

9 Decontamination

9.1 Correct procedure

Responsible organisations should keep patients, staff and visitors safe by having systems to ensure that all reusable medical devices are properly decontaminated prior to use or repair and that the risks associated with decontamination facilities and processes are well managed. See Standards for Better Health, Core Standard C4 (c) [15].

Staff handling used medical equipment should assume that it is contaminated and take precautions to reduce the risk to themselves and others. The use of personal protective equipment/clothing should be considered.

Medical devices should be decontaminated and stored in accordance with legislative and best practice requirements. Where appropriate decontamination should always be carried out in dedicated facilities, for example:

- endoscopes – endoscopy suite
- surgical instruments – sterile services
- home loans – home loans decontamination facility.

There should be a local policy for the management and transport of medical equipment from the point of use to the decontamination facility.

If the manufacturer's instructions appear inappropriate or incomplete, report this to the MHRA as an adverse incident (see section 2.6).

Decontamination requirements should be considered before reusable medical devices are acquired to ensure they are compatible with the decontamination equipment available.

Set up local protocols for decontamination activities, seeking advice from the following:

- manufacturer of the medical device
- manufacturer of equipment used for decontamination/reprocessing
- infection control staff
- sterile services manager
- consultant microbiologist or consultant in communicable disease control or a public health doctor
- risk assessment officer
- device and equipment users
- advice from appropriate government bodies such as the MHRA and NHS Estates
- advice from appropriate professional bodies such as IDSc, ICNA, HIS, NAEP.

9.1.1 Choice of method

Decontamination is a series of processes to remove or destroy contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to start infection or any other harmful response. Differing levels of decontamination are used depending on the device and the procedure involved. The levels of decontamination are:

- cleaning
- cleaning followed by disinfection and or sterilization.

The choice of decontamination method should be related to the degree of infection risk associated with the intended use of the equipment (Table 9).

Table 9 Classification of infection risk associated with the decontamination of medical devices

Risk	Application of item	Recommendation
High	<ul style="list-style-type: none">• In close contact with broken skin or broken mucous membrane.• Introduced into sterile body areas.	Cleaning followed by sterilization.
Medium	<ul style="list-style-type: none">• In contact with mucous membranes.• Contaminated with particularly virulent or readily transmissible organisms.• Before use on immunocompromised patients.	Cleaning followed by sterilization or disinfection. NB: Where sterilization will damage equipment, cleaning followed by high level disinfection may be used as an alternative.
Low	<ul style="list-style-type: none">• In contact with healthy skin.• Not in contact with patient.	Cleaning.

Other factors to consider when choosing a method of decontamination include the:

- nature of the contamination
- time required for processing
- heat, pressure, moisture and chemical tolerance of the object
- availability of the processing equipment
- quality and risks associated with the decontamination method.

All medical devices, decontamination equipment, and surfaces should be appropriately dealt with after use on patients known to have, or who are in a risk category for, CJD.

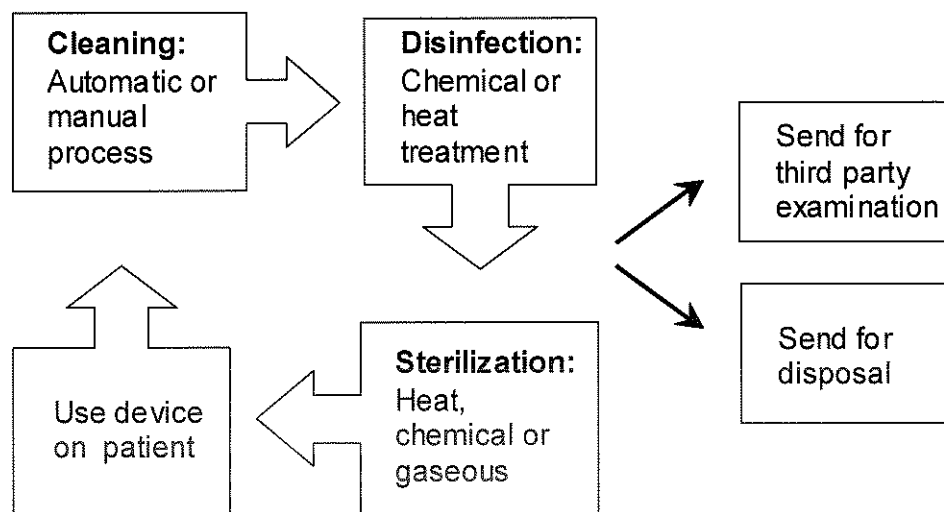
'Advances in decontamination of prion protein contaminated equipment is proceeding at a rapid pace. This work is to be encouraged. It is important that until the efficacy of those products and technologies is established fully against human prions, that clinicians ensure that the current ACDP-TSE guidelines remain extant.' - Comment from the Engineering and Science Advisory Committee on the decontamination of surgical instruments including prion removal.

9.2 When to decontaminate

Items subject to inspection, maintenance, repair or disposal, either on site or at the manufacturer's or agent's premises, should be decontaminated beforehand.

Any loaned items being returned to a manufacturer or supplier should also be decontaminated (Figure 2).

Figure 2 Decontamination process chart for reusable device or for third party examination



Once decontamination has been completed the items should be labelled accordingly, and a declaration of contamination status form completed (see Figure 4). This should be readily accessible to the recipient of the equipment.

Devices intended for single-use only do not require decontamination, except where they are implicated in an adverse incident and may need to be sent to the MHRA or the manufacturer for investigation.

In this situation, contact the manufacturer to find out the most appropriate method of decontamination.

