Introduction

Safe systems of work must be implemented to protect all staff and patients from the transmission of organisms from medical devices, associated consumables and materials used in the treatment, diagnosis and care of patients.

In order to comply with the duty required by the Health and Safety at Work Act 1974 and associated regulations, e.g. Control of Substances Hazardous to Health Regulations (2002), risk to health and safety must be reduced as far as reasonably practicable.

It is essential that all medical devices and other healthcare equipment undergo an appropriate decontamination process following patient use and prior to inspection, service or repair on or off site.

Contamination may be by microbiological or other biological agents; blood, body fluids or chemicals which are corrosive, irritant, toxic, cytotoxic or radioactive. A safe system of work, in compliance with MHRA: Managing Medical Devices will minimise the risk to personnel. As contamination is not always visible, the standard must be that all equipment is cleaned following each patient use and prior to inspection, service or repair.

The Health Act (2008) clearly defines the responsibility of the organisation to protect, patients, staff and others from acquiring Health Care Associated Infections. The decontamination programme identified within the Act is reflected in this policy.

Policy scope

This policy applies to all healthcare professionals working across acute and community services within NuTH. This includes medical staff, nurses, allied health professionals, students, temporary clinical staff, those working in the Trust from other organisations and contractors.

Aim of policy

The aim of this policy is to ensure that all healthcare equipment is appropriately decontaminated to remove or minimise the risk of infection/other hazards prior to transport of equipment for inspection, servicing or repair, either on hospital premises or elsewhere.
4 Duties

4.1 The Chief Executive has overall responsibility for implementation, monitoring and review of this policy. This responsibility is delegated to the Director of Infection Prevention and Control (DIPC).

4.2 The Infection Prevention and Control Committee (IPCC) will review the policy and any new evidence base within the time frame set out in the policy.

4.3 The Infection Prevention and Control (IPC) and Medical Electronics Team are responsible for providing expert advice in accordance with this policy and for supporting staff in its implementation.

4.4 Ward/Department Managers are responsible for ensuring that all staff are trained in the safe use and handling of medical devices within their area. Managers must ensure that staff are aware of how to effectively decontaminate equipment used within their department. Managers must therefore ensure that all staff comply with this policy. It is the responsibility of all staff to ensure equipment is stored clean and ready for use and effectively decontaminated prior to transfer for service or repair.

4.5 Manufacturers’ and suppliers’ have a responsibility to provide information on the compatibility of their particular medical devices or equipment with methods and agents for effective decontamination. Refer to manufacturers instructions for use. Guidance on decontamination has been issued by the MHRA: Managing Medical Devices. Such general guidance will require to be interpreted in the light of particular local situations. Where manufacturer’s guidance differs from Trust Policy guidance must be sought from the IPC Team prior to purchase.

5 Definitions

Medical devices - refers to all products, except medicines, used in healthcare for diagnosis, prevention, monitoring or treatment. The range of products is very wide and includes contact lenses, condoms, heart valves, hospital beds, resuscitators, radiotherapy machines, surgical instruments and syringes, wheelchairs and walking frames.

6 Decontamination of healthcare equipment

6.1 Classification of infection risk associated with the decontamination of medical devices and equipment

The following guidance will determine whether equipment needs sterilisation, disinfection or cleaning following patient use and/or prior to inspection, service or repair. For further guidance on methods of sterilisation, disinfection or cleaning please refer to the Cleaning and Disinfection Procedure.

Classification of infection risk associated with the decontamination of medical devices (MHRA Managing Medical Devices):
<table>
<thead>
<tr>
<th>Risk</th>
<th>Application of Item</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| High   | ▪ In close contact with broken skin or mucous membrane  
▪ Introduced into sterile body areas | Cleaning followed by sterilisation.                                                |
| Medium | ▪ In contact with mucous membranes contaminated with particularly virulent or readily transmissible organisms  
▪ Prior to use on immunocompromised patients | Cleaning followed by sterilisation or disinfection required.  
Where sterilisation may damage equipment, cleaning followed by high level disinfection may be used as an alternative. |
| Low    | ▪ In contact with healthy skin  
▪ Not in contact with patient | Cleaning only                                                                   |

Other factors to be taken into consideration when choosing a method of decontamination include the nature of the contamination, the time required for processing, the heat, pressure, moisture and chemical tolerance of the device, the availability of the processing equipment and the quality and risks associated with the decontamination.

**Note:** Where sterilisation will damage the equipment, cleaning followed by high-level disinfection may be used as an alternative. Contact Infection Prevention and Control Team for advice.

Potential contamination of Healthcare Equipment or Medical Devices with Prion Proteins (CJD/vCJD) will result in the need for decontamination, quarantining or disposal of the device. Refer to [Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD), in hospital patients](#); contact the Infection Prevention and Control Team for advice.

The Trust policy for ensuring a clean patient environment, [Decontamination of Patient Environment (including Terminal Cleaning)](#), provides further explicit guidance on cleaning responsibilities. A comprehensive list of recommended methods of decontamination can be found in the Trust [Cleaning and Disinfection Procedure](#); these lists are not exhaustive.

