BHTA
British
Healthcare
Trades
Association

Decontamination of Medical Devices

The BHTA guide to Decontamination of Medical Devices and other Assistive Technology

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1. Executive summary

This document provides general advice for staff dealing with medical devices returned from or delivered to: individual homes, NHS, Community Units and other Distribution Centres.

It is fundamental that standards are set in place to ensure the appropriate cleaning methods are used, due to a risk of cross infection from the reuse of medical devices issued, and that those devices, once reissued, present no risk to those using the device.

Risk can be minimised by some simple precautions. This document provides advice on the handling of devices to be returned following use, and we give guidance on the nature of decontamination required, as well as the generic methods to be used.

Putting safe systems in place to manage the decontamination of devices will contribute to meeting the requirements of the Department of Health's reduction of cross infection targets.[1]

The operation of this guidance will also promote safer working practices, and a safer working environment for all staff.

All returned Devices should be handled as if contaminated.

1 https://www.gov.uk/government/publications/health-matters-preventing-infections-and-reducing-amr/health-matters-preventing-infections-and-reducing-antimicrobial-resistance

2. Introduction

Decontamination entails a combination of processes used with the intention to make a device safer for handling by staff and for further use.

The effective decontamination of reusable devices is essential in reducing the risk of transmission of infectious agents. This guidance also needs to be applied to demonstration units as these typically move freely between clinical areas and users.

The aims of decontamination are to make reusable devices safe to be handled or used by:

- Patients, carers, or other members of the public;
- NHS and Community staff;
- Maintenance staff;
- Carriers and other transportation services; and
- Supplier employees.

Decontamination is also important because subsequent users of a device expect to receive a device that both looks clean and is clean.

There are three levels of decontamination:

- Cleaning;
- Cleaning, followed by disinfection; and
- Cleaning, followed by disinfection, followed by sterilization.

The decision about the level of decontamination required depends not only on how the device is used, but also the risk of the device transmitting infection or acting as a source of infection. Following a risk assessment, the vast majority of devices may not require much more than cleaning and occasionally disinfection.

Please note that some users of the devices may be immunocompromised, e.g. they have cancer and are undergoing chemotherapy, and thus 'contaminants' that may normally be harmless, can cause a risk to the immunocompromised individual. This is the underlying principle of Barrier Nursing.

Given the nature of their use, it is unlikely that devices loaned for use in the community will require sterilization.

In this document the term 'device' has been used to cover all items, equipment, or products that will be processed. These may be medical devices, or they may be assistive technology which does not fall strictly under the medical device description.

3. Glossary

Adverse Incident – An event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. For example: a patient, user, carer or professional is injured as a result of a medical device failure or its misuse.

Assistive Technology – Any product or service designed to enable independence for disabled and older people.

Audit – A means of measuring processes related to health care delivery as an aspect of quality control.

Barrier Nursing – There are two main types of barrier nursing: one is used to protect patients from infection because their immune system is unable to fight even simple organisms (e.g. after chemotherapy for cancer). The other type is to protect other people from harmful organisms carried by infected patients. Both usually involve segregation and the wearing of protective clothing by carers. For the latter, the room and equipment undergo rigorous cleaning on discharge.

Body Fluids – Any fluid from the body of non-infected or infected individuals can pose an infection risk. The main risk is from blood, urine, faeces, and vomit and to a lesser degree, fluids such as saliva, tears, and sweat. The degree of risk depends on the individual infective organism, proximity, duration of exposure, and level of cleaning.

Cleaning – A process which physically removes inorganic dirt, infectious agents, and the organic matter on which they thrive, but does not necessarily remove all infectious agents. Cleaning is an essential prerequisite to ensure effective disinfection or sterilization.

Clostridium Difficile – A pathogen which in some instances causes acute mild to severe diarrhoea.

Contamination – The soiling or pollution of inanimate objects or living material with harmful, potentially infectious, or other unwanted material. Such contamination may have an adverse effect on the function of a medical device and could be transferred to a person during use or storage.

Cross Contamination – The transfer of contaminants between persons and/or devices.

3. Glossary

Decontamination – A process which removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate infection or any other harmful response. Differing levels of decontamination are used depending on the device and its intended use.

The levels of decontamination are:

- Cleaning;
- Cleaning, followed by disinfection; and
- Cleaning, followed by disinfection, followed by sterilization.

Disinfectant – A chemical agent that, under defined conditions, is capable of disinfection.

Disinfection – A process used to reduce the number of viable micro-organisms, but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection does not necessarily achieve the same reduction in microbial contamination levels as sterilization. Disinfection does not remove any of the micro-organisms that the process has inactivated, and the remaining parts of bacteria may give rise to immune responses, which may be life-threatening.

