Guidance 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 guidance 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 GUIDANCE

Important Note: The version of this policy found on the Infection Prevention & Control (eIPC Manual) on the intranet page is the only version that is controlled. Any other versions either printed or embedded into other documents or web pages should be viewed as uncontrolled and as such may not necessarily contain the latest updates, amendments, or linkages to other documents.

Document Control Summary

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Developed by	Infection Prevention and Control Policy Sub-Group
Related Documents	National IPC Policy Manual NHSGGC SOP Creutzfeldt-Jakob Disease (CJD) NHSGGC Hand Hygiene Guidance NHSGGC SOP Twice Daily Clean of Isolation Rooms NHSGGC SOP Terminal Clean of Ward/Isolation Rooms NHSGGC SOP Cleaning of Near Patient Healthcare Equipment
Distribution/ Availability	NHSGGC Infection Prevention and Control web page www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control
Lead Manager	Director Infection Prevention and Control
Responsible Director	Executive Director of Nursing

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1. Responsibilities

Healthcare Workers (HCWs) must:

- Follow this guidance.
- Attend appropriate training.
- Report to supervisor / manager when they are unable to follow the guidance or if they think there is a problem / issue with equipment.

Clinical Managers / Senior Charge Nurses (SCN) must:

- Review and discuss any new pieces of equipment prior to procurement to ensure that decontamination processes/ products within this document can be followed/used.
- Ensure HCWs involved in implementing this guidance are trained to do so.
- Ensure HCWs have access to and follow this guidance.
- 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 guidance.

Infection Prevention and Control Teams (IPCTs) must:

- Provide teaching opportunities on the implementation of this guidance.
- Act as a resource for guidance with regards to decontamination of blood and body fluid spills.
- Keep this guidance 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

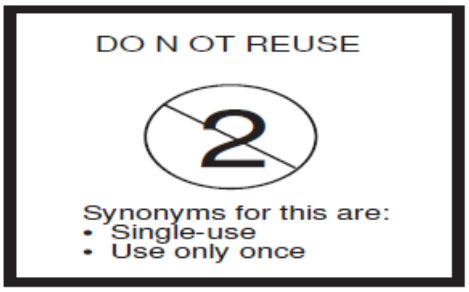
This guidance details the actions necessary for the safe use of medical devices and appropriate use of detergents and disinfectants in NHS Greater Glasgow & Clyde (NHSGGC) to minimise the risk of healthcare associated infection (HAI). Medical devices can pose significant hazards to patients if they are reprocessed inadequately or incorrectly. For equipment such as chairs, lockers, baths etc., please refer to NHSGGC SOP for Cleaning of Near Patient Healthcare 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.



Items marked **"Single-Patient Use"** is equipment that can be 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 Equipment - Re-usable devices are NEVER marked single-use

Re-usable Invasive Equipment – used once then decontaminated e.g surgical instruments

Reusable Non Invasive Equipment (often referred to as communal equipment) – reused on more than one patient following decontamination between each use e.g commode, BP cuff, patient transfer trolley

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

Risk Category	Description	Recommendation
High-Risk	Items in close contact with a break in the skin or mucous membrane or introduced into a sterile body area.	Sterilisation – Decontamination to be undertaken in a specialist facility, e.g. Central Decontamination Unit
Intermediate Risk	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.	Sterilisation or disinfection required. Decontamination to be undertaken in a specialist facility, e.g. Central Decontamination Unit or IPCT Approved Area.
Low Risk	Items in contact with healthy skin or not in contact with patient	Decontamination – may be undertaken in the clinical area.

5.2. Creutzfeldt - Jakob Disease (CJD)

CJD SOP

5.3. 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.

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.

