## Policy Checklist

<table>
<thead>
<tr>
<th>Name of Policy:</th>
<th>Policy for the Management of Medical Devices and Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of Policy:</td>
<td>This policy sets out the systems and processes for managing medical devices and equipment, including; investigation, minimising risk and promoting a culture of continuous improvement. The systems and processes extend across the whole life cycle of any medical device / equipment item (i.e. from procurement to condemnation).</td>
</tr>
<tr>
<td>Directorate responsible for Policy</td>
<td>Lead Director - Acute Services</td>
</tr>
<tr>
<td>Name &amp; Title of Author:</td>
<td>Patient Safety &amp; Quality Manager</td>
</tr>
<tr>
<td>Does this meet criteria of a Policy?</td>
<td>Yes</td>
</tr>
<tr>
<td>Trade Union consultation?</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Equality Screened by</td>
<td>N/A</td>
</tr>
<tr>
<td>Date Policy submitted to Policy Scrutiny Committee:</td>
<td>12 December 2011 and 26 March 2012</td>
</tr>
<tr>
<td>Members of Policy Scrutiny Committee in Attendance:</td>
<td>Vivienne Toal, Head of Employee Engagement &amp; Relations (Chair), Anne Brennan, Senior Manager, Medical Directorate, Trevor Burns, Fire Safety Manager, (Specialist Estates), (for Danny McKevitt), Anita Carroll, Assistant Director of Acute Services – Functional Support Services, Claire Graham, Head of Corporate Records (for Siobhan Hanna), Carmel Harney, Assistant Director of Allied Health Professionals, Governance &amp; Workforce Planning, John Rafferty, Acting Head of Residential Care (for Brendan Whittle)</td>
</tr>
<tr>
<td>Policy Approved/Rejected/Amended</td>
<td>Approved</td>
</tr>
<tr>
<td>Policy Implementation Plan included?</td>
<td>Yes</td>
</tr>
<tr>
<td>Any other comments:</td>
<td>N/A</td>
</tr>
<tr>
<td>Date presented to SMT</td>
<td>02 November 2011</td>
</tr>
<tr>
<td>Director Responsible</td>
<td>Dr Rankin, Acute Services</td>
</tr>
<tr>
<td>SMT Approved/Rejected/Amended</td>
<td>Approved</td>
</tr>
<tr>
<td>SMT Comments</td>
<td>Nil noted.</td>
</tr>
<tr>
<td>Date received by Employee Engagement &amp; Relations for database/Intranet/Internet:</td>
<td>27 March 2012</td>
</tr>
<tr>
<td>Date for further review</td>
<td>January 2014</td>
</tr>
</tbody>
</table>
# POLICY DOCUMENT – VERSION CONTROL SHEET

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>Policy for the Management of Medical Devices and Equipment Version: 003</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Supersedes</strong></td>
<td>Craigavon Area Hospital Group Trust Policy for the Management of Medical Devices and Equipment</td>
</tr>
<tr>
<td><strong>Originator</strong></td>
<td>Patient Safety &amp; Quality Manager</td>
</tr>
</tbody>
</table>
| **Scrutiny Committee & SMT approval** | Referred for approval by: SHSCT Equipment Management Steering Group  
Date of Referral: 18 November 2011  
Scrutiny Policy Committee Approval: 12 December 2011  
SMT approval: 02 November 2011 |
| **Circulation** | Issue Date:  
Circulated By:  
Issued To: As per circulation List (details below) |
| **Review** | Review Date: January 2014  
Responsibility of: Patient Safety & Quality Manager |
SHSCT Policy for the Management of Medical Devices & Equipment

CONTENTS

1.0 Introduction ................................................................................................................. 3
2.0 Definitions .................................................................................................................... 3
3.0 Purpose & Aims ............................................................................................................ 4
4.0 Policy Statement .......................................................................................................... 4
5.0 Scope of Policy ............................................................................................................ 4
6.0 Responsibilities ........................................................................................................... 5
6.1 Responsibilities of the Chief Executive ................................................................. 5
6.2 Responsibility of designated Lead Director ....................................................... 5
6.3 Responsibility of Senior Management ................................................................. 5
6.4 Responsibility of Equipment Management Quality manager ..................... 6
6.5 Responsibility of Ward / Department Managers ........................................... 6
6.6 Responsibility of Department Equipment Controller .................................. 6
6.7 Responsibility of Trust staff .................................................................................... 7

7.0 Legislative compliance, relevant Policies, Procedures & Guidance ................. 7
8.0 Equality & Human Rights Considerations ............................................................. 7
9.0 Policy Approval ........................................................................................................... 8
10.0 Policy Implementation, Training & Education .................................................. 8
11.0 Review of Policy ....................................................................................................... 8
12.0 Sources of Advice & Further Information ............................................................ 8

Appendix 1 – Controls Assurance Criteria for the Management of Medical Devices 9
1.0 Introduction

1.1 This document sets out the Southern Health and Social Care Trust's (hereafter referred to as ‘The Trust’) policy for the management of Medical Devices and Equipment.