Health Care Associated Infection (HCAI) – HCAIs are infections as a result of contact with the healthcare system in the broadest sense. They include hospital and community acquired infections.

Hepatitis – Inflammation of the liver, usually due to infection by one of a number of viruses. The viruses are usually present in blood and body fluids of affected patients.

Human Immunodeficiency Virus (HIV) – The cause of Acquired Immune Deficiency Syndrome (AIDS). It is possible to be infected with HIV, but not have clinical AIDS.

Infectious Agents – The term includes micro-organisms and other transmissable agents, with the potential to cause an infection.

Medical Device – any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- Investigation, replacement or modification of the anatomy or of a

physiological or pathological process or state; and

- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Microbial Resistance – The degree to which a disease-causing organism remains unaffected by antibiotics or drugs.

Methicillin Resistant Staphylococcus Aureus (MRSA) – This is a common hospital pathogen and is a cause of great concern. It is resistant to all commonly used antibiotics.

Prion – A small proteinaceous infectious disease-causing agent that is believed to be the smallest infectious particle.
A prion is neither bacterial nor fungal nor viral and contains no genetic material.

4. Risk management

All returned Devices should be handled as if contaminated.

All premises, equipment, and processes used to decontaminate re-usable medical devices contain elements of risk that need to be identified, monitored, controlled, and managed.

There are two elements of device-related risk. One relates to the risk to the individual from the device, and this is reflected by the CE mark category allocated to a medical device. In a nutshell: Class I products are products like walking frames, and are self-certificated by the manufacturer. If the claim for the medical device is that it entails transfer of energy (e.g. electrically controlled posture adjustment devices in a bed), or affect the physiology of the user (e.g. mattresses that have claims attached that they benefit tissue health), then it is required to be classified as Class IIa. Class III products are those involved in intrusive surgery, such as an implant.

The other area of risk is the likelihood that the device might carry contamination from one person to another, or from one device to another. It is this latter area of risk where these Guidelines provide advice.

In any establishment, contaminated devices should be kept separate from decontaminated devices. The contaminated devices are segregated in a 'dirty' area, and the decontaminated devices in a 'clean' area. Any automated equipment should be 'pass-through' with the devices passing from the dirty area to the clean area through the washer/disinfector. Good practice is that airflow goes from the clean area to the dirty area, to avoid air-borne cross-contamination. Likewise, workflows should remove the risk of carriage of contaminants by staff moving from a dirty area to a clean area.

Any decontamination of devices is superfluous if individuals handling the device do not practice effective infection prevention techniques. Micro-organisms move around the environment in many ways, e.g. they float in the air, flow in water, move in droplets (e.g. sneezing), or are present in body fluids. Two methods of transmission are: through touching surfaces or people (contagious); or in the air (infectious). In hospitals, care homes, and facilities, the most common means of transmission is via the hands of the staff or via objects which are used for patient care.

There should be a great deal of emphasis on hand washing and devices cleaning, but also on looking at the working environment. This is because we need to minimize the possibility that the devices will pose an infection risk. (See the BHTA Get Wise leaflet for details on hand washing techniques.)[2]

2. See BHTA's Get Wise to Hand Hygiene - http://bhta.com/get-wise-leaflets/

5. Safe systems of work

A local protocol for decontamination activities should be established with technical input, as required, from the following:

- Device manufacturers and suppliers of devices and services;
- Infection prevention team;
- Clinical Nurse Specialist for device provision;
- Risk Manager (responsible for risk assessment);
- Health and Safety Officer;
- Quality Management; and
- Standard Operating Procedures (SOPs).

You can also get advice from appropriate government and professional bodies such as the Medicines & Healthcare products Regulatory Agency and the Infection Prevention Society. Examples can be found in Appendix 3.

Reference must also be made to any relevant legislation e.g. Health and Social Care Act 2008: Code of practice on the prevention and control of infections, and related guidance.[3]

Staff handling used medical devices should assume that they are contaminated and take precautions to reduce the risk of transmission of infectious agents. Personal protective equipment (PPE) must be used, in accordance with local policy, for the handling of potentially contaminated and soiled devices, and for decontaminated devices.

All staff (existing and new) should have a full knowledge and understanding of the risks involved in handling a device and should have knowledge of the cleaning procedures for the device. All staff who are likely to be involved in cleaning devices (even if infrequently) should have practical, in addition to theoretical, training. All newly engaged staff should be trained as part of their initial training process. Training should be updated on at least an annual basis, and the staff should prove competency in all appropriate procedures.

Staff should not make alterations and adaptations to a device for cleaning unless these are permitted in the manufacturer's instructions for use. If alterations and adaptations are made over and above these, this will risk liability and possibly warranty issues. Any concerns should be discussed with a representative from the manufacturer or a manufacturer-approved service.

Devices identified as being faulty or incomplete should be reconditioned by a suitably qualified staff member or contractor.

