SOP Objective

To provide Healthcare Workers (HCWs) with details of the actions and responsibilities necessary to ensure that procedures in relation to decontamination do not pose risks to patients or HCWs and comply with current legislation.

This SOP applies to all staff employed by NHS Greater Glasgow & Clyde and locum staff on fixed term contracts.

KEY CHANGES FROM THE PREVIOUS VERSION OF THIS SOP

- Updated wording in Section 1. Replace Sterilise Services Department (SSD) with Central Decontamination Unit (CDU)

Document Control Summary

<table>
<thead>
<tr>
<th>Approved by and date</th>
<th>Board Infection Control Committee 25th November 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Publication</td>
<td>25th November 2019</td>
</tr>
<tr>
<td>Developed by</td>
<td>Infection Prevention and Control Policy Sub-Group</td>
</tr>
<tr>
<td>Related Documents</td>
<td>National IPC Policy Manual</td>
</tr>
<tr>
<td></td>
<td>NHSGGC SOP Creutzfeldt-Jakob Disease (CJD)</td>
</tr>
<tr>
<td></td>
<td>NHSGGC SOP Hand Hygiene</td>
</tr>
<tr>
<td></td>
<td>NHSGGC SOP Twice Daily Clean of Isolation Rooms</td>
</tr>
<tr>
<td></td>
<td>NHSGGC SOP Terminal Clean of Isolation Rooms</td>
</tr>
<tr>
<td></td>
<td>NHSGGC SOP Cleaning of Near Patient Healthcare Equipment</td>
</tr>
<tr>
<td>Distribution/ Availability</td>
<td>NHSGGC Infection Prevention and Control Policy Manual and the Internet</td>
</tr>
<tr>
<td>Lead Manager</td>
<td>Board Infection Control Manager</td>
</tr>
<tr>
<td>Responsible Director</td>
<td>Board Medical Director</td>
</tr>
</tbody>
</table>
CONTENTS

1. Responsibilities ......................................................................................................................... 3
2. Introduction .............................................................................................................................. 4
3. The use of Single-Use and Single-Patient Use Equipment ............................................................ 4
4. Definitions ................................................................................................................................ 5
5. Re-usable Medical Devices (Re-usable devices are NEVER marked single-use) ...................... 5
   5.1. Risk Categorisation for the Decontamination of Medical Devices ........................................... 6
   5.2. Creutzfeldt - Jakob Disease (CJD) ................................................................................................. 6
   5.3. Surgical instruments used on patients with or suspected of having CJD/ vCJD ......................... 7
   5.4. Decontaminating Equipment ....................................................................................................... 8
6. Good Practice Guidelines ........................................................................................................... 8
   6.1. Training ........................................................................................................................................ 8
7. Symbols used on medical packaging and their meanings ............................................................ 9
8. Disinfectants ............................................................................................................................. 9
   8.1. Personal Protective Equipment (PPE) ........................................................................................ 10
   8.2. Spillages on Carpets ................................................................................................................... 10
   8.3. Formulae for disinfectant calculations ...................................................................................... 11
   8.4 Body Fluid Spillage Procedure .................................................................................................... 12
9. Adverse Incident Reporting (Medical Devices) ......................................................................... 13
10. Equipment Sent for Service or Repair ...................................................................................... 13
11. Evidence Base .......................................................................................................................... 14
1. Responsibilities

Healthcare Workers (HCWs) must:
- Follow this SOP.
- Attend appropriate training.
- Report to supervisor / manager when they are unable to follow the SOP or if they think there is a problem / issue with equipment.

Clinical Managers / Senior Charge Nurses (SCN) must:
- Ensure HCWs involved in implementing this SOP are trained to do so.
- Ensure HCWs have access to and follow this SOP.
- Seek advice from the Infection Prevention and Control Team (IPCT) regarding the correct method of decontamination of equipment if required.

Managers must:
- Support Clinical Managers / SCNs in implementing this SOP.

Infection Prevention and Control Teams (IPCTs) must:
- Provide teaching opportunities on the implementation of this SOP.
- Act as a resource for guidance with regards to decontamination of blood and body fluid spills.
- Keep this SOP up-to-date.

Central Decontamination Unit (CDU) Manager, Estates Manager, Procurement Managers must:
- Liaise with the IPCTs on matters relating to decontamination.
- Seek the advice of IPCTs before purchasing new items that require reprocessing and cannot be decontaminated.

