1.0 Policy Statement

The Rotunda Hospital aims to achieve best value for money in all its procurement actions in conjunction with National Legislation and EU Guidelines without compromising the needs of the hospital, staff and its patients.

Purpose

The purpose of the Purchasing and Procurement Policy is to outline clear and accurate procedures and guidelines of the Procurement functions within The Rotunda Hospital.

2.0 Definitions

2.1 Definition of a Medical Device

A medical device is generally described as any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in, or on the human body by pharmacological, Immunological or Metabolic means, but which may be assisted in its function by such means.

Definition of Reusable Invasive Medical Device - RIMD

Any Medical Device as defined above which can be reused after appropriate procedures have been applied to clean, disinfect and sterilise (free from live bacteria or other micro-organisms and their spores).

2.2 The CE Mark

The CE Mark is the public representation of the manufacturer's claim that his device satisfies the relevant Essential Requirements in the Directives is fit for its intended purpose and, where required, has been independently assessed by a Notified Body.

Medical Devices bearing the CE Mark can be freely marketed anywhere in the EU without further control.

All devices, covered by the scope of the relevant directive, should bear the CE Mark when received in the hospital. There are no exemptions.

2.3 Definition of Capital Expenditure

Capital expenditure generally includes any expenditure incurred on Additions, Replacements, Extensions or Improvements to items such as Medical Equipment, Instruments, Buildings, Land, Plant and Machinery, General

Equipment, Computers, Road Vehicles, etc. that are generally bought for long term requirements costing in excess of €5,000 as per HSE Procurement Policy.

2.4 Purchasing & Procurement

This is the term universally used and understood to encompass all the tasks, functions, activities and routines which concern the procurement of external materials (supplies) and services for the hospital and the administration of same until they are used.
In other words, it is the discipline, which integrates Requisitioning, Purchasing, Storage, Stock Management & Control, and Distribution & Use.

2.5 Stock item

A product is generally considered a stock item for the following reasons:
It is held within the Central Stores/Sterile Stores for regular issue
It is frequently used by an individual department
It is held on a shelf location within their department
It is identifiable for requisitioning on their department specific stock sheet
It is used by multiple Wards/Departments.

2.6 Non-Stock Item

A product is generally considered non-stock for the following reasons:
it is required only occasionally
it would be uneconomical to hold in stock (high cost etc.)
it is a once off purchase
it would have a short shelf life
the purchase order may stipulate that the supplier must deliver directly to user, e.g. Fresh Produce, X-Ray film, etc…
it is ordered for one department only and issued immediately upon receipt.

2.7 Location Code

A location code is the exact location identifier (bin or shelf number) for the place of storage of an item in the Central/Sterile Stores. Not currently used in The Rotunda because of space constraints.

2.8 Product Code

A product code is a unique hospital number given to each product for identification, ordering and cost purposes.

2.9 Unit of Measure (UOM)

The unit of measure (UOM) is the agreed minimum unit of a product that can be purchased or issued on request, and all items will be purchased or issued in multiples of the unit of measure.

2.10 Stock Level (Maximum-Minimum)

Maximum Stock levels are the agreed amounts of each stock item to be stored in agreement with stock management. The quantity stored should never rise above the maximum stock level set for the stock item.

Minimum Stock Levels are the agreed amounts items are allowed to reduce to, before re-ordering back to maximum levels.

2.11 Specifications – (the most detailed description of an item).

Once a requirement or need for a product has been established, it is usual to provide a comprehensive description (or specification) of the item to prospective suppliers.

2.12 New, Replacement and Additional items

A new item is a consumable item or equipment that is not currently purchased or used in the hospital. It may or may not have been used in previous years, or be set up on the hospital's supplies system.

A replacement item is a consumable item or equipment that is required to directly replace a similar item which may be currently used or out of service.

An additional item may be an increase of quantity for regularly used products, or extra sizes of a current type used, or additional equipment to carry out a particular function, etc.

2.13 Definition of Medicinal Product.

Under Council Directive 65/65/EEC, the term Medicinal Product is defined as:

Any Substance or combination of substances presented for treating or preventing disease in human beings or animals.

Any substance or combination of substances, which may be administered to human beings with a view to making a medical diagnosis or restoring, correcting or modifying physiological functions in human beings or in animals is likely to be considered a medicinal product.

2.14 Medical Care Equipment

Any item of equipment used for delivery of care to the patient (e.g. Diagnostic Equipment, Reusable Invasive Medical Device) or with which the patient may come in contact (e.g. Wheelchair, Commode, Furniture or fixtures used in clinical areas).

3.0 Scope of Policy

The Purchasing and Procurement Policy refers to the procurement of all supplies and services in The Rotunda Hospital and applies to all staff working within this function. All Rotunda Hospital employees have a responsibility to be aware of the procedures within this policy that have a direct impact on the requisitioning, issuing, receiving and returning of hospital products, equipment and services. All Suppliers and Contractors to The Rotunda Hospital must adhere to the procedures referring to the delivery, collection and introduction of products, equipment and services to the hospital.

4.0 The Rotunda Hospital Purchasing Aims and Objectives

4.1. Aims and Objectives of Hospital Purchasing

- The Hospital will purchase on the best terms available from the most suitable supplier.
- Its purchasing actions will reflect its position as a leading and respected institution in the Irish Health Care sector.
- Its aim is to achieve Value for Money whilst meeting the needs of the hospital and dealing with suppliers and potential suppliers in an equitable manner.

