Trust General Policy

DECONTAMINATION OF RE-USABLE MEDICAL DEVICES
### Executive Summary:
To make sure that there are systems in place to ensure that, as far as reasonably practicable, all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are adequately managed.

### Supersedes:
Decontamination Policy (version number 1).

### Description of Amendment(s):
Version 1 has been updated to accommodate the recent changes in guidance issued by the department of health (DoH) for reusable medical devices requiring effective decontamination.

### This policy will impact on:
This policy will be applicable to all divisions, directorates and departments within the Trust, associated with the process of decontamination.

### Financial Implications:
No financial implication identified with the amendment of this Policy

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<td>Head of Estates Operations</td>
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### APPROVAL RECORD

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# DECONTAMINATION OF RE-USABLE MEDICAL DEVICES POLICY

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EXECUTIVE SUMMARY

Purpose of this Policy

To make sure that there are systems in place to ensure that, as far as reasonably practicable, all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are adequately managed.

Current Decontamination guidance is identified in the following documents:

Department of Health, Choice Framework for local Policies and Procedures (CFPP) series:
- CFPP01-01 Parts A to E: Is the current document relating to the Management & decontamination of reusable surgical instruments used in acute care.
- CFPP01-06: Decontamination of flexible endoscopes
- CFPP01-04: Decontamination of linen for health and social care
- NHS Estates HTM03: Ventilation Decontamination in primary care dental facilities manual

Archived documents that still provide current best practice advice:
- NHS Estates HTM2010: Sterilization. (In relation to laboratory sterilizers)
- NHS Estates HTM2030: Washer Disinfectors. (In relation to bedpan washers)

Associated Policies (Available on the intranet)
- Infection Prevention and Control Policy
- Medical Devices Policy
- Risk assessment Policy and Procedures
- Health and Safety Policy and Related Policy and Procedures
- Nursing and Clinical Procedures Policy
- Risk Management Policy
- Incident Reporting Policy

And applies to all departments who are involved in the process of decontamination and the reprocessing of medical devices within East Cheshire NHS Trust and East Cheshire PCT

Target Audience

Staff responsible for and / or involved with any decontamination process.

Implementation

- **Chief Executive, Heads of Department, Service Managers and Ward Managers** – to appoint the appropriate personnel identified in Roles and Responsibilities.

- **Corporate SQS (Service Quality and Standards) Committee** – include quality and performance measures for the decontamination process as one of the impacts on the quality of clinical service provision.

- **Medical Devices Group**- to consider the full implications of decontamination with
respect to the procurement of medical devices and non-medical equipment.

- **Decontamination Lead** – Monitor the Decontamination Risk Register and report to the Risk Management Group for review. This is then forwarded to the Trust Board.

- **Infection Prevention and Control** – To provide the trust with basic infection prevention related decontamination information and advice.

- **Decontamination Group** – to provide the trust with technical and operational advice and monitoring information.
INTRODUCTION

Hospital acquired infections are expensive for the NHS and may have far reaching consequences for the patient. Whilst some infections cannot be prevented, there are steps that can be taken to reduce the possibility of infection spreading from one patient to another.

One important factor is the effective decontamination of surgical instruments and other medical devices and equipment. This decontamination should ideally take place in centralised departments (such as sterile services and endoscopy) but can be established in a local clinical setting with controlled regulation and appropriate segregation from patient treatment areas.

The level of decontamination required varies according purpose / use of the equipment, the procedure being carried out and the environment in which it is performed. For instance, some equipment needs simply to be washed and disinfected, whilst invasive equipment needs to be washed, sterilised and then protected from further contamination.
GENERAL

Decontamination is the combination of processes (including cleaning, disinfection and sterilization) used to render a reusable medical device safe for further use on patients and handling by staff. The effective decontamination of reusable medical devices is essential in minimising the risk of transmission of infectious agents.

The effectiveness of decontamination is determined by all elements of the decontamination life-cycle which includes purchase of equipment, transport and storage and eventual disposal. All aspects of the life-cycle need to be considered if decontamination is to be fully effective.

It is essential at each stage of the decontamination process to take into consideration the following issues:

- Environment
- Equipment
- Facilities
- Management
- Policies and procedures

Monitoring is required at each stage of the decontamination life cycle process. Refer to the decontamination lifecycle flow diagram shown below.
Cleaning of surgical instruments and endoscopes is an essential pre-requisite to ensure effective decontamination/disinfection.

Product liability and the Consumer Protection Act has implications when reprocessing medical devices used for patient care.

Advice from the Department of Health recommends that decontamination and specifically reprocessing of surgical instruments is undertaken in an accredited central Decontamination Dept, and that reprocessing should not to be undertaken in a local clinical environment.
AIMS

A safe, properly managed and effective decontamination & sterilization process is adopted for all re-usable medical devices/equipment after and between each patient use. This is an essential element of routine infection control practice.

Decontamination of medical devices/surgical instruments are services provided to the organization by the Hospital Sterile & Disinfecting Unit (HSDU) & Endoscopy Treatment Unit (ETU). HSDU provide a service that is accredited to Medical Devices Directive 93/42/EEC (MDD93/42/EEC), BS EN ISO 13485: Quality Management Systems - Medical Devices and BS EN ISO 9001: Quality Management Systems.

Delivery of an effective decontamination service for medical devices requires the five elements documented below:

This policy should be read in conjunction with Trust policies that link with the Decontamination Policy e.g. Infection Control Assurance Framework and Operational Policy, Medical Equipment Policy, Decontamination of Clinical Equipment and Loan of Medical Equipment. Approved documents can be found on the Trust's Document Library. The Policy should also be read in conjunction with HSDU and ETU Quality Management Systems (QMS) and Policies.
ROLES AND RESPONSIBILITIES

Executive Manager – Is the Chief Executive and the person with the ultimate management responsibility for the operation of the premises and the decontamination processes.

