6. EQUIPMENT, MATERIALS AND REAGENTS

6.2. PURCHASING OF EQUIPMENT
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1. INTRODUCTION

There should be a procedure for specification of requirements.
There should be a procedure for validation of performance against specified requirements.
There should be a procedure for assessment of suppliers (ISO certificate) including training, documentation and service.
The head of the laboratory should establish the criteria for selection of equipment.

1.1. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

<table>
<thead>
<tr>
<th>ISO 15189</th>
<th>ISO 9000: 2000</th>
<th>ISO 17025</th>
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<td>4.5. External services and supplies. 4.5.1. and 4.5.2.</td>
<td>7. Product production. 7.4. Purchasing</td>
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1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES


1.5. RELATED DOCUMENTS

6. Equipment, materials and reagents. 6.4. Instructions for use and maintenance.
6. Equipment, materials and reagents. 6.6. Administration of materials and reagents.
6. Equipment, materials and reagents. 6.7. Safety and environment.
??? Procedure for specification of requirements
??? Procedure for validation of performance against specified requirements.
??? Procedure for assessment of suppliers including training, documentation and service
??? File: Suppliers
Appendix: Ordering and requisitioning procedures.

Protocol: Ordering blood products

1.6. ABBREVIATIONS

1.7. RELATED DEFINITIONS

durable goods: laboratory equipment such as machines, apparatus and inspection and measuring devices, as well as resources such as refrigerators, centrifuges, water baths, mixers, stoves and freeze-dryers.
2. GENERAL
The budget made available to the laboratory by the parent institution's directors is used for various purposes including the purchase of durable goods, reagents, chemicals, supplies, consumable goods and storage goods, as well as obtaining services from external organizations. Approval from the directors is ultimately necessary for the purchase of durable goods.

All orders placed by the laboratory go via the Financial Administration Service's Purchasing Department, directly to the supplier or via the parent institution's central storeroom.

The laboratory selects its own suppliers and deliveries are made directly to the laboratory or to the parent institution's Central storeroom, depending on the nature of the goods.

General supplies such as gas, electricity, water and laboratory clothing are the responsibility of the parent institution's directors.

Following delivery, externally sourced goods are transported to the laboratory by the Building Management Service. The Financial Administration Service's Purchasing Department carries out the administrative and financial processing tasks associated with externally sourced goods and services.

3. PERFORMANCE
Goods are selected partly on the basis of safety and, where relevant, ergonomic quality.
Where possible, preference is given to environmentally friendly reagents and consumable goods.

4. SUPPLIERS
All durable goods are normally purchased from approved suppliers capable of providing after-sales service.
Most reagents, chemicals, supplies and consumable goods are obtained from approved suppliers.
A full list of approved suppliers is kept in the Suppliers file.

4.1. SUPPLIERS REQUIREMENTS
Suppliers must meet the following requirements:
- Continuity of production, support and maintenance must be guaranteed as far as possible.
- Demonstrable attention must be paid to safety and environmental matters.
- The supplier must possess expertise in relation to the products supplied and must be willing to pass on information wherever appropriate.
- Where relevant, the supplier must be willing to agree customized maintenance contracts with the laboratory, supported by the Technical Department.
- Where relevant, training in the maintenance and use of the goods must be available.
- The supplier must have a proper procedure for handling complaints.
- Goods must be of a consistent quality.
- Orders must be fulfilled on time.
- Customer-supplier contact must be of a satisfactory nature.
- The supplier must endeavor to comply with the European Union's IVD directive.

Purchase of general-purpose goods such as foodstuffs and domestic, office and nursing supplies is arranged by the central Purchasing Department; purchase of goods specifically for laboratory use is arranged by the Laboratory Supervisor.

5. ORDERING PROCEDURES. BUDGETING
Preliminary selection of durable goods is made on the basis of manufacturers’ information, other publications and literature, trials, shows, discussions with suppliers’ representatives and with fellow clinical chemists, following which the selected items are included in the draft capital expenditure budget.

The Medical Budget Committee considers the proposals contained in the draft budget. Proposals for the purchase of general purpose equipment are drawn up in consultation with the Financial Administration Service Manager.

Similarly, proposals for the purchase of computer equipment are drawn up in consultation with the hospital’s Computer Systems Manager.

If the Medical Budget Committee approves a capital expenditure item, the Clinical Chemist uses an order form to order the goods in question via the Financial Administration Service's Purchasing Department.

In addition to the capital expenditure budget for the coming year, a budgetary forecast is made covering a period of five years ahead.

The Senior Clinical Chemist also draws up a draft budget for the purchase of reagents, chemicals, supplies and consumable goods, on the basis of quantitative estimates made by the Departmental Managers using minimum-maximum stock figures.

This budget is subject to approval by the Medical Budget Committee.

Following approval, the Laboratory Supervisor orders the goods directly from the suppliers or requisitions them from the central storeroom, using the computerized.

6. PURCHASE CONTROL SYSTEM.

The procedures for selecting durable goods and for ordering and requisitioning durable and non-durable goods are contained in the appendix "Ordering and requisitioning procedures".

Blood products are ordered from the Blood Bank by fax or telephone by the Hematology Department Manager or, outside office hours, by the Laboratory Technician on duty, in accordance with the protocol "Ordering blood products".

7. ORDER SPECIFICATIONS

Order specifications for durable goods are drawn up by the Clinical Chemists and Laboratory Supervisor, with technical advice from the Technical Department.

The Departmental Managers are responsible for the accuracy of order specifications relating to reagents, chemicals, supplies and consumable goods.

Reagents and chemicals not previously used in the laboratory are ordered by the Clinical Chemists.

Order specifications relating to general-purpose goods are drawn up by central Purchasing Department staff; those relating to goods specifically for use in the laboratory are drawn up by the Clinical Chemists, giving due regard to environmental considerations and in accordance with all relevant guidelines, statutory requirements and regulations.