

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA v.2.0

## 9. POST-ANALYTICAL PHASE

### 9.7. CONFIDENTIALITY

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

<b>CODE) DOCUMENT: QMM09</b>	(CHAPTER TITLE): <b>POST-ANALYTICAL PHASE</b>	(INSTITUTION): <b>EC4 UNIVERSITY HOSPITAL</b>
(CODE) <b>SECTION: QMM09-S07</b>		<b>EC4 CLINICAL CHEMISTRY DEPARTMENT</b>
(DATE): <b>21/10/01</b>	(SECTION TITLE): <b>CONFIDENTIALITY</b>	
<b>PAGE 2 OF 6</b>		

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. CONFIDENTIALITY

- 2.1. ARCHIVES AND COMPUTER FILES
- 2.2. TRANSMISSION
- 2.3. ACCESS RESPONSIBILITY

3. RESPONSIBILITIES ON "CONFIDENTIALITY OF RESULTS"

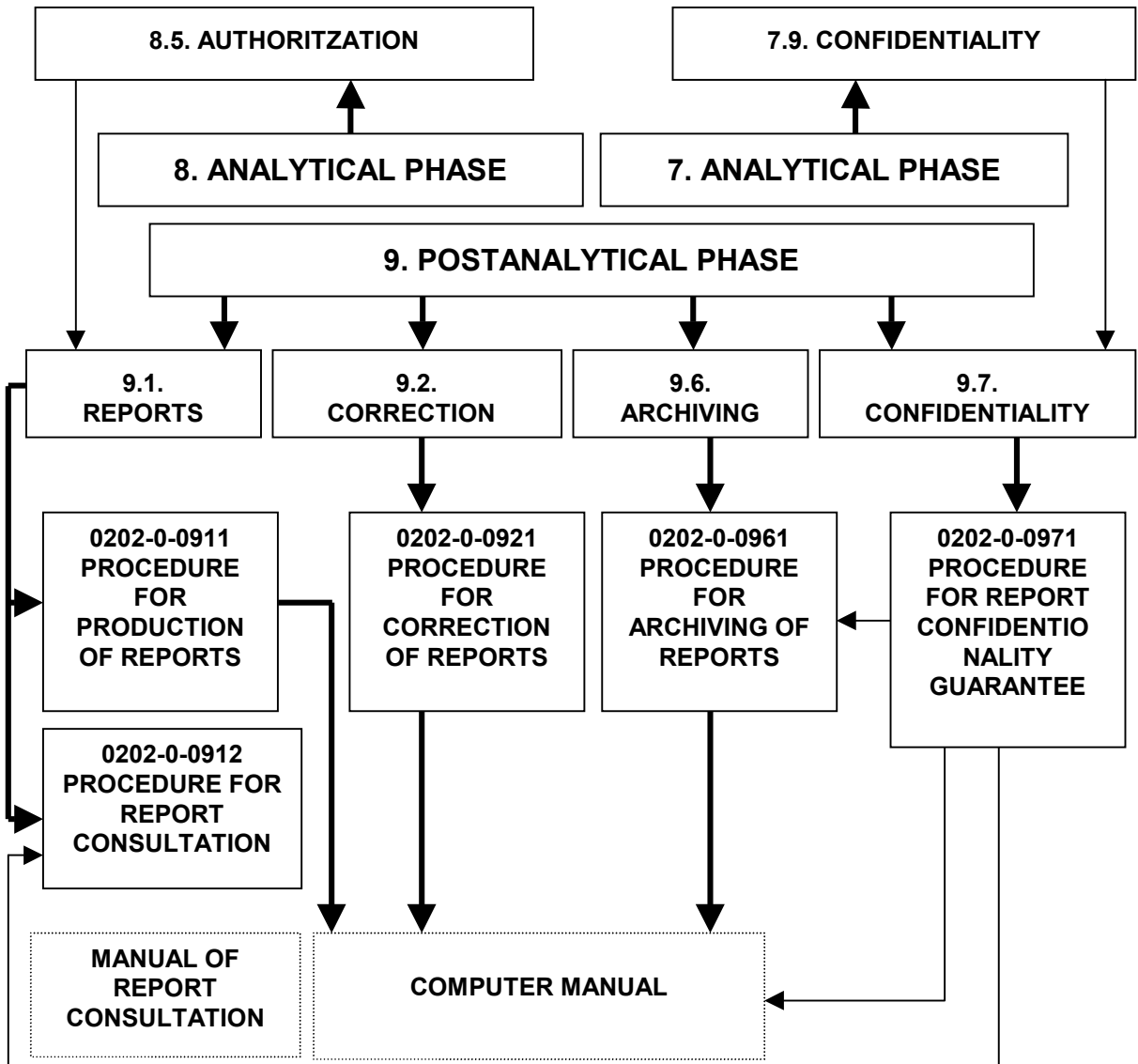
4. DOCUMENT MANAGEMENT

5. REVIEW OF DOCUMENTS

AUTHOR	VERSION	APPROVED BY	DATE	

## 1. INTRODUCTION (1)

There should be a procedure to ensure confidentiality of results (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. Organization and management. 4.1.4. 4.10. Quality and technical registers. 4.10.2 5.1. Personnel. 5.1.8. 5.8. Reporting results. 5.8.9. – 5.8.10. C.6. Report of results. C.6.1. – C.6.2.		

AUTHOR	VERSION	APPROVED BY	DATE

<b>CODE) DOCUMENT: QMM09</b>	<b>(CHAPTER TITLE): POST-ANALYTICAL PHASE</b>	<b>(INSTITUTION): EC4 UNIVERSITY HOSPITAL</b>
<b>(CODE) SECTION: QMM09-S07</b>		<b>EC4 CLINICAL CHEMISTRY DEPARTMENT</b>
<b>(DATE): 21/10/01</b>	<b>(SECTION TITLE): CONFIDENTIALITY</b>	
<b>PAGE 4 OF 6</b>		

