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Review Date: December 2023
Review Lead: Lead Infection, Prevention and Control Nurse

Calderdale and Huddersfield NHS Foundation Trust

Integrated Facilities Management

Section F - Decontamination Policy

Version 9

Important: This document can only be considered valid when viewed on the Trust's Intranet. If this document has been printed or saved to another location, you must check that the version number on your copy matches that of the document online.

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Does this document map to other Regulator requirements?		
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Document Version Control	
Version 9	Update Managing Medical Devices Guidance for healthcare and social services organisations April 2015, Update and add hyperlinks to relevant documents, Update MDD 2007/47/EC to MDR 2017/745/EU
Version 8	Updates of latest policy and legislation in UK amended where necessary including updates to reflect EPR documentation and process to clean/condemn mattress – Appendix 5. Adjustments also made to include 'Plain English'.
Version 7	The pictorial guidelines for cleaning mattress and bedframe has been updated in the policy – Appendix 5.
Version 6	The policy has been updated and a form has been introduced to send faulty medical equipment to Medical Engineering.
Version 5	The general information within the policy has been updated and amended where necessary and includes any up to date guidance from Government bodies etc.

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1. Introduction

This policy is intended for use across Calderdale and Huddersfield NHS Foundation Trust (CHFT), which includes Calderdale and Huddersfield Solutions Limited (CHS). Where responsibilities state all staff, managers senior managers and directors, this also includes CHS staff groups.

Decontamination is a complex process requiring appropriate processing of equipment and the environment. In order to achieve this, appropriately trained and competent personnel, as well as adequate space and continuous monitoring and auditing of decontamination practices are required.

The Health Technical Memorandum (HTM) 2016 supersedes the Choice Framework for local Policy and Procedures (CFPP) series, which was a pilot initiative by the Department of Health.

The CFPP series of documents have reverted to the Health Technical Memorandum title format. This will realign them with HTM 00 – 'Policies and principles of healthcare engineering' and 'HTM 01-05: Decontamination in primary care dental practices' and the naming convention used for other healthcare estates and facilities related technical guidance documents within England. It will also help to address the recommendation to align decontamination guidance across the four nations.

In 01-01 and 01-06 DH will be retaining the Essential Quality Requirements and Best Practice format, this maintains their alignment with HTM 01-05 and the requirement of 'The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance' which requires that "decontamination policy should demonstrate that it complies with guidance establishing essential quality requirements and a plan is in place for progression to best practice".

A safe decontamination service contributes to successful clinical outcomes and the wellbeing of patients and staff. The trust is required by law to comply with essential levels of safety and quality which are assessed by the CQC. These levels are set in law through registration requirements, one of which covers cleanliness and infection control.

HTM draws on current advice to provide comprehensive guidance on the management and decontamination of surgical instruments used in acute care, which includes clear definitions of what constitutes Essential Quality Requirements (EQR) and Best Practice (BP)

Systems of work involving the decontamination and sterilisation of reusable medical devices must be safe so far as it is reasonably practicable under the requirements of the Health & Safety at Work Act 1974 and the Control of Substances Hazardous to Health Regulations (COSHH) 2002. Other guidance includes:

- The Medicines and Healthcare Products Regulatory Agency (MHRA) Sterilisation, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee (2010)
- MHRA. Managing medical devices 2015
- The Controls Assurance Standard 2004
- The Health Service Circular HSC2000/032 - Decontamination of Re-usable Medical Devices
- The National Strategy programme

The MHRA (2010) highlight the importance of the following:

Before purchasing a reusable medical device check that the manufacturer's recommended reprocessing instructions are compatible with the local decontamination processes and products. If not, do not purchase.

Always follow the manufacturer's instructions for use where appropriate and acceptable. If not, do not use.

Only reprocess medical devices which the manufacturer states as being reusable and do not reprocess those designated for single use only.

Reusable medical devices including endoscopes should be decontaminated using validated processes and equipment designated for that specific purpose.

Use of automated decontamination processes are preferable to manual processes as they have the ability to control and monitor their own parameters within strictly controlled tolerances.

Medical devices should be decontaminated away from treatment/clinical areas and preferably within a dedicated area/room. Ideally this would be within a dedicated Sterile Services Department (SSD) either within the hospital or trust or an externally sourced contractor for endoscopes.

The Care Quality Commission Standards and the Health and Social care Act 2008 provide the audit tool, which will be used to improve the overall quality of decontamination including sterilisation practices in the Trust.

The Trust's organisational approach to decontamination is identified in the Decontamination Organisational chart; ***Appendix 1*** and emphasises the responsibility of staff at each level.

1.1 Key points

- Decontamination is the responsibility of ALL Trust staff using equipment.
- ALL reusable equipment should be decontaminated between each use, using only recommended cleaning solutions and or methods.
- Mattresses should be decontaminated and have a 'Declaration of Decontamination' sticker attached to the bag (*Appendix 5)*.

- ALL new equipment purchased should be viewed against the Pre-Purchase Questionnaire and discussed where possible with appropriate teams.
- Specialist decontamination equipment should only be used once training has been undertaken i.e. Endoscopy.
- Information should be followed in conjunction with local policies.

Further advice can be sought from:

• Decontamination Lead	CRH 2186
• Infection Prevention and Control Team	CRH 2376/HRI 2447
• Medical Engineering & Decontamination Service	CRH 2536/HRI 2823

2. Purpose

The purpose of the policy is to ensure that all staff members understand the importance of appropriate, timely and correct decontamination.

3. Definitions

Decontamination: The process of removing or destroying contamination in order that infectious agents or other contaminants are not able to reach susceptible sites in sufficient quantities to initiate infection or other harmful responses. Different levels of decontamination are used depending on the device/equipment and procedure involved (MHRA, 2010). Decontamination renders an article safe to handle, by cleaning with or without disinfection or sterilization.

Cleaning: The physical removal of infectious agents and organic matter but it does not necessarily destroy infectious agents. **Cleaning is an essential pre-requisite to ensure effective disinfection or sterilization** (MHRA, 2010)**.**

Sterilization: 'A validated process of rendering a product free from viable micro-organisms (BS EN ISO 14937:2009)' (MHRA, 2010) Boiling does not sterilise and neither do most chemical agents.

4. Duties (Roles and responsibilities)

The Chief Executive is responsible for ensuring that there are effective infection control arrangements in the Trust. See ***Appendix 1*** for decontamination organisational structure.

The Decontamination Committee meeting is chaired by the Director of Planning, Estates and Facilities, who carries responsibility for decontamination.

Decontamination Committee

This forms part of our governance arrangements, to ensure compliance with the HTMs for Decontamination. The Committee overseas the following areas:

- Endoscopy - including hysteroscopy
- Bbraun surgical decontamination
- Huddersfield Pharmacy Specials
- Linen and micro-fibre cleaning
- ENT equipment decontamination

The Decontamination Lead is 'organisationally responsible for the effective and technically compliant provision of decontamination services' (HTM: 01 series).

The ward or department manager is responsible for ensuring that safe practices are maintained within their area and any concerns are highlighted to the appropriate personnel.

The Infection prevention and Control team are responsible for updating the policy and ensuring that safe systems of practice are in place and adhered to in conjunction with the above personnel.

Individuals are responsible for adhering to correct procedures for ensuring equipment is safe for patient in their care.

5. Principles of Decontamination

a) The objectives for decontamination are:

- To remove organic matter e.g. body fluids, food, soil which may contain or support the growth of pathogenic organisms

- To prevent the accumulation of dust which may contain pathogenic organisms

- May be required to remove chemical hazards (specialist advice may need to be sought from experts outside the Trust)

b) Choice of decontamination method

All equipment will require cleaning. Some equipment will also require disinfecting or sterilising. Decontamination will work less efficiently on equipment that is difficult to clean, and/or in a poor condition.