Designated Person - is the Associate Director of Facilities and is responsible for the management link between the Trust and professional support. Board access is via the Director of Finance. Therefore the Director of Finance is the board level manager whose responsibility it is to inform and update the Board on decontamination issues.

Decontamination Lead – Is the Head of Estate Operations and is responsible for the effective monitoring of decontamination policies and procedures and ensuring a compliant provision of decontamination services for the Acute Hospitals. In this instance the Decontamination Lead reports via the Designated Person to the Director of Finance.

The Decontamination Lead may delegate specific responsibilities to key personnel. Monitoring the implementation of the policy at an operational, departmental level is designated to the department representatives who are nominated members of the Decontamination Group.

Dental Decontamination Lead – Is the Decontamination Lead and is responsible for the effective monitoring of decontamination policies and procedures and ensuring a compliant provision of dental decontamination services in the Community Business Unit.

Senior Operational Manager - The Estates Engineering Manager is the Senior Operational Manager and is technically, professionally, and managerially responsible for the engineering aspects of decontamination.

User – The user is defined as the person designated by management to be responsible for the management of the decontamination processes. The User is also responsible for the Operators. In a hospital the user could be the HSDU (Hospital Sterilization and Disinfection Unit) manager, theatre manager, endoscopy clinic manager, ward manager or laboratory manager, dentist or other health professional. The responsibilities of the user are to:

1. Certify that the decontamination equipment is fit for use.
2. To hold all documentation relating to the decontamination equipment.
3. To ensure the decontamination equipment is subject to periodic testing and maintenance.
4. To appoint operators where required and ensure that they are adequately trained.
5. To maintain production records to establish procedures for product release in line with the QMS (Quality Management System).
6. To ensure that procedures for production quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice.

Competent Person (pressure vessels) - The competent person (pressure vessels) is defined as a person or organisation designated by the management to exercise certain
legal responsibilities with regard to the written scheme of examination of any pressure vessel associated with a steriliser described in the Pressure Systems Safety Regulation 2000.

Authorising Engineer (AE (D)) - is defined in CFPP 01-01, designated by management and provides independent auditing and advice on decontamination, together with reviews and witness/validation of processes. The AE(D) is fully independent of the organisations’ structure for maintenance, testing and management of the decontamination equipment.

The Authorised Person (AP (D)) – is defined as an individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the Designated Person (in connection with the advice provided by the AE (D) Who is responsible for practical implication and operation of Management Safety Policy and Procedure, relating to the engineering aspects of Decontamination Equipment. This role is also performed by the Estates Engineering Manager.

Competent Person (CP (D)) - is designated to carry out validation and periodic testing of decontamination equipment.

Microbiologist (Decontamination) - is defined to be the person responsible for advising the user on microbiological aspects of decontamination.

Director of Infection, Prevention & Control (DIPC) - is filled by the Director of Infection Prevention & Control.

Head of Infection Prevention and Control - is defined as the person designated by management to be responsible for advising the user on all aspects of infection control.

Operator - The Operator is the HSDU, ETU, Pathology, Ward Staff and Dental Nursing staff who carry out decontamination duties.

Surgical Instrument Manager / coordinator - The manager of surgical instruments (medical devices) is designated as the person assuming responsibility for coordinating activity between the theatre, decontamination and supply / purchase teams. This role is performed by HSDU.
INTRODUCTION TO DECONTAMINATION

Decontamination Terminology

Three common definitions used for levels/components of decontamination are explained in the table below:

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<th>METHOD</th>
<th>DECONTAMINATION – DEFINITION</th>
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<tr>
<td>Cleaning</td>
<td>Physical removal of contamination (blood, faeces etc) and many more microorganisms with detergent and water</td>
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<tr>
<td>Disinfection</td>
<td>Reduces the number of micro-organisms to a level that they can cause no harm. Disinfection does not destroy spores</td>
</tr>
<tr>
<td>Sterilization</td>
<td>A process that destroys all micro-organisms including spores</td>
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The decision on what method to use to clean, disinfect and sterilize is dependent on the decontamination recommendations specified in the medical device manufacturers instructions. The method used must be the most effective method available that is compatible with the device and ideally should be a validated terminal sterilization method.

Disinfectants can effectively reduce the number of infecting organisms, but should not be used with the aim of achieving sterility. The presence of organic soiling on equipment or devices will reduce the effectiveness of disinfectants.

Before purchase of devices/equipment liaison with stakeholders must take place with regard to the decontamination of the device e.g. Decontamination Facility, Infection Control, Bio Medical Engineering, user of the device/equipment as appropriate for the device. It must be established prior to purchase what methods of decontamination/sterilization are to be used and if any specific additional equipment is required to support the process ie transport containers, ‘scope cages etc.

Staff associated with decontamination and handling of devices/equipment will be trained and competency assessed recorded and reviewed. Records of training must be maintained by the appropriate departments management system.

All Trust employees receive annual mandatory Infection Prevention and Control induction training.

Classification of Decontamination Risk

The table documented below provides criteria to categorise risk and the level of decontamination required for the reprocessing/use of the medical device/equipment:
| High risk | Items in close contact with a break in skin or mucous membrane or introduced into a normally sterile body area | Surgical instruments, Invasive endoscopes | Sterilization | Cleaning and sterilization conducted in central SSD using appropriate automated sterilization process (usually an autoclave).