Devices returned for reuse, but which are not accompanied with a Certificate of Decontamination (see Appendix 2), should be rejected and returned unexamined.

3 https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance

6. Guidance on decontamination

Decontamination must be carried out in accordance with the device manufacturer's instructions. If there is no processing information provided with the device, then you should contact the manufacturer for guidance. Reusable medical devices placed on the UK market must be provided with processing instructions.

If the manufacturer is unable to provide this information or if it is believed to be inadequate, the Medicines & Healthcare products Regulatory Agency (MHRA)[4] should be notified.

4 https://www.gov.uk/report-problem-medicine-medical-device

Listed below are suggested methods for processing reusable devices.

6.1 Cleaning

This is the removal of dirt and organic material by washing, usually using a suitable detergent solution. Depending on the detergent manufacturer's instructions, the solution may be advised to be heated. If being cleaned manually, the devices should be fully immersed in the detergent solution (see below), and the device scrubbed or brushed if the instructions allow for this. The detergent solution should be rinsed from the device with clean water. Cleaning can be done by hand or by using an automated washer. Brushes used for manual cleaning should be single use. In cleaning, cool water is best for moving some contaminants, such as proteins (which change their shape when heated (like egg white is clear in the raw egg, but solidifies and goes white when heated)), whereas fats are displaced best when the water is warmer. Thus good washing processes need a combination of lower and higher temperature parts of a process.

Devices being washed by hand should be washed under water to avoid the creation of aerosols (spray) which appear when scrubbing a device in the open air. These aerosols can be breathed in by not only the operative, but by others near the washing point.

If you plan to use a high-pressure jet washer or steam cleaner, an assessment of the risks to operators and staff should be undertaken beforehand. Splashes of water and aerosols could carry particles of soil from the device into the air, which could pose a risk to operators and staff in the vicinity. The risk assessment should identify any personal protective equipment necessary, including respiratory protective equipment such as face masks.

Automated washers are available which allow devices to be loaded into a machine and processed through a cycle of defined parameters resulting in cleaning to a consistent standard in a closed environment. This type of device will require regular testing to demonstrate that it is still performing to specification.

Consideration must be given to the ongoing costs of consumables, such as water and energy, which may be high.

However, automated washers might enable a higher turnover of devices and reduced operative hours. The use of an automated system can increase the level of quality assurance and reduce the risk to operatives. However even automated systems may not clean some devices. Refer to the manufacturers' instructions to ensure compatibility with the cleaning process. Ensure that the machine manufacturers have a validation process for their machines.

Devices that cannot be immersed may be decontaminated by wiping with a cloth soaked in detergent solution and wrung out. Wipe all the surfaces of the device. The cloth should be re-immersed periodically, and the detergent solution changed frequently.

Disposable cloths must be used and discarded after use on one device. The detergent should be rinsed or wiped off the device using clean disposable cloths that have been immersed in clean water and wrung out.

If not proceeding to a disinfection stage, devices that have been cleaned must be dried prior to inspection, maintenance, repair, or storage. Drying is ideally by being left to dry in the open air in a clean zone, or by disposable paper towels.

6.2 Disinfection

Reference should be made to the Health Technical Memorandum HTM 01 series[5], e.g HTM (01-04) Decontamination of linen for health and social care.

Devices must first be cleaned using a method suggested above before being disinfected using either (a) thermal disinfection or (b) a chemical disinfectant.

When using heat as the disinfecting methodology, the device should be held at 80°C for a minimum of one minute in order to achieve disinfection. Other time/temperature relationships can also be used to achieve disinfection and the advice of the local infection prevention team should be sought on this issue. This can be more easily achieved using an automated processor where the water can be in continuous contact with the device. The equipment should meet the requirements of BS EN ISO 15883-6: 2015 Washer-disinfectors – Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment.[6]

5 https://www.gov.uk/government/collections/health-technical-memorandum-disinfection-and-sterilization#decontamination-htms

6 https://shop.bsigroup.com/ProductDetail/?pid=000000000030329680

6. Guidance on decontamination

For devices that cannot tolerate exposure to high temperatures, an automated machine providing chemical disinfection process should be used. The equipment should meet the requirements of BS EN ISO 15883-7: 2016 Washer-disinfectors – Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment.[7]

For devices that cannot tolerate immersion in solution, manual disinfection using a clean cloth and a compatible chemical disinfectant shall be applied. The solution should be wiped over the device's surface using a clean disposable cloth.

When using a chemical disinfectant, it is important to ensure that the disinfectant is at the correct concentration and is in contact with the device for the specified minimum contact time. The disinfectant solution should be removed from the device with clean water and the device dried prior to storage. Air drying or wiping down with disposable paper towels are alternative techniques. Once dried, the devices should be packaged to protect them from 'cross-' or re-contamination.