Medical Physics must:
- Report adverse incidents to appropriate authorities, e.g. damage to equipment due to cleaning process.
2. Introduction

This SOP details the actions necessary for the safe use of medical devices and appropriate use of detergents and disinfectants in NHS Greater Glasgow & Clyde (NHSGGC) to minimise the risk of healthcare associated infection (HAI). Medical devices can pose significant hazards to patients if they are reprocessed inadequately or incorrectly. Additionally, risks can arise from equipment that should not be reprocessed, i.e. single-use items. All HCWs involved in the use of medical devices must be aware of their role and responsibilities towards patient safety and IPC. For equipment such as chairs, lockers, baths etc., please refer to NHSGGC SOP for Cleaning of Near Patient Equipment.

A medical device is any piece of equipment that is used on a patient.

3. The use of Single-Use and Single-Patient Use Equipment

Prior to use, packaging must be checked for single-use markings and decontamination instructions.

Items marked “Single-Use” must be used once, on one patient, and discarded as clinical / Healthcare waste.

![Diagram](image)

Items marked “Single-Patient Use” may be decontaminated and only re-used on the same patient provided the manufacturer’s instructions on decontamination and re-use are followed. Once no longer required, discard as clinical / Healthcare waste.
4. Definitions

- **Decontamination**: The combination of processes, including cleaning, disinfection and/or sterilisation, used to render a re-usable item safe for further use.

- **Cleaning**: Is the process which physically removes large numbers of micro-organisms and the organic matter on which they thrive.

- **Disinfection**: Is the reduction of the number of viable micro-organisms on a device to a level previously specified as appropriate for its intended further handling or use.

- **Sterilisation**: A process which if specified conditions are met, renders a device sterile, i.e. free from all micro-organisms and spores. The theoretical probability of there being a viable micro-organism present on the device shall be equal or less than 1 in a million (BS EN 556-2 2003).

5. Re-usable Medical Devices (Re-usable devices are NEVER marked single-use)

Reusable medical devices are devices designed and manufactured to be used more than once on more than one patient. It includes all different types of equipment, e.g. blood pressure cuffs, endoscopes as well as surgical instruments. Different medical devices require different levels of decontamination. The level of decontamination depends on:

- where the device has been used
- the type and amount of contamination
- the complexity of the device

This necessitates a risk assessment before reprocessing begins. There are three categories of risk to be considered for the equipment, the procedure and the patient. They are explained in:

- Risk Categorisation for the Decontamination of Medical Devices (see 5.1).
- Surgical instruments used on patients with or suspected of having CJD/vCJD (see 5.3)
5.1. Risk Categorisation for the Decontamination of Medical Devices

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Description</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-Risk</td>
<td>Items in close contact with a break in the skin or mucous membrane or introduced into a sterile body area.</td>
<td>Sterilisation – Decontamination to be undertaken in a specialist facility, e.g. Central Decontamination Unit</td>
</tr>
<tr>
<td>Intermediate Risk</td>
<td>Items in contact with intact skin, particularly after use on infected patients or prior to use on immuno-compromised patients, or items in contact with mucous membranes or body fluids.</td>
<td>Sterilisation or disinfection required. Decontamination to be undertaken in a specialist facility, e.g. Central Decontamination Unit or IPCT Approved Area.</td>
</tr>
<tr>
<td>Low Risk</td>
<td>Items in contact with healthy skin or not in contact with patient</td>
<td>Decontamination – may be undertaken in the clinical area.</td>
</tr>
</tbody>
</table>

5.2. Creutzfeldt - Jakob Disease (CJD)

There are technical requirements for decontamination for specific instruments in relation to CJD. Normal steriliser temperatures do not inactivate the prion which is thought to cause CJD therefore additional decontamination precautions are required. For further information please refer to the NHSGGC CJD SOP
5.3. Surgical instruments used on patients with or suspected of having CJD/ vCJD

Consider the use of single-use disposable equipment wherever possible.

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Action</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>At risk group:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patients with anti-thrombin deficiency, haemophilia or other familial bleeding disorders.</td>
<td><strong>Endoscopes</strong> - Decontaminate and return to use.</td>
<td>See CJD SOP</td>
</tr>
<tr>
<td>• Recipients of growth hormones or gonadotrophin treatment before 1985 in the UK or at any time whilst abroad.</td>
<td>Depending on procedure, surgical instruments will either be decontaminated and returned to use or sent for incineration in the high-risk (yellow) waste stream.</td>
<td></td>
</tr>
<tr>
<td>• Patients with a family history of familial CJD.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patients who have been contacted by the Public Health Protection Unit (PHPU) and told that they are at risk of CJD / vCJD.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Individuals who have been identified as receiving blood or blood components from 300 or more donors since January 2009.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient suspected of having CJD / vCJD</strong></td>
<td>Quarantine instruments in designated box.</td>
<td>See CJD SOP</td>
</tr>
<tr>
<td><strong>Patient diagnosed as having CJD / vCJD</strong></td>
<td><strong>Endoscopes</strong> - If possible decontaminate and retain for the use of the named patient.</td>
<td>See CJD SOP</td>
</tr>
<tr>
<td></td>
<td>All other instruments should be sent for incineration in the high-risk (yellow) waste stream</td>
<td></td>
</tr>
</tbody>
</table>
5.4. Decontaminating Equipment