4.2 Supplier Selection

- The Hospital has a responsibility to its patients and service providers to find the best supplier for each and every one of its requirements. The supplier selected will be the one who offers best overall value.
- It is the policy of the Hospital to obtain greater efficiency, by reducing the numbers of suppliers providing service to an acceptable level.
- The general criteria, which will be considered for supplier selection, are Quality, Price, Terms, Delivery and Service together with actual historical performance on previous orders and adherence to life cycle cost and environmental disposal.
- Hospital staff will do everything possible to protect the reputation and standing of the Hospital. Any action, which is likely to compromise the Hospital or detract from its reputation in any way, will be avoided.

4.3 Value for Money

- The Hospital staff will endeavour to secure value for money in all of its purchasing actions.
- It is expected that staff will use all available means to obtain Value for Money including the use of Open, Fair and Competitive tendering, Negotiation, and aggregating hospital requirements where possible.

- In obtaining Value for Money the Hospital will ensure the requirements of National legislation and E.U. Directives are fully complied with.

4.4 Payment

- The Hospital believes in paying its suppliers and contractors promptly and staff will ensure compliance with the Prompt Payment of Accounts Act, 1997.

- The Hospital believes that contractors should pay their suppliers promptly, and their performance in this should be taken into account when contractors are being selected.

4.5 Purchasing & Supply Arrangements

- Good Purchasing & Supply arrangements should focus on Minimum Total Cost to the Hospital, rather than simply on price.

  In this respect Hospital staff will do all they can to minimise stock levels.

- Just in time approaches to purchasing are not always suitable for Hospital requirements, but staff will make use of techniques designed to minimise stock levels such as: planned deliveries, supplier stockholding and consignment stock, where these provide the least Cost Option, while ensuring proper service levels are maintained.

- The Hospital will at all times consider any recognised procurement and best commercial practices which may or can assist in lowering the overall cost of orders placed such as Purchase Cards, Blanket/Call-off Orders, Standing Orders, Consignment Stock, E-commerce/EDI etc.

4.5 Purchasing Documentation

- All commitments entered into by the hospital should have the following minimum documentation.

  (a) Relevant evaluation and tendering documents where appropriate.
  (b) Signed Contract or Order.

5.0 AUTHORITY LEVELS

5.1. Authority levels for purchase of goods or services from external suppliers

All Purchase Orders for relevant goods and services must be placed by the Materials Management department, with the exception of goods and services in relation to the following specific areas:

Laboratory supplies – Laboratory Manager
IT software, hardware and service contracts – IT Manager
Catering food supplies - Catering Manager
Technical Services and general maintenance – Support Services Manager
Non clinical support services – Support Services Manager
Pharmacy – Chief Pharmacist
HR services - HR Manager

The above mentioned departments are authorised to purchase goods or services which pertain to their own area of expertise only and within agreed limits and signing protocols as approved by the Secretary / General Manager and Financial Controller. All other purchases not specific to their area of expertise and any new or replacement equipment must be purchased through the Materials Management department in the manner detailed in this policy. New or financially significant purchases of goods or services must be evaluated and approved in advance by Hospital Procurement Management Group as outline in section 5.9 (Forms attached –Appendix 1 & 2)

Additionally, any proposed refurbishment or fit out of premises must be approved in advance by the Secretary / General Manager and procured by the Support Services Manager in the manner described in section 6.7 below.

Authority to engage external professional advisors must be approved in advance by the Secretary / General Manager, except in the case of legal advice. The hospital legal advisors have been appointed and authority to seek their advice is limited to the following staff, within budget constraints:

- Secretary / General Manager
- Master
- Director of Midwifery
- Financial Controller
- HR Manager
- General Services Manager
- Clinical Risk Manager
- Information Manager

No order shall be issued, or commitment entered into, for any item for which there is not financial provision in the authorised hospital budget, without the prior written approval of the Secretary / General Manager or Financial Controller. All required equipment must be validated and approved by the Infection and Prevention Control Team before being approved for purchase.

5.2 Authority levels for internal requisitioning of goods or services

With the exception of approved items which may be part of any top-up service, requests for all goods and services must be submitted on an official requisition form by the head of department or other designated officer, to the approved employees as listed in section 5.1 above.

Requests must be made in writing on the correct requisition documents issued for such goods, and in sufficient time for the procurement process to be carried out correctly. Because of the need to ensure all expenditure is kept within approved budget allocations it is essential that all requisitions submitted must be properly signed and authorised as follows:

Type of requisition	**Approval process**
Stock Replenishment items	Head of Department or designated deputy
Non stock items currently used	Head of Department or designated deputy
New or replacement equipment or goods, or financially significant change in practice	The Management Team approve based on evaluation by the Hospital Procurement Group (Section 6.4)
Refurbishment or fit out of premises	Subject to approval of The Property Committee a sub-committee of The Board
Service/Maintenance Contracts	Head of Department or designated deputy
Training, Courses, Travel	Head of Department or designated deputy
Service Calls, repairs	Head of Department or designated deputy

5.3. Budgetary approval

It is a general principle that all goods and services approved must have a budget allocation to meet the purchase. This will be evaluated and confirmed by The Hospital Procurement Group before progressing to order.

Therefore all requests for new goods and services must be within set budgets before an official purchase order is issued. Where a request is in excess of budgets available it must first have financial approval from the Financial Controller and / or the Executive Management Team.

5.4. Orders for Goods & Services

No goods or services, excepting purchases from petty cash and credit card, shall be ordered unless an Official Hospital Order Number is raised and issued.

5.5. Purchase Order Information

Official Orders raised should be complete with the following information:

The supplier name and address.
The date of order.
Full description, size, weight, measure unit and quantity of the item required.
The unit price, VAT, other charges, total costs and discounts.
The area/department where goods are to be delivered.
Delivery instructions.
Any Quotation or Contract Reference Number.
Any other information pertinent to the order.

