Decontamination of Medical and Laboratory Equipment Prior to Maintenance or Transportation

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<th>Version</th>
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<tbody>
<tr>
<td>Date to be reviewed</td>
<td>January 2020</td>
</tr>
<tr>
<td>To be reviewed by</td>
<td>Medical Engineering Manager</td>
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**Policy Title:** Decontamination Of Medical and Laboratory Equipment Prior to Maintenance or Transportation

**Executive Summary:** This policy provides guidance to all staff regarding the decontamination of medical and laboratory equipment prior to maintenance or transportation.

**Supersedes:** V3.0

**Description of Amendment(s):**
- Reference to Health and Social Care Act 2008 regulations 2014
- Amended managerial and user responsibilities - inclusion of DIPC, Head of Estates, Estates Operations Manager
- Compliance – monitoring and reporting
- Revised safe systems of work flowchart

**This policy will impact on:**
All users of medical equipment and devices

**Financial Implications:**

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<tr>
<th>Policy Area:</th>
<th>Document Reference:</th>
<th>ECT002644</th>
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<td>Medical Device Management</td>
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<th>Effective Date:</th>
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<th>Review Date:</th>
<th>January 2020</th>
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<tr>
<td>Medical Director</td>
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<tr>
<th>Author:</th>
<th>Impact Assessment Date:</th>
<th>N/A</th>
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<tr>
<td>Medical Engineering Manager</td>
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<td>Consultation:</td>
<td>Risk Management Group</td>
<td>11/01/2017</td>
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<td>Infection Prevention and Control Operational Group</td>
<td>15/12/2016</td>
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1 Introduction

Items of reusable medical or laboratory equipment intended for repair and used for the treatment of patients may become contaminated with hazardous substances during use.

This can present a cross-infection risk to staff and patients using this equipment, and also people who come in to contact with it at a later stage, if it is not identified and managed appropriately.

There is a risk that the Trust could be subject to litigation if it could not be proved that there were management systems in place to deal with this.

2 Legislation and guidance

Safe systems of work should be implemented to protect all patients and staff, including those not directly employed by the NHS, from the risk of cross infection from any medical device or equipment used in the treatment, diagnosis or care of patients.

Care Quality Commission: Guidance for providers on meeting the regulations (2015) references Regulation 15 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, in relation to premises and equipment states that – appropriate standards of hygiene must be maintained for the purpose for which they are being used. Equipment must be cleaned or decontaminated after each use and between use by different people who use the service. All staff must understand the risk to people if they do not adhere to this.

East Cheshire NHS Trust has a duty of care towards its patients, employees and contractors, and is required to ensure that they are not put at risk, e.g. from medical devices or other equipment contaminated from use in healthcare or laboratory settings.

The Health and Safety at Work Act 1974 places a number of duties upon employers concerning the requirements of safe working practices. In addition, the Control of Substances Hazardous to Health (COSHH) Regulations (2002) is applicable to both chemical hazards and biohazards.

Employers must conduct their undertakings in such a way as to ensure that, as far as is reasonably practicable, persons not in their employ are not exposed to risks. The Management of Health and Safety at Work Regulations (1999) place a statutory duty of cooperation between the NHS and its contractors to provide each other with clear communication in Health and Safety matters, including any hazards associated with the transfer of material or equipment.

Whilst the advice in this policy document relates to microbiological hazards, equipment may also become contaminated with chemicals that may be corrosive, irritant, toxic, cytotoxic or radioactive. The same regulations apply in such instances.

Failure to comply with the legislative requirements would leave the Trust liable to prosecution.
3 Policy Statement

This policy describes the system to manage and mitigate the risks associated with the contamination of medical devices or equipment from use in healthcare or laboratories prior to maintenance or transportation.

Amongst others, the policy is based on the recommendations of the MHRA document Managing Medical Devices – Guidance for healthcare and social services organisations (April 2015).

4 Managerial and Users Responsibilities

4.1 Chief Executive
The Chief Executive is the duty holder on behalf of the Trust Board and has ultimate responsibility for all policies and their implementation.

4.2 Director of Finance and Facilities (DoFF)
The Director of Finance and Facilities is the Executive Director responsible for maintenance services and assumes the delegated responsibilities of the Chief Executive for maintenance. He/she has overall responsibility for the Estates Services, including Medical Engineering.

4.3 The Director of Infection Prevention and Control (DIPC) has executive responsibility to the Trust board for Infection Prevention and Control, including Decontamination of Medical and Laboratory Equipment, and will undertake actions required to minimise the risk to patients, staff and the general public. In the absence of the DIPC the responsibility will be delegated to the Infection Prevention and Control Dr or the Lead Nurse Infection Prevention and Control. Providing assurance to the board that systems and process are in place to ensure compliance with agreed standards.