Compatibility of equipment with the chosen method of decontamination will be determined from information supplied by the manufacturer. Manufacturers of medical devices are required to provide decontamination guidance for reusable products. (EN ISO 17664-2004 sterilisation of medical devices).

The choice of method also depends on the purpose of the equipment and other risk factors as follows:

Risk	**Application of the item**	**Method of Decontamination**
High	• In close contact with a break in the skin or mucous membrane. • Introduced into a sterile cavity.	Sterilisation (or sterile single-use item)
Intermediate	• In contact with mucous membranes. • Prior to use on an immuno-compromised individual. • Contaminated with virulent or readily transmissible organisms.	Sterilisation, high level disinfection (or single-use item)
Low	• In contact with healthy intact skin. • Items not in direct contact with patient e.g. couches when the patient is dressed.	Cleaning

c) Cleaning

Cleaning is the method of decontamination for non-invasive (low risk) items and is a pre-requisite to disinfection and sterilization, as organic matter such as blood and exudate may neutralise the action of the disinfectant. Cleaning can be achieved through physical cleaning with a neutral detergent, using an automated process or an ultrasonic cleaning system.

d) Disinfection

This procedure is required for most articles that may be contaminated with pathogenic micro-organisms e.g. bedpans/slipper pans, or others that come into contact with mucous membranes e.g. oral thermometers, endoscopes.

The preferred method of disinfection is by heat. Where heat is not an option, chemical agents may be used.

If chemical disinfectants are used they should always be used in liquid form. Disinfectants should **not** be applied in spray form, as this can be wasteful, more expensive and does not necessitate friction, which is essential to obtain optimal disinfection. Chemical disinfectants may cause environmental contamination and can be toxic to skin mucous membranes and/or by vapour inhalation hence why they should not be used in spray form (MHRA, 2010).
It is essential to adhere to pharmaceutical instructions and COSHH regulations regarding the active concentration, shelf-life and correct use of each disinfectant. Disinfectants should be stored in the appropriate labelled container.

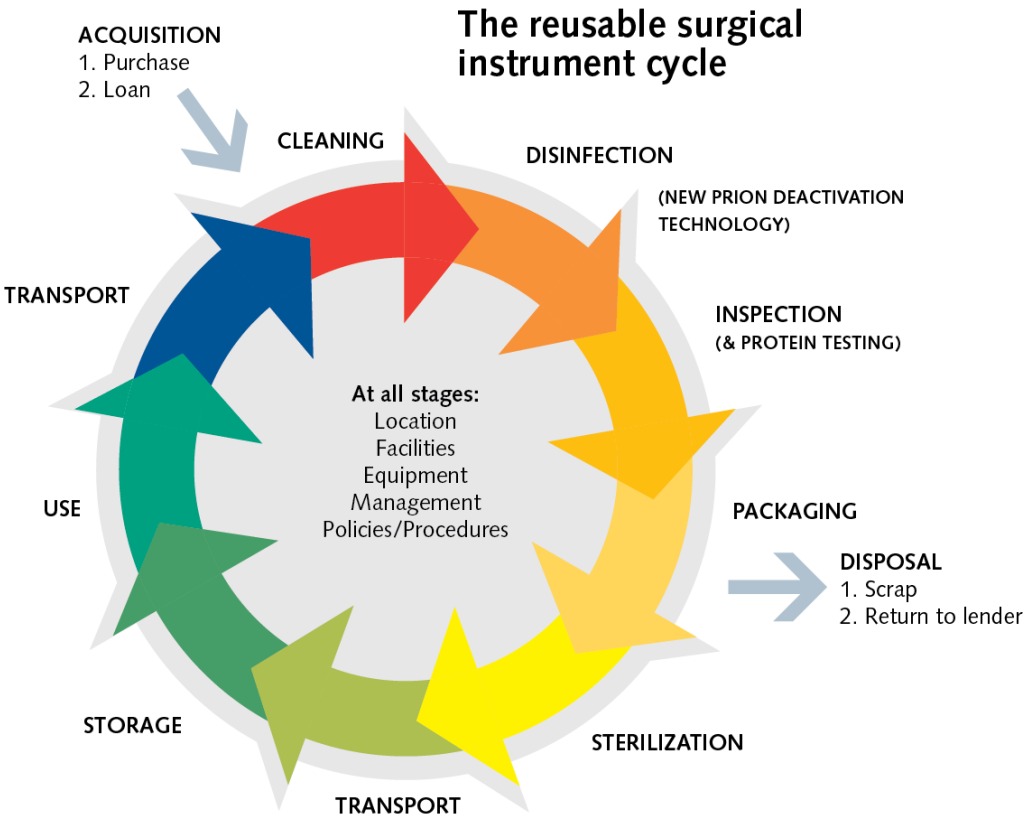
e) Sterilization

This procedure must be used for all instruments or equipment that comes into contact with sterile areas of the body e.g. surgical instruments.

Sterilization of such equipment should take place within a recognised Sterilization Services Department by highly skilled staff using steam sterilization as the method of choice; alternatively, some equipment can be purchased pre-sterilized.

6. Responsibility for Decontamination

The Trust also recognises its responsibilities when ensuring that the provision of a decontamination service is in line with current thinking and practice and is aware that the decontamination life cycle model highlights the extent to which decontamination affects the whole of an organization and not just those areas reprocessing equipment.



The Ward/Departmental Manager has overall responsibility for decontamination of equipment in their area. The Ward/Departmental Manager should nominate a person who is responsible for cleaning equipment. Cleaning schedules should be drawn up and an adequate system should be in place for the recording and monitoring of schedules and standards.

All staff involved with decontamination should have adequate and suitable training.

a) Purchase procedure

It is the responsibility of the budget holder to seek advice from appropriate specialist staff to ensure that infection risks are addressed at the purchasing stage in compliance with MHRA Managing Medical Devices 2014.

Equipment purchased must take account of good design that allows easy decontamination and be constructed with durable materials that support easy cleaning and disinfection. Pre-purchase questionnaire (PPQ) forms obtained from the supplier will indicate recommended cleaning and disinfection processes.

b) Condition monitor

The ongoing condition of the equipment needs to be monitored to ensure that infection risk can still be managed effectively. When the equipment condition has deteriorated to the extent that effective cleaning is no longer achieved easily, the equipment must be disposed of safely in accordance with the Waste Management Policy.

c) Supplies

There should always be available supplies of clean equipment to ensure that the re-use of potentially contaminated or single-use equipment does not happen.

d) Scheduled cleaning

Equipment will be subject to a cleaning schedule which will detail cleaning frequency and cleaning procedure, including cleaning agents to be used and the staff responsible. There are procedures common to all cleaning schedules, but certain items of equipment require particular actions (e.g. the finish or design of an item of equipment may require special attention to ensure that it is effectively cleaned).

e) Training of staff

All Staff need to understand the importance of the measures in place to reduce the infection risk from healthcare equipment. Appropriate ongoing training must be provided to ensure that staff implements the measures required. Appropriate training must also be provided to all staff about the need for high standards of personal hygiene. The effectiveness of training should be monitored regularly as part of performance appraisal.

f) Equipment disposal

Equipment that requires disposal must be decontaminated if it has been in contact with blood or body fluids. Equipment that cannot be cleaned effectively and therefore remains contaminated should be disposed of as clinical waste. Larger pieces of equipment will need special arrangements and further support can be sought from the Trust Waste Manager, Estates Department, HRI.

7. Standard Infection Prevention and Control Precautions

a) Hand Hygiene and Hand Care

Hand hygiene is the single most important measure in preventing infection. Further information can be sought from the Hand Hygiene Policy (Section H).

b) Protective Clothing

Select protective equipment on the basis of an assessment of the risk of transmission of micro-organisms to the patient, and the risk of contamination of health care practitioners' clothing and skin by patient's blood, body fluids, secretions and excretions. In principle, apron and gloves should be worn when decontaminating equipment, face protection may also be required if there is a risk of splashing to the eyes and mouth.

