

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

## 3. ORGANIZATION AND MANAGEMENT

### 3.5. PROFESSIONAL STAFF AND OTHER STAFFING

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CIRCULATION LIST:	NAME	POSITION

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## 1. INTRODUCTION

The professional staff should include appropriate numbers of recognized laboratory specialists, registered at national and European level (e. g. the EC4 Euro Register).

The staff should have defined individual responsibility for consultation, choice of methodology and quality of assays.

There should be a quality officer (e. g. chief-technician) responsible for the maintenance of the quality system and manual, reporting directly to the head of the department.

There should be a safety advisor.

There should be appropriate members of staff with the required training to insure a satisfactory operation of service.

Regular staff meetings should be held to review the organization of services. All staff of varying levels should be involved. Records should be kept and actions audited.

Regular staff meetings should be held to review technical and research aspects. Records should be kept and actions audited.

### 1.1. SCOPE

This document applies to all laboratory areas

### 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. (f), (g). 5.1. Personnel. 5.1.1. to 5.1.6. 5.1. Personnel. 5.1.4. .(i),	5. Management responsibility. 5.1. Management commitment 5.5. Management. 5.5.3. Management deputy 6. Management of the resources. 6.1. Provision of resources.; 6.3. Premises	4.1. Organisation and management.

### 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. 4.1.3. (f), (g).
- 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. (f), (g)., 5.1.1., 5.1.2., 5.1.3., 5.1.4., 5.1.4. .(i), 5.1.5., 5.1.6.
- ISO.DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000; 5.1., 5.5.3., 6.1., 6.3.
- ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998. 4.1.4.(a), (i), (j).
- Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2<sup>nd</sup> rev. ed. Utrecht: NVKC 1996.
- Burnett D. Understanding accreditation in laboratory medicine. London: Association of Clinical Biochemists, 1996, 96-101.

### 1.5. RELATED DOCUMENTS

3.5.1. Clinical Chemist: Job Description

3.5.2. Quality Officer: Job Description

4. Personnel

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## 1.6. ABBREVIATIONS

<b>CC</b>	Clinical Chemist
<b>HHS&amp;EM</b>	Hygiene, Health, Safety and Environmental Management
<b>NVKC</b>	Neederlandse Vereniging voor Klinische Association
<b>QHS&amp;E</b>	Quality, Health, Safety and the Environment
<b>QO</b>	Quality Officer
<b>SCC</b>	Senior Clinical Chemist

## 1.7. RELATED DEFINITIONS

**clinical laboratory (medical laboratory):** a room or building (space) fitted out for scientific examinations (testing) of materials taken from patients for the purposes of diagnosis and treatment.

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

**examination:** activity leading to a value on a nominal, ordinal, difference, or ratio scale. NOTE In some countries and disciplines (e.g. microbiology) examination is the total activity of a number of tests.

**laboratory director:** the person who governs the policy of a laboratory. NOTE A specific person may be director of a number of similar or dissimilar institutions.

**laboratory management:** the collective body of those persons who manage the activities of the laboratory headed by the laboratory director.

**laboratory manager:** a person who carries out the administration of a laboratory in accordance with a policy. NOTE: The policy is usually prepared by the laboratory director in consultation with the laboratory manager.

**qualification:** accomplishments and academic awards necessary to fit a person for a position or purpose.

**quality:** totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

**quality assurance:** all the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality.

**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:** organizational structure, procedures, processes, and resources needed to implement quality management.

**sample:** one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for a decision on the system or its production. EXAMPLES: A volume of serum taken from a larger volume of serum; a simple random subset of measured values of a measurable quantity taken from a set of such values. NOTE 1: The single part forming a cohesive entity and taken from one place and at one time is also called a "sampling unit" or an "item". NOTE 2: Unless otherwise specified, the sample is assumed to be representative of a "static system", that is a system having no appreciable change in relevant measurable quantities during the time of consideration. NOTE 3: When a "dynamic system" is concerned, as is often the case in the clinical laboratory sciences, the calendar time of sampling is a mandatory item of specification to the system of interest. Such a special type of sample has been called a "**specimen**", but this term is not used here. The term specimen has also been used in laboratory medicine as a synonym for a sample, as defined here, of biological origin, or for an entire macroscopic parasite. NOTE 4: The system from which a sample is taken may not be of the same type as that of the measurand. EXAMPLE: A given blood sample may serve for measurement of pH in plasma and haemoglobin concentration) in erythrocytes. NOTE 5: The definition given above covers a sample from any type of system. ISO gives two definitions that apply more to data and materials respectively. (a) sample: One or more sampling units taken from a population and intended to provide information on the population; (b) sample: Representative quantity of material extracted from a batch of reference material). NOTE 6: In some countries the term specimen is used for primary sample (or a subsample of it) which is the sample prepared for sending to or as received by the laboratory and intended for measurement.