4.4 Head of Estates
The Head of Estates has responsibility for the Estates Services, including Medical Engineering, and ensuring that all aspects of building and equipment design, purchasing, use, decommissioning, inspection, maintenance and repair activities are carried out in compliance with relevant legislation and safe practice within available resources.

4.5 Estates Operations Manager
The Estates Operations Manager has operational responsibility for the Estate Services, including Medical Engineering, and ensuring that existing resources are used in an efficient manner.

4.6 Medical Engineering Manager
The Medical Engineering Manager is the author of the policy and will monitor, evaluate and review the policy within the Medical Engineering Department.

4.7 Infection Prevention and Control Team (IPCT)
The infection prevention and control team has responsibility for supporting the implementation of the policy across the Trust and will ensure compliance as part of a sustainable audit program.

4.8 Deputy Directors/Heads of Service and Ward/Department Managers
The managerial responsibility for the implementation of this policy remains with the Deputy Directors/Heads of Service and Ward/Department Managers. Ward/Departmental Managers will monitor and ensure that their staff are appropriately trained in the decontamination of medical equipment and that they comply with the policy.
4.9 All users of medical equipment
Unless specifically advised otherwise by anyone providing a repair or investigation service, users of medical equipment will be responsible for ensuring that it has been appropriately decontaminated prior to maintenance or transportation.

Users will be responsible, for example, for ensuring that:

- Suction equipment jars are emptied, washed and dried
- Contaminated suction tubing and filters are discarded
- Patient ventilation breathing tubing and filters are discarded
- Infusion device giving sets and syringes are discarded

5 Guidance on safe systems of work

Anyone, who inspects, services, repairs or transports reusable medical equipment, dental or laboratory equipment has the right to expect that this equipment has been appropriately treated as to remove or minimise the risk of infection or other hazards. (See appendix A for flowchart).

Staff handling used medical equipment must assume that they are contaminated and take precautions to reduce the risk to themselves and others. The use of personal protective equipment is required.

Suppliers of medical equipment have a responsibility to provide information on the compatibility of their devices with methods and cleaning agents for decontamination. If the manufacturer’s instructions appear inappropriate or incomplete, the user must report this to the Trust’s medical device facilitators or medical engineering manager.

All items intended for inspection, service, repair or transportation, either within or external to the Trust, MUST be provided with a Medical Equipment Fault Reporting and Contamination Status Form. (See Appendix B for example). These forms are available in duplication booklet format from the Medical Engineering Department.

If medical equipment is presented for inspection, service or repair on Hospital premises, or is dispatched to a maintenance provider, without a Fault Reporting and Contamination Status Form and without prior agreement, they may rightly refuse to handle such items until suitable documentation has been provided. This may result in delays to the repair and/or incur additional costs.

6 Medical equipment under investigation

In particular situations, for example when the condition of an item of medical equipment which is the subject of complaint or investigation may be altered or influenced by a decontamination process, the investigator may wish the item not to be decontaminated. In situations such as these seek advice from the investigator or contact the Trust’s medical device facilitators or medical engineering manager immediately. For incidents that occur Out of Hours the equipment must be quarantined and not decontaminated until advice is sought and approval given.

Consumable items, such as giving sets or breathing tubes, used in conjunction with reusable medical equipment under investigation must be retained if there is any possibility that they may have influenced the performance of the equipment.
7 Dispatching items from Trust Premises

Equipment subject to investigation must not be decontaminated or released outside the Trust without the consent of the Trust’s medical devices facilitators.

All items of reusable medical equipment must be decontaminated wherever possible before inspection, service or repairs are carried out. If the device has to be dispatched from Trust premises and cannot be decontaminated then:

a) Prior warning should be given to the intended recipient
b) The condition of the item should be clearly labelled and the reasons given for not decontaminating the item
c) The packaging should be sufficiently robust to withstand transport
d) The packaging method must ensure that the contents of the inner pack cannot contaminate the outer one.

It is essential that the agreement of any carrier (local staff, commercial courier, Post Office) used to transport a contaminated item be sought before dispatch. Check with the chosen carrier before arranging transport as transportation of contaminated items may be forbidden by one or more carriers.

8 Methods of Decontamination

The decontamination methods used must not damage the item and any of its components. For equipment that cannot be decontaminated without disassembly advice must be sought from the maintenance provider or agent.

If there is any doubt regarding the appropriate decontamination method advice must be sought from:

a) Ward/Department Manager
b) Infection Control Team (Ext 1597 MDGH)
c) Medical Engineering Department (Ext 1930 MDGH)
d) HSDU (Ext 1920 MDGH)
e) Estates Services (Ext 1616 MDGH)
f) Medical Devices Facilitators
g) Manufacturer or their agents

Clinical staff / equipment users are responsible for the equipment in use within their ward or department, and must ensure decontamination guidelines are adhered to before arranging for investigation, inspection, service, repair or transportation.