### 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), 5.8.10., B.6.
3. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2<sup>nd</sup> rev. Ed. Utrecht: NVKC 1996.
4. Burnett D. Understanding accreditation in laboratory medicine. London: Association of Clinical Biochemists, 1996, 130-170-178.

### 1.5. RELATED DOCUMENTS

MQ 09-01. Post analytical phase. Reports.

MQ 09-06. Post analytical phase. Archives.

MPD 0202 0 0911 Procedure for production and edition of analytical reports

MPD 0202 0 0912 Consultation of analytical reports

Manual of analytical reports consultation

### 1.6. ABBREVIATIONS

**LIS:** Laboratory information system

### 1.7. RELATED DEFINITIONS

**document:** a piece of written or printed matter that provides a record or evidence of events.

**measurement** set of operations having the object of determining a value of a measurable quantity. NOTE: The terms method of measurement, measurement procedure, "test", "assay", measurable quantity, and result of measurement are not synonyms for measurement.

**result of a measurement:** value attributed to a measurand, obtained by measurement. NOTE 1: When the term result of a measurement is used, it should be made clear whether it refers to (a) the uncorrected result of a



measurement; (b) the corrected result of a measurement; (c) a single observation or an average of the values obtained by several observations. NOTE 2: A complete statement of the result of a measurement includes information about the uncertainty of measurement and about the values of relevant influence quantities.