**specimen:** in some countries the term specimen is used for primary sample.

**test:** technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specific procedure. NOTE: In medical laboratories this is usually part of an examination (see: examination).

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## 2. LABORATORY SPECIALISTS

The professional staff include the following recognized laboratory specialists, in possession of the XXXXXX or an equivalent qualification, have fulfilled the ZZZZZ training requirements, and are registered at national and European level (e. g. the EC4 Euro Register).

## 3. PROFESSIONAL RESPONSABILITIES

The staff should have defined individual responsibility for consultation, choice of methodology and quality of assays.

## 4. QUALITY OFFICER

There should be a quality officer (e. g. chief-technician) responsible for the maintenance of the quality system and manual, reporting directly to the head of the department.

Management of the quality system, in particular the quality assurance and maintenance arrangements, is the duty of the Quality Officer. He or she is also responsible for management of the health, safety and environmental management system, in consultation with the Health and Safety Coordinator and the hospital's Environmental Coordinator, as well as with the HHS&EM Committee.

Ultimate responsibility in this area lies with one of the Clinical Chemists.

The Quality Officer has day-to-day responsibility for quality, health, safety and environmental management.

Details of the Quality Officer's role within the organization, the requirements of the post, his or her duties and contacts are given in the relevant job description in the Document 3.5.2. *Quality Officer: Job Description* (10)

## 5. SECURITY OFFICER

There should be a safety advisor.

The Quality Officer is also the Health, Safety and Environmental Management Officer.

## 6. OPERATION OF SERVICE

There should be appropriate members of staff with the required training to insure a satisfactory operation of service.

## 7. QUALITY MEETINGS

Regular staff meetings should be held to review the organization of services.

All staff of varying levels should be involved.

Records should be kept and actions audited.

## 8. STAFF MEETINGS: WORK DISCUSSION MEETINGS

Regular staff meetings should be held to review technical and research aspects. Records should be kept and actions audited.

All work discussion meetings are briefly minuted.

- Arrangements for liaison between the Clinical Chemists and external contacts (directors of the parent institution and service users) are described in section 3.4.
- Clinical Chemists' meetings The Clinical Chemists meet once a week to discuss professional and organizational matters; meetings are briefly minuted.
- Clinical Chemists - Laboratory Supervisor The Clinical Chemists meet the Laboratory Supervisor once a week to discuss organizational matters.
- Clinical Chemists - Section Managers All Section Managers, the Laboratory Supervisor, the Quality Officer and the Clinical Chemists meet once a week to discuss organizational matters. Individual Departmental Managers, the Quality Officer and the Clinical Chemist responsible for the relevant department meet every two weeks to discuss professional matters. Meetings are briefly minuted and decisions recorded in the Work Discussion Meetings file by the Quality Officer.

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- Clinical Chemists - Quality Officer. The Quality Officer and the Clinical Chemists meet once a month to discuss external quality assurance, changes to the manual and the performance of the QHS&E system. Meetings are briefly minuted and decisions recorded in the Work Discussion Meetings file by the Quality Officer.
- Clinical Chemists - Laboratory Technicians. The Clinical Chemists meet the Laboratory Technicians every two weeks to explain changes in organizational arrangements or standard operating procedures and to discuss other matters. Staff are notified in writing of any changes, which are also recorded in the Laboratory Organization file, which can be consulted at any time.
- Laboratory Supervisor - Laboratory Technicians. The Laboratory Supervisor meets the Laboratory Technicians every two months to discuss organizational matters. Meetings are briefly minuted and decisions recorded in the Work Discussion Meetings file by the Laboratory Supervisor.

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