

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

1. GENERAL INFORMATION

1.3. LEGAL IDENTITY

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

CODE) DOCUMENT: QMM01	(CHAPTER TITLE):	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
(CODE) SECTION: QMM01-S03	GENERAL INFORMATION	EC4 CLINICAL CHEMISTRY DEPARTMENT
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1. INTRODUCTION

The legal identity (type, name, address) of the laboratory should be stated (1, 2, 4). Also, the name and title of the director of the laboratory should be stated (3).

The position of the laboratory within the parent organisation should be clearly showed, e.g. in an organisational diagram

The laboratory or the organisation of which it is a part shall be legally identifiable (5)

1.1 SCOPE

1.2. AIMS

To fulfil the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
4.1. Organisation and management. 4.1.1.	5. Management responsibilities	4.1. Organisation and management. 4.1.1., 4.1.3. and 4.1.4.(c)

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

1. 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. Page. 124, 1.3.
2. EN 45001: 1989. General criteria for the operation of testing laboratories. European Committee for Standardization. 2.
3. ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998; 4.1.1, 4.1.3., 4.1.4.
4. ISO.DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000; 5.
5. ISO/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality Management in the Medical Laboratory (December 1998), 4.1.1.
6. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model Quality Manual. 2nd rev. Ed. Utrecht: NVKC 1996.
7. Plebani M. Sistema qualità de accreditamento nel laboratorio clinico (II). Aspetti applicativi. Milano: Biomedica, 1999; 11-15.

1.5. RELATED DOCUMENTS

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

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

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 institution. (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.

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2. LEGAL IDENTITY

Type of laboratory: Clinical Chemistry, non-profit

Name: Clinical Chemistry Department
Division of Clinical Diagnostics
EC4 University Hospital

Address: Healthcare Street, 123
Z-09878 the City
THE COUNTRY

	Telephones	Fax	E Mail
General	(123) 12 34 00	(123) 12 34 90	
Emergency laboratory	(123) 12 34 01	(123) 12 34 91	Clinchem.stat@hosp.xx
Secretariat	(123) 12 34 02	(123) 12 34 92	Clinchem.secret@hosp.xx
Director	(123) 12 34 03	(123) 12 34 93	Clinchem.manag@hosp.xx
Toxicology	(123) 12 34 04	(123) 12 34 94	Clinchem.toxicol@hosp.xx
Lipids	(123) 12 34 05		Clinchem.lipids@hosp.xx
Molecular pathology	(123) 12 34 06		Clinchem.dna@hosp.xx
Proteins	(123) 12 34 07	(123) 12 34 95	Clinchem.prot@hosp.xx
...

Map / directions:

3. DIRECTOR OF THE LABORATORY

Name: Prof. John Manager

Title: M.D., pH.D., Pharm.D., EurClinChem

Contact: Clinical Chemistry Unity
Department of Clinical Diagnostics
University of the City Hospital

Healthcare Street, 123
Z-09878 the City
THE COUNTRY

Telephone number (123) 12 34 03

Fax: (123) 12 34 93

E Mail Clinchem.manag@hosp.xx

4. THE PARENTAL ORGANISATION

4.1. STATEMENT:

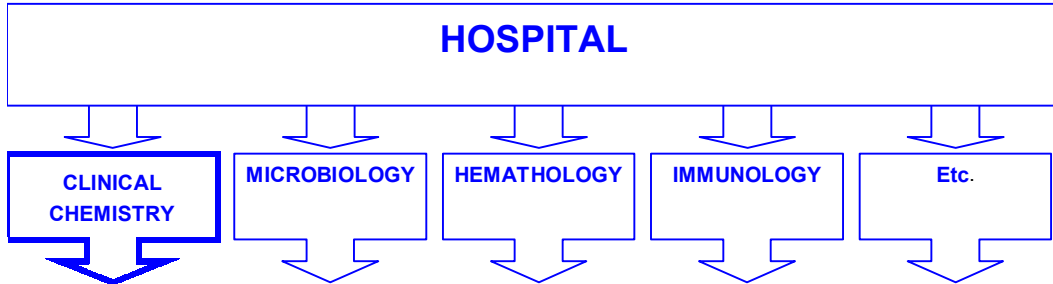
The *Clinical Chemistry Unit* is one of the *City Hospital's* service Departments. The *Clinical Chemistry Unit* Manager is answerable directly to the *City Hospital's* directors

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4.2. DIAGRAM

Figure 1.



4.3. University City Hospital's ORGANIGRAM

- Board of Supervisors: Chairman:
- Members:
- Board of Managers: President:
- Members:
- Medical Staff Directorate: Director:
- Financial Administration Service: Manager:
- Directorial Secretariat:
- Personnel and Organisation
- Technical and Maintenance Department Building Management Service: Manager:
- Clinical Care: Director
- Nursing Director
- Psychosocial and pastoral care: Director
- Other relevant areas:
- ...

4.4. HISTORICAL INFORMATION

The *University of the City Hospital* was created in 1878 by the merger of two medium sized hospitals, which previously served the region. The merger involved centralisation of all clinical activities and care support services, including the laboratory, at one of the two sites.

The *University of the City Hospital* has 785 beds and serves a population of 256350

148 specialists covering 29 medical specialities are employed at the *University of the City Hospital*.

There are 8 specialist in the Medical Laboratory.

The laboratory carries out 2 500 000 test a year, 800 000 of which are for general practitioners.

42 people work at the laboratory, the workforce consisted of 40 full-time equivalents.

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