

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

6. EQUIPMENT, MATERIALS AND REAGENTS

6.4. INSTRUCTIONS FOR USE AND MAINTENANCE

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

CODE) DOCUMENT: QMM06	(CHAPTER TITLE): EQUIPMENT, MATERIAL AND REAGENTS	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
(CODE) SECTION: QMM06-S04		EC4 CLINICAL CHEMISTRY DEPARTMENT
(DATE): 21/10/01	(SECTION TITLE): INSTRUCTIONS FOR USE AND MAINTENANCE	
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(INSTITUTION): EC4 UNIVERSITY HOSPITAL	(CHAPTER TITLE): EQUIPMENT, MATERIAL AND REAGENTS	(CODE) DOCUMENT: QMM06
EC4 CLINICAL CHEMISTRY DEPARTMENT	(SECTION TITLE): INSTRUCTIONS FOR USE AND MAINTENANCE	(CODE) SECTION: QMM06-S04
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1. INTRODUCTION

There should be procedures describing the use and operation of instruments.

There should be procedures for periodic maintenance.

There should be logbooks for all major equipment in which maintenance and trouble shooting should be recorded.

Diagnostic testing equipment outside the laboratory (e. g. near patient or point of care testing) should be ordered, operated, maintained and controlled according to procedures from the laboratory.

1.3. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
5.3. Laboratory equipment. 5.3.6., 5.3.7., 5.3.8., 5.3.10., 5.3.12. A.8.	7.5. Product and service operations. 7.5.1. Operations control	5.5. Equipment. 5.5.3., 5.5.6., 5.5.7., 5.5.8., Note 5.5.10.

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

- 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.
- International Organization for Standardization. ISO/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality management in the medical laboratory (December 1998). 5.3.6., 5.3.7., 5.3.8., 5.3.10., 5.3.12., A.8.
- ISO/DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000. 7.5.1.
- ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998. 5.5.3., 5.5.6., 5.5.7., 5.5.8., Note 5.5.10.
- Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.
- Burnett D. Understanding accreditation in laboratory medicine. London: Association of Clinical Biochemists, 1996, 133-137.

1.5. RELATED DOCUMENTS

- Equipment, materials and reagents. 6.1. Administration of equipment.
- Equipment, materials and reagents. 6.2. Purchasing of equipment.
- Equipment, materials and reagents. 6.3. Calibration.
- Equipment, materials and reagents. 6.5. Computer facilities.
- Equipment, materials and reagents. 6.6. Administration of materials and reagents.
- Equipment, materials and reagents. 6.7. Safety and environment.
- ??? Procedures describing the use and operation of instruments.
- ??? Procedures for periodic maintenance
- ??? Logbooks for all major equipment.

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

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2. INSTRUCTIONS

According to the published recommendations the user manual should contain the following items:

1. General introduction	
2. Identification	
3. Precautionary measures and warnings	
4. Symbols	
5. Installation	General
	Action upon delivery
	Preparation prior to installation
	Bringing into operation
6. Theory	
7. Functions	
8. Performance criteria and limitations	
9. Operating procedure	Preparation, including calibration
	Measuring procedure
	Presentation of data
	Shut down procedure
	Emergency analysis
	Internal quality control
	Special functions
	Disposal instructions
10. Maintenance	(Including decontamination)
11. Troubleshooting	
12. Technical specification	
13. Supplementary information	General
	Brief operating instructions
	Lists of uses and applications
	Warranty limitations
	Ordering information
	Possibilities of extension
	Assistance
	Supplementary theoretical information

3. PERFORMANCE OF AND RESPONSIBILITY FOR MAINTENANCE

3.1. MAINTENANCE CONTRACTS

Maintenance contracts details are kept in a separate record sheet.

3.2. DAY-TO-DAY MAINTENANCE

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Day-to-day maintenance is performed in accordance with the standard operating procedures by the Laboratory Technicians, who are answerable to the Departmental Managers.

3.3. PERIODIC MAINTENANCE

Periodic maintenance is performed by the Departmental Managers, service contractors and staff from the parent institution's Technical Department.

Periodic maintenance frequencies are specified in the standard operating procedures.

The standard operating procedures give due attention to the risk management aspects of equipment maintenance (e.g. disinfection and electrical safety during assembly and disassembly).

4. MAINTENANCE LOGBOOKS

A logbook, in which all preventive maintenance work is recorded, is kept with each item of equipment.

Records of service visits (scheduled or unscheduled) are kept in a separate record sheet

Maintenance service form				
IDENTIFICATION:			MANUFACTURER:	
DESCRIPTION / NAME:			SERIAL NUMBER:	
DATE	DAMAGE / MALFUNCTION / MODIFICATION / REPAIR	OPERATOR	AUTHORISATION	ANNEXES
When the maintenance was done	What was done	who did the work	who approved the maintenance action	Documents or copies if these documents can end up in the accounting department

The log-book is located near the instrument.

5. SPARE PART STOCKS

The Departmental Managers and the Technical Department together maintain a separate record of spare part stocks, which is kept in the Laboratory Equipment and Resources file.

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