Disinfectants should be used and stored in accordance with the manufacturer's instructions. This includes the use of lockable cupboards in which to store the chemicals. Use of personal protective equipment when handling chemicals will be required.

6.3 Track, trace, and match

Within medical device legislation, and within quality assurance processes for ISO 9001[8] or ISO 13485[9], there is a requirement to keep Device Records which show the history of a medical device, including maintenance records. This principle should be followed for any relevant devices used by patients/carers/affected members of the public.

Each device should have a Unique Identifier, or GTIN (which is a series of numbers for identification) and also should display a Batch and/or Serial Number, Date of Manufacture, and, if applicable, a Use By Date (see BHTA guidance on barcoding[10] for more information).

The identification system in the NHS and Social Services uses GS1 coding[11] and requires the Supply Chain to identify to whom the device has been sent, and the patient for whom it was used, to enable a device recall, if required.

7 https://shop.bsigroup.com/ProductDetail?pid=000000000030235351

8 https://www.iso.org/iso-9001-quality-management.html

9 https://www.iso.org/iso-13485-medical-devices.html

10 http://bhta.com/gs1-barcoding/

11 https://www.gs1.org/healthcare/udi

Unique Identifiers are being phased in as a legal requirement for medical devices under the new EU Medical Device Regulations[12].

Likewise, each Medical Device should have a record of when and how it was processed, again for the purposes of recall in case the processing procedure was found to have had a fault.

6.4 Training and certification

Operatives should have annual retraining on the Health and Safety aspects of their jobs, and the equipment they use. This should be certificated, and records kept of the training and certification.

12 https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

7. Workflow and processes

7.1 Transport

A local policy for the management and transport of devices from the point of use to the place of decontamination should be implemented. Vehicles used for the delivery and collection of loan devices should ideally only be used for either clean or dirty devices. Containers and trolleys/carts must be easy to clean and disinfect, properly maintained, provide protection for the load, and be designed so that devices can be securely and safely held during transit.

Any vehicle that is used for deliveries and/or collections of devices should be issued with and kept supplied with suitable Personal Protective Equipment (PPE) e.g. masks, aprons and gloves.

Should the use of separate vehicles not be possible, a suitable vehicle which allows for the segregation of those devices being collected from those being delivered may be used, and a procedure must be in place to ensure devices are secured to reduce the risk of any air borne cross contamination. Devices should be enclosed in non-permeable packaging.

The inside of the vehicle should be cleaned and disinfected on a regular basis e.g. ideally daily, and on every occasion when visibly soiled. Unless appropriately sealed, wood/soft surface vehicle liners must not be used as they cannot be decontaminated effectively.

7.1.1 Transportation after decontamination

A processed device to be delivered to a user must be in clean, secure transit packaging which protects the device from damage or contamination, in accordance with local policy.

7.2 Receipt of contaminated devices into a decontamination area

Receive devices into the designated dirty section of the decontamination, or 'dirty' area. The decontamination area must be separated from clean areas by walls or other solid barriers.

A log should be maintained of all goods received and processed.

7.3 Choice of decontamination method

The choice as to which method of decontamination is the most suitable will depend upon many factors including:

- The manufacturer's instructions;
- The nature of the contamination;
- The ultimate use of the device;
- The heat, pressure, moisture, or chemical tolerance of the device or of individual components;
- Availability of processing equipment;
- The risks associated with the decontamination process; and
- The physical nature of the device to be decontaminated, e.g. size.

7.4 Disassembly of contaminated devices

Where appropriate, devices should be disassembled by trained staff (wearing appropriate personal protective equipment), in line with the instructions provided by the manufacturer. A designated, trained member of staff should be responsible for ensuring that the decontamination process is undertaken. Care must be taken for the safe handling and disposal of sharp devices.

7.5 Application of decontamination method

After dismantling, the device must be cleaned and, where needed, disinfected, thoroughly. Methods of cleaning, and disinfection are described in Section 6.

The devices should be dry on completion of the decontamination process.

A certificate of decontamination or other means of identifying the status of the device should be completed (see Appendix 2).

7.6 Re-assembly of decontaminated devices

Re-assembly of devices has to be performed to the manufacturer's instructions and/or local policy.

7.7 Inspection, maintenance, or testing of devices

Devices subject to investigation, service, or repair in the Acute Environment must be decontaminated prior to inspection, maintenance, or testing (see MHRA's Managing Medical Devices – Guidance for healthcare and social services organisations: April 2015[13]). Likewise, devices requiring service or repair elsewhere should be safe to be handled by service personnel. Any loaned devices being returned to a manufacturer or supplier must also be decontaminated before return.

Inspection, maintenance, or testing of devices must be carried out by trained persons in accordance with the manufacturer's instructions. Records of all work performed, including test results must be maintained. Contact the manufacturer if there are any issues in assembling or testing the device.

