Standard Operating Procedure 8 (SOP 8)

Adverse Incidents- Reporting Adverse Incidents for Medical Devices

Why we have a procedure?

This procedure is intended to rationalise the action taken for the reporting and investigation of adverse incidents relating to medical devices. This procedure is supplementary to and must be implemented in conjunction with the Trust Incident Reporting Policy for reporting accidents, incidents, near misses and complaints. The procedure has been written in accordance with MHRA guidelines, to establish clear lines of responsibility for the implementation, control, reporting, audit and investigation for all adverse incidents pertaining to medical devices. Implementation of the procedure will contribute to the safety of patients, users and others.

This procedure is in compliance with CQC Fundamental Standards- section B and E of Regulation 12: Safe Care and Treatment and sections C, D and E of Regulation 15: Premises and Equipment. The intention of regulation 12 is to ensure that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and used in a safe way. The intention of regulation 15 is to ensure equipment used by the service provider is suitable for the purpose for which it is being used, properly used and properly maintained.

What overarching policy the procedure links to?

Medical Devices Policy

Which services of the trust does this apply to? Where is it in operation?

<table>
<thead>
<tr>
<th>Group</th>
<th>Inpatients</th>
<th>Community</th>
<th>Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental Health Services</td>
<td>✓</td>
<td>✓</td>
<td>all</td>
</tr>
<tr>
<td>Learning Disabilities Services</td>
<td>✓</td>
<td>✓</td>
<td>all</td>
</tr>
<tr>
<td>Children and Young People Services</td>
<td>x</td>
<td>✓</td>
<td>all</td>
</tr>
</tbody>
</table>

Who does the procedure apply to?

- Authorised Staff of diagnostic and therapeutic equipment
- Ward/Department Managers
**When** should the procedure be applied?

When there is an incident concerning a medical device that has led to:
- A death or serious injury
- Medical or surgical intervention (including implant revision) or hospitalisation
- Unreliable test results
- Other minor safety or quality problems should also be reported as these can help demonstrate trends, such as highlighting inadequate manufacturing or supply systems

**How** to carry out this procedure

All incidents involving a medical device must be reported within 24 hours to MPCE, immediately followed up with an incident report and completed MHRA Paperwork.

**Retain the Device for Inspection**
- All medical devices, including any packaging and / or consumables associated with the incident, must be quarantined and labelled ‘Do Not Use under Investigation’
- Groups and Departments must ensure that action is taken as necessary to ensure safety of patients, users and others following any incident with a medical device
- The Health & Safety Officer (HSO) will initiate the appropriate method of investigation with the appropriate departments and / or enforcing authorities. In the absence of the HSO the investigation and notification should be initiated by the Group Risk Facilitator
- The Group Governance Team must inform the Procurement Manager of any faulty consumables, who will liaise with the supplier and co-ordinate any returns
- No equipment, materials or substances must be brought back into service / use without the authority of the HSO and / or MPCE / Estates / Procurement
- Groups and Departments must ensure that measures are in place for the procedure to operate effectively and efficiently to demonstrate compliance with CQC Regulation 12: Safe Care and Treatment
- Devices must only be decontaminated upon MHRA approval and prior to investigation, the Decontamination Label to be attached following approval. Under no circumstances can medical devices be sent through the post without prior decontamination. Devices that need to be dispatched must be sent via Trust approved courier service. Appropriate methods of decontamination must be identified through the manufacturers, or relevant department. Appropriate methods of decontamination must be arranged following advice obtained from the manufacturer and the Infection Prevention and Control Team. (See **Standard Operating Procedure 7 (SOP 7) Decontamination of Medical Devices Prior to Service, Repair or Disposal**)

**Report the Incident**
- Groups and Departments must ensure that a Trust Incident Report Form is completed and reported on the DATIX system. Group to nominate responsible officer to conduct a full investigation and submit full report to Governance and Risk Team within specified time scales as requested by the Governance and Risk Manager
• Groups and Departments are to ensure that all staff, including bank, agency and contractors, at all levels are aware of their responsibilities, and of the procedures to be used with regard to the reporting of incidents, and isolation and retention of defective items
• MPCE are responsible for reporting the incident to MHRA. They will ensure appropriate MHRA Adverse Incident Report Form is filled in

Return of Equipment - MHRA Guidance
• Equipment to be returned to the appropriate body (e.g. MHRA, manufacturer) only upon receipt of MHRA instructions
• Consumables - appropriate method of return to supplier to be arranged via the Procurement Department

Defective or Contaminated Items and Evidence

Evidence:
1. All material evidence should be labelled, appropriately bagged and kept secure including products and, where appropriate packaging material or other means of batch identification
2. The evidence is not to be interfered with in any way except for safety reasons or to prevent loss. If necessary, a record should be made of all:
   • readings
   • settings
   • position of switches
   • valves
   • dials
   • gauges
   • indicators
3. Photographs may be taken where appropriate
4. All persons involved must make witness reports
5. In serious cases witness reports are to be countersigned by another person

Defective Items:
1. Must not be repaired before investigation
2. Must not be returned to supplier or discarded before investigation
3. Must be appropriately decontaminated only after approval by MHRA prior to any investigation and before being allowed to move within or outside of the Trust, in which case use approved Trust Courier where applicable
4. The manufacturer or supplier must be informed promptly of the incident, by the HSO
5. The manufacturer or supplier must not be allowed to inspect the item without the presence of the HSO or relevant Department, i.e. MPCE, Estates, Procurement
6. The manufacturer or supplier must not to be allowed to exchange, interfere with or remove any part of the product without the approval of the HSO or relevant Department, i.e. MPCE, Estates, Procurement
What do these terms mean?