Further information can be sought from the Standard Precautions Policy (Section C).

8. General Principles for Cleaning Equipment

a) Cleaning where possible, should take place in a dedicated area away from patient care.

b) Equipment should be dismantled where necessary in line with the manufacturers' instructions before cleaning.

c) Avoid splashing.

d) Always use a fresh solution of detergent and water, rinse and dry.

e) A clean, disposable cloth should be used.

f) Electrical equipment must not be immersed in water and **must be** disconnected from mains supply. Cleaning may be carried out using a detergent wipe or, alternatively, an alcohol wipe if there is no visible soiling.

g) Detergent wipes provide a good alternative to detergent and water.

h) If visibly soiled with blood or body fluids clean first and then disinfect with a chlorine-based solution – please see Section 10 'Disinfectants'.

9. Use of Disinfectants and Antiseptics

a) General Considerations

Dilution

Chemical disinfectants must be used at the recommended strength. Too high a concentration is wasteful; too low a concentration is ineffective.

Preparation

Many disinfectants deteriorate after dilution. Solution should always be freshly prepared, usually daily and used as per manufacturers instructions.

Contact time

No disinfectant/antiseptic acts instantaneously. Therefore, it is essential that the correct contact time is observed as recommended by the manufacturer.

Approval

Only disinfectants and antiseptic that have been approved by the Infection Control Committee can be used within the Trust. Some may also be required to have approval from the Medicines Management Committee.

b) COSHH Regulations

The Control of Substances Hazardous to Health (COSHH) Regulations 2002 require that an assessment is made of any health risks that may arise from exposure to hazardous substances, and that appropriate control measures must be provided to avoid the risks.

Most disinfectants are hazardous to some degree and are therefore subject to COSHH regulations. A full assessment of the risks should be available in all places of use and should be consulted by users for further information. Managers are required to ensure that their staff are properly trained and fully aware of the dangers associated with the use of the various disinfectants.

10. Disinfectants and their Uses

a) Disinfection of the skin and mucous membranes

Alcohol hand gel	For hand disinfection as an alternative to hand washing. Alcohol gel should conform to EN

	standards and only be used when hands are visibly clean. Alcohol gel should **not** be used prior to preparing food, after using the toilet and for any diarrhoeal illness in particular *Clostridium difficile* infection where soap and water hand wash should be used. **NB: The current alcohol hand gel available in the dispensers is not suitable for use by theatre surgical teams**.
Chlorhexidine 1% dusting powder (CX powder)	Umbilical cord treatment for SCBU patients only.
Chlorhexidine Gluconate Solution 1%, Aqueous (pink)	Used in gynaecological theatre as a skin antiseptic.
Chlorhexidine 0.05%	Skin prep for neonates on SCBU
Chlorhexidine Gluconate Solution 0.5% in 70% IMS (Colourless or red staining)	Used for skin disinfection before the following procedures, and aftercare: 1 Lumbar punctures and epidurals. 2 Sternal marrow punctures. 3 Chest aspiration and drainage. 4 Major and minor surgical procedures.
Chlorhexidine Obstetric Cream 1%	Used in vaginal examinations.
Chlorhexidine Surgical Scrub 4%	Used for hand washing prior to surgical and high risk invasive procedures e.g. insertion of central venous catheters, chest aspiration and drainage, lumbar punctures and epidural insertion. Used as a skin wash as part of the MRSA colonisation suppression treatment for patients and staff colonised with MRSA (further advice can be found in **section T multi-resistant organism policy.** Used as a skin wash for all patients with CVAD
Chlorhexidine impregnated dressing	Used on the CVAD site for confirmed MRSA patients or those deemed high risk (on d/w infection control)
Chlorhexidine 2% and alcohol wipes	Pink packet: Injection sites: intramuscular and subcutaneous, venepuncture and cannulation. Rub the site and **allow drying as per instructions**. Blue packet: Used for cleaning intravenous hubs and connectors and injection ampoules – see section G aseptic technique policy and ANTT guidelines
Chlorhexidine 2% and alcohol sterile solution	For skin preparation for taking blood cultures intravenous infusion sites and central venous access device insertion AND **allow drying as per instructions**
Lignocaine Hydrochloride 2% Sterile Antiseptic Gel	Contains Chlorhexidine. Used for preparing urethra prior to catheterisation

Octenisan Antimicrobial Wash Lotion	Octenisan is the Trust's **second line wash** treatment for **MRSA** for patients unable to tolerate chlorhexidine and include the following: • Neonates aged ‹ 12 months • Those with previous sensitivity to Chlorhexidine • Those patients with sensitive skin e.g. eczema. **Please refer to MRSA suppression flow chart in the section T multi drug resistant policy**
Povidone Iodine Surgical Scrub Solution 7.5% w/v	Alternate scrub for invasive procedures.
Povidone Iodine 10% alcoholic solution (i.e. tincture)	Alternative pre-operative skin preparation before major surgery, especially before surgery below the umbilicus, where there is a greater risk of clostridial infections. It is also advisable to prepare the operation site on the ward before the operation with Povidone Iodine.
Povidone Iodine Antiseptic Solution half strength (Povidone Iodine 5%) containing 0.5% available Iodine	Disinfection of skin near the eyes before ophthalmic procedures in theatre.

Please note the above table does not consider the use of antiseptics in wound care treatment. Antiseptics used for wound care treatment can be found in the Wound Care Formulary.

b) Disinfection of equipment and the environment

The general environment i.e. the walls, floors, ceilings and furniture do not require disinfection unless contaminated with blood and body fluids. Hot water and a neutral detergent are normally sufficient. Disinfectants must never be poured down drains in an attempt to disinfect them. This is ineffective.

Sodium Dichlorisocyanurate Soluble Tablets 500 mg (Presept sterilising tablets)	• Disinfecting breast pump nipple shells, shields, tubing and collection bottles • Disinfection of tonometer heads in ophthalmic clinic and electronic ear syringe in ENT services
Tristel (Fuse for Surfaces) Tristel Jet (Chlorine based solution)	• Blood and body fluid spillages • Terminal cleaning of isolation rooms • Environmental cleaning of side rooms where patients are being nursed with *Clostridium difficile* • During outbreaks

	• Other environmental cleaning • As directed by Infection Control
Chlorine Dioxide	Used to reprocess heat labile instruments e.g. flexible endoscopes. Must only be used in automated washer disinfectors.
Chlorine Dioxide wipes	Used for disinfecting non-lumened nasal endoscopes and transoesophageal endoscopes (TOE).
Peracetic Acid	Used to reprocess heat labile instruments e.g. flexible endoscopes. Must only be used in approved areas.
Klercide 70/30 IMS spray	Used in Pharmacy Aseptic Unit only.

11. Medical Devices supplied for Single Use Only

Devices designated for single use should be **discarded** after use. (MHRA DB2006(04)).

There are a number of potential hazards associated with reprocessing and re-using medical devices intended for single use; such reprocessed devices **should not be reprocessed or re-used on patients**.

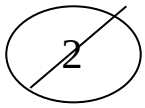
Users, who disregard this information and prepare single-use products for further use, may be transferring legal liability for the safe performance of the product from the manufacturer to themselves, or to the organisation that employs them.

a) Labelling and Meaning of "Single Use"

Single use on packaging of medical devices indicates that the manufacturer:

- Intends the items to be used once and then discarded;
- Considers the items are not suitable for use on more than one occasion; or has insufficient evidence to confirm that re-use would be safe.