1.2 The arrangements within this policy set out the systems and processes for managing medical devices and equipment, including; investigation, minimising risk and promoting a culture of continuous improvement. The systems and processes extend across the whole life cycle of any medical device / equipment item (i.e. from procurement to condemnation).

1.3 This policy has been developed in accordance with the Trust’s key principles for policy development.

1.4 This policy has been developed in consultation with internal stakeholders.

1.5 The principles of this policy apply to the management of all medical devices and equipment across the Trust regardless of which Directorate is charged with responsibility for the control and use of medical devices and equipment.

2.0 Definitions

2.1 Medical Device:
The term ‘medical device’ covers a broad range of products including those used every day in most health and social care settings and is defined as:

Any device, instrument, apparatus, implement, material substance, or other article (used singly or in combination), together with any accessory thereto, which is intended by the manufacturer for:

a. diagnosis, prevention, monitoring, treatment or alleviation of human disease or injury;

b. investigation or modification of human anatomy or of human physiological process; which does not achieve it’s principle intended action by pharmaceutical means, but which may be assisted in it's functioning by such means.

2.2 A more extensive list of products which fall within the definition of medical device is provided on the Northern Ireland Adverse Incident Centre (NIAIC) website at www.dhsspsni.gov.uk/niaic

2.3 Equipment:
Products that are not medical devices but are used in Health and Social Care settings by clients or users (e.g. stair lifts, blood tissue storage systems, fluid warming cabinets and some disinfecting and sterilising equipment) are included under the term “Equipment” in this policy.
3.0 Purpose and Aims

3.1 The purpose and aims of this policy are to:

- Ensure that the Trust has in place suitable and robust arrangements to support the management of medical devices and equipment.
- Support the development and maintenance of local medical device/equipment user training, (incorporating aspects of risk management and incident reporting)
- Ensure development and maintenance of robust systems (in line with best practice) to support the procurement, maintenance, repair, renewal/replacement of, modification, trial and storage of medical devices and equipment
- Support the development and management of appropriate systems to manage medical device and equipment related information.

3.2 This policy should be read in conjunction with the DHSSPSNI Controls Assurance Standard for the management of medical devices (Appendix 1)

4.0 Policy Statement

4.1 The Trust promotes an open and positive approach to medical devices and equipment management.

4.2 The Trust will maximise benefits, and minimise risks to patients, clients and staff through the management system of equipment and medical devices.

5.0 Scope of the Policy

5.1 This policy applies to all medical and devices/equipment that are either:

- Owned by the Trust or
- Loaned to community clients
- Other arrangements for example, on loan to the Trust by device manufacturers or other providers

5.2 All Trust employees must adhere to this policy and associated procedures.

5.3 Patients and their carers must also adhere to the principles of care and maintenance of medical devices and/or equipment where medical devices and/or equipment is on loan to patients.
6.0 Responsibilities

6.1 Responsibility of the Chief Executive

- The Trust’s Chief Executive, as “Accountable Officer” has overall responsibility for ensuring the aims of this policy are met.
- The Chief Executive delegates the day to day responsibility for establishing and monitoring the implementation of this policy to Directors.
- The Chief Executive is responsible for ensuring periodic review of the Trust management of medical devices and equipment systems and associated processes.

6.2 Designated Executive Director

- The Acute Services Director is the designated Executive Director with lead responsibility for the management of medical devices and equipment. This responsibility includes the need to ensure that there are sufficient resources in place for the effective implementation of this policy across the organisation.
- The Acute Services Director is the Chairperson of the Trust Equipment and Medical Devices Management Steering Group.
- The Acute Services Director will report to the Chief Executive on matters relating to the management of medical devices.

6.3 Responsibility of Senior Management

- All Trust Directors, Assistant Directors, Associate Medical Directors, Heads of Service and Senior Managers have responsibility for the effective management of medical devices and equipment within the areas of their remit and control, and for ensuring that processes are fully implemented and monitored as part of the Trust’s integrated governance requirements.
- All Trust Directors, Assistant Directors, Associate Medical Directors, Heads of Service and Senior Managers must ensure that they have adequate arrangements in place to meet the responsibilities of the nominated Department Equipment Controllers in relation to equipment management.
- All Trust Directors, Assistant Directors, Associate Medical Directors, Heads of Service and Senior Managers have responsibility to ensure that information required in relation to affecting this policy is provided in an accurate and timely manner.
6.4 **Responsibility of Equipment Quality Manager** *(referred to within Acute Services as the Patient Safety & Quality Manager)*

The Equipment Quality Manager will have a lead role in the management of the Quality Management System for medical devices / equipment. This is to ensure on-going management and improvement of the system against the DHSSPS Controls Assurance Standard and external ISO accreditation requirements. Where non-compliance / risk issues are identified these must be escalated to the Designated Executive Director for appropriate risk management.