5.6. Signing of Purchase Orders – Issuing Verbal Requests

Excepting Drugs and Pharmaceuticals, all official orders must be signed by an authorised officer from Purchasing & Procurement, or Office designated as per listing Section 5.1.

- Where verbal requests to supply goods or services are unavoidable, such as cases of emergency or urgent necessity, such verbal requests shall include the appropriate Official Order Number to the Supplier, and the Official Order bearing such number shall be completed forthwith and clearly marked: "Confirmation".

- In exceptional circumstances when it becomes necessary for an authorised member of hospital staff to request goods or services without an Official Order Number, (e.g. emergency or urgent need demanded by clinical necessity outside normal working hours) all details and supporting documentation for the request must be given to the Purchasing and Procurement Manager on the next working day after the request is made.

- Under no circumstance is it permissible for any member of hospital staff to request goods or services from any Supplier or outside crediting agency during normal working hours unless officially authorised as per section 5.1

5.7. Adding items or Amendments to a Purchase Order

- All additions or amendments to an official purchase order may only be made by the authorised officer who signed and issued the original order, or in his/her absence, by the Purchasing and Procurement Manager or other Purchasing Officer/Supplies Officer instructed by him.

- Under no circumstances may any member of hospital staff add to, delete, amend or alter in any way, any official order issued, or communicate any such alterations, deletions or changes to an order directly to any supplier.

A breach of this policy will be considered as gross misconduct

5.8. Contacting Suppliers

- Hospital staff are not permitted to give Order Commitments directly to a supplier. These must be channelled through, and placed by an authorised Purchasing Official. Exceptions to this will only be as outlined under section 5.7.
- All requests for Quotations, Price Lists, etc. must be issued to suppliers by the Purchasing & Procurement Department or Pharmacy Department. Exceptions to this will only be as directed and authorised by the General Manager/Financial Controller.
- Authorised hospital users may discuss with supplier's technical or other product or service applications related to the use or performance of such product or service.
- All invitations to supplier's representatives to visit hospital user departments in connection with products they supply or commercial activity must be channelled through an authorised Purchasing Officer/Purchasing officer.
- Supplier's representatives who call to a hospital user department unsolicited should not be entertained but should be directed to the Purchasing & Procurement/Stock Management Department.

5.9. Trialling of Products and Equipment

- Generally products offered or requested for evaluation should comply with nationally agreed clinical and infection control standards.
- Product Evaluation Request and Result forms must be initiated, completed and submitted for the results to be considered and any decisions taken. These forms are available from the Materials Department.
- Arrangements for equipment to be received for evaluation may not be made with any Supplier/Manufacturer without prior notification to the Materials Manager, Clinical Engineering Manager, Chief Pharmacist or

Support Services Manager where appropriate. Exceptions to this will only be as authorised by the General Manager/Financial Controller.

- The results of any such equipment evaluation will be recorded on any Equipment Evaluation Form provided for evaluation and/or will be subject to critical review or analysis by Clinical Engineering Manager, Chief Pharmacist, Support Services Manager or other appropriate staff authorised by the General Manager/Financial Controller

When equipment/products are to be used for direct patient care it is the responsibility of the user arranging the evaluation to ensure that the equipment/product is compatible with the decontamination methods

6 RISK MANAGEMENT

6.1 Minimisation of risk

One of the primary objectives of any contract for the supply of goods or services entered into on behalf of the hospital should be the minimisation of risk to the hospital. To ensure this the following principles should be applied.

6.2 Quality and Reliability

Supplies of materials, which are critical to safety, should be sourced only from suppliers who have appropriate quality systems in place. Where necessary critical materials purchased should be subjected to testing prior to any award of contract.

6.3 Equipment or products standards and evaluation

All equipment, products or services purchased by or loaned to the hospital for reasons of use, evaluation, education or training must comply with all relevant National and International Standards and Guidelines. The use of such equipment and any consumables or parts used in the operation of this equipment must meet will all policies and procedures applicable under Infection Prevention and Control, Health and Safety and Occupational Health Regulations. To this end they will be evaluated by The Hospital Procurement Group as set out in section 6.4 below.

6.4 Hospital Procurement Group

The Hospital procurement Group has responsibility for ensuring that procurement of goods and services is undertaken in line with EU regulations and National Guidelines and also conforms to the hospital's standards in relation to infection control, hygiene and health and safety. It also has responsibility for ensuring that appropriate cost / benefit analysis has been undertaken to establish if any such procurements achieve value for money.

All new or replacement equipment, and new or financially significant changes in products or services procured by the hospital must be evaluated by the group prior to purchase. The group will ensure any such purchases comply with all relevant National guidelines and standards, and meet with standards in the following areas:

- **Infection prevention and control standards** – to ensure that the physical environment, facilities and resources of the hospital are developed and managed to minimise the risk of service users, staff or visitors acquiring healthcare associated infections. Regarding materials for cleaning and disinfection, e.g. antiseptics, wipes, disinfectants, etc., and items for waste disposal any planned change or introduction of new products should be referred to the Infection Control team.

- **Hygiene management standards** – Hygiene is defined as "the practice that serves to keep people and environments clean and prevent infection. In the healthcare environment it incorporates the following key areas: environment and facilities; hand hygiene; catering; management of laundry, waste, sharps and equipment." In this context all procurements must be evaluated to ensure that they are of sufficient quality to maintain the required standards and contribute to organisational effectiveness.