NOTE: Alternative expressions on medical devices **meaning single use** are:



'**Do not re-use'**

b) Potential Hazards with Re-Use

- Materials becoming adversely affected, leading to device failure
- **Infection** arising due to inadequate cleaning, disinfection or sterilization
- **Patient injury - device failure from reprocessing or reuse because of fatigue, material alteration and embrittlement**
- The status of the reprocessed device being unclear as a result of inadequate labelling

c) Single Patient Use

Equipment marked with 'single patient use' may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use.

d) Unsterile Single Use

Consideration to purchase single use items requiring sterilisation before use on a patient must seek advice from infection control and / or the decontamination manager as to the availability of such a process to achieve a compliant product in line with current regulations.

12. Reusable Medical Devices

This may be an instrument, apparatus, appliance, material or other article intended for use on human beings for one of three purposes:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring and treatment of disability
- Investigation, replacement or modification of the anatomy or a physiological process

Medical device regulations apply to accessories used with reusable medical devices to enable them to fulfil the intended purpose. Washer / disinfectors and sterilisers are categorised as accessories.

The choice of decontamination method will be related to a number of factors:

- The intended use of the equipment
- The nature of the contamination

- The time required for processing
- The heat, pressure, moisture and chemical tolerance of the object
- The availability of the processing equipment
- The risk assessment exercise associated with the decontamination method

13. Management of medical devices

The process to follow when sending equipment for investigation, inspection, service or repair is outlined in ***Appendix 2*** at the end of this policy.

Further information is also available in the MHRA document 'Managing Medical Devices': Guidance for healthcare and social services organisations 2014

a. Equipment should be decontaminated prior to repair, service or inspection following the general principles for cleaning. Disinfection will be required for equipment contaminated with blood or body fluids.

b. Equipment which can be autoclaved should be dismantled and sent to a Sterile Services dept or company. Consult either the Decontamination Manager or the Medical Engineering Department before sending. It may be necessary to use a water-soluble bag for transportation.

c. For equipment which cannot be decontaminated without dismantling by the engineer, advice should be sought from the Medical Engineering Department and the equipment should be cleaned and then sealed in a clear plastic bag and should have an infection risk sticker (obtained from Pathology Stores) attached.

d. If equipment is the subject of a complaint or investigation, decontamination may prevent a full investigation. In these circumstances the investigation body must be consulted.

e. All equipment must be packed and dispatched with a declaration of contamination status. Where decontamination has taken place this should be declared (section 15).

14. Local Reprocessing Medical Devices

- Decontamination of reusable medical devices including flexible endoscopes should be undertaken centrally wherever possible.
- Decontamination of reusable medical devices including flexible endoscopes should be carried out in an area specifically designed for the purpose.

- Reusable medical devices including flexible endoscopes should be decontaminated and sterilised using an automated process, where this is not possible a full risk assessment should be performed by the user and the decontamination manager.

- Systems should be in place to identify and trace reusable medical devices and endoscopes through the decontamination processes, and back to the patient through logging in patients' case records.

- Decontamination should be undertaken in such a way as to protect the health and safety of patients and staff.

- Decontamination equipment must be operated and maintained according to approved guidelines Health Technical Memorandum 01-01 and 01-06 decontamination of flexible endoscopes.

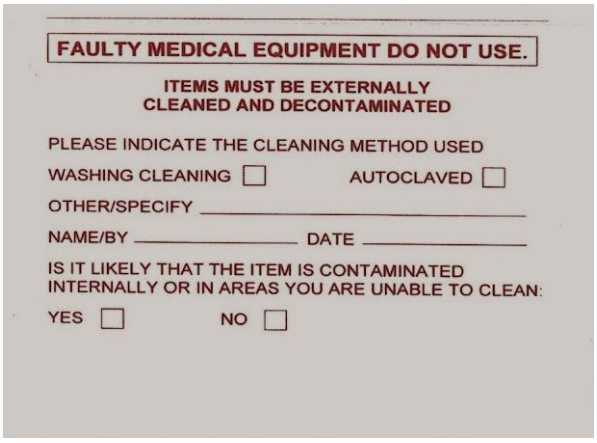
- Decontamination facilities must comply with Health Building Note(s) (HBN)

- The purchase of reusable medical devices must include consideration of decontamination issues.

15. Declaration of Decontamination for local investigation, inspection, service, repair or disposal

It will be assumed that most equipment that is being sent for investigation, inspection, service, repair or disposal, may have been in contact with body fluids or microbial pathogens and that it will be necessary for the receiving person to know it has been decontaminated.

The standard form below attached to the Medical Engineering Department repair request, tie on tags should be completed. ‘Declaration of Decontamination’ (tags are available from Medical Engineering Department).



FAULTY MEDICAL EQUIPMENT DO NOT USE.

ITEMS MUST BE EXTERNALLY CLEANED AND DECONTAMINATED

PLEASE INDICATE THE CLEANING METHOD USED

WASHING CLEANING ☐ AUTOCLAVED ☐

OTHER/SPECIFY _____

NAME/BY _____ DATE _____

IS IT LIKELY THAT THE ITEM IS CONTAMINATED INTERNALLY OR IN AREAS YOU ARE UNABLE TO CLEAN:

YES ☐ NO ☐

16. Declaration of decontamination for managing medical devices

For equipment that requires external investigation, inspection service or repair, please refer to ***Appendix 3***.

17. Procedures for dealing with deficiencies in the decontamination of reusable medical devices

Where staff concerns are raised relating to the decontamination of reusable medical devices, the User, Decontamination Manager and where appropriate the Infection Control Team will ensure that:

- The hazard associated with the reusable medical device has been correctly identified.
- A Datix form is completed where an incident has been identified.
- The risk assessment of the use of the reusable medical device is correct and up to date.
- Necessary controls are in place and are adequate.
- Any observed deficiencies in the control of the use of the reusable medical device are corrected.
- Inform the member of staff of the results of the investigation and the actions taken.

If an identified malfunction has taken place, those affected and their line managers will be informed immediately by the Decontamination Manager.

It is the responsibility of the User to ensure that written procedures and records are maintained. Local procedures for receiving, cleaning, disinfection/ sterilization of all reusable medical devices to be decontaminated must be held locally. These policies and procedures should be readily available for reference by all departmental staff.

18. Decontamination of Surgical Instruments

The Trust receives its decontamination service from a third-party provider, BBraun Sterilog Yorkshire Limited. They use British and European Standards to demonstrate compliance with the essential requirements of the Medical Devices Regulation (MDR 2017/745/EC) and have a quality system in place, ISO13485 against which they are independently audited by the British Standards Institute (BSI). This therefore offers assurance to the Trust that the service delivered is safe and achieves recognised standards.

The Decontamination Services Agreement (DSA) contract offers the Trust:

- Service delivered from a Health Building note compliance unit 13 (HBN)
- Health technical memorandum compliance in relation to HTM 00-06 series of documents on decontamination and will ensure compliance against any future variations to these documents
- Documented robust and comprehensive policies and procedures to ensure the health, safety and welfare of our patients are not compromised
- An effective management control system that accords with ISO 13485
- An effective independent external auditing regime carried out by the British Standards Institute (BSI)
- The ability to track sets of surgical instruments through the decontamination process and back to the patient on whom they were used
- Transportation system that accords with the 'The Carriage of Dangerous Goods and Use of Transportable Pressure Receptacles Regulations' 2009
- A system that meets Medical Devices Agency SN 2000 (18) Handling of surgical instruments on loan from another Company
- A joint management board ensures the strategic direction of the service will continue to meet national standards and local infection control guidelines

The contract is audited via the Trust Decontamination Manager and the Performance Management Team.