For difficult to clean medical devices/equipment a disposable single use option should be used where possible e.g. narrow lumen devices. (Refer to the Trust’s Single Use Policy) |
| Intermediate risk | Items in contact with mucous membranes or other items contaminated with particularly virulent or readily transmissible organisms; or items to be used on highly susceptible people | Gastroscopes, and non-invasive medical equipment such as respiratory equipment | Disinfection required, by heat where possible | Cleaning, disinfection or sterilization conducted in the HSDU. Decontamination of flexible endoscopes conducted in the ETU (or in the case of nasoendoscopes in the relevant OP clinic) using an automated process for lumend endoscopes. Use of an appropriate disinfection wipe system for non-lumend, non-invasive endoscopes where an automated process is not available. |
| Low Risk | Items in contact with normal and intact skin | Incubators, beds drip stands | Cleaning and drying usually adequate | Manual clean with detergent and warm water. Dry thoroughly. Use of appropriate wipe system. |

Further advice on the applicability of decontamination methods is provided in the MAC manual Part 1 Principles 3rd edition May 2010, published by the MHRA.

**Health & Safety**

It is essential that all decontamination practices should be carried out with regard to the health and safety of patients, staff, and visitors. This includes assessing practices against guidance and regulations, and monitoring these to ensure that proper procedures are being followed. In addition, it involves assessing equipment, and ensuring that proper maintenance procedures are followed to check that equipment is properly installed and maintained, and that it is functioning safely.
It is important to note many substances used in decontamination such as chemical disinfectants and some detergents will be subjected to the Trust COSSH assessment process to see if control measures above are required.

In most cases PPE is required for handling such chemicals. In addition it should be noted that PPE must also be worn when handling blood and bodily fluids as per the Infection Prevention and Control Good Practices policy and when undertaking manual decontamination processes.
APPROVAL COMMITTEES

There is a Trust Decontamination Group with a Terms of Reference agreed by the group membership. Minutes of the meetings can be made available on the Trust intranet. Policies and procedures which are reviewed and updated by the Decontamination Group are put on the agenda of the Trust Infection Prevention & Control Group for final approval.

Trust Infection Prevention and Control Group meetings are held quarterly.

Risk Management (RAG) is a permanent agenda item for the Trust Decontamination Group. Decontamination risks are assessed and monitored through the Decontamination Group.

There is a Medical Devices Group. Capital investment for purchase of medical devices, are discussed at Medical Devices Group. Advice on aspects associated with decontamination suitability, are communicated to members of the Medical Devices Group before purchase.
PROCESS FOR MONITORING EFFECTIVENESS OF THE DECONTAMINATION POLICY

Annual Audit Program

HSDU is subjected to an independent surveillance audit every six months by an appointed Medical Device “Notified Body” to ensure that its activities and management systems are complaint with the requirements of MD 93/42/EEC, BS EN ISO 13485 and BS EN ISO 9001 and the terms of its accreditation are adhered to. Every three years, the Notified Body performs a certification renewal audit.

Risk Register

The risk register is a matrix of risks that affect the ward/department or the whole Trust. The Risk Register is a living document, which shows the status of risk affecting the Trust. The risk register is essential to the direction the Trust takes in assigning resources to control or eliminate risks of a financial, organization or clinical nature or even deciding when a risk is acceptable.
EDUCATION & TRAINING

Training is undertaken for all Decontamination Services personnel associated with decontamination of medical devices/equipment. Through staff Individual Performance Review (IPR) areas of skill knowledge are recognized. Support is provided to retain a competent multi-skilled workforce. Personnel working in the Trust who may be associated with elements of the decontamination process receive awareness training for handling of medical devices/equipment.

All Trust employees receive mandatory Infection Prevention and Control induction training. Update training is repeated on an annual basis. Staff involved in the decontamination process should receive formal, ongoing training to current recommendations.

Staff in clinical units carrying out local decontamination should be trained in the appropriate use of the equipment available within their department. All staff should be properly supervised and their performance monitored. Training should include:

- Departmental policies, procedures and standards.
- Infection control.
- Quality issues in the department
- Health and Safety issues including:
  - Chemical and environmental hazards.
  - Health and Safety at Work etc Act.
  - COSHH regulations.
  - Accident/incident reporting.
- Lifting and handling techniques.
- Safe operation of equipment.
- Personal hygiene and dress codes.
- Fire hazards and regulations.
- Awareness of HTM’s and their implementation
- Medical Devices Decontamination Processes and Procedures
- Equipment Training where required

The following issues are addressed in the training of other clinical staff:

- The Trust’s decontamination policy.
- Graphical symbols described in EN 980 (current version)

Attendance records must be kept of all staff who receive training.
FLEXIBLE ENDOSCOPES

Decontamination of a flexible endoscope with or without lumen channels must be conducted immediately after patient use in accordance with the scope manufacturer’s decontamination and reprocessing instructions and the British Society of Gastroenterologists (BSG) Guidelines (if appropriate).

Lumend Flexible Endoscopes

Decontamination should begin as soon as the endoscope has been removed from the patient. Before the endoscope is detached from the light source/videoprocessor a preliminary cleaning routine should be undertaken. Manual cleaning and rinsing of all exposed internal and external surfaces should then be undertaken within the reprocessing area. This will involve an operative dismantling the contaminated endoscope and cleaning with care with single use cleaning brushes. ALL lumen channels in a flexible endoscope must be cleaned. On completion of the manual clean and leak test the flexible endoscope will be placed in an Automatic Endoscope Reprocessor (AER) then exposed to the disinfection cycle for which a validated record is available.

When the scope has been disinfected the scope will be placed in a clean scope tray covered with a clean protective cover then placed in the endoscope transport trolley and taken to the procedure room ready for use or placed in a HEPA filtered storage cabinet where the scope can be stored for seventy two hours when the scope storage time expires and is reprocessed again.

