

Decontamination of Reusable Medical Equipment

**Policy and supporting guidelines, including
equipment subject to inspection,
service or repair**

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1.0 Introduction

Stoke-on-Trent Primary Care Trust is committed to ensure there is a system in place that, as far as reasonably practicable, makes sure that all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are adequately managed.

Patients and staff (including those not employed by Stoke-on-Trent Primary Care Trust) must be protected from the transmission of infection from medical devices (mechanical and laboratory equipment together with consumables and material used in the treatment, diagnosis and care of patients - MHRA (2003) guidance includes risks from biological, chemical and radioactive hazards) and other equipment, which comes into contact with patients or their body fluids. Medical devices intended for single use only must not be reprocessed for reuse.

Anyone who inspects, services, repairs or transports medical, dental or laboratory equipment, either on Stoke-on-Trent Primary Care Trust premises or elsewhere, has a right to expect that medical devices and other equipment have been appropriately treated in order to remove or minimise the risk of infection or other hazards.

The Medical Devices Agency defines a medical device as any device, instrument, apparatus, implement, material, substance or other article (used singularly or in combination) together with any accessory thereto which is intended by the manufacturer for: -

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiological process; and
- Control of conception.

Note: This policy should be read in conjunction with the PCT's Waste Policy and Management of Medical Devices and Equipment Policy

2.0 Aims of the Policy

The aim of this policy is to:

- Set a framework for the decontamination of reusable medical devices, including equipment which is subject to inspection, service or repair;

- Ensure that single use items are never reutilized under any circumstances;
- Necessary information, instruction/ supervision, training and guidance is provided to staff to ensure that those involved in the decontamination processes are enabled to fulfill their personal duties and responsibilities.

3.0 Scope of the Policy

The scope of this policy is restricted to the decontamination of equipment by staff employed by Stoke-on-Trent Primary Care Trust and its premises.

The main aspects covered include procedures, additional guidance, maintenance and replacement, suitability of locations and ensure adequately trained staff perform the decontamination processes.

In this policy, the term 'reusable medical device' applies to all such devices whether owned by the organisation, rented, on loan or acquired by any other means.

4.0 Limitations of Application of the Policy

The policy will apply to independent contractors* but it should be noted that the PCT is not, at this point in time, in a position to enforce the policy on non-contracted individuals. However, the policy will be promulgated as good practice throughout individual practices and where there is cause for concern the PCT may consider withdrawing services that place staff at risk.

**Note: Independent Contractors includes General Practitioner, Dentists, Pharmacists and Optometrists.*

5.0 Decontamination

Decontamination is the combination of processes, including cleaning, disinfection and or sterilization, used to render reusable medical devices safe for further episodes of use. As a general rule the PCT will seek to replace reusable devices with single use items where the cost and benefit analysis can be demonstrated.

The Medical Devices Committee will consider decontamination issues prior to the acquisition of key reusable medical devices and decontamination equipment. Wherever possible the decontamination will take place in an accredited unit.

Advice on decontamination of equipment will be sought from appropriate personnel, including the medical devices committee, infection control team and decontamination lead.

The Microbiology Advisory Committee (MAC) manual provides generic advice on the decontamination information that users should expect to receive from manufacturers.

6.0 Procedure for Decontamination of Reusable Medical Equipment

Reusable medical devices will be handled, collected, separately bagged and transported in an appropriate manner for the equipment being decontaminated. Reusable medical devices will be separated from clinical waste at the point of use and will be transported as soon as possible to the decontamination area. **Medical devices intended for single use only will not be reprocessed for further use.** Contaminated medical devices and equipment will be separated from clean medical devices and equipment during transportation.

In order to decontaminate medical devices effectively, all organic debris (e.g. blood, tissue and other body fluids) will be removed from the item prior to disinfection or sterilization. Devices should be cleaned in accordance with manufacturers instructions and local decontamination protocols.

Where appropriate procedures should exist as a point of reference and should be available for all personnel involved in the decontamination process.

Systems will be developed to ensure surgical sets of instruments can be tracked through the decontamination processes, in order to ensure that all aspects of the process have been carried out effectively.