6.5 **Responsibility of the Department / Ward Manager**

Each Department / Ward Manager is responsible for ensuring that the necessary arrangements are in place to comply with the safe use of equipment and medical devices from assessment of need through use to disposal. The Department / Ward Manager will also be responsible for ensuring the maintenance of all records, which are required to meet the requirements of the DHSSPS Controls Assurance Standard and external ISO accreditation requirements.

6.6 **Responsibility of the Department Equipment Controller**

There will be a dedicated Department Equipment Controller appointed within each ward or department. Whilst the roles and responsibilities are outlined within the Operational Procedures the key responsibilities of the Department Equipment Controller include the following:

- Ensure that there is an up to date equipment inventory in place by liaising with the Estates Management Department and advising of any changes (additions; loans; disposals / transfers);
- Ensure that all records pertaining to medical devices / equipment are properly managed and maintained. This will include the need for all decontamination records / training records being kept up to date;
- Be involved in the commissioning equipment and medical devices as appropriate;
- Be involved in the acceptance process for newly purchased equipment and conduct initial inspection when equipment is delivered to department.
- Ensure that all equipment needing repair or maintenance is brought to the attention of the ward/department manager
- Ensure that there are effective / traceable processes in place for any medical device / equipment interdepartmental loans
- Participate in Process Audits of QMS.
6.7 Responsibility of Trust Staff

All Trust staff have a responsibility to adhere to the principles and aims of this policy and ensure that they operate in accordance with its supporting procedures. This includes the need for staff to ensure equipment is properly looked after and used in accordance with approved Operational Procedures.

7.0 Legislative Compliance, Relevant Policies, Procedures and Guidance

7.1 Statutes, guidance, circulars and other publications relevant to this policy are listed in the HPSS Controls Assurance Standard for Medical Devices and Equipment, and can be located at www.dhsspsni.gov.uk.

This policy should be read in conjunction with the following documents:
- The Southern Trust equipment and medical devices procedures manual, process maps and forms;
- The Quality Manual for ISO accreditation (equipment management) which contains a condensed version of this policy.

8.0 Equality and Human Rights Considerations

8.1 This policy has been screened for equality implications as required by Section 75, Schedule 9, of the Northern Ireland Act, 1998

8.2 Using the Equality Commission’s screening criteria, no significant equality implications have been identified. This policy will therefore not be subject to an equality impact assessment.

8.3 This policy has been considered under the terms of the Human Rights Act, 1998, and was deemed to be compatible with the European Convention Rights contained in that Act.

8.4 This policy will be included in the Trust’s register of screening documentation and maintained for inspection whilst it remains in force.

8.5 This document can be made available on request in alternative formats, e.g. Braille, disc, audio cassette and in other languages to meet the needs of those who are not fluent in English.
9.0 Policy Approval

9.1 During development, this policy circulated for consultation to Trust Directors and Assistant Directors.

9.2 This policy was presented in final draft to the Trust Policy Committee and subsequently approved in March 2008.

9.3 Following the significant changes to the Trust’s governance arrangements this policy was revised and presented and approved by the Senior Management Team at its meeting in October 2011.

10.0 Policy Implementation, Training and Education

10.1 Following approval by the Trust’s Senior Management Team, the Director of Acute Services circulated this policy to all service Directors in November 2011.

10.2 The Patient Safety & Quality Manager will ensure that this policy is regularly reviewed in order to ensure that it is up to date and reflective of any statutory change, DHSSPS guidance or Trust requirement.

10.3 A copy of this policy was placed on the Trust’s intranet.

10.4 All Trust managers must ensure that their staff have access to this policy, understand its content, and are aware of its aims and purpose within a reasonable time period upon its release.

10.5 All Trust staff must comply with this policy.

11.0 Review of policy

11.1 The Trust is committed to ensuring that all policies are kept under review to ensure that they remain compliant with relevant legislation, Departmental guidance or Trust requirements.

11.2 This policy will be reviewed by the Equipment Management Steering Committee in October 2013 or earlier if required. That review will be noted on a subsequent version of this policy, even where there are no substantive changes made or required.