Where practicable single use endoscopic accessories are used

ETU is responsible for decontamination of flexible endoscopes for Bronchoscopy, Thoracotomy, Gastro, Interventional Radiology (ERCP) and Outpatient services.

Non-Lumend Flexible Endoscopes

Nasendoscopes are used for the examination of nasopharynx, larynx and hypopharynx. They are short flexible endoscopes, usually without lumens. Nasoendoscopes used in Ear Nose and Throat procedures are often decontaminated near the point of use using a manual method such as disinfectant wipes when insufficient scopes or excessive travel distance makes the use of a central endoscope disinfection unit impractical.

All manual methods should include efficient cleaning of the used nasendoscope followed by controlled wiping with, or immersion in, an effective, compatible disinfectant. If selective immersion is used, non-immersible components also need to be disinfected, for example by wiping. Cleaning and disinfection are required even if single use sheaths are used.

Transoesophageal Chocardiography, Transvaginal and Trans-rectal Ultrasound Probes

Transoesophageal echocardiography (TOE) allows real-time visualisation of the heart via the stomach and oesophagus using ultrasonic emission from the distal end of a flexible probe. These probes do not have lumens. Only the patient insertion tube can be immersed in liquid.

Trans-rectal ultrasound (TRUS) probes and transvaginal ultrasound (TVUS) probes are
used to examine the prostate gland and female reproductive organs, respectively. These do not generally have lumens but some TRUS probes have an internal lumen that allows passage of a biopsy needle through the probe and then into the prostate gland via the rectal wall.

The cleaning and decontamination of TOE, TVUS and TRUS probes that do not have internal lumens is normally carried out manually directly after they have been used. This includes wiping until clean with detergent-soaked cloths or sponges, followed by wiping with a disinfectant-soaked cloth or sponge several times. The probe is then rinsed with water or an appropriate rinse wipe and dried. The manufacturer’s instructions should be followed carefully. A local policy should be drawn up to describe the decontamination procedure.

It is essential that the whole of the probe and not just the insertion tube is effectively decontaminated. Cleaning and disinfection are required even if single use sheaths are used.
BEDPANS AND URINE BOTTLES

The Trust has a policy that bedpans and urine bottles are reusable and decontaminated in a purpose designed washer-disinfector after each use. These are located within various wards and departments within the Trust. At each location a “User” should be identified as described with CFPP01-01.

HTM 2030 currently gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of washer-disinfectors (WDs) used for processing sanitary products.
VARIANT CREUTZFELDT–JAKOB DISEASE

Uncertainty associated with Variant Creutzfeldt-Jakob Disease (vCJD) can have an impact on the management of medical devices e.g. flexible endoscopes and neurosurgical instruments. The National Institute for Health and Clinical Excellence (NICE) issued guidance in November 2006 (IPG196) to Minimise Risk in Transmission of vCJD via Interventional Procedures.

The guidance lists critical procedures for neurosurgery and posterior ophthalmic surgery. Patients born after 1 January 1997 should ideally have surgery with instruments that have not been exposed through surgery on patients before this date, or have surgery with single use devices.

The above guidance is restated and updated within CFPP01-01 Part A.

Advisory Committee for Dangerous Pathogens (ACDP) Transmissible Spongiform Encephalopathy’s (TSE) group issue regularly updated guidance on the Department of Health website containing advice on further reducing potential risk from surgery on a asymptomatic individuals possible incubating vCJD.

Reference should be made to the Trust Infection prevention and Control Policy “Transmissible Spongiform Encephalopathies (TSE’s) including Creutzfeldt-Jakob Disease (CJD)”
STORAGE AND TRANSPORT

Decontaminated Medical Devices fit for purpose must be stored in a cool, dry, well ventilated area. Devices should not be stored on the floor but on shelving that can be cleaned and allow for cleaning underneath the shelving. Shelving should appropriate for the purpose and environment and should be adequately sized so as not to be overcrowded and risk damaging the integrity of the device’s packaging and sterility.

- Medical equipment must be stored in a clean state
- Equipment should be checked for cleanliness when being removed from the storage
- Storage areas should be kept dust free, good housekeeping should be applied

Instruments must be transported and stored in a way that segregates sterile and used instruments whilst protecting the sterile product. Staff must wear appropriate protective clothing when handling contaminated equipment. Clinical waste should be clearly segregated and sharps placed in properly constructed containers (BS 7320:1990).

Transit containers must:
- protect the instruments and equipment;
- prevent inadvertent contamination during transportation; and
- prevent contamination of staff etc

When transporting used instruments for reprocessing. They should have the following Characteristics:
- be waterproof;
- be easy to clean (ideally suitable for decontamination in an automated washer-disinfector);
- be rigid in order to protect instruments from damage;
- be capable of being closed securely;
- be fitted with a tamper-proof seal;
- be constructed in such a way so as to prevent damage to the products being transported;
- be clearly labelled to identify the delivery address.

Sterile Medical Devices when provided by a third party provider must be provided from a provider that is accredited to MDD 93/42/EEC and quality system BS EN ISO 13485:2003.
ACQUISITION OF MEDICAL DEVICES/EQUIPMENT

Capital purchase of medical devices/equipment is discussed through the Trust’s Capital and Space Management Group and Medical Devices Group. Procurement provides the companies involved with the process a Pre Qualification Questionnaire (PQQ) to ensure required criterion is met e.g.