- **Decontamination of Reusable Invasive Medical Devices (RIMD) standards** – any procurement must take account, if relevant, of infection control issues relating to the use of single use items, single patient use items and RIMD with restricted use components or single use parts. Therefore the Infection Control team and the Decontamination committee should be notified of any proposed change to, or introduction of, these products. All medical equipment procured must come with complete instructions from the manufacturers relating to decontamination.

- **Health and Safety regulations** – all procurement of goods and services by the hospital must be in compliance with the requirements of the Safety, Health and Welfare at Work Act 2005 and all other Health and Safety legislation.

- **Environmental Health regulations** – all catering department purchases need to comply with Environmental Health Standards, National Food Safety and Hygiene standards and the standards of the Excellence Ireland Quality Association (EIQA).

The Procurement Group will evaluate proposed purchases using an evaluation form which will be signed by the relevant members of the group to indicate compliance with the various policies. Where considered necessary or appropriate, written justification, a clinical evaluation report or supporting documentation may be required to support a procurement proposal. On foot of its investigations it will make recommendations to the Executive Management Team of the hospital as to whether or not to proceed with any procurement proposal.

The membership of the Procurement Group comprises:

- Financial Controller
- Support Services Manager
- Materials Manager
- Infection Control Manager
- Health and Safety Manager
- Clinical Engineering Manager
- Assistant Director of Midwifery & Nursing representative

Other Senior Managers input will be required with regard to submissions pertaining to their relevant area.

6.5 Capital projects

The hospital Board must approve in advance all capital projects with a value of €200,000 or more (exclusive of VAT). In exceptional circumstances (e.g. extreme urgency) where it is not possible to obtain prior Board approval, the Secretary / General Manager has the authority to approve projects which have previously been notified to the Board, provided that the Board is notified of all such projects at the next scheduled meeting.

6.6 IT Capital projects

Approval to procure IT software must comply with the regulations set down by the CMOD unit of the Department of Finance. The hospital IT Manager is responsible for coordinating applications to this unit.

6.7 Minor Building and Refurbishment projects

Any proposed minor refurbishments or fit out of premises and buildings must be notified by the Support Services Manager for approval by Hospital Procurement Group, subject to budget constraints. Any major build projects need to be approved by the Hospital Property Committee which is a subcommittee of the Board.

6.8 Medical Devices Supply

A medical device is generally described as any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

And which does not achieve its principal intended action in or on the human body by Pharmacological, Immunological or Metabolic means, but which may be assisted in its function by such means.

The manufacture, supply and use of medical devices to and within the Rotunda Hospital, must comply with the European Medical Devices directives, and the regulations governing CE marking.

All Users of Medical Devices should ensure they comply with the relevant sections of appropriate directives particularly in relation to the reporting of adverse incidents concerning medical devices.

There are three European Directives governing medical devices as follows:

- The Active Implantable Medical Devices Directive (90/385/EEC), which came into force on 01 January 1995.

- The Medical Devices Directive (93/42/EEC), which came into force in June 1998, and covers the large majority of Medical Devices. This directive was amended in Directive 2000/70 and 2001/104 to extend its scope to those devices incorporating stable derivatives of human blood or human plasma.

- The In-Vitro Diagnostic Medical Devices Directive (98/79/EC), which came into force in June 2000 but with a 5-year transitional period. This directive covers any Reagent, Reagent Product, Calibrator Control Material Kit, Instrument, Apparatus, Equipment or System intended for use in the in-vitro examination of specimens, including blood and tissue donations, derived from the human body.

The CE Mark is the public representation of the manufacturer's claim that his device satisfies the relevant Essential Requirements in the Directives is fit for its intended purpose and, where required, has been independently assessed by a Notified Body. Medical Devices bearing the CE Mark can be freely marketed anywhere in the EU without further control. All devices, covered by the scope of the relevant directive, should bear the CE Mark when received in the hospital. There are however some specific exemptions as follows:

- Custom-made devices.
- Devices undergoing a clinical investigation.
- Devices for performance evaluation.

6.9 Conditions of Contract

Only the approved employees mentioned in section 5.1 are authorised to enter into contract negotiations with any supplier. Any proposed contract must be evaluated in advance, prior to signing, by the Financial Controller to establish the financial and legal implications for the hospital. Contracts entered into shall comply with the Hospital standard terms and conditions of contract or a contract specially prepared for a particular order the terms and conditions of which must be approved by the Secretary / General

Manager and/or legal representatives selected by the hospital. A copy of any contract entered into by the hospital must be sent to the Financial Controller for entering on the Hospitals Contract Register/Fixed Asset Register

It is the responsibility of the authorised officer appointed to manage the contract during its duration. Complaints in relation to the conduct of the contract should be dealt with speedily, and brought to the attention of the contractor or supplier for any necessary action. Where considered appropriate, review meetings to include the contractor or supplier should be held during the term of the contract.

6.10 Insurance

Contractors and suppliers must, at a minimum have an up to date tax clearance certificate and Public and Employer's Liability Insurance. An order should not be placed with a contractor or supplier until the relevant documents have been provided.

Any supplier of goods or services to the hospital shall at all times insure and keep itself insured with a reputable insurance company against all insurable liability in respect of the supplies maintaining where appropriate the following insurances:

- Public Liability insurance
- Professional Indemnity policy in relation to professional services
- Product Liability insurance
- Employer's Liability insurance in relation to employees of the Supplier servicing or installing Supplies on the Purchaser's property.
- Third Party Commercial Motor vehicle liability cover

In the event of Supplies being supplied and then installed by the Supplier, evidence of All Risks insurance, in the joint names of the Purchaser and the Supplier, on the Supplies should be presented until such time as the Purchaser accepts responsibility following the installation.

