Western Health and Social Care Trust

Policy for Decontamination of Reusable Invasive Medical Devices

December 2020

Western Health and Social Care Trust

Policy Title	Policy for Decontamination of Reusable Invasive Medical Devices		
Ownership	Executive Director of Nursing/Director of Primary Care & Older People's Services		
Approval by:	Trust Board	**Approval Date:**	3 December 2020
Original Implementation Date:	October 2013	**Revised**	April 2016 September 2018 December 2020
Review Date	July 2022		
Version No:	4	**Supercedes:**	• Version 1 (October 2013) • Version 2 (April 2016) • Version 3 (September 2018) • Policy for the Management of Decontamination (Ref: PrimCare13/002).
Policy Reference Number	PrimCare13/001		
Links to other Policies, Procedures, Guidelines or Protocols	• Policy on Disinfection and Decontamination – Patient Care Equipment (Ref: Med11/001) • Policy on the Control of Transmissible Spongiform Encephalopathy including CJD/vCJD (Ref: Med14/007) • Policy for the Management of Medical Device (Ref: Corp09/14).		

1.0 INTRODUCTION

This policy covers the decontamination of reusable medical devices used in invasive procedures i.e. surgical instrumentation, endoscopes and specialist ultrasound probes within the Western Health and Social Care Trust. This Policy will also define management and accountability arrangements for the decontamination processes within the Western Health and Social Care Trust.

All surgical instruments including those used in minor procedures must be decontaminated within the Hospital Sterilisation Disinfection Unit either at Altnagelvin Hospital or Omagh Hospital & Primary Care Complex (OH&PCC).

All endoscopes including ENT, Urology and Transesophageal flexible probes must be decontaminated within the Endoscopy Decontamination Unit either at Altnagelvin Hospital, OH&PCC or South West Acute Hospital (SWAH).

Other policies within the Trust detail guidelines that are interlinked with this policy and are therefore also referred to:-

- Policy on Disinfection and Decontamination – Patient Care Equipment and Immediate Patient Environment
- Policy on the Control of Transmissible Spongiform Encephalopathy including CJD/vCJD
- Policy for the Management of Medical Devices.

1.1 Definitions

Decontamination involves the destruction or removal of any organisms present in order to prevent cross infection. It is a combination of processes which includes cleaning, disinfection and sterilisation. The definitions of the critical processes in decontamination are given below.

Cleaning

The removal of micro-organisms and the organic matter on which they thrive. The reduction of microbial contamination depends on many factors including the effectiveness of the cleaning process and the removal of initial bio burden. Cleaning is an essential prerequisite to disinfection and sterilisation. The preferred method of cleaning is by an automated process i.e. via a Washer – Disinfector (WD) or Endoscope Washer Disinfector (EWD). Where this is contraindicated manually cleaning may be performed according to manufacturers' instructions.

Disinfection

The removal or destruction of microbes so that the item is safe to handle. Disinfection is used to reduce the number of viable infectious agents but may not necessarily inactivate some microbial agents such as certain viruses and bacterial spores. Disinfection may be carried out through a thermal process i.e. heat or chemical.

Sterilisation
The destruction of micro-organisms including bacterial spores so that the item is considered sterile and may be reused in invasive procedures. Sterilisation is carried out using a combination of heat and steam within an autoclave.

1.2 General Principles

Effective decontamination requires the attainment of acceptable standards at all stages of the process cycle. Failure to address issues in any of these stages will result in inadequate decontamination. During all stages of the decontamination process the following must be in place: -

- Effective management arrangements
- Policies and procedures for all aspects of the decontamination process
- The location and facilities where decontamination takes place must meet all current standards
- The equipment used must be validated and tested to decontamination standards so as to be rendered fit for purpose
- An effective Quality Management System that covers all aspects of the decontamination process
- A system to track instrument trays and endoscopes through the decontamination process to the patient
- Documented training records for all staff involved in the decontamination process.

1.3 Medical Devices

The Medical Device Regulations 2017 defines a medical device as 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, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or physiological process
- Control of conception.
- Provide 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 function by such means.
- Products specifically intended for the cleaning, disinfection or sterilisation of devices

Medical Devices are classified into categories according to the Spaulding Classification and infection risk to patients associated with their decontamination.

