The Medical Devices Procurement Policy

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 on the key areas to be considered prior to the selection/purchase of a Medical Device.

2 Scope

The Supplies Department, by means of the Medical Devices Policy aims to ensure that all Trust Staff are aware of the processes, value thresholds and legal requirements relating to the procurement of a Medical Device.

3 Aims

The Medical Devices Policy has been established to make all Trust staff aware of the processes required to ensure that all Medical Devices are procured in accordance with Trust Standing Financial Instructions and Public Procurement Regulations and that they are procured in a way that achieves value for money on a whole-life basis, not only generating benefits to the organisation but also to society and the economy, whilst minimising damage to the environment.

4 Duties (Roles and Responsibilities)

It is the responsibility of all Supplies staff to ensure that Medical Devices are procured in accordance with Trust Standing Financial Instructions and Public Procurement Regulations and it is the responsibility of all Trust staff to ensure that the Supplies Department take the lead in all issues relating to the procurement of a Medical Device.

5 Definitions

5.1 Medical Devices Steering Group:

Medical Devices Steering Group is a group tasked with developing, implementing and monitoring compliance with policies and procedures relating to Medical Devices.
5.2 The Supplies and Services Procurement Committee:
The Supplies and Services Procurement Committee is a Standing Committee of the Trust Board. Its purpose is to exercise the executive powers of the Trust Board in respect of Tendering and Contract procedures; to ensure compliance with the Trust's Standing Financial Instructions and legal obligations in respect of Tendering and Contract procedure; to ensure compliance with guidance, codes of conduct and good practice in respect of procurement and supply. The Trust Board remains accountable for all the functions of the Committee.

5.3 Standing Financial Instructions:
Standing Financial Instructions are issued to regulate the conduct of the Trust, its directors, officers and agents in relation to all financial matters.

5.4 Public Contract Regulations:
Public Contract Regulations regulate the purchasing by public sector bodies and certain utility sector bodies of contracts for goods, works or services. The law is designed to open up the EU's public procurement market to competition, to prevent "buy national" policies and to promote the free movement of goods and services.

6 Policy Guidelines

6.1 Requisitions, Value Thresholds & Authorisation

6.1.1 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.

6.1.2 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.

6.1.3 Capital equipment should be requested on a Capital Requisition 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 budget) prior to final authorisation by the Chief Executive, coding by Financial Services and procurement by the Supplies department.

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

6.2 Quotations & Tenders

6.2.1 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.

6.2.2 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. Details relating to competitive quotations are maintained on a quotations register held in the Supplies Department, such details to include suppliers invited to quote, award decision and reasons to support award decision.

6.2.3 Competitive Tenders:
Formal competitive tendering is required when the intended expenditure is expected to exceed £50,000 including VAT. Following a competitive tender process, all contract award recommendations must be reported to, and receive approval from, either the Supplies & Services Procurement Committee or the Trust Board depending on the value of the contract (Contracts valued up to £1m are reported to the Supplies & Services Procurement Committee; over £1m to the Trust Board).

6.2.4 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 1st January 2014 they exclude VAT and relate to the full life of the contract.  
Supplies/Services Contracts - £111,676  
Works Contracts - £4,322,012

6.2.5 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 offer was not chosen are to be in a permanent record and recorded/reported as detailed in 6.2.2 & 6.2.3 above.

6.3 Safety – Technical & Clinical

6.3.1 Pre-Purchase Questionnaire (PPQ):
Prior to the purchase of any electrical medical device, the Supplies Department will request the supplier/manufacturer to complete a PPQ. These forms are intended to provide the Trust with information about the
equipment being considered for purchase and to clarify issues relating to compliance with appropriate technical standards, 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 to proceed.

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

6.3.3 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.

6.4 Standardisation

Consideration should be given to maintaining continuity by standardising with existing goods or equipment particularly in terms of user familiarity, the cost of spare parts and equipment maintenance.

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

6.5 Sustainable Procurement

In accordance with the Trust’s Sustainable Procurement Policy, the Supplies Department will procure the Trust’s requirements for Medical Devices in a way that achieves value for money on a whole-life basis, not only generating benefits to the organisation but also to society and the economy, whilst minimising damage to the environment. Working closely with the Trust’s Sustainability Working Group and in line with the Trust’s Sustainability Policy, the Supplies Department will identify key areas where sustainable procurement can be achieved, measured and monitored.