7.8 Packaging

Following the inspection process, the device should be wrapped in impermeable packaging material (wrapper, bag, or pouch). In circumstances where devices are processed at the point of immediate use, packaging may not be necessary.

13 https://www.gov.uk/government/publications/managing-medical-devices

7. Workflow and processes

7.9 Storage

All processed devices must be stored on clean impermeable off-floor shelving in well ventilated and secure stores to avoid damage or tampering. Devices should be sealed within impermeable packaging. A record of devices in store and available for use should be retained within the storage administrative area. The despatch of any device from this area must be documented and consideration given to the rotation of stock.

7.10 Disposal considerations

Any device that is being sent for disposal is required to be decontaminated beforehand.

If electric or electronic devices are found to be beyond normal repair, decontamination shall be undertaken prior to disposal as per the Waste Electrical and Electronic Equipment (WEEE) Directive[14].

14 http://www.hse.gov.uk/waste/waste-electrical.htm

7.11 Adverse incident reporting

Organisations should have in place a system to ensure adverse incidents involving medical devices are reported to the manufacturer and serious adverse incidents also to the Medicines and Healthcare products Regulatory Agency (MHRA)[15].

15 https://www.gov.uk/report-problem-medicine-medical-device

7.12 After decontamination of devices

Once the decontamination process has been completed, devices should be inspected, and any maintenance carried out to ensure that the devices are safe and fit for reuse. They should then be labelled i.e. supplied, with a certificate of decontamination. An example of a certificate of decontamination is provided in Appendix 2.

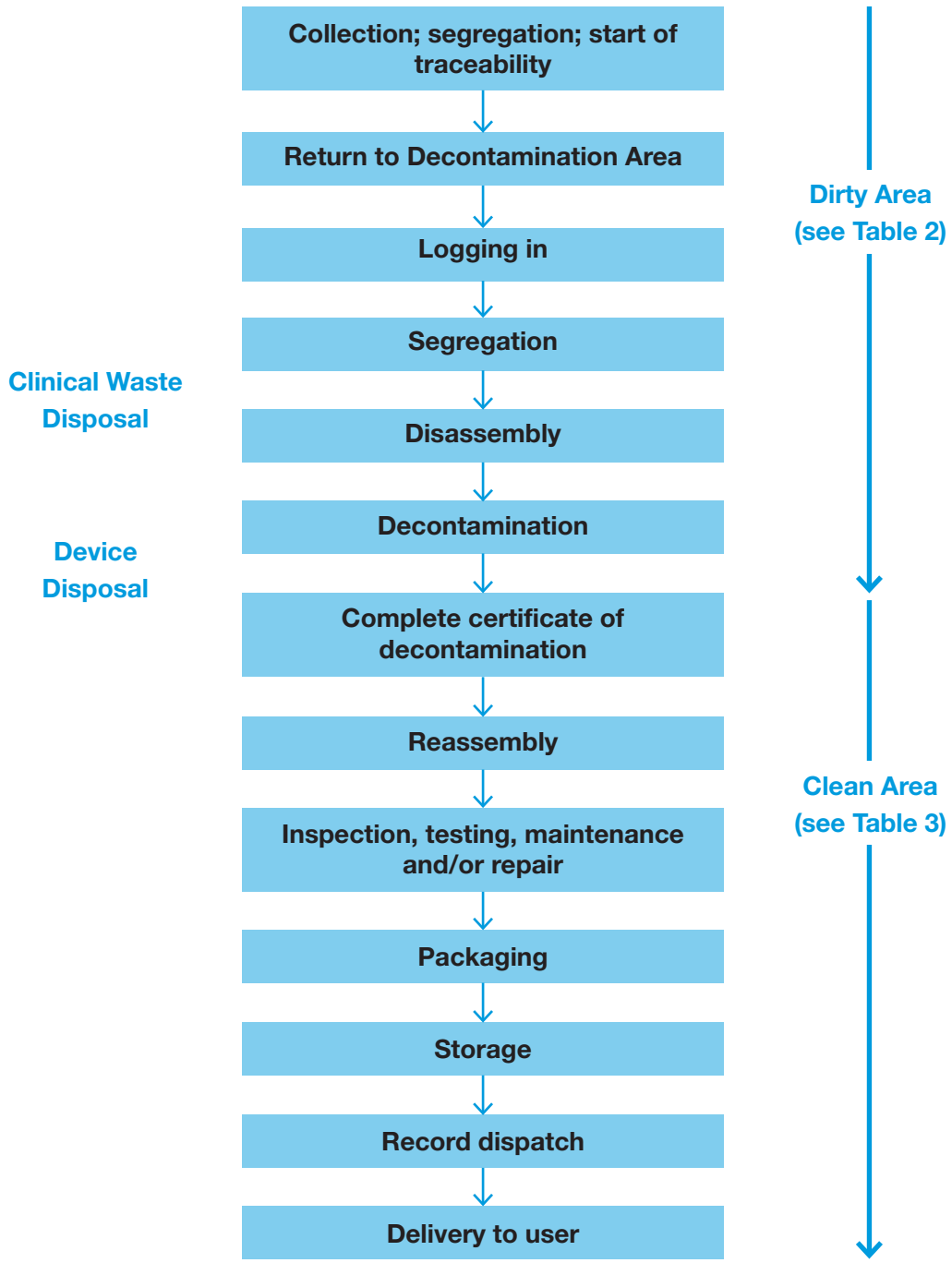
Whilst a certificate of decontamination for every single device processed may seem unachievable, in reality the supplier needs to consider ways of documenting the processes undertaken. There may be other ways of recording this information and a local protocol should be established based on device throughput, and resources available.