The DSA includes the agreed procedures listed below which can be viewed by contacting the Decontamination manager at CRH extension 2186:

- Fast track
- On loan
- Logistics
- Missing instruments
- Instrument repairs
- Internal distribution
- Delivery and Receipt
- Primary and Secondary scanning – [tracking and tracing]
- Majax
- Quarantining of high-risk TSE instruments (see also trust policy on TSE policy 'O')

19. Decontamination of Flexible Endoscopes

Currently the reprocessing of flexible endoscopes as an integral part of their design takes place in 3 centralised locations across the Trust. These being:

Huddersfield Royal Infirmary **Calderdale Royal Hospital**

Endoscopy Unit Endoscopy Unit

Acre Mill

ENT Decontamination Unit

Departmental managers in these areas in addition to their general responsibilities must ensure that:

- An inventory of all reusable medical devices stored and / or used in the area under their control is maintained with appropriate information about safe decontamination and sterilisation

- Competent persons are appointed to carry out risk assessments of the decontamination process and to advise on maintenance

- Decontamination equipment conforms to legal requirements, the minimum specification set out in British and European Standards and any additional requirements of the UK health departments. Planned preventive maintenance (PPM) and annual performance monitoring will achieve this

- All staff and others who work in affected areas are informed of the purpose and safe operation of all engineering controls

- Decontamination equipment is subjected to documented validation schemes comprising installation checks and tests, commissioning tests and performance qualification tests before being put into service

- Ensure that suitable and appropriate Personal Protective Equipment (PPE) is available

- Risk assessments of decontamination are reviewed annually or more frequently if circumstances dictate and all decontamination of reusable medical devices is reassessed every three years

- Health surveillance where indicated to be necessary by the assessment, is carried out by the Occupational Health Department

- All staff are provided with comprehensible information and appropriate training on the nature of the decontamination equipment with which they are working, the risks associated with the process, safe systems of work, and of any information relating to their personal monitoring or health surveillance results

- Changes to decontamination methods and Personal Protective Equipment (PPE) are properly assessed by competent and suitably trained staff i.e.

Head of Medical Engineering & Decontamination Service, infection prevention and control and decontamination manager and that no new equipment is introduced to Trust premises without prior assessment of its suitability to be effectively decontaminated and maintained.

- Comply with loan policy where appropriate

- Systems must be in place to ensure that all endoscopes can be tracked and traced through the decontamination process to the patient

Safe systems of work

Poorly maintained or inadequate decontamination equipment can result in inadvertent exposure to harmful micro-organisms or biological agents, which would be hazardous to health. Staff should be encouraged to report defects. Systems must be in place for prompt repair and the provision of temporary replacement controls.

The following steps can be taken to minimise risks:

- Ensure user information is kept up to date

- Ensure Planed Preventative Maintenance is kept up to date and assessments are reviewed annually. The sterilizers and washer/disinfectors undergo revalidation and performance testing in accordance with Health Technical Memoranda

- Ensure staff are trained in the nature of the risks and the use of the decontamination equipment

- Ensure all documentation is comprehensible and comprehensive

- Ensure incidents are reported using the Trust reporting system

Record keeping

The following records must be retained:

- Training given to employees

- An inventory of decontamination and sterilization equipment

- The assessment of risks of use of the decontamination equipment

- The control measures provided when using the decontamination equipment

- The examination, testing and repair of the decontamination equipment

- Instrument tracking for 11 years
- A record of use of decontaminated equipment within individual patients' case record
- All decontamination process records including the wash and the sterilisation processes

Endoscopes that do not have lumens or instrument channels i.e. Nasendoscopes used in ENT outpatient areas should adhere to the same decontamination of flexible endoscopes practices.

20. Operating Theatre Gowns and Drapes

The Medical Devices Agency considered operating theatre gowns and drapes as infection control products and Class 1 medical devices as they provide protection for the patient, even though they may also provide protection for the surgeon and or other theatre staff.

In order to meet the European standard EN 13795 i.e. resistance to microbial penetration, wet and resistance to liquid penetration the Trust sought to procure a product and service that effectively reduce the risk of transmission of infection via blood or other body fluids.

As such all theatre linen is reprocessed by an outside agency as per the NHS national framework agreement for linen and laundry service terms and conditions.

21. Suspected Contamination with Prions

If equipment/instruments are believed to be contaminated with prions (Prions are an abnormal protein thought to be the causative agent of Transmissible Spongiform Encephalopathies (TSE) e.g. Creutzfeldt Jacob Disease (CJD) and variant Creutzfeldt Jacob Disease (vCJD)). Then the equipment/instruments should not be decontaminated without seeking further advice. All patients undergoing any surgical, endoscopic or invasive procedure should be assessed for their risk. The prion protein is remarkably resistant to conventional methods of disinfection and sterilisation. Further information can be found in the TSE Policy (Section O) or seek advice from the Infection Control Team. Information can also be found on the TSE website: https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

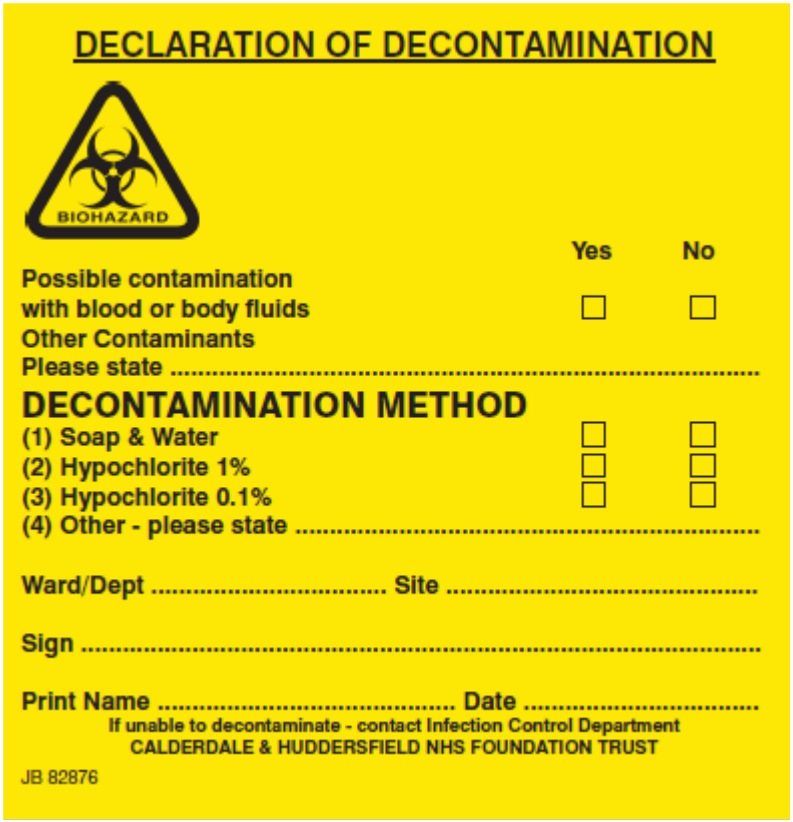
22. Guidelines for the decontamination of mattresses and bed spaces; cleaning, contamination and disposal

Mattresses

Mattresses should be checked, cleaned and decontaminated fully, prior to reuse or prior to returning to mattress store following guidance in ***Appendix 5 & 6.***

All mattresses leaving the ward or department should have a yellow decontamination sticker completed prior to leaving the area as shown below.

'Declaration of Decontamination' stickers are available from Medical Engineering and Tissue Viability.



In the case of foam mattresses these should be checked and bagged in clear plastic bag if not breached or damaged with a completed and signed yellow decontamination sticker.

Appendix 5 outlines a pictorial guide to facilitate the risk assessment and safe moving and handling for cleaning mattresses and bed frames. The emphasis is on **risk assessment** prior to undertaking any moving and handling procedure.

If the foam mattress is damaged or breached, then it should be placed in a yellow plastic bag and again the yellow decontamination sticker should be completed stating that the mattress is for destruction.

For decontamination and storage etc. of air mattresses please see ***Appendix 6***.