Systems will also be developed over a period of time, to enable the identification of patients on whom instrument sets have been used within primary care. This will enable patients to be identified in the event of exposure to potential risk.

7.0 Procedure for Decontamination of Equipment Subject to Inspection, Service or Repair

All equipment and items, which have a risk of contamination * prior to being released for examination, inspection, service or repair shall carry a 'Declaration of Contamination Status Certificate' (the format of which is identified on page 12).

** e.g. blood, body fluids, respired gases, pathological samples, chemical/hazardous substances and any other hazards.*

All equipment and items that have been contaminated will require decontamination before being released for examination by estates engineering staff, manufacturers or other appropriate staff. All patient equipment **must** be decontaminated after **each and every** patient contact (EPIC Guidelines) and also before maintenance or repair.

The manufacturer's instructions should always be followed as some equipment is highly specialized.

Manual cleaning should be carried out in accordance with NHS Estates local decontamination protocols. These can be accessed at the following website: www.decontamination.nhsestates.gov.uk

Unless the item to be sterilized is a large piece of equipment or known to be damaged by the application of heat or moisture, then moist heat sterilization using steam under pressure should always be used in preference to other methods. This method is more reliable and can be monitored more effectively.

In addition departments must ensure that the following action is taken:

- (i) A record is maintained detailing the date and method of decontamination for a given piece of equipment prior to examination, inspection or repair;
- (ii) Ensure that "The Declaration of Contamination Status Certificate" has been completed and is attached to the item; and
- (iii) Where the equipment is to be sent direct to the manufacturer 'The Declaration of Contamination Status Certificate' should be placed in an envelope attached to the packing and marked clearly: 'EXAMINE ENCLOSED DOCUMENTS BEFORE UNPACKING'.

Note:

It is illegal to send contaminated equipment via the postal system.

Suppliers have a responsibility to provide information on the compatibility of their particular medical device or equipment with methods and agents for decontamination.

8.0 Written Procedures

Individual departments/services will prepare written procedures and standards on the decontamination of equipment used in that particular service. This procedure should contain the following details:

- (i) An identified member of staff who will be responsible for overseeing decontamination procedures;

- (ii) The types of equipment used and details of the cleaning required; and
- (iii) The types of equipment used and details of the decontamination process required.

9.0 Additional Guidance

The incorrect handling, collection, and transportation of medical devices may negate any decontamination process they are subjected to, and also present a risk to patients and staff. Additional guidance for the decontamination process is outlined below:

- Personnel should be trained to handle, collect and transport contaminated medical devices/ equipment and should wear protective clothing in accordance with local safety policies and procedures;
- Staff aware of the potential infection hazards should separate reusable devices from clinical waste at the point of use;
- Sharps should not be removed; the needle and syringe should be discarded as a single unit and placed into approved containers conforming to BS 7320 and UN 3291 at the point of use. If needles are of the lock type they should be removed using needle removing devices;
- Re-usable textiles should be placed in soiled linen bags and returned to the laundry service in accordance with the requirements set out in HSG(95)18;
- Contaminated liquids should be solidified and placed into leak proof containers for disposal unless facilities exist for the user to empty them into a clinical sluice;
- Contaminated medical devices should be confined and contained in closed leak-proof plastic bags or containers to avoid spills or contact with staff and environmental surfaces. They should be transported as soon as possible after use to the decontamination area; the contents of the containers should be labelled to facilitate processing;
- Used equipment should be safely contained and transported to the decontamination area, and records kept of vehicles and containers used;
- Contaminated medical devices and equipment must be kept separate from clean medical devices/equipment during transportation. This is achieved by using separate containers to provide physical barriers between clean and dirty items; and
- Contaminated medical devices / equipment shall only enter the department through the decontamination area.
- Within the Waste Disposal Policy.

Note: decontamination of large items beds, hoists, commodes etc take place on the wards.