9.2.1 Who is responsible for decontamination?

In each responsible organisation a senior member of staff should manage all aspects of decontamination. The importance of correct decontamination needs to be clearly understood at all levels throughout the organisation to avoid cross contamination.

There should be clear lines of responsibility for decontamination matters across the organisation leading to the board.

Senior managers and the board should monitor and regularly review decontamination procedures.

9.2.2 How should decontamination be carried out?

All decontamination processes should be operated and carried out in accordance with the equipment manufacturer's instructions and the process be able to decontaminate all contaminated areas of the device.

Assurances shall be obtained from the medical device manufacturer that the decontamination process chosen is appropriate and not harmful to the device.

Use only chemicals compatible with the device and at the correct concentration as recommended by the various manufacturers involved.

Decontamination equipment should be properly:

- commissioned
- validated and revalidated
- subject to planned maintenance by properly trained and competent staff.

Only appropriately trained staff, provided with suitable equipment/clothing should carry out decontamination.

Staff involved in decontamination should be aware of legal requirements and best practice and be up to date in these areas.

Training in appropriate aspects of decontamination practice should be provided to relevant healthcare staff, including those working in a clinical environment.

Figure 3 Decontamination flow chart for devices being sent for investigation/repair or service

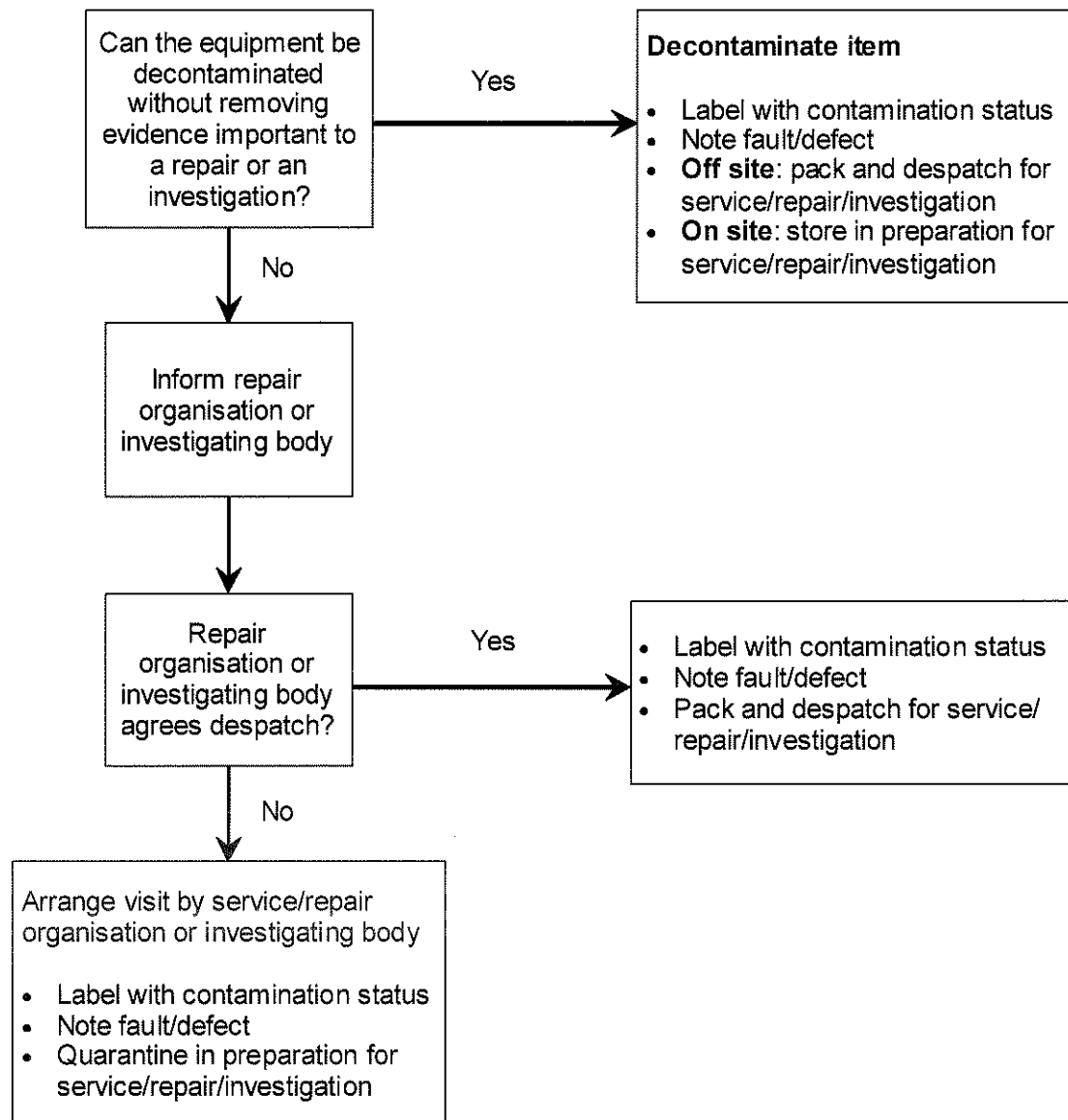


Figure 4 Sample form – declaration of contamination status

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?

.....

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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

Key points on decontamination

- A local policy sets out the management and transport of medical devices from the point of use to the decontamination facility.
- The method of decontamination selected takes account of the degree of infection risk associated with the use of the equipment.
- All items subject to inspection, service, repair, or disposal should be decontaminated beforehand.
- A senior member of staff is managing all aspects of decontamination.
- Decontamination has been carried out in accordance with the manufacturer's instructions.
- All relevant staff have been fully trained in decontamination protocols.
- It is illegal to send contaminated items through the post.