Each time a piece of equipment is decontaminated it must be examined by the HCW intending to use it, to ensure it remains fit for purpose and does not pose an infection hazard (i.e. is it torn, worn or damaged in such a way that impedes cleaning). Equipment that cannot be decontaminated must be replaced.

There must be sufficient equipment to allow for effective decontamination between patients. Where there is insufficient equipment this must be reported. SCN / Department Leads must have a process in place for replacing re-usable equipment that cannot be decontaminated safely and effectively.

6. Good Practice Guidelines

Before using any equipment check the manufacturer’s instructions regarding reprocessing. (See Section 7 - Symbols on medical packaging and their meaning).

- Decontaminate your hands before using any equipment.
- Check the wrapper and identify the markings on the medical device (See Section 7).
- When cleaning medical devices or the environment, follow the manufacturer’s instructions for volume of detergent / disinfectant to water.
- All new equipment must be CE marked. See Section 7 for Symbols.

If wrapped:
- Check the expiry date has not passed. If beyond the expiry date DO NOT USE.
- Check the wrapping is intact. If not intact DO NOT USE.
- Check there is no staining on the wrapper or indication that it has been wet after sterilisation. If staining present DO NOT USE.

6.1. Training

Managers must ensure that all HCWs are appropriately trained and have access to detailed instructions illustrating the correct procedure taking into account the manufacturer’s instructions. Seek the advice of the IPCT where necessary.
7. Symbols used on medical packaging and their meanings

These symbols are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the British and European Standard BS EN 980: 2008 Graphical symbols for use in the labelling of medical devices. Symbols appearing on medical devices and/or their packaging must be adhered to. If a user does not understand a symbol they should first look in the instructions for use or user manual for an explanation.

8. Disinfectants

Disinfectants are chemicals that are subject to the Control of Substances Hazardous to Health (COSHH) Regulations (2002). Any substance which is listed under COSHH requires a written risk assessment to be undertaken. This assessment must include a copy of the substance Material Safety Data Sheet (MSDS). Their use in hospitals or healthcare premises is limited to:

- Disinfection of body fluid spillages.
• Disinfection of heat labile equipment (such procedures must be approved of by the IPCT and take place in a designated central decontamination unit (CDU)).
• Terminal or twice daily cleans of isolation rooms.
• Routine cleaning during outbreak of infection.
• Terminal clean after outbreaks of infection
• Winter cleans

To comply with COSHH all disinfectants must be kept in locked cupboards. Instructions for use must be displayed close to the cupboard. When using disinfectants the approved procedure must be followed – this is to ensure that the disinfectant works and does not cause harm to equipment, the environment, HCWs or others. The approved procedure is detailed in Section 8.4.

8.1. Personal Protective Equipment (PPE)

Protective clothing must be worn in accordance with Body Fluid Spillage Procedure Section 8.3 and the local COSHH assessment for the disinfectant used. The HCW prior to any procedure must undertake a risk assessment where any chemicals including DISINFECTANTS and DETERGENTS are used.

8.2. Spillages on Carpets

Please note carpets are not recommended for clinical areas. Carpets in healthcare premises should be able to withstand 10,000 ppm available chlorine. If there are areas that do not meet this standard discolouration will occur during decontamination. Contact the Facilities team if large volume body fluid spillages occur on carpets.

Spillages within the patient's own home: HCWs cannot use disinfectant to deal with blood and body fluid spillages occurring in the patient’s own home because of the possibility of damage to carpeting or furnishings. HCWs should wear the appropriate PPE, e.g. gloves and aprons and where possible, remove spillages with paper towels and dispose of in the domestic waste stream. If required, spillage area should be cleaned with detergent, water and paper towels. Gloves and aprons should be removed and disposed of in the domestic waste stream and hands thoroughly washed.
8.3. Formulae for disinfectant calculations

*Please note that where Actichlor Plus requires to be rinsed off to avoid damage to specific surfaces, the recommended contact time must be achieved before rinsing.