9 Medical Equipment and Transmissible Spongiform Encephalopathies (TSE’s), Creutzfeldt-Jakob Disease (CJD) or Variant CJD (vCJD)

Items of reusable medical equipment requiring maintenance that have been used in the care of patients known to be or at increased risk of CJD or vCJD must not be repaired by Trust staff or sent away for repair. See Trust policy Transmissible Spongiform Encephalopathies (TSE’s) including Creutzfeldt-Jakob Disease (CJD) and seek immediate advice from the Trust Infection Prevention and Control Team. Out of hours speak with the on-call consultant microbiologist.
10 Monitoring Compliance

Infection Prevention and Control and the Risk Management Group will receive and approve:
- Review of Decontamination of Medical and Laboratory Equipment Prior to Maintenance or Transportation policy and periodic policy updates
- 6 monthly compliance audit reports

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<th>Monitoring Frequency</th>
<th>Information reported to</th>
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<td>Detailed audit undertaken to ensure policy compliance in relation to reactive maintenance requests.</td>
<td>Estates Compliance and Performance Officer</td>
<td>6 monthly</td>
<td>Infection Prevention and Control Team and Decontamination Group</td>
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<td>Medical Engineering Manager</td>
<td>3 yearly</td>
<td>Infection Prevention and Control Team, Risk Management Group</td>
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11 Policy Review

A formal review of the policy will be undertaken by the Medical Engineering Manager within 3 years of the date of issue or as necessary due to the publication of new legislation or guidance.

12 References

Care Quality Commission: Guidance for providers on meeting the regulations (2015)
Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
The Health and Safety at Work Act 1974
The control of substances hazardous to health (COSHH) regulations 2002
The Management of Health and Safety at Work Regulations 1999
MHRA: Managing Medical Devices – Guidance for Healthcare and Social Services Organisations April 2015
Appendix A  Decontamination Flow Chart

Can the equipment be decontaminated without removing evidence important to a repair or an investigation?

**YES**
Decontaminate the item
Label item with Medical Equipment Fault Reporting and Contamination Status Form.
Note: Fault/defect must be declared.
On MDGH site: Store in preparation for inspection, service or repair
Off site: Pack and dispatch for inspection, service or repair.

**NO**
Inform repair organisation or investigating body

Repair organisation or investigating body agrees dispatch

**YES**
Label item with Medical Equipment Fault Reporting and Contamination Status Form.
Note: Fault/defect must be declared.
Pack and dispatch for inspection, service or repair.

**NO**
Arrange visit to site by repair organisation or investigating body.
Label item with Medical Equipment Fault Reporting and Contamination Status Form.
Note: Fault/defect must be declared.
Quarantine in preparation for inspection, service or repair.
Part 1 Equipment

<table>
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<th>Device Type/Model/Name</th>
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Description of Fault/Condition: (report the last settings & what you consider to be the problem)

Incident Report: If this equipment was involved in a clinical incident, please quarantine the device along with any other material evidence (e.g. infusion giving-sets etc) and supply the incident report number: ............

Part 2 Declaration of Contamination Status (tick ✔ box A or B giving details as required)
Advice on decontamination can be obtained from the Cleaning Policy contained in the Infection Control Manual and also the policy for the Decontamination of Reusable Medical and Laboratory Equipment and Devices Prior to Repair, Service, Inspection or Transportation.

A □ This equipment / item HAS NOT been used in any invasive procedure or been in contact with blood, other body fluids, expired gases or pathological samples. It has been externally cleaned prior to inspection, service, repair or transportation. (now go to part 3)

B □ This equipment / item MAY have become exposed internally or externally to hazardous materials as indicated below (please ✔ appropriate box). It has been externally cleaned prior to inspection, service, repair or transportation.

<table>
<thead>
<tr>
<th>Blood</th>
<th>Chemicals</th>
<th>Any other Biohazard (Please state)</th>
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<tbody>
<tr>
<td>Body Fluids</td>
<td>Substances Hazardous to Health</td>
<td></td>
</tr>
<tr>
<td>Pathological Samples</td>
<td>Radioactive Contamination</td>
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If the device could not be decontaminated please state why:

………………………………………………………………………………………………………………………………………

It is illegal to send contaminated items through the post

Part 3  I declare I was the last user of this equipment and have taken all reasonable steps to ensure the accuracy of the above information.

Signature: .................................................. Name of Trust or organisation: ..................................................
Print Name: .................................................. Ward/Department: ..............................................................
Job title: .................................................. Date: .................................................. Tel no: ..................................................
Equipment sent to: ........................................................................................................................................