

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

3. ORGANIZATION AND MANAGEMENT

3.4. HEAD OF THE LABORATORY

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

CODE) DOCUMENT: QMM03	(CHAPTER TITLE): ORGANIZATION	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
(CODE) SECTION: QMM03-S04	(SECTION): HEAD OF LABORATORY	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 16/10/01		
PAGE 2 OF 4		

0. CONTENTS

1. INTRODUCTION

- 1.1. SCOPE
- 1.2. AIMS
- 1.3. PUBLICATION CREDITS
- 1.4. REFERENCES
- 1.5. RELATED DOCUMENTS
- 1.6. ABBREVIATIONS
- 1.7. RELATED DEFINITIONS

2. LABORATORY MANAGER

3. ULTIMATE RESPONSIBILITY FOR LABORATORY TESTING

AUTHOR	VERSION	APPROVED BY	DATE	

(INSTITUTION): EC4 UNIVERSITY HOSPITAL	(CHAPTER TITLE): ORGANIZATION	(CODE) DOCUMENT: QMM03
EC4 CLINICAL CHEMISTRY DEPARTMENT	(SECTION): HEAD OF LABORATORY	(CODE) SECTION: QMM03-S04
		(DATE): 16/10/01
		PAGE 1 OF 4

1. INTRODUCTION

The head of the laboratory should be a laboratory specialist (e. g. clinical pathologist, clinical biochemist, biologiste clinique) recognized at national and or international level (e.g. registered in the EC4 Euro Register).

The head of the laboratory should be responsible for management and scientific direction and should be individually responsible for giving clinical advice.

1.1. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
4.1. Organisation and management. 4.1.3.	5. Management responsibility. 5.1. Management commitment	
4.2. Quality management system. 4.2.2.	5. Management responsibility. 5.6. Management review.	
4.12. Management review. 4.12.1. to 4.12.3.		
5.1. Personnel.5.1.2. to 5.1.4., 5.1.7.,		

1.3. PUBLICATION CREDITS

EC4 WG

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), 4.1.3., 4.2.2., 4.12.1., 4.12.2, 4.12.3., 5.1.2., 5.1.3., 5.1.4., 5.1.7.
3. ISO.DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000; 5.1, 5.6.

1.5. RELATED DOCUMENTS

3. Organisation and Management. 3.4. Head of the laboratory. 3.4.1. Job description
3. Organisation and management. 3.5. Professional staff and other staffing. 3.5.1. Clinical chemist: job description

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

clinical chemist: member of the staff who has the responsibility for a definite area of the Clinical Chemistry Department.

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.

laboratory director: the person who governs the policy of a 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 institutions. See: **laboratory management**.

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

AUTHOR	VERSION	APPROVED BY	DATE

CODE) DOCUMENT: QMM03	(CHAPTER TITLE): ORGANIZATION	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
(CODE) SECTION: QMM03-S04	(SECTION): HEAD OF LABORATORY	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 16/10/01		
PAGE 4 OF 4		

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.

2. LABORATORY MANAGER

The Laboratory Manager has general responsibility for laboratory operations.

He or she acts as Service Manager and is registered with the national and European EC4 Register.

Details of the Laboratory Manager's role within the organisation, the requirements of the post, and his or her duties and contacts are given in the relevant job description in the Document: 3. *Organisation and Management*. 3.4. *Head of the laboratory*. 3.4.1. *Job description*

3. ULTIMATE RESPONSIBILITY FOR LABORATORY TESTING

The three Clinical Chemists, Managers of each Section, share ultimate responsibility for the laboratory; in addition, each has special responsibility for a particular area.

Each has his or her own consultative duties and shares organisational responsibility.

All three are registered with the national and European EC4 Register

Details of the Clinical Chemists' role within the organisation, the requirements of the post, and their duties and contacts are given in the relevant job description in the Document: 3. *Organisation and management*. 3.5. *Professional staff and other staffing*. 3.5.1. *Clinical chemist: job description*.

AUTHOR	VERSION	APPROVED BY	DATE	