10.0 Contaminated Equipment Subject to Complaint or Investigation

In certain situations, for example when the condition of an item that is the subject of complaint or investigation and it may be altered or influenced by a decontamination process, the investigator may wish the item not to be decontaminated. In such situations, the advice of the investigating body should be sought and, if the item is to be dispatched from Stoke-on-Trent Primary Care Trust premises:

- (i) prior warning should be given to the intended recipient;
- (ii) the condition of the item should be clearly labeled so that it can be determined prior to the opening of the inner packaging;
- (iii) the packaging should be sufficiently robust to withstand transport;
- (iv) consideration of taking digital photographs should be undertaken; and
- (v) the packaging should ensure that the content of the inner pack cannot contaminate the outer one.

Note: It is illegal to send contaminated equipment via the postal system

In addition, agreement of any carrier used to transport a contaminated item may be required. The above also applies to items that are not subject to investigation but cannot be decontaminated before inspection, service or repair (see flowcharts 1 and 2).

11.0 Planned Maintenance

Planned maintenance is very important but it is not an actual part of the decontamination process. Equipment (washer-disinfectors, sterilizers etc.) to be used in validated processes requires planned preventative maintenance and periodic calibration and testing to ensure it remains in the same condition as when validated. Validated processes require monitoring of critical variables of each cycle and this should be independent of any monitoring used to control the decontamination equipment. Processes that require validation should only be carried out using automated equipment to ensure reproducibility.

Failure to maintain the equipment and its systems gives rise to the potential for inadequate decontamination.

HTM 2010, HTM 2030, MDA 9605, MDA DB 9804 and MDA 2000 (05) define the minimum standards required to ensure safe operation of the decontamination process.

12.0 Replacement of Equipment

Decontamination processes are less effective on instruments that are difficult to clean or are in poor condition.

All decontamination equipment that does not meet the requirements of current standards and test methods will be upgraded or replaced as soon as practicable in accordance with a planned replacement programme.

All medical devices that cannot be easily cleaned and/or those in poor condition, will be identified and subject to a planned replacement programme with equipment that is easier to clean, or replaced by a single use alternative.

13.0 Decontamination Locations

All locations in which the decontamination of re-usable medical devices is carried out will be properly designed, maintained and controlled.

Any location in which the decontamination process takes place will:

- Be physically separated from all other work areas, including patient treatment areas (except larger items e.g. beds etc);
- Be accessible from a service corridor;
- Be mechanically ventilated (HTM 2025/ 2040);
- Have walls and other surfaces finished with flush junctions, be smooth, water resistant and able to withstand frequent cleaning;
- Have floors sealed with a washable non-slip finish;
- Have adequate lighting available to permit good working practices; and
- Have hand washing and personal protective equipment facilities located in or near to the decontamination area.

14.0 Risk Management

The risk management process contained within the Risk Management standard will be applied to all aspects of decontamination of re-usable medical devices.

The following risk management elements of the Risk Management Standard will be put in place:

- All identified risks should be documented as part of a local or corporate risk register (depending on the level of risk) and systematically assessed and prioritised;
- Risk treatment plans should be developed and implemented in order of priority and alongside other risk treatments, which are necessary to deal with the wider risks, faced by the organisation;

- Risks and the effectiveness of implemented risk treatments will be monitored and reviewed frequently; and
- Senior management and the Board will be informed of any significant risks and associated risk treatment plans.

15.0 Qualified Personnel

Appropriately qualified key personnel will be in place in accordance with legislative and best practice guidance for the decontamination of equipment.

Key persons and responsibilities (defined in detail in HTM 2010 and/or HTM 2030) are as follows:

- The Chief Executive is ultimately accountable for the operation of the premises and the decontamination process;
- The Operator is defined as the person designated by management to be responsible for particular elements of the decontamination process. In primary care he /she could be a GP, practice manager, dentist or other health professional;
- The Competent Person (pressure vessels) is defined as a person or organisation designated by management to exercise certain legal responsibilities;
- The Authorised Person (sterilizers), {AP (S)}, provides independent auditing, and advice on decontamination, together with reviews and witness/validation of processes;
- The Test Person (sterilizers), {TP (S)}, is designated by management to carry out validation and periodic testing of sterilizers;
- The Maintenance Person (sterilizers,) {MP (S)}, is designated by management to carry out maintenance and periodic testing on sterilizers;
- The Microbiologist (sterilizers) is designated by management to be responsible for advising the User on microbiological aspects of decontamination; and
- The Infection Control Doctor is defined as the person designated by management to be responsible for advising the User on all aspects of infection control.