Bed Space Cleaning

Bed space cleaning incorporates all of the patient's bed space, including the following:

- Mattress and bed frame
- Locker and Table
- Patient Chair
- Call bell, lamp and other touch points
- Hand gels and soap dispensers
- En suite toilets and commodes
- Hand wash basins and waste bins
- Curtains and curtain rails including shower curtains (curtains should be changed if visibly soiled or damaged or from an infection risk area - see Section K, Isolation Policy, Appendix 2 - Methods used in standard isolation or contact infection control for advice if required)
- General clean to area including floor and bathroom

Bed space cleaning will involve both health care workers and domestic staff and will depend on area and local arrangements as to who is responsible for each aspect of the bed space cleaning.

Following cleaning of the bed space, a sticker is placed on the bed to demonstrate to the patient that the area has been cleaned; **Appendix 4** shows an example of the current sticker in use. The cleaning process is also documented within EPR system to give assurance.

23. Audit of Decontamination Processes

The Trust is responsible for the appropriate processing of reusable medical devices to limit exposure to patients from harmful micro organisms or biological agents, which may affect their health by direct contact with used reusable medical devices. It is therefore important that the processes for decontamination are monitored by audit to provide assurance that the policies and procedures in place are being adhered to and to ensure that the instruments used on procedures can be tracked to their use on a patient.

24. Training and Implementation

The Trust will ensure the provision of sufficient information and training to ensure full understanding of the risks to health posed by decontamination of

reusable medical devices in the workplace, and the importance of the control measures provided. The information will also be given to others who may be affected, such as contractors, temporary staff, and where appropriate, patients and visitors.

All staff employed by the Trust shall receive some basic training in decontamination as part of Trust's Corporate Induction.

Trust-wide training programmes will be arranged and co-ordinated by the Trust Decontamination Manager working closely with the Trust Training Department who will maintain the training records.

Training will be delivered in the following ways:

- General Trust Staff

  At induction, staff will be given general information about decontamination which will include a basic introduction to decontamination and how / where to find more detailed information.

  Clinical Staff will receive training by the Infection prevention and control team periodically via mandatory training programmes 'Right from the Start' and 'Beyond the Basics' and other department/ward-based training when required.

- Departmental Induction and On-going Instruction where appropriate.

  Individual departments (i.e. Endoscopy) will be responsible for providing information, instruction and training about the procedures and equipment used in that area. This should include information on the specific procedures used in the area and the local control measures needed. Departments should also provide periodic updates to all staff on any new substances introduced, charges to work practices, Trust policy etc.

25. Trust Equalities Statement

Calderdale and Huddersfield Foundation Trust aims to eliminate discrimination, harassment and victimisation and advance equality of opportunity through fostering good relationships, promoting inclusivity and embedding the "One Culture of Care" approach throughout the organisation. Stakeholder engagement is vital to analyse the equalities impact of this policy and ensure where there are any negative impacts, mitigation has been discussed and acted on.

26. Monitoring Compliance with this Procedural Document

Compliance with the policy will be monitored through audit and surveillance on an on-going process. Staff should be informed of the results of any environmental monitoring in their area of work.

27. Associated Documents

Infection Prevention and Control policy sections should be read in conjunction with those documents detailed in the reference list: *Standard Precautions* 'C', *Hand hygiene* 'H', *Transmissible Spongiform Encephalopathy*: 'O'.

28. References/suggested further reading/advice

Carriage of Dangerous Goods and Use of Transportable Pressure Receptacles Regulations' London: HMSO 2009.

Control of Substances Hazardous to Health (COSHH). 2002. https://www.hse.gov.uk/coshh/index.htm

Department of Health (DH) (DH, 2012, updated 2015). *Guidance on prevention of CJD and vCJD by Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Risk Management Subgroup*. Downloaded from website: https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group

DH (2016) Health Technical Memorandum 01-01: management and decontamination of surgical instruments (medical devices) used in acute care. Parts A – E (HTM 01-01). https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care

DH (2016). Health Technical Memorandum 01-06: Decontamination of flexible endoscopes parts A –E (HTM 01-06) London. https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes

DH (2004) Health Building Note 13: Sterile services department NHS Estates ISBN 0-11-322492-3. https://www.gov.uk/government/publications/the-planning-and-design-of-sterile-services-departments

DH (2013) Health Building Note 00-09: Infection control in the built environment. NHS Estates. https://www.gov.uk/government/publications/guidance-for-infection-control-in-the-built-environment

Health and Safety at Work Act 1974. London: HMSO 1974.
http://www.legislation.gov.uk/ukpga/1974/37/contents

International Organization for Standardization (2008): EN ISO 17664-2004 sterilisation of medical devices.
https://www.iso.org/standard/31456.html

Loveday. H.P et al. (2014). epic 3: National Evidence-based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England. *Journal of Hospital Infection,* 86. S1-S70.

Medical Devices Agency (2000) (Medical Devices and Equipment Management: Repair and Maintenance Provision) and in Safety Notice SN2000(18) (Handling of Surgical Instruments on Loan from another Organisation).

MHRA (Medicines and Healthcare products Regulatory agency) *Oct 2019: Single-use medical devices: implications and consequences of re-use V2.3.* Medical Devices Agency London.
https://www.gov.uk/government/publications/single-use-medical-devices-implications-and-consequences-of-re-use

1. MHRA (Medicines and Healthcare products Regulatory agency) (2010) *Sterilization, Disinfection & Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee.* Medicines and Healthcare products Regulatory Agency London.

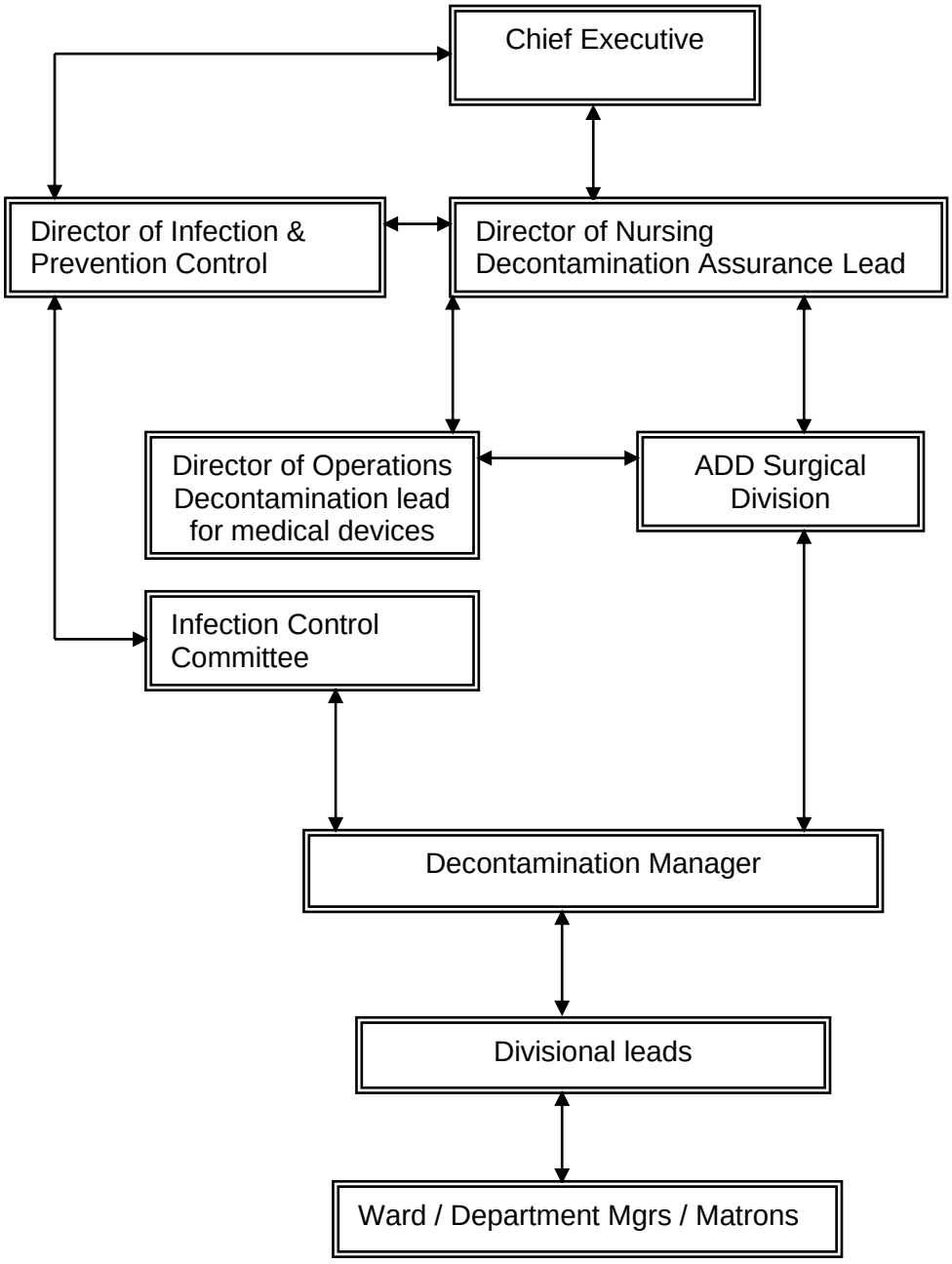
2. MHRA (Medicines and Healthcare products Regulatory agency) (*2014 (2015) Managing Medical Devices Guidance for healthcare and social services organisations.* Medicines and Healthcare products Regulatory Agency London.