However the process should always include:

1. Validation – that the cleaning and disinfection processes and equipment are effective
2. Traceability – Track, Trace, and Match protocols are in place
3. Training and Certification – carried out within the specified retraining periodicity

A diagrammatic representation of the recommended workflow using a 'dirty in/clean out' approach is given in Figure 1. The facilities and equipment required in each of these areas for the activity being undertaken are outlined in Tables 2 and 3.

Figure 1: Workflow from Dirty Area through Clean Area to Delivery



7. Workflow and processes

Table 1: Examples of devices and suggested methods of decontamination

This table provides some examples of reusable devices along with a suggested method of decontamination in between each use. This list is not exhaustive and staff decontaminating devices must always first refer to the device manufacturer's instructions.

Examples of devices	Suggested method of decontamination
Blanket support; Domestic lighting Fall alarm; Flashing doorbell Gas escape alarm; Lever tap Liquid level indicator; Low vision optical aid	Cleaning
Assistive listening device; Bed lever Communication aid for speech impediment Special cutlery; Split leg table Stool; Teapot tipper Text phone; Transfer board Trolleys; Walking aids Grab rail; Hoist Bedside rail; 2 - and 4 -Section bed frame Bath board; Lift and seat Bed pan; Commode / bedpan support Hoist sling; Male and female urinal Mattress and cover; Pressure relief mattress Raised toilet seat; Shower chair and seat Special seating; Toilet frame and seat Wheelchair frame; Wheelchair seating	Cleaning and disinfection

Table 2: Facilities and equipment for the dirty area

Activity	Facilities
Collection of device	• suitable vehicle to allow segregation of clean and dirty devices • the inside of the vehicle shall be able to be cleaned and disinfected on a regular e.g. daily basis and when visibly soiled • the vehicle driver must have access to personal protective equipment and a first aid kit. The driver must be adequately trained to handle contaminated devices
Logging in of returned devices **Segregation** of devices to be sorted by level of decontamination required	• impermeable off-floor shelving which shall be cleaned regularly • dedicated hand decontamination facility e.g. hand wash basin • foot operated pedal bin and black bags for domestic waste stream • foot operated pedal bin and yellow bags for clinical waste stream • personal protective equipment e.g. plastic aprons, latex/nitrile/vinyl gloves, and face visors
Disassembly of device where necessary	• personal protective equipment • dedicated hand decontamination facility • sharps bin • device manufacturer's reprocessing instructions
Cleaning or **cleaning & disinfection** depending on the type of device and the nature of contamination **Completion of certificate of decontamination**	• utility sink and drainer • water softener and heater • automated processing equipment • adequate ventilation • appropriate drainage facilities • lockable chemical storage cupboard • appropriate cleaning/disinfection equipment • personal protective equipment e.g. coveralls, latex/nitrile/vinyl gloves, non-slip footwear, and face visors • changing rooms • dedicated hand decontamination facility • sharps bin • pedal operated clinical waste bin • COSHH assessments & material safety data sheets available

Table 3: Facilities and equipment for the clean area

Activity	Facilities
Reassembly of device following completion of decontamination process **Inspection** and **testing** for **maintenance** and/or **repair** as part of the **quality control** process	A certificate of decontamination (or some other means to identify that it has been decontaminated) must accompany all devices from here onwards • device manufacturer's instructions • personal protective equipment • dedicated hand decontamination facility
Packaging of device as appropriate for storage or dispatch	• personal protective equipment • dedicated hand decontamination facility
Storage of devices prior to dispatch	• impermeable off-floor shelving which shall be cleaned regularly • robust, secure outer door
Record of dispatch of device for **delivery** to user	• suitable vehicle to allow segregation of clean and dirty devices • the inside of the vehicle shall be able to be cleaned and disinfected on a daily basis and when visibly soiled

8. Legal and other requirements

8.1 Postal system

It is illegal to send contaminated devices via the postal system, as detailed in the Royal Mail's guidance on prohibited and restricted items[16] wherein it states: "Infectious substances and pathogens (UN2814 or UN2900) as classified in the latest edition of the Technical Instructions for Safe Transport of Dangerous Goods by Air published by the International Civil Aviation Organization (ICAO) may not be transported by post" – or by any other means in the public, unless in a container designed to meet the requirements laid out in the UN documents quoted.