RISK	APPLICATION OF MEDICAL DEVICES	DECONTAMINATION RECOMMENDED
HIGH	Items in close contact with a break in the skin or mucous membrane Items introduced into a sterile cavity	CLEANING, DISINFECTION AND STERILISATION
INTERMEDIATE	Items in contact with intact skin or mucous membranes after use on an infected patient. Items prior to use on immuno-compromised patients	CLEANING, DISINFECTION AND POSSIBLY STERILISATION
LOW	Items in contact with healthy skin Items not in contact with a patient	CLEANING

2.0 PURPOSE AND AIMS

The purpose and aims of this policy are to: -

- Ensure the effective decontamination of reusable medical devices including flexible endoscopes
- Reduce the risk of infection through the transmission of infectious agents.
- Ensure the health and safety of patients and staff through a robust decontamination process
- Ensure that the responsibility for management and control of decontamination processes is clearly defined and in place.
- Ensure that all staff involved in the decontamination of reusable medical devices and endoscopes are appropriately trained and competency assessed
- Ensure that all equipment involved in the decontamination of reusable medical devices and endoscopes meets current standards for testing and validation and is fit for purpose
- Ensure that risk management processes are applied to all aspects of decontamination processes and that all processes are in line with corporate governance.
- Ensure adherence to current guidelines and legislation applicable to decontamination of reusable medical devices and endoscopes.

3.0 SCOPE

The scope of this policy covers the management of decontamination of all reusable invasive medical devices including flexible endoscopes and the decontamination equipment used to render such devices safe for use. The policy extends to all Trust staff involved in the decontamination of reusable invasive medical devices, endoscopes and ultrasound probes.

4.0 OBJECTIVES

The objectives of this policy are: -

- To ensure the risk of infection through transmission of infectious agents from the reuse of invasive medical devices and endoscopes is minimised
- To ensure the safety of patients and staff
- To ensure that the Trust has suitable robust governance arrangements in place to support the decontamination of reusable invasive medical devices and endoscopes
- To comply with current decontamination guidelines and legislation.

5.0 ROLES AND RESPONSIBILITIES

Appropriate management structures must be in place to oversee the overall process of decontamination including acquisition, inspection, packaging, storage and transport. These arrangements must facilitate ongoing monitoring and review of processes and controls. The key responsibilities of those involved in managing and controlling the decontamination processes and their role are clearly defined in Health Technical Memorandum 01-01 Management and Decontamination of Surgical Instruments Used in Acute Care July 2016 and are as follows within the Trust: -

Executive Manager - *Chief Executive*
The Executive Manager is defined as the person with ultimate management responsibility for all aspects of the decontamination process including the implementation of statutory requirements.

Decontamination Lead - *Executive Director of Nursing & Director of Primary Care and Older People's Services*
The Decontamination Lead is the nominated lead at Trust Board Level with responsibility for decontamination and should report directly to the Executive Manager. The Decontamination Lead is organisationally responsible for the effective, and technically compliant, provision of decontamination services. The Decontamination Lead has responsibility for ensuring that policies exist and that they take account of best practice and national guidance.

The Decontamination Lead has oversight responsibility for the effective and technically compliant provision of decontamination services. He / she is responsible for: -

- The implementation of an operational policy for decontamination. This policy should clearly define the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of decontamination equipment.
- Monitoring the implementation of the policy.
- Presenting an annual report of the controls and systems in place in relation to all aspects of decontamination to the Trust's Corporate Governance Sub Committee.

Designated Person – *Decontamination Manager*
The Designated Person provides the essential senior management link between the organisation and professional support and should also provide an informed position at Board level. The Designated Person should work closely with the Senior Operational Manager to ensure that provision is made to adequately support the decontamination system.

Senior Operational Manager – *Decontamination Engineer*
The Senior Operational Manager is technically, professionally and managerially responsible for the engineering aspects of decontamination. The Senior Operational Manager is accountable to the Decontamination Lead.

