

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

2. QUALITY POLICY AND STRATEGY

2.4. CONFIDENTIALITY

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

CODE) DOCUMENT: QMM02	(CHAPTER TITLE):	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
(CODE) SECTION: QMM02-S04	QUALITY POLICY	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 16/10/01	(SECTION TITLE): CONFIDENTIALITY	
PAGE 2 OF 4		

0. CONTENTS

1. INTRODUCTION

- 1.1. SCOPE
- 1.2. AIMS
- 1.3. PUBLICATION CREDITS

REFERENCES

- 1.4. RELATED DOCUMENTS
- 1.5. ABBREVIATIONS
- 1.6. RELATED DEFINITIONS

2. CONFIDENTIALITY

- 2.1. DATA
- 2.2. OBTENTION OF SPECIMENS

AUTHOR	VERSION	APPROVED BY	DATE	

(INSTITUTION): EC4 UNIVERSITY HOSPITAL	(CHAPTER TITLE): QUALITY POLICY	(CODE) DOCUMENT: QMM02
EC4 CLINICAL CHEMISTRY DEPARTMENT	(SECTION TITLE): CONFIDENTIALITY	(CODE) SECTION: QMM02-S04
		(DATE): 16/10/01
		PAGE 3 OF 4

1. INTRODUCTION (1)

Information about patients should be treated confidentially and measures to ensure this should be defined. (2,3)

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. (b).		
B.6.1.		

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.,(b), B.6.1.
3. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.
4. 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.

AUTHOR	VERSION	APPROVED BY	DATE	

CODE) DOCUMENT: QMM02	(CHAPTER TITLE):	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
(CODE) SECTION: QMM02-S04	QUALITY POLICY	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 16/10/01	(SECTION TITLE): CONFIDENTIALITY	
PAGE 4 OF 4		

2. CONFIDENTIALITY

Staff is obliged to preserve the confidentiality of patient data.

New employees sign an undertaking to this effect.

2.1. DATA

Patient data is recorded in accordance with the Data Protection Act.

All relevant data is covered by the parent institution's confidentiality rules.

2.2. OBTENTION OF SPECIMENS

Specimens are obtained from outpatients in closed cubicles.

Every reasonable precaution is taken to preserve confidentiality.

AUTHOR	VERSION	APPROVED BY	DATE	