Note: It should be noted that some of this expertise may be provided via the University Hospitals of North Staffordshire and Combined Healthcare NHS Trust, via an Agency function and underpinned by a Service Level Agreement.

16.0 Education & Training

Education and training in appropriate aspects of decontamination practice will be provided to relevant healthcare staff, including those working in a non-clinical environment.

Personnel at all levels will have a general knowledge of the principles and practice of decontamination processes. Staff involved in the operation of decontamination equipment will be trained in those types and models with which they are concerned. Examples of appropriate training are:

- Departmental policies, procedures and standards;
- Infection control;
- Quality issues in the department;
- Accident / incident reporting;
- Health and Safety issues including chemical and environmental hazards;
- Moving, lifting and handling techniques;
- Safe operation of equipment;
- Personal hygiene and dress codes;
- Communications within the organisation;
- Fire hazards and regulations;
- Awareness of legislation and best practice guidance;
- The correct and safe method of cleaning medical devices;
- The use of bench top sterilizers; and
- Graphical symbols described in EN 980.

17.0 Access to Legislation

All staff involved in decontamination processes will have access to up-to-date legislation and guidance. Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the Department of Health.

As a minimum, staff will have access to the key references listed on the front of the Controls Assurance standard.

There are many sources of information on European and national legislation and decontamination guidance this includes, but is not limited to:

- NHS Estates website contains such information and guidance at <http://www.decontamination.nhsestates.gov.uk>
- Dept. of Health guidance can also be accessed on the Internet on the Department of Health COIN database (<http://www.doh.gov.uk>).
- Advice and guidance documents are listed on the Medicines Healthcare Regulatory Agency web address <http://www.mhra.gov.uk>
- The Health and Safety Executive's website (<http://www.hse.gov.uk>) contains up-to-date information on legislation and guidance.

- Full text copies of all legislation issued from 1st January 1997 can be downloaded from (<http://www.official-documents.co.uk>) which contains information on UK official documents.
- Wherever possible, the Controls Assurance Support Unit website (<http://www.casu.org.uk>) and CD-ROM contains electronic copies of relevant legislation and guidance.

18.0 Improvement Indicators

The Medical Devices Committee will develop improvement indicators, which demonstrate increased performance in decontamination processes over a given period of time. These will be tabled to the Board for agreement in due course.

19.0 Review by the Board

The management team and Board of Directors will review the system in place for the decontamination processes, including risk management arrangements in order to make improvements to the system. This review will include:

- Review of this Policy and supporting guidance;
- Accountability arrangements;
- Processes, including risk management arrangements;
- Capability;
- Outcomes; and
- Internal Audit findings.

Additionally the Board will, from time to time seek, independent assurance that an appropriate and effective system of managing medical devices is in place.

DECLARATION OF CONTAMINATION CERTIFICATE

Prior to the Inspection, Servicing, Repair or Return of Medical and Laboratory Equipment

To:	Make and Description of Equipment:
NSPCT Ref/ Order No.	Model/Serial/Batch No:
	Recipients service or return authorisation reference or contact name:

Tick box A if applicable, otherwise complete all parts of box B, providing further information as requested or appropriate.

A.

This equipment/item has not been used in any invasive procedure or been in contact with blood, other body fluids, respired gases, or pathological samples. It has been cleaned in preparation for inspection, servicing, repair or transportation.

B.

1. Has this equipment/ item been exposed internally or externally to hazardous materials as indicated below?

Delete as Appropriate	Contamination Agent	Provide further details here
YES/NO	Blood, body fluids, respired gases, pathological samples	
YES/NO	Other biohazards	
YES/NO	Chemicals or hazardous substances	
YES/NO	Other hazards	

