

# The Newcastle Upon Tyne Hospitals NHS Foundation Trust

## Medical Devices Procurement Policy

Effective: December 2010

Review date: December 2013

### 1. Introduction

The Medical Devices Procurement Policy has been established to ensure that all medical devices are procured by the Supplies Department in accordance with Trust Standing Financial Instructions and European Public Procurement Regulations. This policy provides guidance to potential purchasers in the key areas to be considered prior to the selection/purchase of a Medical Device.

### 2. Authorisation

#### 2.1 Revenue

Medical equipment defined as a single item with a value < £1,000 including VAT should be requested on a non stock (revenue) requisition to be authorised by the ward/department's budget holder.

#### 2.2 Major Revenue

Medical equipment defined as having a lifespan of over 1 year and an individual item value between £1,000 and £4,999.

#### 2.3 Capital

Medical equipment defined as a tangible asset with a life span of over 1 year and an individual item value of £5,000 or higher.

2.4 Major Revenue/Capital should be requested on a Capital/Major Revenue Requisition by the person originating the request and authorised by the Specialty Manager, Clinical Director or Head of Department. The requisition should be forwarded to the Director of Estates and Facilities (who manages the Trust Capital Programme and Major Revenue budget) prior to final authorisation by the Chief Executive, coding by Financial Services and purchase action by the Supplies department.

2.5 Equipment purchased via charitable funds should satisfy the same product selection criteria as those purchases made through exchequer monies.

### 3. Quotations & Tenders

#### 3.1 Thresholds

Financial thresholds determine the route via which a medical device can be procured. The financial thresholds which competitive quotations and/or competitive tenders **must** be sought are clearly defined in Trust Standing

Financial Instructions (Paragraph 8). Formal tendering procedures may be waived by officers to whom powers have been delegated by the Chief Executive and these are clearly defined in Trust Standing Financial Instructions (Paragraph 8.5.3). These financial thresholds are subject to review

### **3.2 Competitive Quotations**

Competitive quotations are required (and sourced by the Supplies department) where formal tendering procedures are not adopted and where expenditure or income exceeds, or is reasonably expected to exceed £10,000 including VAT but not exceed £50,000 inc VAT. To ensure fair and adequate competition, no less than 3 competitive quotations should be sought.

### **3.3 Competitive Tenders**

Formal competitive tendering is required when the intended expenditure is expected to exceed £50,000 including VAT.

### **3.4 Public Procurement Regulations**

The EU Procurement Rules apply to public authorities (as defined by the Public Sector Procurement Directive 2004/18/EC and utility companies (as defined by the Utilities Procurement Directive 2004/17/EC). The rules set out detailed procedures for contracts where the value equals or exceeds specific thresholds. The following thresholds apply from 1 January 2010, they exclude VAT and relate to the full life of the contract.

Supplies/Services Contracts - £101,323  
Works Contracts - £3,927,260

- 3.5 The Chief Executive or his nominated officer will evaluate the tenders/quotations in conjunction with an agreed evaluation group (against agreed evaluation criteria) and select the one which gives best value for money. If this is not the lowest then this fact and the reasons why the lowest quotation was not chosen are to be in a permanent record and approved by the Supplies & Services Procurement Committee (a Standing Committee of the Trust, appointed to exercise the executive powers of the Trust Board in respect of Tendering and Contracting procedures).

## **4. Safety – Technical & Clinical**

### **4.1 Pre-Purchase Questionnaire (PPQ)**

Prior to the purchase of any medical device, the Supplies Department will request the supplier/manufacturer to complete a PPQ & Revenue Impact form. These forms are intended to provide the Trust with information about the equipment being considered for purchase and to clarify issues relating to the maintenance and the whole-life costs of the equipment. The Supplies Department will forward all completed documents to the Trust's EME department for approval with an

accompanying PPQ Cover Note. This cover note is returned to the Supplies department with their approved instruction.

#### **4.2 Maintenance**

Post warranty maintenance contracts are progressed by the Supplies department in conjunction with EME/Users

- 4.3 It is up to the originator of the request to seek advice from the appropriate specialist staff to ensure that infection risks and decontamination processes are addressed prior to the purchasing stage.

### **5. Standardisation**

- 5.1 There is a clear benefit to be gained from maintaining continuity by standardising with existing goods or equipment particularly in terms of user familiarity, the cost of spare parts and equipment maintenance.

Examples of existing Trust standard equipment;

Dialysis machines

Anaesthetic machines

CVVH machines

Infusion pumps

Syringe pumps

Tympanic thermometers

External defibrillators

Electric profiling beds

Paediatric/adult ventilators

Patient chairs

Blood gas analysers, Blood Glucose meters (ref POCT Policy)

The EME/Supplies department can advise on equipment currently recognised as Trust standard.

### **6. Monitoring and Review**

- 6.1 The Trust's Internal Audit department develop an annual audit programme which is approved by the Trust's Audit Committee. Procurement monitoring forms part of this annual audit programme.

- 6.2 The Procurement Strategy is agreed and monitored by the Supplies and Services Procurement Committee (a Standing Committee of the Trust, appointed to exercise the executive powers of the Trust Board in respect of Tendering and Contracting procedures).

6.3 The Annual Procurement Workplan is agreed by the Management Executive Group.

## **7. References**

[Trust Standing Financial Instructions](#)  
[Management of Medical Devices Policy](#)  
The Public Contract Regulations 2006

Policy Author(s):  
Assistant Purchasing & Supply Manager (Purchasing)  
Deputy Assistant Purchasing & Supply Manager

**THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST**  
**IMPACT ASSESSMENT – SCREENING FORM A**

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy Title:	<b>Medical Devices Procurement Policy</b>	Policy Author:	<b>Lesley Fallon</b>
		Yes/No?	You must provide evidence to support your response:
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		All medical devices are procured in accordance with NHS Terms and Conditions of Contract which include a section on Equality and Non-Discrimination Compliance
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems.	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	n/a	
4(a).	Is the impact of the policy/guidance likely to be negative? <i>(If “yes”, please answer sections 4(b) to 4(d)).</i>	No	
4(b).	If so can the impact be avoided?	n/a	
4(c).	What alternatives are there to achieving the policy/guidance without the impact?	n/a	
4(d)	Can we reduce the impact by taking different action?	n/a	

<b>Comments:</b>	<b>Action Plan due (or Not Applicable):</b>
	N/A

Name and Designation of Person responsible for completion of this form: ..... Lesley Fallon, Deputy Assistant Supplies Manager Date: 21/3/11

Names & Designations of those involved in the impact assessment screening process: ..... Lesley Fallon, Deputy Assistant Supplies Manager .....

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)

*For advice on answering the above questions please contact Helen Lamont, Director of Nursing, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) [steven.stoker@nuth.nhs.uk](mailto:steven.stoker@nuth.nhs.uk) together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation, with relevant stakeholders, to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker within six weeks of the completion of this form.*