CQC - Care Quality Commission is the independent regulator of health and adult social care in England. They make sure health and social care services provide people with safe, effective, compassionate, high-quality care and encourage them to improve.

MPCE - Medical Physics and Clinical Engineering Department provides a device management service to the Trust. Medical device management includes a wide range of activities:
- Advice and assistance with equipment evaluation prior to purchase
- Help with Deciding on the model that most fits the user department needs
- Preparation ready for implementation of the device which includes commissioning the equipment and training the staff how to use it
- Technical and clinical support of the equipment and staff during its life time
- Planned end of life replacement
- Correct disposal of the old equipment

MHRA - Medicines and Healthcare products Regulatory Agency is a government body which was set up in 2003 to bring together the functions of Medicines Control Agency (MCA) and Medical Devices Agency (MDA). These include the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents.

HSO - Health and Safety Officers are responsible for providing a professional health and safety service to all levels of staff working for a specific NHS organisation. Their work ensures that the employing organisation meets the requirements of Health and Safety legislation and corporate Health and Safety strategy and arrangements.

DATIX - Datix is a web-based software that helps organisations manage their risks, incidents, service user experience, CQC Standards compliance and more through a variety of integrated modules enabling you to provide a comprehensive oversight of your risk management.
Adverse Incident Occurrence

Department/Group to quarantine faulty device/consumable and retain all packaging etc. and label device “Do Not Use Under Investigation”.

Department/Group to complete DATIX within 24 hours and inform MPCE (Geoff Nixon) and HSO.

MPCE reports incident to MHRA and liaises with HSO.

MPCE/HSO advises department/Group of further action following MHRA advice.

Department/Group carry out necessary actions e.g. ensure faulty device is decontaminated prior to return.

Department/Group update DATIX to reflect actions taken.

MPCE to co-ordinate return of faulty medical equipment.

Estates to co-ordinate repairs of faulty hoists, wheelchairs etc.

Department/directorate/Group to liaise with Receipt and Distribution manager for return of faulty consumables.
**Where** do I go for further advice or information?

**Medical Devices Group**
- Ensure that the Trust has access to appropriate expert advice as required to support this procedure
- Review incidents including governance issues relating to medical device management
- Receive quarterly incident analysis reports related to medical device related incidents reported to MHRA
- Receive quarterly performance reports related to the dissemination of MHRA medical device alerts across the Trust

**Governance Assurance Unit**
- Provide central point of contact for the Medicines and Healthcare products Regulatory Agency (MHRA)
- Disseminate safety alerts and other notices issued by agencies such as NHS England, Medicines and Healthcare Products Regulatory Agency (MHRA) and NHS Estates to a nominated representative in each Service when relevant, including the Governance Lead in each Group/Division.
- Maintain a record of actions taken by each Group/Division as a result of the safety notices/alerts
- Produce a monthly Central Alerting System (CAS) status for the Quality & Safety Steering Group
- Ensure failure to meet deadlines for action is recorded on the Trust risk register and escalated in line with the Trusts escalation procedures
- Ensure incidents involving medical devices are appropriately investigated and reported to MHRA

**Nominated Medical Device Leads (Clinical Groups) and Team Leaders in Community Services**
- Key point of contact for ensuring Medical Device Alerts, Patient Safety Notices and other Safety Alerts are acknowledged by their managers and to act on the managers’ behalf when they are unavailable

**Team Leaders/Ward & Department Managers/Senior Nurses/Operational Managers**
- Report incidents associated with medical devices in line with Trust policy and to MHRA if appropriate

**Infection Prevention & Control Team**
- Advise accordingly in line with this procedure

**The Medical Physics and Clinical Engineering department**
- Assist the Trust with the investigation of incidents involving medical devices

**Training**
Staff may receive training in relation to this procedure, where it is identified in their appraisal as part of the specific development needs for their role and responsibilities.
Please refer to the Trust’s Mandatory & Risk Management Training Needs Analysis for further details on training requirements, target audiences and update frequencies.

**Monitoring / Review of this Procedure**
In the event of planned change in the process(es) described within this document or an incident involving the described process(es) within the review cycle, this SOP will be reviewed and revised as necessary to maintain its accuracy and effectiveness.

**Equality Impact Assessment**
Please refer to overarching policy.

**Data Protection Act and Freedom of Information Act**
Please refer to overarching policy.
### Standard Operating Procedure Details

| **Unique Identifier** for this SOP is | BCPFT-CLIN-POL-12-8 |
| **State if SOP is New or Revised** | Revised |
| **Policy Category** | Clinical |
| **Executive Director** whose portfolio this SOP comes under | Deputy Chief Executive & Director of Resources |
| **Policy Lead/Author** Job titles only | Medical Devices Group |
| **Committee/Group Responsible for Approval of this SOP** | Medical Devices Group |
| **Month/year consultation process completed** | June 2019 |
| **Month/year SOP was approved** | September 2019 |
| **Next review due** | September 2022 |
| **Disclosure Status** | ‘B’ can be disclosed to patients and the public |
| **Key words** relating to this SOP | Serious incident, HSO, Incident reporting, MHRA guidance |

### Review and Amendment History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Jun 2019</td>
<td>SOP Reviewed with no changes made</td>
</tr>
<tr>
<td>1.0</td>
<td>Dec 2015</td>
<td>New Procedure established to supplement Medical Devices Policy</td>
</tr>
</tbody>
</table>