Further advice can be sought from:

Decontamination Lead	CRH 2186
Infection Prevention and Control Team	CRH 2376/HRI 2447
Medical Engineering & Decontamination Service	CRH 2536/HRI 2823

APPENDIX 1

Decontamination Organisational Structure

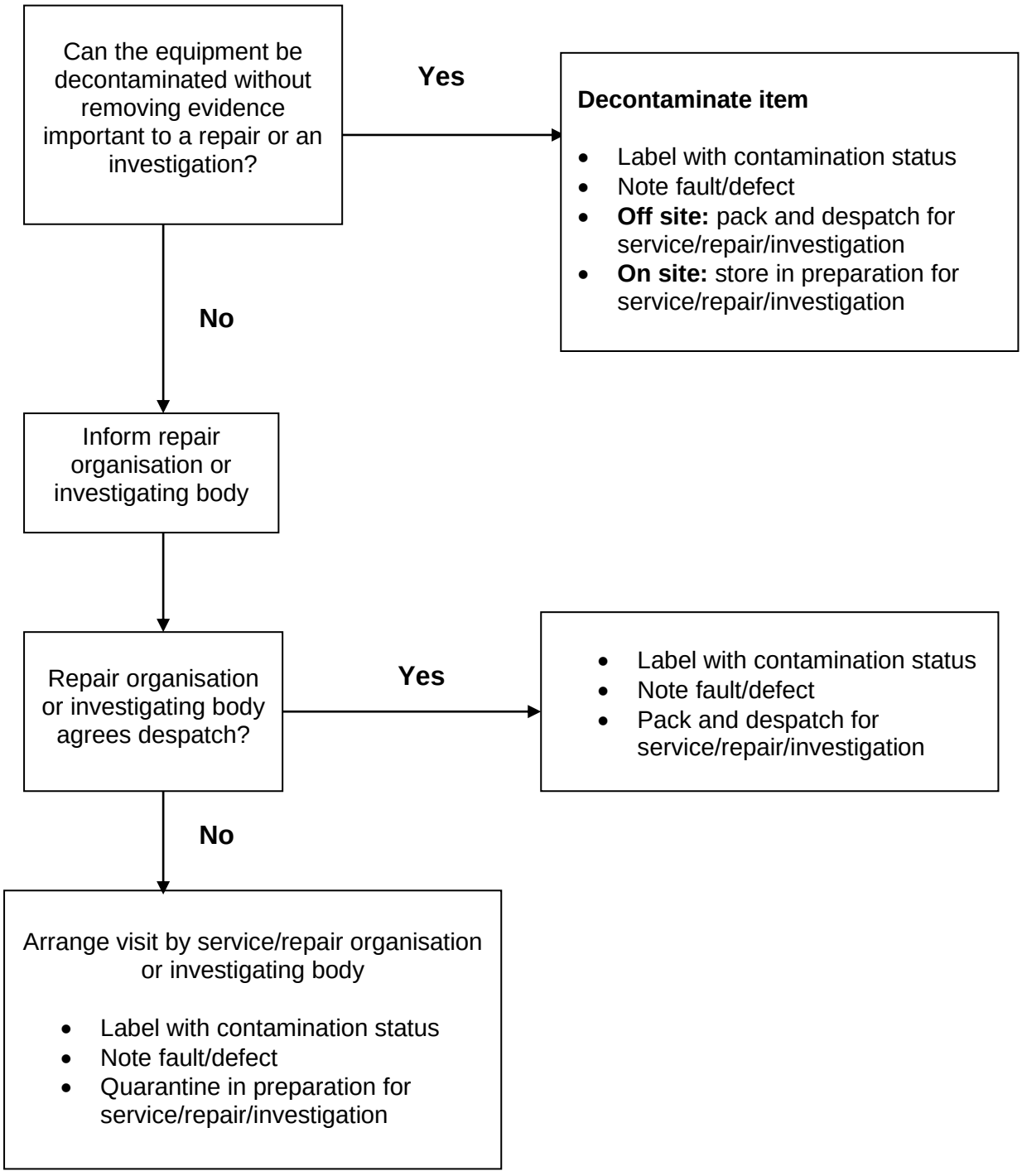


APPENDIX 2

(adapted from MHRA, 2006)

Handling of equipment prior to inspection, service, repair, return to lending organisation or investigation of adverse incident

Note: it is illegal to send contaminated items through the post



APPENDIX 3

Figure 4 Sample form – declaration of contamination status

From (consignor): ..... **To** (consignee): .....

Address ..... Address .....

....

....

Reference ..... Reference .....

Emergency tel .....

Type of equipment ..... Manufacturer .....

Description of equipment .....

Other identifying marks .....

Model No. ..... Serial No. .....

Fault .....

Is the item contaminated? **Yes*** ☐ **No** ☐ **Don't know** ☐

* State type of contamination: blood, body fluids, respired gases, pathological samples, chemicals (including cytotoxic drugs), radioactive material or any other hazard .....

Has the item been decontaminated? **Yes†** ☐ **No‡** ☐ **Don't know** ☐

† What method of decontamination has been used? Please provide details

Cleaning .....

Disinfection .....

Sterilization .....

‡ Please explain why the item has **not** been decontaminated?

.....

.....

Contaminated items should not be returned without prior agreement of the recipient

This item has been prepared to ensure safe handling and transportation:

Name ..... Position .....

Signature .....

Date ..... Tel .....

MHRA DB2006(05) November 2006 54/66

APPENDIX 4

Example of clinell® sticker to be placed in patient's admission documentation (the sticker should be taken from the cleaned bed space area)

Calderdale and Huddersfield NHS
NHS Foundation Trust

Guidelines for Cleaning Mattress and Bed Frame

START

A

Raise bed to hip height, clean half of the mattress nearest to you including the sides (stand facing bed). Repeat on opposite side. Clean both sides of bed head and foot rest.

B

Clean both sides of side rails, repeat on opposite side. Clean bed controls.

C

Check mattress top, unzip and check top underside of cover (whilst still damp from cleaning) and all areas of the inner mattress. If any breaches condemn as protocol. Close zip and put side rails up on one side of the bed.