6.6 Consignment Stocks

In accordance with the Trust’s Consignment Stock Policy, all medical Devices consigned to the Trust by suppliers, will have arrangements put in place when appropriate, that appropriate records are maintained, that product liability is clearly documented, that the ownership of products is clear and differentiated from conventionally procured Trust-owned products and that responsibility and accountability for the management of consigned products is defined and understood.

6.7 Code of Practice by Supplier Representatives (other than Pharmaceutical)

If the procurement of a Medical Device requires a supplier representative to visit a ward or department, the representative must be provided with a copy of the Code of Practice by Supplier Representative and confirm compliance.
7 Training

The Medical Devices Policy is provided to Trust staff for information only (no training required). All Supplies staff are trained on procurement procedures at commencement of employment. Changes in Procurement Legislation courses are attended by senior members of staff as required.

8 Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This document has been appropriately assessed.

9 Monitoring Compliance

<table>
<thead>
<tr>
<th>Standard/process/issue</th>
<th>Monitoring and Audit</th>
<th>Method</th>
<th>By</th>
<th>Committee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trust Standing Financial Instructions</td>
<td>Auditing sample procurement documents, requisitions and contracts</td>
<td>Internal Audit</td>
<td>Internal Audit</td>
<td>Annually</td>
<td></td>
</tr>
<tr>
<td>Public Procurement Regulations</td>
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</table>

10 Consultation and Review

The Medical Devices Policy has been prepared following consultation with the Supplies and Procurement Director and will be reviewed bi-annually in line with the revised EU Procurement value thresholds.

11 Implementation of Policy (including raising awareness)

The Medical Devices Policy is available to all Trust staff via the Trust’s intranet and provided to all Supplies staff as part of their training.

12 Associated Documentation

This policy should be read in conjunction with the following:

- [Code of Practice for Supplier Representatives (other than Pharmaceutical)]
- [Consignment Stock Policy]
- [Contractor Policy]
- [Medical Devices Management Policy]
- [Medical Devices Procurement Procedure]
- [Standing Financial Instructions]
- [Sustainable Procurement Policy]

- Public Procurement Regulations (2006)
### IMPACT ASSESSMENT FORM A

**Policy Title:** Medical Devices Policy  
**Policy Author:** Lesley Fallon

<table>
<thead>
<tr>
<th>Yes/No?</th>
<th>You must provide evidence to support your response:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> Does the policy/guidance affect one group less or more favourably than another on the basis of the following: (* denotes protected characteristics under the Equality Act 2010)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Race *</td>
<td>No</td>
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<tr>
<td>• Ethnic origins (including gypsies and travellers)</td>
<td>No</td>
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<tr>
<td>• Nationality</td>
<td>No</td>
</tr>
<tr>
<td>• Gender *</td>
<td>No</td>
</tr>
<tr>
<td>• Culture</td>
<td>No</td>
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<tr>
<td>• Religion or belief *</td>
<td>No</td>
</tr>
<tr>
<td>• Sexual orientation including lesbian, gay and bisexual people *</td>
<td>No</td>
</tr>
<tr>
<td>• Age *</td>
<td>No</td>
</tr>
<tr>
<td>• Disability – learning difficulties, physical disability, sensory impairment and mental health problems *</td>
<td>No</td>
</tr>
<tr>
<td>• Gender reassignment *</td>
<td>No</td>
</tr>
<tr>
<td>• Marriage and civil partnership *</td>
<td>No</td>
</tr>
</tbody>
</table>

| **2.** Is there any evidence that some groups are affected differently? |
| No |

| **3.** If you have identified potential discrimination which can include associative discrimination i.e. direct discrimination against someone because they associate with another person who possesses a protected characteristic, are any exceptions valid, legal and/or justifiable? |
| n/a |

| **4(a).** Is the impact of the policy/guidance likely to be negative? (If "yes", please answer sections 4(b) to 4(d)). |
| 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 |

**Comments:**

**Action Plan due (or Not Applicable):** n/a

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**Name and Designation of Person responsible for completion of this form:** Lesley Fallon Deputy Assistant Supplies Manager  
**Date:** 17 December 2013

**Names & Designations of those involved in the impact assessment screening process:** Mr David Hume, Supplies and Procurement Director, Mrs 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.)

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For advice on answering the above questions please contact Frances Blackburn, Head of Nursing, Freeman/Walkergate, 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 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.

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**IMPACT ASSESSMENT FORM A**  
**October 2010**