- How effectively can the device/equipment be cleaned / decontaminated? Does the device require to be dismantled before decontamination? Does the Trust have the mechanism to achieve this?
- Does the device/equipment have electrical components?
- Does the device/equipment have a limited life? How many times can it be decontaminated
- Can the Trust provide the recommended cleaning/disinfection/sterilization method
- Do the manufacturers recommendations comply with the Trust’s Infection Control and Health and Safety Policies and requirements
- Does a risk assessment demonstrate a single use alternative may provide safer clinical practice
- Is the purchase compatible with existing equipment and Trust methods for Decontamination
- A copy of the Device “Instruction for Use” be supplied to each stakeholder i.e. User, HSDU etc.

Only a CE marked re-usable or single use medical device/equipment in accordance with MDD93/42/EEC is procured
BUSINESS CONTINUITY

To ensure surgical activity level can be achieved Business Continuity plans are in place.

HSDU has formal, reciprocal contingency arrangements in place with Stockport NHS Trust. Should the Trust require emergency or additional capacity in the event of a disaster or operating contingency then this arrangement can be invoked. Additional informal arrangements have also been explored with 2 further reprocessing centres. All additional centres used will be accredited to the Medical Devices Directive 93/42/EEC.

There are further operational contingency measures within the HSDU including:
- Sufficient processing capacity within the numbers of plant to cope with short term failure of a single heat sealer, washer-disinfector, sterilizer or steam generator.
- Operating procedures in place to minimise the effect of a breakdown in ventilation plant.
- Essential electrical supply status for parts of the department.

The ETU decontamination rooms serve mainly the areas within its immediate department. If the decontamination area of ETU suffers a disaster rendering it out of use for a significant period of time, it would be likely that the rest of EDU would be affected and no procedures could be performed. Therefore there is no requirement for specific reprocessing centres to contracted outside of the Trusts wider arrangements for endoscopy business continuity as a whole. Additionally the cost of additional endoscopes would make an off-site reprocessing contingency unaffordable.

As with HSDU, There are operational contingency measures within the EDU including:
- Sufficient processing capacity within the numbers of plant to cope with short term failure of a single RO plant, Automatic Endoscope Reprocessor bay or disinfectant generator.
- Operating procedures in place to minimise the effect of a breakdown in ventilation plant.
- Essential electrical supply status for parts of the department.
DECONTAMINATION PREREQUISITES

Appropriate equipment is provided for decontamination – Equipment maintenance

Planned maintenance is an essential part of the decontamination process. Equipment (washer-disinfectors, sterilizers etc.) must be used as part of a validated, maintained processes. These processes should include planned preventative maintenance and periodic testing to ensure that equipment remains in the validated condition and fit for purpose. Failure to maintain the equipment and its systems gives rise to the potential for inadequate decontamination.

Current legislation is identified in the Executive Summary & defines the minimum standards required to ensure safe operation of the disinfection/sterilization process.

Appropriate equipment is provided for decontamination – Equipment validation and monitoring

Equipment should be regularly tested, monitored and calibrated to the definitions set out in Choice Framework for local Policies and Procedures, Health Technical Memoranda, European Standards and departmental best practice guidance. Processes should be validated and independently monitored, i.e. the equipment which monitors the process should be independent of the control of the process. Processes that require validation should only be carried out using automated equipment to ensure reproducibility.

A product release procedure should be followed after reprocessing in automated equipment.

Appropriate facilities are provided for decontamination

There should be enough space to allow staff to work in comfort and safety, with good segregation of clean and dirty activities. Lighting should be adequate to allow proper inspections of instruments. HBN 13, specifies the necessary centralised environment for effective decontamination. CFPP0106 specifies an appropriate environment for endoscope reprocessing.

The facilities used for the decontamination, inspection & assembly and sterilization of invasive surgical instruments should be accredited via a registered Medical Device Notified Body to the most recent versions of the European Medical Device Directive 93/42/EEC and ISO 13485 Quality Management Systems – Medical Devices.

At a local level decontamination should be undertaken away from patient areas and in facilities with appropriate segregation of processes, only.
RECORDS

Records must be kept of decontamination processes in the immediate vicinity of the equipment to which they refer. Records older than 5 years should be archived and kept for the minimum period specified by the NHS Code of Practice for Records management. A destruction date should be set for all archived records. Records kept should include details of the operating cycle used, the required parameters and the load processed, periodic test records and validation records.

Systems are in place to trace instruments through the decontamination cycle and link them to patients on which they have been used.

Ideally it should be possible to trace all instruments individually, and identify the patients on whom they have been used. Even where individual instruments cannot be traced, it is good practice to be able to trace sets of instruments, identifying which patient they were used on, and what equipment they were processed in. In the situation where local reprocessing is carried out instrument traceability is still required.

As a minimum record keeping should include:

- the cleaning and sterilization method used
- a record of the decontamination equipment and cycle
- the identity of the person(s) undertaking decontamination at each stage of the cycle
- the patients on whom they have been used and details of the procedures involved.

In Primary Care Dentistry please refer to the “Decontamination in primary care dental facilities” manual published by the Department of Health.
TECHNICAL REQUIREMENTS

Automated washer-disinfectors

Washer-disinfectors should be specified, in accordance with Model Engineering Specification C30 and BS EN ISO 15883. They should be commissioned and monitored in accordance with BS EN ISO 15883 (Parts 1 and 2) and CFPP01-01 Part D for Surgical Instrument washers, HTM2030 “Washer disinfectors” for bed-pan washers and BS EN ISO 15883 (Parts 1 and 4) and CFPP01-06 for Automatic Endoscope Reprocessors.

Manual Decontamination

Manual decontamination should not be undertaken when a suitable automatic decontamination process is available.