16 www.royalmail.com/sites/default/files/royal-mail-prohibited-and-restricted-items-jan-30-2017.pdf

8.2 Reusable medical devices

The Health & Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance[17] applies. An extract follows:

17 https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance

"j. Decontamination of reusable medical devices

- Effective decontamination of reusable medical devices is essential. There should be a system to protect patients and staff that minimizes the risk of transmission of infection from medical devices and other equipment that comes into contact with patients or their body fluids
- Decontamination is the combination of processes, including cleaning, disinfection and sterilization, used to render a reusable item safe for further use on patients and handling by staff.
- Reusable medical devices and other devices should be decontaminated in accordance with manufacturers' instructions and current guidelines.
- Systems should ensure adequate supplies of reusable medical devices and should allow reusable medical devices to be tracked through decontamination processes in order to ensure that the processes have been carried out effectively.
- Systems shall also be implemented to enable the identification of patients on whom the medical devices have been used."

8.3 Safety at work

The Health and Safety at Work etc Act (1974)[18] places a number of duties on employers and employees concerning the requirements of safe working practices and specifically the Management of Health and Safety at Work Regulations (1999) (amended 2005) place a statutory duty of co-operation between employers and employees to provide each other with clear communication in health and safety matters including any hazards associated with their activities e.g. decontamination, transfer of material or devices, etc.

8.4 Hazardous substances

The Control of Substances Hazardous to Health (COSHH) Regulations (2002)[19] is applicable to both chemical hazards and biohazards.

The above list is not exhaustive and any risk analysis regarding processes and controls should review all relevant documentation.

18 http://www.hse.gov.uk/legislation/hswa.htm

19 http://www.hse.gov.uk/nanotechnology/coshh.htm

Appendix 1 – Staff guidance

When to wash hands[20]

- At the start and end of each shift.
- Before moving out of a "dirty" area which holds equipment that has been in patient contact and not been cleaned.
- After each piece of equipment has been cleaned.
- Before and after breaks.
- Before and after using the toilet.
- Before and after any contact with used equipment.
  - Rinse under running water keeping hands below level of elbows
  - Dry thoroughly with paper towels, use hand cream if necessary
  - Dispose of paper towels in the correct manner.

Note: Staff with chronic skin conditions e.g. dermatitis, eczema, should be discouraged from working in a decontamination area to avoid exacerbating their condition

20 See BHTA's Get Wise to Hand Hygiene http://bhta.com/get-wise-leaflets/

Vaccination

Any employee who has contact with devices that may be contaminated by blood or bodily fluids has an "Occupational Exposure" to Hepatitis B. It is recommended that they undergo vaccination, or that it should be standard practice to offer Hepatitis B vaccination.

Whilst vaccination does not guarantee immunity from Hepatitis, nor does it protect from other blood borne diseases such as HIV, it is essential that all first line precautions are taken.

Appendix 2 – Sample certificate

CERTIFICATE OF DECONTAMINATION

Type of device ..... **Model** .....

Manufacturer ..... **Serial no** .....

Inventory number .....

Method of decontamination

Please tick appropriate box

☐ Cleaning ☐ Cleaning followed by disinfection

☐ Other (please specify) .....

Decontaminated by ..... on .....

Inspected and packaged by ..... on .....

Site location .....

Notes

This item has been prepared to ensure safe handling and transportation

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

Signature ..... Tel .....

Appendix 3 – Advice providers

This is not an exhaustive list.

Regulators

Health & Safety Executive (HSE)
The HSE's work covers a varied range of activities; from shaping and reviewing regulations, producing research and statistics and enforcing the law.

Redgrave Court, Merton Road
Bootle, Merseyside L20 7HS
Telephone: 0300 003 1747
www.hse.gov.uk

Medicines and Healthcare products Regulatory Agency (MHRA)
The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the Department of Health and Social Care.

151 Buckingham Palace Road
London SW1W 9SZ
Email: info@mhra.gov.uk
Telephone: 020 3080 6000
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Inspectorates

England
CQC (Care Quality Commission)
Established in 2009, the CQC is the independent health and social care regulator for England, responsible for the registration, regulation, inspection and rating of all providers. Its central aim is to ensure that health and social care services provide patients with high quality, safe and effective care, while encouraging improvement.