### 6.2 Procedure following patient use and when sending medical devices for service or repair

Following use on a patient or when requiring inspection or service, all medical devices must be checked for visible evidence of contamination by the user/clinician; however, as contamination is not always visible, all equipment must be cleaned following patient use. Every attempt must be made by the...
user to adequately decontaminate the equipment prior to transfer for repair or servicing. If it is not possible to decontaminate, then the equipment must be safely contained and clearly identified as ‘contaminated’ until advice is obtained from the Infection Prevention and Control Team and the Medical Electronics Department.

All equipment MUST be accompanied by the Trust Declaration of Decontamination Status of Healthcare Equipment Following Use and Prior to Service or Repair form, (see Appendix 1).

If items are dispatched to suppliers, or presented for service or inspection on the Trust’s premises without a declaration of decontamination, the receiver will refuse to accept the item and it will be returned to the ward/department until it is accompanied by the aforementioned form.

In some instances total decontamination may not be possible at source i.e. point of use, due to internal contamination of the equipment, requiring additional tools to gain access to the affected parts. The equipment must be removed to a suitable designated area for appropriate decontamination prior to inspection, service or repair. In this instance, the nature of contamination must be clearly communicated to the receiving organisation using the Trust Declaration of Decontamination Status of Healthcare Equipment Following Patient Use and Prior to Service or Repair form.

6.3 Items that have been involved in an incident

In particular situations, for example when an item of equipment has been involved in an incident, its condition may be altered or influenced by the decontamination process. In such situations, advice must be sought from those investigating the incident, the Infection Prevention and Control Team and Medical Electronics.

6.4 Transporting items of equipment internally and externally to Trust

Any packaging must be sufficiently robust to withstand transport and if possible packaging specifically designed for the item of equipment must be used in accordance with the Carriage of Dangerous Goods Regulations 2007.

The condition of the item must be clearly labelled indicating content and contamination status. This is so that it can be clearly determined prior to opening the package. E.g. biohazard label if required and Trust Declaration of Decontamination Status of Healthcare Equipment Following Patient Use and Prior to Service or Repair form.

Transport of contaminated equipment within the Trust must be in a suitable container via internal hospital transport. Where appropriate all external parts of large items of mobile equipment should be covered in orange clinical waste bags and suitably labelled.
It is illegal to send contaminated items by any form of postal system e.g. Royal Mail, or courier. It must be transported via an approved contractor who is licensed to transport such goods. It is the responsibility of the ward/department manager to ensure a safe system of packaging and transport is in place for all equipment moved within and external to the Trust. Contact Health and Safety for advice.

6.5 Management of Macerators

When a macerator fails, it is the responsibility of the nursing staff in that area to report the fault immediately to the Estates Department or Interserve FM via Helpdesk 21000.

Nursing staff responsibilities:-
- Label the macerator as out of commission as soon as the fault is identified
- On consultation with Estates/Interserve FM staff, remove any whole bed pans stacked in the macerator, wearing PPE in accordance with Trust Standard Precautions Policy
- Staff must not attempt to use the macerator until the fault has been fixed
- Seek advice from IPC Nurses if required, regarding alternative disposal of pulp products during this time

Estates/Interserve FM responsibilities:-
- Isolate water and electrical supply to prevent further use and inadvertent powering of the unit
- Remove any pulp/waste material at blade level wearing PPE in accordance with Trust Standard Precautions Policy. This task must be risk assessed and control measures adhered to
- Please follow Estates guidance as agreed with Trust Health & Safety
- Repair the macerator
- Source temporary replacement macerator if the problem cannot be rectified

It is accepted nursing staff will be unable to effectively decontaminate the macerator prior to repair and therefore all personnel working on this equipment must assume it is contaminated. For this reason a Declaration of Decontamination Status of Healthcare Equipment following Patient use and Prior to Service or Repair for is not required.

7 Training

All staff working on Trust premises, including Trust employed staff; agency and locum staff are responsible for accessing IPC Policies via the intranet in order to assist in maintaining safe practice.
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 policy has been appropriately assessed.

9 Process for monitoring compliance

<table>
<thead>
<tr>
<th>Standard/process/issue</th>
<th>Monitoring and audit</th>
<th>Committee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct completion of Declaration of Decontamination Status of Healthcare Equipment Following Patient Use and Prior to Service or Repair form</td>
<td>Audit</td>
<td>Medical Electronics Department</td>
<td>Trust Decontamination Group</td>
</tr>
</tbody>
</table>

10 Consultation and review

Consultation of this policy was undertaken by members of IPCC and IPC Nurses. This policy will be reviewed every two years by IPCC or when significant changes make earlier review necessary.

11 Implementation of policy (including raising awareness)

This policy is a revision of a previous Decontamination of Healthcare Equipment following Patient Use and Prior to Service or Repair Policy. Clinical Directors/Matrons/Sisters/Charge Nurses and Clinical Leads should ensure that staff are aware of this policy.

This policy is available for staff to access via NuTH intranet.