Where necessary an order should not be placed with a contractor until the relevant documents have been submitted and approved.

Any supplier of goods or services to the hospital must warrant to the Purchaser that the Supplies will be of merchantable quality and fit for any purpose held out by the Supplier, will be free from defects, will correspond in all respects with the Specifications and/or any sample, and will comply with all statutory requirements and regulations relating to the manufacture, packaging, packing, distribution, supply, sale and purchase of the Supplies.

The Supplier shall indemnify and keep indemnified the Purchaser in full against any liability in connection with breach of any warranty given by the Supplier in relation to the Supplies, or for any liability in respect of loss, injury or damage arising from any act, error or negligence of the Supplier.

6.11 Regulations

Contractors and Suppliers to the Hospital must comply with all relevant Governmental regulations including Tax Clearance Requirements, Relevant Contracts taxation requirements, Constructions Procedures and Safety and Employment legislation and regulations.

Suppliers, Contractors and Service Providers who are expected to carry out business with the hospital should be pre-qualified and should meet the following minimum criteria:

- They must be registered for VAT
- They should have at least one year's relevant experience in the areas in which they wish to do business with the hospital.
- They must be in possession of a valid C2 or Tax Clearance Certificate.
- They must hold satisfactory levels of insurance.
- They must provide satisfactory reference sites for their business.
- They should complete any company profile document issued and required by the hospital (New suppliers/Supplier Profile documentation)-Appendix 3
- They must comply with the hospitals Contractors policy for workers and visitors to the hospital site. This policy will help each Department to ensure that the highest possible work standards and security are adhered to by all those engaged to carry out work.

6.12 Leasing of Goods

Current policy does not allow public hospitals to engage in the leasing of equipment.

6.13 Disposal of Equipment

Authorisation from the relevant department head must be received for the disposal of all equipment. When equipment has been sanctioned for disposal the holder of the Fixed Asset Register (Finance) must be informed prior to the disposal taking place.

6.14 Procurement of advertising

Hospital employees are not authorised, unless expressly approved by the Secretary/ General Manager, to purchase advertisements in magazines, newspapers or any media outlets.

7 PURCHASING PROCEDURES

7.1 Procedures to be used for purchasing

All purchasing carried out in the hospital needs to comply with the Department of Finance's National Procurement Guidelines and EU Public Procurement Directives. A formal tender process must be used for any contracts or purchases in excess of €25,000 Therefore all purchasing in the Rotunda Hospital must be carried out using one of the following procedures:

- Formal EU tender process - to comply with EU directives for procurement of supplies or services with a value greater than €209,000 or works value greater than €5,225,000
- National tender process - for high value services or supplies valued greater than €25,000 up to the EU limit
- Request for minimum 3 Quotations for services or supplies between €5,000 and €25,000
- Small Value Order less than €5,000
- Stock Replenishment Order

7.2 Formal EU tender process

Where the value of the goods or service to be procured exceeds or is expected to exceed the following thresholds (exclusive of VAT) the Invitation to Tender must be advertised in the Official Journal of the European Union. This is a legal requirement per EU Directive 2015/2171/EC November 2015 for award of Public Works, Supply, and Service Contracts.

- Works value greater than €5,225,000
- Supplies or Services value greater than €209,000

Detail of the process to be followed is in section 8 below.

7.3 National tender process

Where goods or services to be procured are expected to cost between €25,000 up to the EU limits of €209,000 (services and supplies) or €5,225,000 (works), then the hospital follows the guidelines for National Public Procurement as produced by the Department of Finance. This requires suppliers or contractors to submit sealed tenders by a given closing date, which are then opened together by at least two authorised officers nominated by the Secretary / General Manager or Financial Controller. A minimum of three competitive quotations is required.

Unless specifically sanctioned by the Secretary/ General Manager or Financial Controller, formal tender procedures must be used for public contracts or purchases in excess of €25,000 (exclusive of VAT).

7.4 Request for Quotation

The request for quotation procedure permits suppliers to submit quotations by unsealed letter, fax or e-mail. This procedure must be used for contracts and purchases with an estimated value, excluding VAT, greater than €5,000 and less than €25,000. A minimum of three competitive quotations is required to be sought.

All requests for quotation must include a sufficient and clear description of the materials required, or works to be carried out, as well as reference to the standard hospital conditions of contract that will apply.

All requests for quotation must be issued through the purchasing departments as detailed in section 5.1 above. Exceptions will only be as authorised by the Secretary / General Manager.

All requests for quotations must be marked returnable to the relevant departmental manager by Post, Fax or E-Mail. Sufficient time should be allowed to permit suppliers to prepare and submit a competitive quotation.

Quotations shall be invited from at least three suppliers, except as provided in Section 7.7 below.

Unpriced purchase orders may not be placed except in exceptional circumstances.

7.5 Small Value Order

This procedure may be used for the purchase of items having an estimated value, excluding VAT, of €5,000 or less. Quotations may be received by telephone. It is not necessary to obtain three quotes and orders must be placed with approved suppliers. Confirmation of price details may also be received in writing by Fax, E-mail or post to support transactions. An approved supplier is one who has been vetted for necessary compliance by the authorised employees detailed in section 5.1 above and approved for entry on the Supplier Register by the Financial Controller.

7.6 Stock Replenishment Order

Stock replenishment items may be ordered from approved suppliers by issuing of official orders by the approved officers as detailed in section 5.1 above.

7.7 Exceptional Circumstances

Only in exceptional circumstances will the requirement for a minimum of three competitive quotations for contracts and purchases over €5,000 not apply. In such circumstances certification from the requester and the approval of the Secretary / General Manager or Financial Controller will be required.