Non-abrasive implements should be used to prevent damage to instruments. Devices with lumens/ cannulated or small holes should be cleaned with designated cleaning brushes of appropriate diameter where manual cleaning is unavoidable. Particular attention should be paid to the following:

- Where manual cleaning is carried out, it should be undertaken in an appropriate area, which is separate to the sink provided for hand washing and segregated from the patient area.
- Staff are to be trained in manual washing techniques.
- Staff are to be immunised against Hepatitis B.
- Appropriate personal protective equipment is to be issued.
- There are to be procedures for monitoring the adequacy of cleaning and rinsing.
- Manual washing procedures are to be recorded.
- Detergents are to be used in accordance with Material Safety Data Sheets (MSDS). A COSHH Risk Assessment should have been performed for the detergent and process as per the Trust COSHH Policy.

Sterilizers

Sterilizers should be specified, in accordance with Model Engineering Specification C14 and BS EN 285 for steam sterilizers. They should be commissioned and monitored in accordance with BS EN ISO 17665 and CFPP01-01 Part C for surgical instrument sterilizers. HTM2010 applies for laboratory sterilizers.

Managers should pay particular attention to the following areas:

- Monitoring of the steam supply of porous load sterilisers using CFPP01-01 Part C.
- Frequent periodic review of the effectiveness of bench top steam sterilisers against relevant guidance to be undertaken.
- Ensuring bench top sterilisers are fitted with independent process monitoring or recording equipment.
FURTHER INFORMATION

There are many sources of information on legislation and decontamination guidance. Up-to-date National guidance can be accessed on the Internet on the following sites:

http://www.mhra.gov.uk/
http://www.dh.gov.uk
http://www.official-documents.co.uk
## APPENDIX 1 – GLOSSARY

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DEFINITION</th>
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</thead>
<tbody>
<tr>
<td>Microbiological</td>
<td>Equipment of accessory which has become soiled by one or more of the following:</td>
</tr>
<tr>
<td>Contamination</td>
<td>- bloody or body secretions or excretions</td>
</tr>
<tr>
<td></td>
<td>- pathological specimens or samples</td>
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<tr>
<td>Soiled Condition</td>
<td>Equipment or accessory that is dirty, dusty, splashed or stained with liquid, smeared with medical lubricants, gels etc.</td>
</tr>
<tr>
<td>Cleaning</td>
<td>The removal of all foreign material</td>
</tr>
<tr>
<td>Decontamination</td>
<td>A procedure that removes most harmful micro-organisms or other hazardous substances from objects, rendering them safe to handle.</td>
</tr>
<tr>
<td>Disinfection</td>
<td>The process of making objects safe to handle by the removal or destruction of viable microbes, not usually including bacterial spores. This is necessary if the equipment or accessory has been exposed to blood or body secretions and excretions.</td>
</tr>
<tr>
<td>Sterilization</td>
<td>The process used to render an object free from viable infectious agents, including viruses and bacterial spores. This level of decontamination is not usually necessary when dispatching equipment for maintenance N.B follow manufacturer’s guidelines/recommendations.</td>
</tr>
<tr>
<td>Medical Equipment</td>
<td>Healthcare equipment that comes into contact with patients their specimens, samples or body fluids and other potentially hazardous substances. This equipment includes medical, dental and laboratory equipment.</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>An instrument, apparatus, appliance, material or other article used alone or as a combination, or decontaminated, sterile medical devices are routinely used for diagnosis, prevention, monitoring, treatment or alleviation of disease due to the nature of use. Medical devices must be free from viable micro-organisms and rendered “fit for use”.</td>
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<tr>
<td><strong>ITEM</strong></td>
<td><strong>DEFINITION</strong></td>
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<tr>
<td><strong>Maintenance</strong></td>
<td>Includes both planned preventative and corrective maintenance:</td>
</tr>
<tr>
<td></td>
<td>a) Planned preventative maintenance (PPM)</td>
</tr>
<tr>
<td></td>
<td>b) Corrective maintenance</td>
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<td></td>
<td>Servicing</td>
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<tr>
<td></td>
<td>Repair</td>
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<td></td>
<td>Routing maintenance</td>
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<td></td>
<td>Breakdown work</td>
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<td></td>
<td>Periodic maintenance</td>
</tr>
<tr>
<td><strong>End users</strong></td>
<td>Healthcare providers with departmental responsibilities including the operation and supervision of procedures for cleaning/decontamination and maintenance contracts for equipment used in their area of responsibility.</td>
</tr>
<tr>
<td><strong>Maintenance Engineers</strong></td>
<td>Personal in-house and contracted technical personnel selected by the Trust to undertake maintenance and testing work on equipment e.g. manufacturers, suppliers, contractors.</td>
</tr>
<tr>
<td><strong>Single use</strong></td>
<td>Single use means: <strong>DO NOT RE-USE</strong>. A single use device is used on an individual patient during a single procedure, and then discarded. The device is not manufactured to be reprocessed and used again even on the same patient.</td>
</tr>
<tr>
<td><strong>Single patient use</strong></td>
<td>Single patient use means the medical device may be used for more than one episode of use on <strong>ONE PATIENT ONLY</strong>. The device may undergo some form of reprocessing between each use.</td>
</tr>
<tr>
<td><strong>Creutzfeldt-Jakob Disease (CJD)</strong></td>
<td>CJD is a prion disease, or Transmissible Spongiform Encephalopathy (TSE), are a group of neurodegenerative diseases that can affect man and animals. They are not treatable and are invariably fatal. In man, prion diseases can be inherited, sporadic or acquired.</td>
</tr>
<tr>
<td><strong>Health Care Associated Infection HCAI</strong></td>
<td>Encompasses any infection by any infectious agent acquired as a consequence of a person’s treatment by the NHS or that is acquired by a Health Care Worker in the course of their NHS duties.</td>
</tr>
<tr>
<td>ITEM</td>
<td>DEFINITION</td>
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<tr>
<td>Manufacturer</td>
<td>An organisation with responsibility for the design, manufacture, packaging and labeling of a device.</td>
</tr>
<tr>
<td>WEEE Regulations and Guidance</td>
<td>European Directive – Waste Electrical and Electronic Equipment encourages recovery of equipment at its end of life to prevent more land filling and potential polluting of the soil and ground water from hazardous materials present in the equipment.</td>
</tr>
<tr>
<td>Serious untoward incident SUI</td>
<td>An accident or incident when a patient, member of staff including those working in the community, or member of the public suffers serious injury, major permanent harm or unexpected death in hospital, other health service premises or other premises where NHS care is provided and where actions of health service staff are likely to cause significant public concern.</td>
</tr>
</tbody>
</table>
APPENDIX 2 – REFERENCE DOCUMENTS

