

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

# 1. GENERAL INFORMATION

## 1.7. SUBCONTRACTORS

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

(CODE) DOCUMENT: QMM01	(CHAPTER TITLE):	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
(CODE) SECTION: QMM01-S07	GENERAL INFORMATION	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 10/10/01	(SECTION TITLE):	
<b>PAGE 2 OF 4</b>	<b>SUBCONTRACTORS</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. LIST OF SUBCONTRACTORS

3. DETERMINATION OF COMPETENCE

4. REFERRAL ARRANGEMENTS

RECORD KEEPING

5. FINANCIAL ASPECTS

AUTHOR	VERSION	APPROVED BY	DATE	

(INSTITUTION): <b>EC4 UNIVERSITY HOSPITAL</b>	(CHAPTER TITLE):	(CODE) <b>DOCUMENT: QMM01</b>
<b>EC4 CLINICAL CHEMISTRY DEPARTMENT</b>	<b>GENERAL INFORMATION</b>	(CODE) <b>SECTION: QMM01-S07</b>
	(SECTION TITLE):	(DATE): <b>10/10/01</b>
	<b>SUBCONTRACTORS</b>	<b>PAGE 3 OF 4</b>

## 1. INTRODUCTION

### 1.1. SCOPE

There should be a list of activities performed by subcontractors, that is laboratories to which specialised or infrequently requested assays are sent (1)

Subcontractors should be known, recognised or accredited institutes or laboratories (1)

The Clinical Chemists decide whether tests are to be conducted in the laboratory or contracted out. The Clinical Chemists also select the institutions to which tests are to be contracted out, sometimes in consultation with the doctors or specialists making the service requests. (2)

### 1.2. AIMS

ISO 15189	ISO 9000: 2000	ISO 17025
4.4. Referral of examinations to other laboratories. 4.4.1. to 4.4.3.		4.5. Subcontracting of tests and calibrations. 4.5.1. to 4.5.5.
4.5. External services and supplies. 4.5.1. to 4.5.3.		
5.1. Personnel. 5.1.4. .(o).		
5.8. Reporting results. 5.8.9.		

### 1.3. PUBLICATION CREDITS

EC4 WG

### 1.4. REFERENCES

- 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.
- Jansen RTP, Bank CMC, Huisman W, Penders T.J. NVKC Model quality manual. 2<sup>nd</sup> rev. Ed. Utrecht: NVKC 1996.
- ISO/TC 212/WG 1. Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality management in the medical laboratory (December 1998), 4.4.1, 4.4.2., 4.4.3., 4.5.1., 4.5.2., 4.5.3., 5.1.4.(o), 5.8.9.
- Burnett D. Understanding accreditation in laboratory medicine. London: Association of Clinical Biochemists, 1996, 170-178.
- Plebani M. Sistema qualità de accreditamento nel laboratorio clinico (II). Aspetti applicativi. Milano: Biomedica, 1999.

### 1.5. RELATED DOCUMENTS

1.7.1. General Information. Subcontractors. List of subcontractors and tests available.

1.7.2. General Information. Subcontractors. Form to record subcontracted tests.

### 1.6. ABBREVIATIONS

**EQA:** External Quality Assurance

**LIS:** Laboratory Information System

**PAU:** Purchase Administrative Unit

### 1.7. RELATED DEFINITIONS

**reference measurement laboratory:** laboratory that performs reference measurement procedures and provides results with stated uncertainties (see: **subcontractor**)

**referral laboratory** laboratory organization to which a sample is submitted for an examination procedure and report (see: **subcontractor**).

**subcontractor:** laboratories to which specialised or infrequently requested assays are sent (see **reference measurement laboratory, referral laboratory**). **reference measurement laboratory**

AUTHOR	VERSION	APPROVED BY	DATE

(CODE) DOCUMENT: QMM01	(CHAPTER TITLE):	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
(CODE) SECTION: QMM01-S07	GENERAL INFORMATION	EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 10/10/01	(SECTION TITLE):	
<b>PAGE 4 OF 4</b>	<b>SUBCONTRACTORS</b>	

## 2. LIST OF SUBCONTRACTORS

The types of test which are contracted out and the institutions to which they are contracted out are listed in the appendix, under the heading "Name of the Laboratory" This list contains:

- Name of the laboratory
- Address, telephone number, fax number, email
- Contact person
- Competence
- Requested assays
- Specimen needed
- Quantity
- Transport requirements
- Any other valuable information.

## 3. DETERMINATION OF COMPETENCE

In almost all cases, the institutes to which tests are contracted out are reputable and preferably accredited organizations such as a number of university laboratories. The basis of such laboratories are selected are:

- The subcontracted institution proves that it is registered in an appropriate quality assurance system, or
- The subcontracted institution is the sole supplier of the particular assay, or
- The subcontracted institution proves its reliability without being in a quality assurance system

All laboratories to which tests are contracted out are known to have arrangements for the protection of confidentiality.

## 4. REFERRAL ARRANGEMENTS

Specified in the appendix 1.7.1. *General Information. Subcontractors. List of subcontractors* are the type and quantity of material needed for each type of test and the conditions under which the sample is to be obtained and transported.

Consignments of materials sent elsewhere for testing are accompanied by the appropriate documentation for the external laboratory. 1.7.1. *General Information. Subcontractors. Form to record subcontracted tests.*

Up-to-date copies of the documents that must be used to instruct the most frequently used external laboratories are kept in the Administration Area and completed by Administrative Officers.

Service users always have to submit their initial requests using the internal laboratory's own request forms, not the documents for the external laboratories.

## 5. RECORD KEEPING

A daily record is kept of all research that is contracted out.

The daily lists are filed in the laboratory's Administration Area.

On receipt, results are noted on the same lists and the turnaround times checked.

The results of completed tests are either entered in the Laboratory Information System (LIS) by the Administrative Officers or signed and, if appropriate, annotated by a Clinical Chemist, then forwarded to the service user.

## 6. FINANCIAL ASPECTS

The Purchase Administration Unit (PAU) handles the financial administration associated with contracted-out tests.

AUTHOR	VERSION	APPROVED BY	DATE	