Examples of what constitutes "Exceptional Circumstances" are:

- Need for compatibility and standardisation with existing equipment/ product
- Sole Supplier
- Urgent Requirement
- Proprietary materials
- Confidentiality needs
- Statutory essential services
- Clinical decision based on patient need

Use of "Exceptional Circumstances" does not permit a departure from EU procurement Directives.

7.8 Contract Value

When determining which procedure to use, the maximum possible value of a contract must be taken into account. Under no circumstances may a contract be split in order to alter or circumvent the procedure to be used.

8 FORMAL TENDERING PROCEDURES

8.1 Invitation to Tender

- Tender invitations should be issued to a minimum of three suppliers.
- All invitations to tender and requests for quotations must be issued through the Materials Manager or other authorised hospital officer as detailed in section 5.1 above.
- However, authority to issue tenders and requests for quotations rests with the Materials Manager, for general goods and services, and with the Chief Pharmacist for pharmaceutical items.

- All tenders/advertisements will specify where the documents and tender forms may be obtained and should indicate a tender reference number.

- All tenders must be marked returnable to a designated officer and must include a firm closing Date and Time.

- Tender documentation/specifications should be expressed clearly and not give rise to ambiguity. Award criteria should be clearly identified in the tender documentation.

- Award criteria/specifications cannot be changed once the tender process commences, and tender documents have been issued.

- Tax clearance procedures are obligatory in all cases.

- All contracts for pecuniary interest must be in writing.

- Where an omission has occurred in the tender documentation it should be amended and all participants expressing interest in the tendering process informed. Where the omission significantly alters the nature of the tender process the tender may have to be re-advertised.

- When requested all unsuccessful tenderers should be informed as to why they were unsuccessful. However, care should be taken that no commercially sensitive data submitted by tenderers is released as part of the debriefing exercise.

- Open-ended contracts should not be entered into. The contract should have a commencement date and a termination date.

- Details of the tender process should be recorded in writing on file.

- A mechanism must exist in contracts to terminate in the event of non-compliance/non-performance.

- Fees must be agreed in advance for service contracts and the price must be agreed in advance for goods contracts and the amounts should be specified in Euro.

- A current Tax Clearance Certificate must be obtained for all contracts.
- For EU contracts – notification of the contract and the award of the contract must appear in the Official Journal of the European Communities (O.J.E.C.).

- Disaggregation or contract splitting to avoid the E.U. tendering process is illegal, and may not be practised.

- Extension of the closing date for receipt of tenders shall only be permitted when authorised in advance by the Secretary / General Manager or Financial Controller. All tenderers must be advised of the extension.

- The Secretary / General Manager or Financial Controller shall authorise persons to open formal tenders. The Materials Manager must retain a list of persons so authorised and samples of their signatures.

- The award of contracts shall only be made by the Secretary / General Manager or an officer of the hospital authorised to do so by the Secretary / General Manager.

- Under no circumstances are non-authorised employees permitted to communicate or indicate to a supplier the intention or decision of the hospital in relation to any contract being determined.

8.2 Receipt, custody and opening of tenders

- On receipt, tenders must be held unopened, locked in a safe place, until the formal opening date.
- On or after the formal opening date all tenders must be opened together, in the presence of two authorised officers.
- Each tender must be stamped with the date and time of opening, and signed and numbered by the authorised officers present.
- Particulars of the tenders received will be entered in a Register of Tenders, which is signed by the authorised officers present.
- Verbal or Faxed tenders may not be accepted under any circumstances.
- The number allotted to the tender will denote the serial number of each tender, and the total number of tenders received for the particular goods or contract advertised, e.g. if 8 tenders have been received the first shall be numbered 1 of 8, and the final 8 of 8.
- The total number of tenders received will be entered at the bottom of each page, and the officers in whose presence the tenders are opened will sign each page.

8.3 Late tenders

- Tenders received after the appointed time for the receipt of tenders should not be accepted and should be returned unopened to the relevant tenderers.
- A Tender Closing Reminder Notice should be published prior to the closing date of any tender.

8.4 Tender evaluation

The Materials Manager or other authorised officer per section 5.1 carries out a commercial assessment of the tenders for preparation of a commercial recommendation. The authorised officer should consult with the Financial Controller regarding appropriate discounting methods, interest rates, inflation rates, currency conversion rates and any other factors to be used in the commercial assessment.

A technical evaluation when required must be completed. This evaluation report is sent to the Materials Manager or other authorised officer for consideration in conjunction with the Commercial assessment.

8.5 Performance monitoring

The performance of awarded contracts should be monitored by the appropriate function manager, e.g. Supplies Officer for Stock Items, Support Services Manager for Household and utility contracts, Lab Manager for Pathology etc., using pre agreed

criteria or KPIs and any concerns should be brought to the attention of the Materials Manager.

8.6 Notification of Contract Award

- The Materials Manager or deputy should notify Tenderers, in writing; of the award of the contract as soon as possible after a contract has been formally approved by the relevant authorised authority.
- In the case of contracts subject to EU regulations a Notice containing details of the contract, the award procedure, and the identity of the successful tenderer must be sent for publication in the Official Journal of the European Communities within two months of the contract award.

8.7 Electronic Procurement

Section 8 may be subject to change in light of any e-procurement guidelines or directives which may be issued

9 PROCEDURES FOR RECEIVING, ISSUING, AND RETURNING OF GOODS

9.1 General rules

Under the terms of the Prompt Payment of Accounts Act 1997, the hospital is held responsible for ensuring compliance of the Act and that Suppliers are paid within time-limits set.