1. Health & Safety at Work Act, 1974
2. The Management of Health & Safety at Work Regulations, 1992
3. The Control Of Substances Hazardous to Health Regulations (COSHH)
4. Medical Device Directive 93/42 EEC
6. HBN 13 Sterile Services Departments
7. CFPP01-01 Management and decontamination of surgical instruments (medical devices) used in acute care:
   - Part A the formulation of local policy and choices manual
   - Part B Common elements
   - Part C Steam sterilizers
   - Part D Washer-disinfectors
   - Part E Alternatives to steam for the sterilization of reusable medical devices
8. CFPP01-06 Decontamination of flexible endoscopes (Parts A to E)
   - Policy and management manual
   - Design and installation manual
   - Operational management manual
   - Validation and verification manual
   - Testing methods manual
9. Decontamination in primary care dental facilities manual
10. HTM 2010 Sterilization (for laboratory elements only)
11. HTM 2030 Washer / Disinfectors (for bed-pan washer elements only)
12. HTM 2025 Ventilation
13. The Reporting of Injuries, Disease and Dangerous Occurrences (RIDDOR)
14. HSC 1999/179 Controls Assurance in Infection Control. Decontamination of Medical Devices
15. HSC 1999/178 Variant Creutzfeldt-Jakob Disease: Minimising the Risk of Transmission
16. HSC 2000/32 Decontamination of Medical Devices
17. HSC 1999/123 Risk Management and Organizational Controls
20. Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from Microbiology Advisory Committee to Department of Health Medical Devices Agency (MAC Manual)
22. MHRA DB 2002/05 Decontamination of Endoscopes
23. MHRA Top Ten Tips for Endoscopy
24. MHRA DB 2006/05 Managing Medical Devices Guidance for Healthcare and Social Services Organizations
25. MHRA SN 2010 (01) Reporting Adverse Incidents and Disseminating Medical Device Alerts
26. MHRA MDA2004/028 Flexible and rigid scopes
27. MHRA DB 2000 (02) Medical Devices and Equipment Management
28. BS EN 285: Steam Sterilizers: Large Sterilizers
29. BS EN ISO 17665 Sterilization of Healthcare Products – Moist Heat
30. BS EN ISO 15883 Washer Disinfectors
32. BS 5295 Environmental Cleanliness in Enclosed Spaces
33. BS EN ISO 13485:2003 Medical Devices: Quality Management Systems
34. Coding for Success
35. Matron’s Charter for Cleaner Hospitals 2004
36. Winning Ways
37. The Health Act 2008
38. The Health and Social Care Act 2008 – Code of Practice for Prevention and Control of Infections
APPENDIX 3 – DECONTAMINATION GROUP TERMS OF REFERENCE

Purpose
The purpose of the Decontamination Group (the Group) is to monitor compliance with the Trust’s decontamination policy and to provide technical and operational guidance to the Trust Infection Prevention & Control Group, the Trust Risk Management Group, the Trust Medical Devices Group and to all those responsible for, or involved in, medical device decontamination.

Functions of the Group
• To receive and review reports from those responsible for, or involved in, medical device decontamination within the Trust;
• As a result of the point above, to monitor decontamination issues and update the decontamination risk register;
• To provide details and make recommendations on financial implications of decontamination to the Trust;
• To provide guidance to the Trust on purchases of decontamination equipment;
• To be responsible for keeping up-to-date with all decontamination regulations, standards and guidance and to disseminate information to members of the group regarding changes in decontamination practice, regulation, standards or guidance;
• To recommend and implement policies or procedures that comply with current decontamination regulations, standards and guidelines;
• To monitor the Trust’s compliance with the decontamination aspects of Care Quality Commission Outcome 8 (regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010);
• To form any sub-groups as necessary to conduct the business of the Group.

Reporting Arrangements
The Decontamination Group is responsible to the Trust Infection Prevention & Control Group and with respect to the Decontamination Risk Register, the Trust Risk Management Group.

Minutes of the Group can be made available on the Trust intranet if requested.

Decisions made by the Group and policies and procedures which are reviewed and updated shall be put on the agenda of the Trust Infection Prevention & Control Group for final approval.

Chair
The Group shall be chaired by the Trust Decontamination Lead. The Lead may temporarily delegate chairmanship to a nominated deputy during times of absence.

Membership
The membership shall include:
• The Trust Decontamination Lead;
• The Trust Dental Decontamination Lead;
• Director of Infection, Prevention & Control (DIPC) or nominated Trust microbiologist;
• Representative of Infection Prevention and Control;
• The Estates Engineering Manager (Senior Operational Manager and Authorised Person (Decontamination));
• The Trust’s appointed Authorising Engineer (Decontamination);
• Competent Persons (Decontamination);
• Those responsible for providing/managing directly or indirectly the decontamination
services across the Trust (Users and department representatives) including but not limited to:

- HSDU Manager;
- Endoscopy manager;
- Representation from Operating Theatres;
- Representation from wards and departments as applicable;

**Quorum**
Attendees must include the Group’s Chair (usually the Decontamination Lead) and the representative of Infection Prevention and Control for the meeting to be quorate.