CQC National Customer Service Centre, Citygate, Gallowgate, Newcastle-upon-Tyne NE1 4PA
Telephone: 03000 616161
www.cqc.org.uk

Northern Ireland
RQIA (Regulation and Quality Improvement Authority)
The RQIA was established in 2005 and is responsible for registering, monitoring and inspecting health and social care services in Northern Ireland, while encouraging improvement in their quality.

9th Floor, Riverside Tower, 5 Lanyon Place, Belfast BT1 3BT
Telephone: 028 9051 7500
Email: info@rqia.org.uk
https://www.rqia.org.uk

Scotland

HIS (Healthcare Improvement Scotland)

HIS began operating in 2011, replacing QIS (Quality Improvement Scotland) as the national healthcare improvement organisation for Scotland. HIS regulates and inspects healthcare providers in Scotland, and works with them to improve the quality of services. It is also responsible for informing the public about healthcare quality.

Gyle Square, 1 South Gyle Crescent,
Edinburgh EH12 9EB
Telephone: 0131 623 4300
Email: comments.his@nhs.net

Delta House, 50 West Nile Street, Glasgow G1 2NP
Telephone: 0141 225 6999
http://www.healthcareimprovementscotland.org/

Care Inspectorate

Established in 2010 as the independent regulator for social care and social services in Scotland, the Care Inspectorate took on the roles of the Care Commission, the child protection unit of Her Majesty's Inspectorate for Education (HMIe) and the Social Work Inspection Agency. It currently regulates approximately 15,000 services. The Care Inspectorate works closely with HIS and the two regulators carry out joint inspections of services for children and young people and services for older people.

Compass House, 11 Riverside Drive,
Dundee DD1 4NY
Telephone: 0345 600 9527
Email: enquiries@careinspectorate.com
http://www.careinspectorate.com/

Wales

HIW (Healthcare Inspectorate Wales)

The HIW is responsible for the registration, inspection and review of all NHS and independent healthcare providers and services in Wales, measuring their performance against published standards and regulations.

Welsh Government, Rhydycar Business Park, Merthyr Tydfil CF48 1UZ
Telephone: 0300 062 8163
Email: hiw@gov.wales
http://hiw.org.uk

CSSIW (Care and Social Services Inspectorate Wales)

The CSSIW regulates social care and social services in Wales, with the aim of providing independent assurance of the quality of services. CSSIW inspects and monitors a range of services, including domiciliary care, care homes and nurseries.

Welsh Government Office
Rhydycar Business Park
Merthyr Tydfil CF48 1UZ
Telephone: 0300 7900 126
Email: ciw@gov.wales
http://careinspectorate.wales

Appendix 3 – Advice providers

Professional bodies

Healthcare Infection Society (HIS)
The Healthcare Infection Society (HIS) is a charity (no.1158172) whose objectives are to advance knowledge of, foster scientific interest in, and disseminate information about, the prevention and control of hospital and other healthcare associated infections (HCAIs), to medical and allied professionals for the benefit of the public.

HIS Enquiries, 162 King's Cross Road,
London WC1X 9DH
Telephone: 020 7713 0273
Email: admin@his.org.uk
https://www.his.org.uk/

Infection Prevention Society (IPS)
"Our vision is that no person is harmed by a preventable infection.
Our mission is to inform, promote, and sustain expert infection prevention policy and practice in the pursuit of patient or service user and staff safety wherever care is delivered."

c/o Fitwise Management Limited
Blackburn House, Redhouse Road
Seafield, Bathgate
West Lothian EH47 7AQ
Telephone: 01506 811077
Email: ips@fitwise.co.uk
https://www.ips.uk.net

Institute of Decontamination Sciences (IDSc)
The IDSc embraces the challenges faced in helping to reduce the risks of infection and is committed in ensuring the provision of competent staff that can meet the technical and operational challenges of medical device decontamination and is recognised as a key professional body in the UK framework, managing all of the risks associated with Health Care Acquired Infections (HCAI) in medical devices processing.

c/o Fitwise Management Limited
Blackburn House, Redhouse Road
Seafield, Bathgate, West Lothian EH47 7AQ
Telephone: 01506 811077
Email: idsc@fitwise.co.uk
http://www.idsc-uk.co.uk

National Association of Equipment Providers (NAEP)
The National Association of Equipment Providers (NAEP), founded in 1996, is an established membership association, which represents a broad spectrum of personnel working in all sectors of community equipment provision and their associated services in the United Kingdom.

PO Box 34, Camelford, Cornwall PL32 9WZ
Telephone: 01840 211115
Email: enquiries@naep.org.uk
http://naep.org.uk/

British Healthcare Trades Association
Suite 4.6
The Loom
14 Gowers Walk
London
E1 8PY

Telephone: 020 7702 2141
Email: bhta@bhta.com
www.bhta.com

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