<table>
<thead>
<tr>
<th>PURPOSE</th>
<th>ACTICHLOR Granules (suitable for use)</th>
<th>ACTICHLOR PLUS Tablets</th>
<th>Dilution Strength</th>
<th>Contact Time*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disinfection of dried blood spills</td>
<td>N/A</td>
<td>1.7gm tablet in 100mls of cold / lukewarm tap water or ten tablets in one litre of cold / lukewarm tap water</td>
<td>10,000 ppm available chlorine</td>
<td>Minimum 2 mins</td>
</tr>
<tr>
<td>Disinfection of wet blood spills</td>
<td>Yes</td>
<td>N/A</td>
<td>10,000 ppm available chlorine</td>
<td>Minimum 2 mins</td>
</tr>
<tr>
<td>General environmental disinfection</td>
<td>N/A</td>
<td>1.7gm tablet in 1 litre of cold / lukewarm tap water</td>
<td>1,000 ppm available chlorine in detergent</td>
<td>5 mins</td>
</tr>
<tr>
<td>For a sporicidal effect e.g. Patient with CDI</td>
<td>Yes</td>
<td>1.7gm tablet in 1 litre of cold / lukewarm tap water</td>
<td>1,000 ppm available chlorine in detergent</td>
<td>10 mins</td>
</tr>
</tbody>
</table>
8.4 Body Fluid Spillage Procedure

As part of Standard Infection Control Precautions (SICPs) spilloages of blood and body fluids must be decontaminated as follows:

<table>
<thead>
<tr>
<th>WET BLOOD SPILLAGES</th>
<th>DRIED BLOOD SPILLAGES</th>
<th>ALL OTHER BODY FLUID SPILLAGES e.g. to include vomit/urine/faeces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Get someone to guard the area whilst you collect the necessary equipment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Put on protective clothing, gloves, apron, and eye protection if necessary.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply Chlorine releasing granules, e.g. ACTICHLOR Granules. Leave granules over spillage for a minimum of 2 minutes. The spillage should no longer have a fluid consistency. If the spillage is still liquid apply more granules and leave for a further 3 minutes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Put paper towels over the spillage. Make up 10,000ppm available chlorine disinfectant, e.g. by putting a 1.7gm tablet of ACTICHLOR PLUS into 100mls of cold / lukewarm tap water, safely securing the lid of the container and leave for 3 minutes. Then invert the container to ensure the tablets are dissolved.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using paper towels – or incopad if necessary – remove spillage contents and discard into an orange healthcare waste bag.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Make up a solution of a chlorine based detergent, e.g. ACTICHLOR PLUS, 1.7gm tablet in 1 litre of cold/ lukewarm tap water.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove spillage with a scoop, if available, or envelop spillage in paper towels, and discard into an orange healthcare waste bag.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pour enough of the solution over spillage to saturate the paper towels and leave for minimum of 2 minutes. Still wearing protective clothing, pick up the paper towels and place in an orange healthcare waste bag.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Still wearing protective clothing, pick up the paper towels and place in an orange healthcare waste bag. Wipe over area with chlorine based detergent and allow to dry (contact time of 5 mins). Dispose of any paper towels as clinical waste.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean spillage area with neutral detergent.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean spillage area with neutral detergent.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If still required, clean spillage area with neutral detergent.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dry the area thoroughly

Remove gloves and apron and wash hands thoroughly
9. **Adverse Incident Reporting (Medical Devices)**

An adverse incident is an event which causes, or has the potential to cause unexpected or unwanted effects involving the safety of patients, users or other persons. Any adverse incident involving a medical device should be reported following the local Incident Reporting System. See [http://www.shs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/adverse-incidents](http://www.shs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/adverse-incidents) for how to report incidents.

10. **Equipment Sent for Service or Repair**

- Before equipment is presented for repair it must be appropriately decontaminated. Single-use items that are found to be faulty should be decontaminated before being sent back to the manufacturers or to pharmacy – seek advice from IPCT.
- In addition to the repair slip, a Certificate of Decontamination Label must be completed and attached to the item for repair by a suitably trained HCW aware of the likely contamination and whether the equipment has been appropriately decontaminated.
- No equipment will be accepted for repair if visibly soiled.
- No equipment will be accepted for repair if a Certificate of Decontamination has not been completed.
11. Evidence Base

- Advisory Committee on Dangerous Pathogens. Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection. 2017
- https://www.hps.scot.nhs.uk/a-to-z-of-topics/decontamination/
- Medicines and Healthcare products Regulatory Agency DB 2003 (05) Decontamination of equipment prior to inspection, service or repair.
- Medicines and Healthcare products Regulatory Agency DB 2011 (01) – Reporting Adverse Incidents and Disseminating Medical Device Alerts. 2008/001

Websites:
- http://www.nipcm.hps.scot.nhs.uk/
- http://www.cjd.ed.ac.uk/