12 References and associated documentation

- Health and Safety at Work Act (1974)
- Management of Health and Safety at Work Regulations 1999 Approved Code of Practice and guidance
- MHRA Managing Medical Devices
- Microbiology Advisory Committee (MAC) to Department of Health. Sterilisation, Disinfection and Cleaning of Medical Equipment Guidance on Decontamination
- The Carriage of Dangerous Goods Regulations, 2007
- 90/679/eeec Council Directive on the protection of workers from risks related to exposure to biological agents at work
13 Associated Documents

- Cleaning and Disinfection Procedure
- Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD), in hospital patients
- Decontamination of Patient Environment (including Terminal Cleaning)
- Standard Precautions

Author: EME Services Officer, Medical Electronics
Matron Infection Prevention and Control
Appendix 1

Declaration of Decontamination Status of Healthcare Equipment Following Patient Use and Prior to Service or Repair
(Form must be completed for all medical devices including: e.g. Patient Monitors, Infusion Devices, Anaesthetic Machines, Ventilators and patient equipment including: e.g. Armchair, Commode, Wheelchair, Low Level Bed, Mattress)

<table>
<thead>
<tr>
<th>DEVICE NAME &amp; MODEL:</th>
<th>ASSET ID: (If applicable)</th>
<th>FAULT REPORT REF. No: 0025000</th>
</tr>
</thead>
</table>

IF REPORTING A FAULT (This section only to be completed if reporting a fault)

DESCRIPTION OF FAULT: (Report the last settings and what you consider to be the problem)

Was this device involved in an adverse incident? YES / NO
If YES, please supply the Datix Incident Report No. …………………

Declaration of Contamination Status (This section to be completed for all medical devices and patient equipment)

☐ This equipment 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 cleaned in preparation for inspection, servicing, repair or transportation,

or

☐ This equipment has been exposed internally or externally to hazardous materials as indicated below (*delete as appropriate).

* BLOOD - BODY FLUIDS - RESPIRED GASES - PATHOLOGICAL SAMPLES - CHEMICAL - RADIOACTIVE CONTAMINATION OR OTHER SUBSTANCES HAZARDOUS TO HEALTH (Please state):

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

Please give details of the decontamination methods used:

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

☐ If the equipment could not be decontaminated please indicate why. (Such equipment must not be returned without prior agreement of the recipient).

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

I DECLARE THAT I HAVE TAKEN ALL REASONABLE STEPS TO ENSURE THE ACCURACY OF THE ABOVE INFORMATION, IN ACCORDANCE WITH THE TRUST POLICY ON DECONTAMINATION OF HEALTHCARE EQUIPMENT FOLLOWING PATIENT USE AND PRIOR TO SERVICE OR REPAIR.

Authorised Signature: …………………………. Print Name: ………………………………………
Department: ………………………………… Position: ………………………………………
Date: …………………………………… Tel. No: ………………………………………

NOTE: IT IS ILLEGAL TO SEND CONTAMINATED ITEMS BY POST
Devices returned for service/repair without a completed Fault Reporting and Contamination Status Form will not be accepted by the receiving department. For assistance contact the Electronics & Medical Engineering Department, the Health and Safety Team or the Infection Control Team.

White copy to be attached to device – Yellow copy to be retained by department
This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

### IMPACT ASSESSMENT – SCREENING FORM A

<table>
<thead>
<tr>
<th>Policy Title: Decontamination of Healthcare Equipment following Patient Use and Prior to Service or Repair</th>
<th>Policy Author: Louise Hall, Matron Infection Control</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>Yes/No? You must provide evidence to support your response:</td>
</tr>
<tr>
<td>• Race *</td>
<td>No</td>
</tr>
<tr>
<td>• Ethnic origins (including gypsies and travellers)</td>
<td>No</td>
</tr>
<tr>
<td>• Nationality</td>
<td>No</td>
</tr>
<tr>
<td>• Gender *</td>
<td>No</td>
</tr>
<tr>
<td>• Culture</td>
<td>No</td>
</tr>
<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>
<tr>
<td>• Pregnancy and maternity *</td>
<td>No</td>
</tr>
<tr>
<td><strong>2.</strong> Is there any evidence that some groups are affected differently?</td>
<td>No</td>
</tr>
<tr>
<td><strong>3.</strong> 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?</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>4(a).</strong> Is the impact of the policy/guidance likely to be negative? (If “yes”, please answer sections 4(b) to 4(d)).</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>4(b).</strong> If so can the impact be avoided?</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>4(c).</strong> What alternatives are there to achieving the policy/guidance without the impact?</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>4(d).</strong> Can we reduce the impact by taking different action?</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Comments:**

**Action Plan due (or Not Applicable):** N/A

Name and Designation of Person responsible for completion of this form: Louise Hall, Matron Infection Control

Date: 02/06/2014

Names & Designations of those involved in the impact assessment screening process: IPCC

(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 Frances Blackburn, Head of Nursing, Freeman, or, Karen Pearce, Senior HR Manager (Projects). 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.