKS, RESPONSIBILITIES AND COMPETENCIES

The Clinical Chemistry Department has four main sections, each with a Head of Section.

In addition, there are three units:

- Business / Financial unit
- Common services and Maintenance Unit
- Health and safety Unit

and one committee:

- Quality Committee

which provide the supporting services for the Clinical Chemistry Department.

Each of these units and committee has a manager or supervisor.

3.1. MANAGEMENT BOARD

The Management Board of the Clinical Chemistry Department is composed as follows:

- Laboratory Manager
- Heads of Sections
- Quality Manager
- Business Manager
- Common Services Manager

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- The Safety Officer

The Management Board is conducted according to the document 3.2.1. *Procedure for the organization and management of pathology*.

3.2. HEAD OF SECTIONS

In departments with more than one Consultant Pathologist or Scientist, the headship is held on a rotating basis.

The Managers are responsible directly to the Director.

3.3. LABORATORY SPECIALISTS

The professional staff (laboratory specialists) is:

Biochemistry	Horonology	XXXXX	ECC
		XXYYZZ	
	Toxicology	MMMNN	ECC
		BBBNN	ECC
	Tumor markers	SSSTT	ECC
	General biochemistry	ZZZRR	
		FFGGE	ECC
Hematology
...

Note: ECC stands for European Clinical Chemist, that is, registered at national and European level (e. g. the EC4 Euro Register).

The staff has a defined individual responsibility for consultation, choice of methodology and assay quality. These responsibilities are included in the specific job description.

3.4. BUSINESS MANAGER

The Business Manager is full time and responsible for the laboratory's Business and Computing Systems.

The Computer Manager reports to the Business Manager.

3.5. COMMON SERVICES MANAGER

The Common Services Manager is full time and responsible for the reception, secretarial and clerical services, for blood collection, for transport, maintenance and purchasing.

3.6. QUALITY OFFICER

The Quality Officer (Miss XXX) is employed half time on Quality Assurance and half time as the Safety Officer.

As Quality Officer the maintenance of the quality system and manual, reporting directly to the head of the department.

she has responsibility for ensuring that the requirements of the National Accreditation System Standards are met on a day-to-day basis

She has also responsibility for management of the health, safety and environmental management system, in consultation with the Health and Safety Coordinator and the hospital's Environmental Coordinator.

Details of the Quality Officer's role within the organization, the requirements of the post, his or her duties and contacts are given in the relevant job description in the document 5.3.2. *Job Description*.

The Quality Officer has direct access to the Director of the Department.

3.7. SECURITY/SAFETY OFFICER

The Quality Officer is also the Health, Safety and Environmental Management Officer.

The Safety Officer attends the Management Board as required.

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