As failure to carry out the procedures for receiving of goods correctly would prevent the hospital meeting payments within these time-limits, the procedures laid out under this section will be strictly adhered to by all staff.

9.2 Goods Delivery Location

- All stock items delivered to the Rotunda Hospital must arrive and be processed through the Goods Inwards Section of Central Stores. Goods as per order instruction delivered directly to departments outlined under section 5.1 must be processed by approved purchasing departments.

- Authority to receive goods through any other Hospital entrance must be received in writing from the Secretary/ General Manager and must be notified to the Materials Manager. In this eventuality it is the responsibility of the head of such user department to ensure delivery documentation is correctly checked against goods delivered, signed, and submitted to the Materials Manager on next working day following such delivery.

9.3 Goods Delivered Outside Normal Working Hours

Only in exceptional circumstances (e.g urgent requirement) may goods be requested for delivery outside normal working hours and in such case the procedure outlined in paragraph 7.7 must be adhered to.

Any such delivery should only be made on foot of an Official Purchase Order issued by an authorised officer.

9.4 Delivery documentation

All goods delivered from Suppliers must be accompanied by a Delivery docket for retention by the hospital. Each delivery docket should contain as a minimum:

- A Serial Number
- Suppliers Name
- Purchase Order Number
- List of items being delivered to include Quantity, Size, Type Weight, etc.
- Section for Signature of person receiving

Couriers delivering goods on behalf of a supplier should present a good receipt note from the supplier. This safeguard against disputes over 'Proof of delivery'

9.5 Checking goods inward

- It is the responsibility of the Materials Manager, or equivalent officer in a purchasing department as outlined in section 5.1 above, to ensure that goods are receipted and handled in accordance with policy and that all documentation is properly checked and processed.

- All delivery dockets are to be checked against the Official Purchase Order for the following:

    1. Correct order and Delivery address
    2. Quantity ordered agrees
    3. Items are as specified on purchase order

- The person receiving goods must check the goods at point of entry to hospital to ensure correct item, quantity, type, size, weight, etc.

- The receiving officer must sign all delivery dockets at time of receipt after the goods have been checked. The receiving officer must ensure that the quantity advised on the delivery docket agrees with the quantity delivered.

- Any discrepancies found, or any other matters to be noted (e.g. "Contents of Crate not checked") must be recorded immediately and signed by Person Receiving and Person Delivering.

- In exceptional circumstances when sufficient time is not available to adequately examine the consignment the delivery document should be signed and endorsed

"Unchecked or U/C". Subsequent shortages/damages/differences discovered must be notified to Supplier immediately.

- When shortages in weight or quantity, or incorrect goods or size are received, or goods are damaged or missing, or any other discrepancies are found the Supplier must be notified immediately. Delivery documents must be amended and endorsed with details of it.

- When goods are rejected for reasons of damage, shortage, incorrectness etc., the relevant purchasing department shall, within five days of discovering the fault, notify the supplier.

- Rejected goods must be kept isolated from other stocks until collected by the supplier

- All delivery dockets will be recorded, by the purchasing department as identified in section 5.1, on the appropriate computerised/manual stock control system daily immediately after receipt.

- After goods have been checked and cleared for receipt into the Hospital the relevant purchasing department will ensure the immediate transfer of the goods to appropriate destination.

- Stock items should be placed into correct location within Central Stores. This should be on day of receipt.

- Non-Stock items will be issued to appropriate requisitioning department.

- Where appropriate the relevant technical or clinical staff must check equipment upon receipt to certify it meets with specification requirements, and functions properly in use.

9.6 Dealing with Goods in Excess

- When good are received which are found to be in excess of the quantity ordered on the official purchase order, it must be brought to the attention of the Materials Manager immediately.
- If the Materials Manager authorises acceptance of the goods in excess, the purchase order must be amended prior to receiving and signing of delivery documentation.
- If the Materials Manager does not authorise acceptance of the goods in excess, the excess quantity must be rejected and retained by supplier and delivery documentation amended to show correct quantity and signed by both Hospital Officer receiving and supplier delivery staff.

9.7 Responsibility of User Departments

Where goods are received in an authorised user department, as detailed in section 5.1 of this document, it is the responsibility of the head of department to ensure that the procedures outlined under Section 9.5 are adhered to in full.

9.8 Issuing goods from Materials Management department

The following are the procedures for issuing of goods from the Materials Management Department and the returning of goods from hospital areas to the Materials Management department and to suppliers.

- The responsibility for requesting stock items lies with the individual departments
- Issuing of goods from the Materials Management department for stock and non-stock items will only be on foot of a written or electronic requisition as detailed in section 10 below.
- Requisitions received for stock goods should be entered onto the Exact system as soon as possible after receipt in Materials Management.
- A FIFO (First In First Out) system is in place for stock items within the centralised stores which ensures that previously held stock is rotated to the front of the appropriate bin location and newly delivered goods placed at the back. This eliminated the possibility of stock going out of date.
- Delivery of goods to the user departments is via the pool portering service that will collect the goods from Stores and ensure delivery of the goods in good condition to the relevant department.
- It is the responsibility of the Head of Department to ensure that no items of goods or equipment are returned to the Materials Management Department without prior approval of the Materials department.
- In the event of a department requiring emergency goods outside of normal working hours the following procedure is in place:

The Assistant Director of Midwifery on duty can gain access to Central Stores accompanied by a member of security who has keys and alarm deactivation codes.
A signed requisition should be left for any goods removed from Stores. This requisition should be left in the "Outside Normal Hours" box. Security should report all such incidents of entry to Stores to a member of the Materials department on the next day that they (Materials) are on duty.