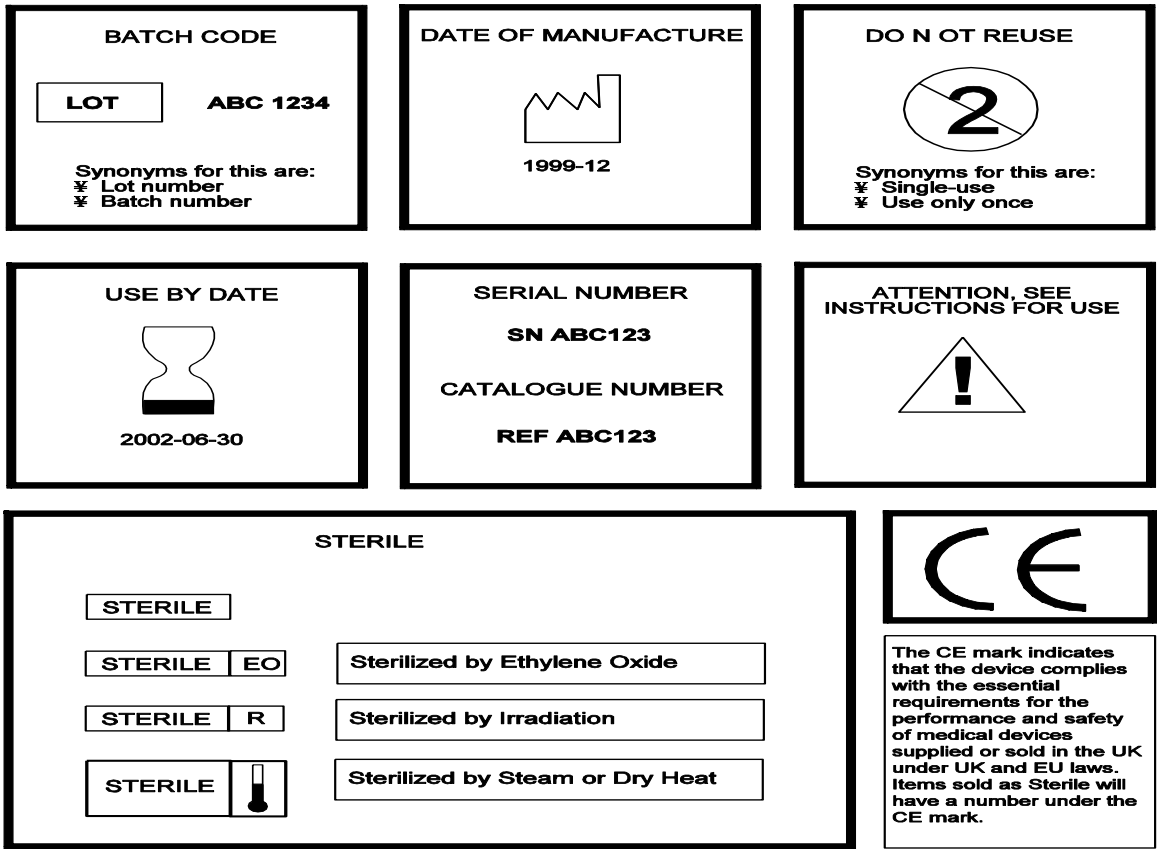
If wrapped:

- 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.

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

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. 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 chlorine based detergent requires to be rinsed off to avoid damage to specific surfaces, the recommended contact time must be achieved before rinsing.

PURPOSE	Chlorine Granules (suitable for use)	Chlorine based detergent Tablets	Dilution Strength	Contact Time*
Disinfection of dried blood spills	N/A	1.7gm tablet in 100mls of cold / lukewarm tap water or ten tablets in one litre of cold / lukewarm tap water	**10,000ppm available chlorine**	Minimum 3 mins
Disinfection of wet blood spills	Yes	N/A	**10,000ppm available chlorine**	Minimum 3 mins
General environmental disinfection	N/A	1.7gm tablet in 1 litre of cold / lukewarm tap water	**1,000ppm available chlorine in detergent**	5 mins
For a sporicidal effect e.g. Patient with CDI	Yes	1.7gm tablet in 1 litre of cold / lukewarm tap water	**1,000ppm available chlorine in detergent**	10 mins

8.4. Body Fluid Spillage Procedure

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

WET BLOOD SPILLAGES	**DRIED BLOOD SPILLAGES**	**ALL OTHER BODY FLUID SPILLAGES e.g. to include vomit/urine/faeces**
Get someone to guard the area whilst you collect the necessary equipment.		
Donn protective clothing, gloves, apron, and eye protection if required.		
Apply Chlorine releasing granules**.** Leave granules over spillage for a minimum of 3 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.	Put paper towels over the spillage. Make up 10,000ppm available chlorine disinfectant, e.g. by putting a 1.7gm tablet of chlorine based detergent 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.	Using paper towels – or incopad if necessary – remove spillage contents and discard into an orange healthcare waste bag. Make up a solution of a chlorine based detergent, 1.7gm tablet in 1 litre of cold/ lukewarm tap water.
Remove spillage with a scoop, if available, or envelope spillage in paper towels, and discard as clinical/ healthcare waste.	Pour enough of the solution over spillage to saturate the paper towels and leave for minimum of 3 minutes. Still wearing protective clothing, pick up the paper towels and place in clinical / healthcare waste bag.	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 / healthcare waste.
Clean spillage area with neutral detergent.	Clean spillage area with neutral detergent.	If still required, clean spillage area with neutral detergent.
Dry the area thoroughly		
Remove gloves and apron, discard as clinical/healthcare waste 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 - 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.
- 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.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group
- management-subgroup-formerly-tse-working-group
- Control of Substances Hazardous to Health. Departments of Health. 2002.
- https://www.hps.scot.nhs.uk/a-to-z-of-topics/decontamination/
- NHS Scotland Guidance for Decontamination of Semi-critical Ultra sound probes Semi-invasive and Non-invasive Ultrasound probes (2016)
- 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
- Medicines and Healthcare products Regulatory Agency Dec 2018 Single-use Medical Devices: Implications and Consequences of Reuse.
- National Institute for Health and Clinical Excellence: patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD via interventional procedures. November 2006 (Guidance endorsed by NHS QIS for implementation by NHS Scotland)
- Sterilizing Practices | Disinfection & Sterilization Guidelines | Guidelines Library | Infection Control | CDC (Page last updated 2016)

Websites: -
http://www.nipcm.hps.scot.nhs.uk/
- http://www.cjd.ed.ac.uk/
- https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group