**Majority**
A course of action requires support from the Group chair, the representative of Infection Prevention and Control and more than 50% of group members who attend the meeting.

**Meeting Frequency**
The Group shall meet at quarterly intervals.

**Agenda, Minutes and documentation**
A package will be prepared and sent to members of the Group a minimum of three business days in advance of a meeting. This package will include the following:

- Agenda for the upcoming meeting;
- Minutes of the previous meeting;
- The decontamination risk register;
- Any other documents/information to be considered at the meeting.
APPENDIX 4 – EQUALITY AND HUMAN RIGHTS IMPACT ASSESSMENT FORM

Now that you have looked at the purpose, etc. of the document (part 1) and looked at the data and research you have (part 2), this section asks you to assess the impact of the document on each of the strands listed below. Only complete the boxes which are relevant to the data you have looked at – for any other boxes, you can write “N/A”

RACE – testing of disproportional and adverse impact

<table>
<thead>
<tr>
<th>a. How are racial groups reflected in the numbers of people affected by this document?</th>
<th>N/A</th>
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<tbody>
<tr>
<td>b. From the evidence available does the document affect, or have the potential to affect, racial groups differently?</td>
<td>Yes ☐ No x</td>
</tr>
<tr>
<td>c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination?</td>
<td>Reason/evidence/comment</td>
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GENDER (INCLUDING TRANSGENDER) – testing of disproportional and adverse impact

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<thead>
<tr>
<th>a. How are different gender groups reflected in the numbers of people affected by this document?</th>
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<tr>
<td>b. From the evidence available does the document affect, or have the potential to affect, different gender groups differently?</td>
<td>Yes ☐ No x</td>
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<tr>
<td>c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? Reason/evidence/comment</td>
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**DISABILITY – testing of disproportional and adverse impact**

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<thead>
<tr>
<th>a. How are disabled people reflected in the numbers of people affected by this document?</th>
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<tr>
<td>N/A</td>
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<tr>
<td>b. From the evidence available does the document affect, or have the potential to affect, disabled people differently?</td>
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<tr>
<td>Yes ☐</td>
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<tr>
<td>No x</td>
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<tr>
<td>c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? Reason/evidence/comment</td>
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**AGE – testing of disproportional and adverse impact**

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<thead>
<tr>
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<tr>
<td>b. From the evidence available does the document affect, or have the potential to affect, age groups differently?</td>
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<tr>
<td>Yes ☐</td>
</tr>
<tr>
<td>No x</td>
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<tr>
<td>c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? Reason/evidence/comment</td>
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</table>
### LGB – testing of disproportional and adverse impact

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<thead>
<tr>
<th>a. How are people with different sexual orientations reflected in the numbers of people affected by this document?</th>
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<tr>
<td>b. From the evidence available does the document affect, or have the potential to affect, LGB people differently?</td>
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<tr>
<td>Yes □</td>
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<tr>
<td>No x</td>
</tr>
<tr>
<td>c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? Reason/evidence/comment</td>
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</table>

### Religion/Belief – testing of disproportional and adverse impact

<table>
<thead>
<tr>
<th>a. How are people with different RELIGIONS OR BELIEFS reflected in the numbers of people affected by this document?</th>
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<tbody>
<tr>
<td>N/A</td>
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<tr>
<td>b. From the evidence available does the document affect, or have the potential to affect, RELIGIOUS/BELIEF groups differently?</td>
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<tr>
<td>Yes □</td>
</tr>
<tr>
<td>No x</td>
</tr>
<tr>
<td>c. If yes, do any of the differences amount to barriers, negative impact or unlawful discrimination? Reason/evidence/comment</td>
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</table>

### Carers – testing of disproportional and adverse impact

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<thead>
<tr>
<th>a. How are people with caring responsibilities reflected in the numbers of people affected by this document?</th>
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Head of Estate Operations  
V2 March 2013
### Part 4 - Safeguarding Assessment

For advice on completing this section, contact the Named Nurse for Safeguarding Children and Young People

**CHILDREN - testing of disproportional and adverse impact**

| a. Is there a direct or indirect impact upon children? | Yes ☐ | No ☐ |
N/A

b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people:

<table>
<thead>
<tr>
<th>N/A</th>
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c. If no please describe why there is considered to be no impact / significant impact on children

The decontamination process has no direct impact upon children.
Part 5 – CONSULTATION WITH EQUALITY AND DIVERSITY LEAD AND NAMED NURSE FOR SAFEGUARDING

At this point, you should forward the template to:
- The Trust’s Equality and Diversity Lead
- The Named Nurse for Safeguarding Children

and arrange a meeting or telephone call. You will be asked a number of final questions based on your responses to date.

You can record the results of those conversations here:

| Equality and Diversity: Impact assessment agreed
| Safeguarding Children: |

Part 6 - CONCLUSIONS AND RECOMMENDATIONS

6.1 Summary of changes implemented

*VERY briefly, list changes made as a consequence of conducting this assessment*

6.2 Is there anything which you think may have an adverse impact but which you have not been able to address in writing your document?

6.3 Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?

*List all actions (large and small) that have been identified during the assessment and include a named person and date for completion.*

<table>
<thead>
<tr>
<th>Action</th>
<th>Name Lead</th>
<th>Date to be Achieved</th>
</tr>
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</table>
6.4 When will the document be reviewed? (Include dates for completion and officer(s) responsible.)

Date completed:

Signed by (Manager):…………………………

The Trust’s Equality and Diversity Lead:…

The Named Nurse for Safeguarding Children:.......... Melanie Barker