10 REQUISITIONING OF GOODS

10.1 Process for Requesting Stock or non-stock Items

- The responsibility for ordering stock items lies with the individual department.
- All requests must be either submitted in writing on the official Requisition form or electronically, from departments licensed to do so, in accordance with agreed scheduled days and times.

- Where appropriate, requisitions must be available for collection by the Materials Management Staff at the time agreed with the Materials Manager for any such arrangements, or are placed in any post box or other facility provided in the Materials Management Department, or are sent through internal post systems in sufficient time to allow necessary processes to take place.

- Requests should be made in accordance with agreed stock levels unless otherwise arranged with the Materials Manager.

- A designated approved person must sign completed requisition forms as outlined in section 5.2 above.

- A request for a product different to one currently issued for the same procedure must be supported by evidence for the need to change, and if a financially significant change must be evaluated by the Hospital Procurement Group as outlined in section 6.4 above.

- Requisitions for non-stock or special items should indicate whether it is a New, Replacement or Additional.

- For new and additional items, these will have a financial impact on the Hospital, therefore requests must be accompanied by written justification for the request which must be reviewed and signed off firstly by Hospital Procurement Group.

- Under no circumstances are Hospital employees, other than those authorised, permitted to give order commitments directly to a supplier. These must be channelled through the Materials Management or other authorised purchasing department as outlined in section 5.1 of this document.

10.2 Requirement Planning – New Staff

All departmental heads should ensure that following the appointment of new Consultants, Clinicians, etc., and prior to them taking up their positions, arrangements are made for them to meet with the Materials Manager or other authorised officer as per section 5.1 above in sufficient time to discuss their requirements and allow any necessary purchasing processes to take place within appropriate timescales.

10.3 Requesting items which may contain a Medicinal Product

If an item contains a medicinal product, even if it is licensed as a Medical Device, it is the responsibility of the head of the requesting department to ascertain whether it is appropriate for it to be purchased by the Pharmacy or Materials Management Department.

A Medicinal Product is defined as:

Under Council Directive 65/65/EEC, the term Medicinal Product is defined as:

Any Substance or combination of substances presented for treating or preventing disease in human beings or animals.

Any substance or combination of substances, which may be administered to human beings with a view to making a medical diagnosis or restoring, correcting or modifying physiological functions in human beings or in animals is likely to be considered a medicinal product.

11 CODE OF ETHICS

11.1 General rules

It is the policy of the Rotunda Hospital, to maintain its high reputation for ethical behaviour and transparency and fair dealing in the conduct of its business.

In many cases decisions as to what is ethical or fair are clear-cut and will be obvious to any reasonable person. In some situations, however, there may be circumstances where an element of doubt or ambiguity arises. To help in these circumstances and to protect and guide individual employees of the Hospital, it is necessary to have a written code of ethics.

It is not possible to provide for every situation in the code of ethics. If there is doubt about the probity of any particular situation the Materials Manager or Financial Controller must be consulted by the individual concerned.

The Code of Ethics applies to all the employees of the Rotunda Hospital and to those contracted by the Hospital and who are engaged in the purchase and evaluation, negotiation, placement of contracts, and approval of payments for goods or services including those involved in advisory and decision making capacities.

Hospital Employees shall never use their authority of office for personal gain and shall seek to uphold and enhance the reputation of the Rotunda Hospital by:

- Maintaining an unimpeachable standard of integrity in all their business relationships both inside and outside the hospital.
- Fostering the highest possible standards of professional competence amongst those for whom they are responsible.
- Optimising the use of resources for which they are responsible.

11.2 Disclosure of interest

Any personal interest, which may impinge or might reasonably be deemed by others to impinge on a member of staff's impartiality in any matter relevant to his or her duties, should be disclosed.
Where a conflict of interest situation could arise for an employee, he/she must desist from dealing with the contract-giving rise to that situation, and may not attempt in any way to influence the Hospitals decision on the matter.

11.3 Confidentiality and Accuracy of Information

The confidentiality of information received in the course of duty should be respected and should never be used for personal gain. Information given in the course of duty should be true and fair and never designed to mislead.

11.4 Integrity

Each employee of the hospital is expected to observe the highest standards of honesty and integrity in all business dealings.

The employee must therefore:

- Refuse bribes, gifts or hospitality, which may affect the ability to make independent judgement, and report any such approaches to the Secretary/ General Manager or the Materials Manager.
- Avoid misrepresenting one's position within the hospital or being ambiguously misleading
- Reject any business practice, which might reasonably be deemed to be improper
- Not misuse one's position in the hospital for personal gain

11.5 Legality

In order to ensure that the Hospital complies in its business dealings with all National and European Legislation employees are required to:

- Fulfil all regulatory and supervisory obligations imposed on the Hospital
- Co-operate with relevant regulatory and supervisory bodies
- Avoid false, inaccurate or misleading entries in records
- Ensure that all relevant legislation is upheld
- Ensure one's actions comply with relevant contractual obligations
- Encourage effective and fair competition at all times
- Comply with all purchasing and tendering procedures and with prescribed levels of authority for sanctioning any relevant expenditure
- Avoid engaging in any illegal or criminal activities

11.6 Competition

While recognising the advantages to the hospital of staff maintaining a continuing relationship with a supplier, any arrangement, which might in the long term prevent the effective operation of fair competition, should be avoided.

11.7 Gifts, Sponsorship and Hospitality

The giving or receiving of corporate gifts, sponsorship, hospitality, preferential treatment or benefits which might affect or appear to affect the ability of the donor or the recipient to make independent judgement on business transactions should be avoided.