12.0 Sources of Advice and Further Information

12.1 Further advice and information regarding this document can be obtained from the Patient Safety & Quality Manager (Acute Services).
Appendix 1: Controls Assurance Criteria for the Management of Medical Devices

The Controls Assurance Standard for the management of Medical Devices stipulates 30 criteria and these include the following requirements:

<table>
<thead>
<tr>
<th>Ref</th>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Board level responsibility for Medical Devices and Equipment management is clearly defined and there are clear lines of accountability throughout the organisation leading to the Board.</td>
</tr>
<tr>
<td>2</td>
<td>There is a broad-based Medical Devices and Equipment group, established in accordance with NIAIC Device Bulletin DB 9904(NI).</td>
</tr>
<tr>
<td>3</td>
<td>There is a comprehensive organisation-wide implemented policy and procedure for the management of Medical Devices and Equipment</td>
</tr>
<tr>
<td>4</td>
<td>All Medical Devices and Equipment are selected and acquired in accordance with the Health Estates (NIAIC) and National Audit Office recommendations.</td>
</tr>
<tr>
<td>5</td>
<td>All Medical Device developments, modifications and trials are conducted in accordance with relevant legislation and guidance.</td>
</tr>
<tr>
<td>6</td>
<td>All professional users and end-users have access to manufacturer's instructions and all users sign statements to the effect that they have received instructions on the safe use of Medical Devices or Equipment.</td>
</tr>
<tr>
<td>7</td>
<td>Where Medical Device/Equipment manufacturers automatically send copies of revised instructions to a named recipient, these are appropriately dealt with.</td>
</tr>
<tr>
<td>8</td>
<td>All instructions supplied by the user organisation are evaluated for their adequacy.</td>
</tr>
<tr>
<td>9</td>
<td>Delivery and pre-use checks are carried out on all newly delivered Medical Devices/Equipment</td>
</tr>
<tr>
<td>10</td>
<td>All newly delivered Medical Devices and Equipment are properly stored after acceptance.</td>
</tr>
<tr>
<td>11</td>
<td>Medical Devices designated for single use are not reused under any circumstances</td>
</tr>
<tr>
<td>12</td>
<td>All Medical Devices and Equipment prescribing decisions are made by staff with appropriate professional qualifications and suitable experience, backed by appropriate administrative and technical support</td>
</tr>
<tr>
<td>13</td>
<td>All necessary information required to properly manage the user organisation's range of Medical Devices/Equipment is recorded on a suitable system.</td>
</tr>
<tr>
<td>14</td>
<td>All Medical Devices/Equipment are properly maintained and repaired.</td>
</tr>
<tr>
<td>15</td>
<td>The in-house Medical Device/Equipment maintenance department is externally accredited</td>
</tr>
<tr>
<td>16</td>
<td>All Medical devices/Equipment returned for servicing and repair are properly decontaminated</td>
</tr>
<tr>
<td>17</td>
<td>Medical Devices/Equipment are replaced in accordance with an agreed policy</td>
</tr>
<tr>
<td>18</td>
<td>All loaned Medical Devices/Equipment are collected when no longer needed.</td>
</tr>
<tr>
<td>19</td>
<td>All adverse incidents involving Medical Devices and Equipment are reported in accordance with NIAIC Medical Device/Equipment Alert MDEA (NI) 2005/01.</td>
</tr>
<tr>
<td>20</td>
<td>A complete record of guidance issued by the NIAIC is maintained; warning /alert notices are distributed to the appropriate people in the organisation; and recommendations contained in the notices are implemented.</td>
</tr>
<tr>
<td>21</td>
<td>The risk management process contained within the risk management system standard is applied to the management of Medical Devices and Equipment risk.</td>
</tr>
<tr>
<td>22</td>
<td>Staff are made aware of and, where necessary, trained in adverse incident reporting and investigation requirements for Medical Devices and Equipment.</td>
</tr>
</tbody>
</table>
23 All professional users are trained in the safe operation of Medical Devices and Equipment.
24 All technical supervisors are trained in the safe operation of Medical Devices and Equipment.
25 All end-users are given appropriate training in the safe and effective use of Medical Devices and Equipment.
26 All staff are provided with appropriate training in the safe use of Medical Devices and Equipment.
27 Key indicators capable of showing improvements in Medical Devices/Equipment management and/or providing early warning of risk are used at all levels of the organisation, including the Board, and the efficacy and usefulness of the indicators is reviewed regularly.
29 The organisation participates in benchmarking its management of Medical Devices/Equipment.
28 The system in place for Medical Devices and Equipment management, including risk management arrangements, is monitored and reviewed by management and the Board in order to make improvements to the system.
30 The Board should seek independent assurance that an appropriate and effective system of managing Medical Devices and Equipment is in place and that the necessary level of controls and monitoring are being implemented.