

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

5. PREMISES AND ENVIRONMENT

5.6. PROVISIONS FOR WORKING ENVIRONMENT

AUTHOR	VERSION	APPROVED BY	DATE	

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1. INTRODUCTION

There should be adequate provisions for temperature control, power supply and lighting (with back-up facilities in case of power failure), ventilation, water and gases.

1.1. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
5.2. Accommodation and environmental conditions. 5.2.4., 5.2.5., 5.2.8. and 5.2.11.	6. Management of the resources. 6.4. Working environment.	5.3. Accommodation and environmental conditions. 5.3.1. and 5.3.2.

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. Page. 126, 4.4.
- ISO/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality Management in the Medical Laboratory (December 1998. 5.2.4., 5.2.5., 5.2.8., 5.2.11.
- ISO.DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000; 6.4.
- ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998. 5.3.1., 5.3.2.
- 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. Chapter 7. Facilities and equipment. Association of Clinical Biochemists: London. 1996; 129-130.

1.5. RELATED DOCUMENTS

Safety Manual

Technical Ground-plan

1.6. ABBREVIATIONS

LIS: Laboratory Information System

1.7. RELATED DEFINITIONS

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2. TEMPERATURE CONTROL

The Clinical Chemistry Department provides environmental conditions for staff in order to the proper performance of their respective duties. Accordingly, all rooms in the Clinical Chemistry Department are air-conditioned.

The Hospital Maintenance Department serves maintenance of air-conditioned devices. This Department (Phone number: #####) should be contacted immediately when a system down is detected.

3. VENTILATION

Organic solvents and volatile compounds are handled in a restricted area, according the Safety Manual.

The Technical Ground-plot of the laboratory contains all the ventilation points available.

4. POWER SUPPLY

The Technical Ground-plot of the laboratory contains a detailed map of the available power lines, plugs etc.

The Hospital Maintenance Department (Phone number: #####) has the responsibility of power maintenance (including lighting)

4.1. PROCEDURES IN CASE OF POWER FAILURE

In case of power failure, the Hospital Maintenance Department (Phone number: #####) should be contacted immediately.

The Operational Standard Procedures for each instrument from the Department of Clinical Chemistry contains the specific directions for stopping, saving or re-initiate ongoing work.

4.2. BACK-UP FACILITIES IN CASE OF POWER FAILURE

The following instruments are connected to a power-failure proof system:

- Abbott Axysm®
- Roche Modular Analyser®
- LIS

The LIS Manual contains detailed instructions to follow in case of power failure.

5. WATER

The Technical Ground-plot of the laboratory contains a detailed map of the available water taps available.

The Hospital Maintenance Department (Phone number: #####) has the responsibility of water supply maintenance.

In case of interruption or any problem with of water supply, contact immediately the Hospital Maintenance Department (Phone number: #####).

6. GASES. SUPPLIES

The Technical Ground-plot of the laboratory contains a detailed map of the available gas connections and gas supply available.

The Safety Manual contains detailed instructions with reference to handling analytical gases.

The GGGG Company (Phone number: #####), supplies gases. GGGG Co. has also the responsibility of gas tubing maintenance

7. CLEANING

Regular cleaning and disinfecting protocols are employed and the laboratory environment is microbiologically monitored at least once a year.

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If at any time the results of environmental monitoring are found to be unacceptable, appropriate investigation and action is taken according to the Hospital Safety Procedures.

There are Standard Procedures pertaining to cleaning, disinfecting and environmental monitoring of the Clinical Chemistry Department, according to the Safety Manual.

8. HOUSEKEEPING

Staffs maintain good housekeeping throughout the laboratory at all times.

The Laboratory Supervisor has the responsibility to keep the environment clean and tidy.

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