AUTHOR	VERSION	APPROVED BY	DATE	

(INSTITUTION): <b>EC4 UNIVERSITY HOSPITAL</b>	(CHAPTER TITLE): <b>POST-ANALYTICAL PHASE</b>	(CODE) DOCUMENT: <b>QMM09</b>
<b>EC4 CLINICAL CHEMISTRY DEPARTMENT</b>	(SECTION TITLE): <b>CONFIDENTIALITY</b>	(CODE) SECTION: <b>QMM09-S07</b>
		(DATE): <b>21/10/01</b>
		<b>PAGE 5 OF 6</b>

## 2. CONFIDENTIALITY

The maintenance, transmission or access to all documents and computer files of the clinical Chemistry Department containing:

- (a) patient data
- (b) examination results
- (c) specimens of patients

are covered by a security system, which protects confidentiality in compliance with the Data Protection Act and the regulations from the parent institution.

This means that laboratory examination results can be attributed to an individual patient are confidential otherwise there is an specific authorisation.

### 2.1. ARCHIVES AND COMPUTER FILES

All patient data is kept in archive files or card files.

### 2.2. TRANSMISSION

It is ensured that confidential information on patients transmitted by fax or from one computer to another is sent to the correct location and that only the intended recipient will be able to access it. Both sender and recipient have been established arrangements to allow this.

There is a procedure (*MPD 0202 0 0911 Procedure for production and edition of analytival reports*) which contains the necessary details about who is authorized to send results and to whom. The procedure includes rules to send the results to the patient.

The transmission of results may be done by means of

- (a) printed paper. If it contains sensitive information, it is done within envelope marked "confidential";
- (b) electronic transmission. The LIS guarantees:
  - 1. the correct address;
  - 2. the access limited to the authorized persons;
  - 3. the purpose for it was requested
- (c) by telephone. In these cases, a register will be maintained, including:
  - 1. name of the clinician requesting the test result, (and department);
  - 2. date and time of the phone call;
  - 3. information trasmitted;
  - 4. reasons to transmit the results by phone;
  - 5. authorization by a member of the Clinical Chemistry Department staff.

As in the case of electronic transmsion, the identity of the recipient should be verified.

A printed report will follow as soon as possible any verbal communication.

Sensitive information will not be communicate orally.

### 2.3. ACCESS RESPONSIBILITY

Access to patient data held in a computer system is controlled by a password system, according the law and the rules of the parent Institution

The procedure *MPD 0202 0 0912 Consultation of analytical reports* and the *Manual of analytical reports consultation* contains detailed instructions for access to the computer system.

The primary responsibility lies with the sender and a key step is to establish that the receiving fax transreceiver is in safe.

### 2.4. ACCESS RESPONSIBILITY TO DATA FOR RESEARCH PURPOSES

Results which have been split from patient's identification can be used for epidemiological, demographic or statistical research. Access to these data is make according the *MPD 0202 0 0912 Consultation of analytical reports* and the rules of the parent institution.

AUTHOR	VERSION	APPROVED BY	DATE

<b>CODE) DOCUMENT: QMM09</b>	<b>(CHAPTER TITLE): POST-</b>	<b>(INSTITUTION): EC4 UNIVERSITY HOSPITAL</b>
<b>(CODE) SECTION: QMM09-S07</b>	<b>ANALYTICAL PHASE</b>	<b>EC4 CLINICAL CHEMISTRY DEPARTMENT</b>
<b>(DATE): 21/10/01</b>	<b>(SECTION TITLE): CONFIDENTIALITY</b>	
<b>PAGE 6 OF 6</b>		

### 3. RESPONSABILITIES ON “CONFIDENTIALITY OF RESULTS”

The Head of the Clinical Chemistry Department is the final responsible for the policy and procedures concerning the protection of confidential information.

The production, maintenance and revision of documents concerning the protection of confidential information is a duty of the Quality Officer.

### 4. DOCUMENT MANAGEMENT

Updated documents concerning the protection of confidential information are available in the document volume of the LIS. One copy is kept in the Quality System Files. Staff members of the Clinical Chemistry Department receive an update copy as soon as it is available.

### 5. REVIEW OF DOCUMENTS

documents concerning the protection of confidential information are revised at least annually.

AUTHOR	VERSION	APPROVED BY	DATE	