1. Has the equipment/ item been suitably prepared to ensure safe handling transportation?

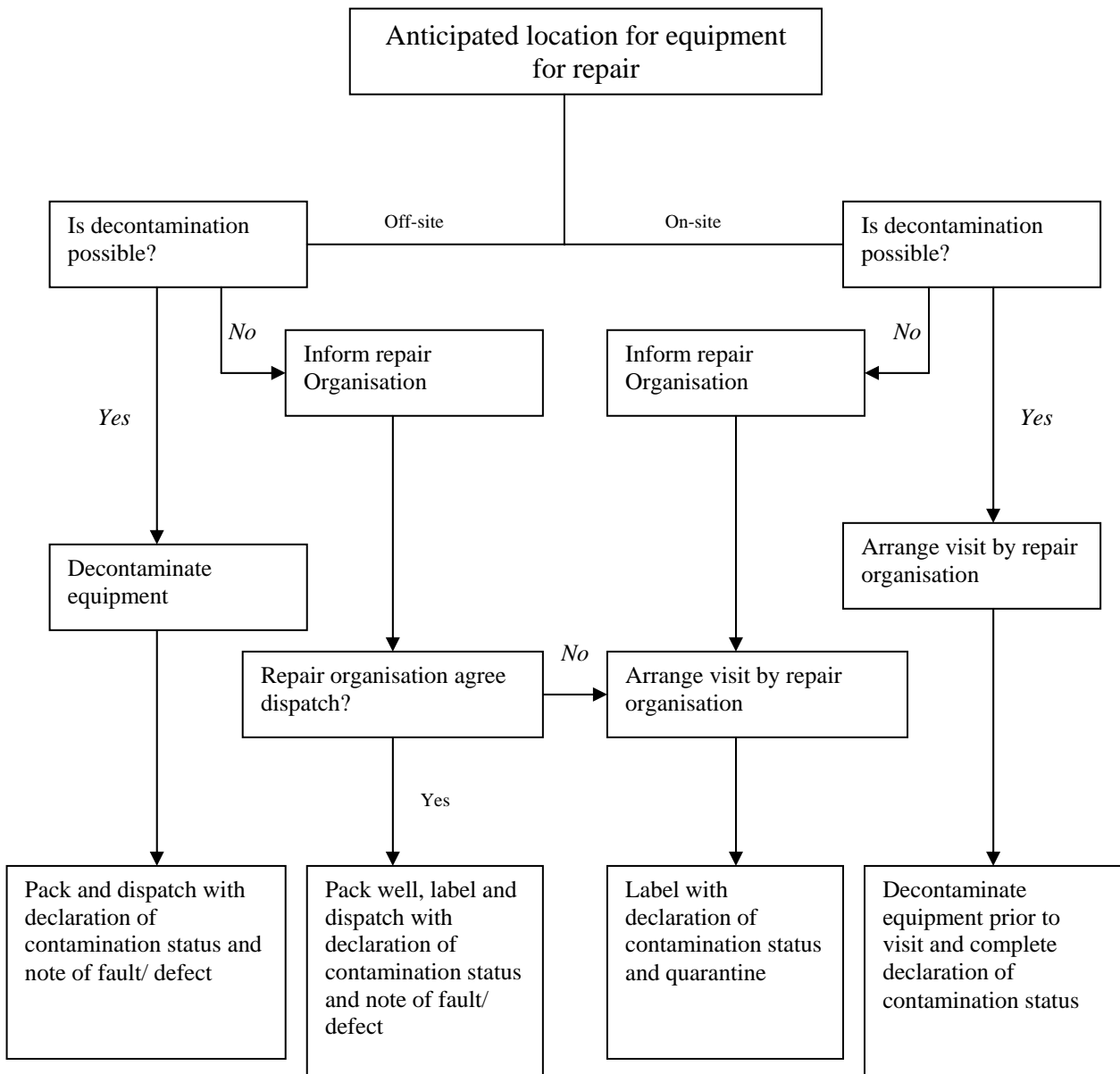
Delete as Appropriate	Method/Materials Used	Provide further details here
YES/NO		

I declare that I have taken all reasonable steps to ensure the accuracy of the above information, in accordance with NSPCT's 'Decontamination of Equipment Prior to Inspection, Service or Repair Policy'.

Authorised Signature..... Site/Location.....
 Name (printed)..... Department.....
 Position..... Telephone No.....
 Date.....

Flowchart 1

Decontamination of Equipment for Repair, Service or Inspection



Flowchart 2

Decontamination of Equipment that is the Subject of Complaint or Investigation

