

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

## 6. EQUIPMENT, MATERIALS AND REAGENTS

### 6.6. ADMINISTRATION OF MATERIALS AND REAGENTS

AUTHOR	VERSION	APPROVED BY	DATE	

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## 1. INTRODUCTION

There should be procedures for selecting reagents and materials.

There should be procedures for purchasing and ordering of reagents and materials.

The criteria of these should be established by the head of the laboratory.

There should be a procedure for assessment of suppliers (ISO certificate).

There should be procedures to ensure that reagents and materials are checked for condition upon delivery, that they are stored correctly (temperature and other conditions) and that they are used only before the expiry date.

There should be procedures to control inventory (minimum maximum stock).

Reagents and materials should be correctly identified and dated, including name of responsible organization or person, name, concentration, date of first use, date of expiry, danger/safety indication.

### 1.1. SCOPE

### 1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
4.5. External services and supplies. 4.5.1. to 4.5.3.		4.6. Purchasing services and supplies. 4.6.1. to 4.6.5.
5.3. Laboratory equipment. 5.3.1.		

### 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.
- ISO/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality management in the medical laboratory (December 1998). 4.5.1., 4.5.2., 4.5.3., 5.3.1.
- ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998. 4.6.1., 4.6.2., 4.6.3., 4.6.4., 4.6.5.
- Jansen RTP, Bank CMC, Huisman W, Penders T.J. NVKC Model quality manual. 2<sup>nd</sup> rev. Ed. Utrecht: NVKC 1996.

### 1.5. RELATED DOCUMENTS

??? Procedures for selecting reagents and materials.

??? Procedures for purchasing and ordering of reagents and materials

??? Procedure for assessment of suppliers

??? Procedures to ensure that reagents and materials are checked, stored and use.

??? Procedures to control inventory.

??? File: Storeroom Article Stocks

??? File: Material Safety Data Sheets.

??? Appendix: Environmental (Waste) Management Manual.

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## 1.6. ABBREVIATIONS

**PAU:** Purchase Administrative Unit  
**TD** Technical Department

## 1.7. RELATED DEFINITIONS

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## 2. ADMINISTRATION

### 2.1. GENERAL

All administrative data on the reagents, chemicals, supplies and consumable goods is entered into the computerized Purchase Control System.

Reagents, chemicals, supplies and consumable goods are used in accordance with the relevant standard operating procedures, which are formulated to take full account of the safety and environmental issues associated with the items and substances in question.

The quality of reagents, chemicals, supplies and consumable goods is checked during the course of their use.

Administrative processing is then undertaken by the Purchase Administration Unit (PAU).

Staff are subsequently instructed in the use of the item in question by the relevant Departmental Manager, and the Quality Officer draws up a standard operating procedure.

### 2.2. HAZARDOUS SUBSTANCES

Material safety data sheets (provided by the suppliers) for all hazardous substances are kept in the *Material Safety Data Sheets* file.

Information regarding the purchase and storage of hazardous substances is also retained in the *Material Safety Data Sheets* file.

Hazardous substances are disposed of in the manner described in the document *Environmental (Waste) Management Manual: dealing with laboratory waste*.

Hazardous reagents, chemicals, supplies and consumable goods bear appropriate warnings applied by the suppliers. Radioactive material is stored in the Isotope Laboratory. Other products bearing hazard warnings are stored in special cupboards.

Stocks are held in the so-called "liquid park": a closed, brick building in the hospital complex.

### 2.3. PRODUCTS FROM THE BLOOD BANK

On arrival in the laboratory, blood products from the Blood Bank are immediately booked into the computer system by the Blood Transfusion Department Manager or, in his absence, by the Laboratory Technician on duty.

Storeroom staffs maintain a computerized record of the goods supplied to the laboratory by the storeroom, from which listings are produced. These listings are retained in the Storeroom Article Stocks file, a copy of which is held by the Laboratory Supervisor. To facilitate budgetary checks, the same data is also held in the laboratory's computerized Purchase Control System.

## 3. IDENTIFICATION

Incoming reagents, chemicals, supplies and consumable goods are booked into the computerized Purchase Control System by the Laboratory Supervisor.

A seven-figure article code, which can be reproduced as a bar code, is assigned to each storeroom article by central storeroom staff.

Blood products supplied by the Blood Bank are booked into the computerized Blood Transfusion System.

## 4. RECEIPT AND INSPECTION

Following delivery to the central storeroom, durable goods are transported to the laboratory, where they are unpacked, installed and identified, all under the supervision of Technical Department (TD) staff.

Reagents, chemicals, supplies and consumable goods are delivered to the central storeroom.

Where appropriate (e.g. where items with a short shelf life are concerned), such deliveries are immediately transported to the laboratory by storeroom staff.

The Laboratory Supervisor receives the products and checks the accompanying documentation.

### 4.1. RADIOACTIVE REAGENTS

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Radioactive reagents are taken directly to the Isotope Laboratory by the delivering party, where they are received by the Isotope Laboratory Manager; the Laboratory Supervisor checks the accompanying documentation.

#### 4.2. BLOOD BANK PRODUCTS

Blood products from the Blood Bank are received and the accompanying documentation checked by the Blood Transfusion Department Manager or, in his absence, by the Laboratory Technician on duty.

#### 5. RELEASE

Reagents, chemicals, supplies and consumable goods are released by the Laboratory Supervisor, radioactive reagents by the Binding Analysis Department Manager and blood products by the Blood Transfusion Department Manager or, in his absence, the Laboratory Technician on duty.

#### 6. STORAGE AND STOCK CONTROL

##### 6.1. GENERAL

The Laboratory Supervisor stores reagents, chemicals, supplies and consumable goods in the appointed places.

The Laboratory Supervisor using the computerized Purchase Control System controls stocks of reagents, chemicals, supplies, consumable goods and the like.

##### 6.2. BLOOD BANK PRODUCTS

Blood products are stored in a special refrigerator by the Blood Transfusion Department Manager or, in his absence, by the Laboratory Technician on duty.

The Blood Transfusion Department Manager controls stocks of blood products; each time an order for blood products is placed, sufficient quantities are ordered to restore stock levels to the maximum.

##### 6.3. RADIOACTIVE MATERIAL

Upon receipt, radioactive reagents are immediately stored in the Isotope Laboratory's decay area.

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