D

Lift up mattress and hold close to you. Move down mattress repositioning your hands to hold it whilst cleaning the underneath of it as you go.

E

Once cleaned move mattress back to lean against the side rails *(see step F)* Move the mattress in stages, push head end, back end, then middle.

F

Mattress leant against side rails.

G

Clean all tops of bed base panels, facing the bed bend hips and knees to avoid stooping. Move along side of the bed from head to foot.

H

Remove head end base panel to clean underneath bed base panel *(see step I)*. Bring it close to you. Once cleaned flip onto middle panel and clean the side, rest against mattress.

I

Cleaning underneath base panels.

J

Clean the bed frame in the space where you have moved the panel, including under raised mattress, then replace base panel. Repeat step H to I on all base panels and bed frame to foot of bed.

K

Stand at the base of the mattress and lower down. Pull shelf out from the foot of the bed and clean.

L

Clean under the base of the bed, go down on knees, hold side of bed, move along side of bed cleaning each section. Keep the bed at its highest level whilst doing this. Finally clean wheels. (some beds can lock bed height).

Issued by IPCN Susan Cotterill / Moving and Handling Imran Bhatti 11/07/2016 Ref No. Technical/ 9507/16

compassionate care

UNIQUE IDENTIFIER NO: C-73-2013
Review Date: December 2023
Review Lead: Lead Infection, Prevention and Control Nurse

Processes for checking and condemning foam mattresses and cleaning air mattresses

PROCESS FOR CHECKING FOAM MATTRESSES, AND FOR CONDEMNING IF NECESSARY

To be carried out after each patient, or when mattress is to be taken off bed (i.e. when air mattress is needed instead).
If you have any doubts/queries about a mattress/this process, please call the Equipment Co-ordinators

This is a list of bags that should be kept on your ward; extra stock is kept in the clean mattress stores at both sites. Please ensure that you *always* use the correct bag:

Bags for Foam Mattresses

✓CLEAR **(thin, extra large size): for CLEAN foam mattresses *only***

✓YELLOW **(thin, extra large size): for CONDEMNED foam mattresses *only***

Bags for Air Mattresses

✓CLEAR **(thick, large size): for CLEAN air mattresses *only***

✓RED **(thick, large size): for CONTAMINATED/REPAIR air mattresses in need of deep-cleaning & repairing– if mattress needs repair, clearly attach note to bag stating the problem**

1. Clean and check the mattress as per bed cleaning protocol.

2. Breaches or staining found?

YES → 3A. **Yes**: Zip cover back up, put in yellow bag, mark bag with your ward and date, plus date & code mattress went into service (marked in marker pen on outer cover on side of mattress) and leave a message on HRI x5396 to report before calling porters to remove.

To move mattresses, call porters helpdesk: Porters should collect all mattresses within one hour *remember to state yellow bagged*

NO → 3B. **No**: Zip cover back up. Is it staying on bed?

YES → 4A. **Yes**: Ensure mattress is checked as per protocol (on discharge or if patient is incontinent risk assess and check twice weekly).

NO → 4B. **No**: (i.e. if air mattress needed for patients with or at *very high risk* of Pressure Ulcers) Take off bed, put in **clear bag**, attach yellow decon sticker and call porters to take to clean mattress store for storage – **do not leave lying around on ward/corridors!**

N.B. Ensure that no sharp objects (e.g. syringes, scissors) are placed on or near mattress as they may tear cover. Please be careful when using side rails as damage is being caused to side of mattresses.

Tissue Viability Equipment Co-ordinators 05/2011 (v4)

Calderdale and Huddersfield NHS
NHS Foundation Trust

Your Care Our Concern

PROCESS FOR CONDEMNING ATMOSAIR / FOAM MATTRESSES
ALL CONDEMNED MATTRESSES WILL BE INCINERATED

ALL mattresses must be cleaned and checked , if a mattress has been deemed condemned (breached, tear or odour related), please follow this process

YELLOW BAG THE MATTRESS (thin, large size): NOT TO BE USED FOR CLEAN MATTRESSES - **CONDEMNED MATTRESSES ONLY**
All condemned mattresses should be collected within 1 hour

TO GET THE MATTRESS REMOVED FROM THE WARD - HRI

⇩

Using EPR (CAP MAN) report condemned mattress needs to be collected, if no access to EPR, ring helpdesk on 4600

TO GET THE MATTRESS REMOVED FROM THE WARD - CRH

⇩

During normal working hours mattresses are collected twice daily by estates department, but please ring the porters helpdesk on 7167 to report outside of these hours

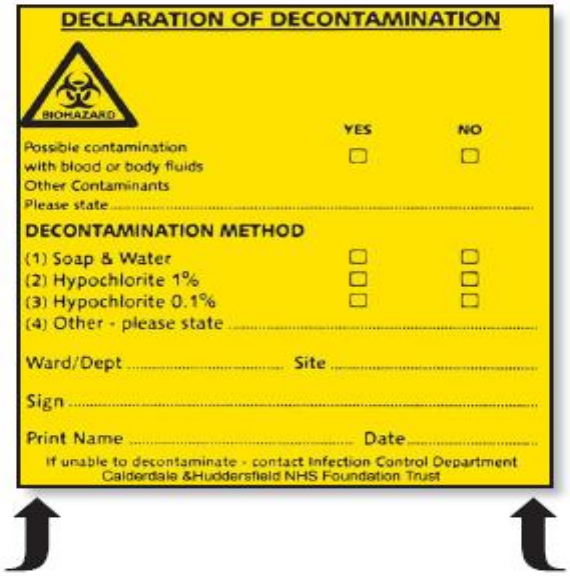
Porters / Estates department to take all condemned mattresses to condemned mattress store room, and Equipment co-ordinators will then arrange disposal of the mattresses
Please keep all store rooms tidy

AIR MATTRESS CLEANING

Calderdale and Huddersfield NHS

GENERAL CLEANING

1. Air mattress either going into store or for repair
2. The mattress must be cleaned inside and out with Tristel fuse (this product replaces chlor-clean and haz-tabs). Please ensure disposable gloves and apron are worn prior to cleaning the mattress
3. Clean the electric box with a detergent wipe and place this with the mattress in the extra large clear plastic bags provided by EBME at HRI and equipment room Ward 6 at CRH
4. Complete decontamination sticker and attach to plastic bag
5. Contact portering services for mattress to be removed to the designated area



DECLARATION OF DECONTAMINATION

BIOHAZARD

	YES	NO
Possible contamination with blood or body fluids	☐	☐
Other Contaminants		
Please state		

DECONTAMINATION METHOD

(1) Soap & Water	☐	☐
(2) Hypochlorite 1%	☐	☐
(3) Hypochlorite 0.1%	☐	☐
(4) Other - please state		

Ward/Dept ..... Site .....

Sign .....

Print Name ..... Date .....

If unable to decontaminate - contact Infection Control Department
Calderdale &Huddersfield NHS Foundation Trust

SPECIALISED CLEANING

(C difficile; heavily soiled or from an outbreak ward)

1. The mattress must be cleaned inside and out with Tristel fuse (this product replaces chlor-clean and haz-tabs)Please ensure disposable gloves and apron are worn prior to cleaning the mattress
2. Copy down the **serial** number onto the decontamination sticker
3. Place the mattress only **(not the electric box)** in red plastic 'contaminated mattress bag' provided by EBME at HRI and equipment room Ward 6 at CRH
4. Complete the decontamination sticker stating the mattress serial number and attach to the red plastic bag
5. Clean the electric box. Place it in a separate clear bag and attach a yellow decontamination sticker. Then place it with the mattress, inside the mattress bag.
6. Contact portering services for mattress to be removed to the designated area

Always make sure that all mattresses & equipment are cleaned & a decontamination sticker attached before they leave the ward.