User – *Decontamination Services Manager*
The User is the person designated by Management to be responsible for the day to day management of the decontamination process. The User also has the responsibility to: -

- Certify that all decontamination equipment is fit for use
- Ensure that all decontamination equipment is subject to periodic testing and maintenance and hold all documents relating to same
- Appoint operators where required and ensure that they are adequately trained and competency assessed
- Maintain production records and establish procedures for product release
- Ensure that procedures for production, quality control and safe working are documented and adhered to according to statutory requirements and best practice
- Ensure that procedures are in place for product recall where necessary.

Operator – *HSDU Assistants*
The Operator is any person with the authority to operate decontamination equipment, including the recording of instrument readings. The Operator should have their tasks defined in a job description and should have documented training records that demonstrate their competency.

Competent Person CP (D) – *Decontamination Technical/Maintenance Officer*
The CP is responsible for carrying out the maintenance, validation, periodic testing and repair of the decontamination equipment. The CP must be suitably competent and qualified to a standard outlined in Health Technical Memorandum 0101 Part B 2016.

Authorised Person AP (D) – *Decontamination Engineer*
The AP (D) will be an individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the AE (D) Designated Person who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of decontamination equipment including the operation of the permit-to-work system.

The AP (D) should be able to undertake the safe and effective management aspects of the service. The role of AP (D) is intended to provide the organisation with an individual who, as part of the management infrastructure, will provide day-to-day operational management responsibility for the safety of the system.

The AP (D) is appointed by management to provide independent auditing and advice on decontamination. The AP (D) should review processes and witness validation work where appropriate. The AP (D) must be suitably qualified to a standard outlined in Health Technical Memorandum 0101 Part B 2016. The AP (D) is also responsible for: -

- The engineering management of decontamination equipment and line management of the CP (D)
- The safe and effective systems of work for all installed decontamination equipment within his/her area of responsibility
- The acceptance criteria for operational and performance testing of all decontamination equipment
- Liaison with the Authorising Engineer Decontamination (AED), Decontamination Lead and other interested professionals
- Authorising the use of decontamination equipment after major repair or refurbishment and after quarterly or annual tests.

Authorising Engineer (Decontamination Assurance) – *AE (D), Safety & Strategy Unit, Department of Health (DoH)*
The AE (D) is defined as a person designated by the Trust to provide independent auditing and technical advice on decontamination procedures, The AE (D) is fully independent of the Trust's structure and is required to provide professional and technical advice on decontamination procedures, washer-disinfectors, sterilisers and sterilisation and to review and witness documentation on validation.

The AE (D) is required to liaise closely with other professionals in various disciplines and, consequently, the appointment should be made known in writing to all interested parties. The AE (D) should assist healthcare organisations in the appointments and interviews of the AP (D)s and their consequent annual assessments.

The AE (D) should have a reporting route to the Decontamination Lead and should provide professional and technical advice to the AP (D)s, CP (D)s, Users and other key personnel involved in the control of decontamination processes in all healthcare facilities.

The principal responsibilities of the AE (D) are as follows: -

- to provide to Management and others, general and impartial advice on all matters concerned with decontamination;
- to advise Management and others on programmes of validation and testing;
- to audit reports on validation, revalidation and yearly tests submitted by the AP(D);
- to advise Management and others on programmes of periodic tests and periodic maintenance;
- to advise Management and others on operational procedures for routine production;
- to advise Management on the appointment of the AP(D);
- to provide technical advice on purchasing and selection of decontamination equipment for the users;
- to provide technical advice on the relevant guidance on decontamination equipment and procedures.

Control of Infection Officer – *Head of Infection and Prevention Control*
The Control of Infection Officer is defined as the person designated by management to be responsible for advising the User on all infection prevention aspects.

Microbiologist
The Microbiologist is defined as a person designated by management to be responsible for advising the User on the microbiological aspects of handling, washing, disinfecting and sterilising reusable medical devices.

6.0 DECONTAMINATION WORKING GROUP

The Trust has a Decontamination Working Group which is chaired by the Decontamination Lead. It is a sub-group of the Trust's Corporate Governance Sub-Committee which reports to the Trust's Governance Committee. The Decontamination Lead provides regular reports of the work of the Decontamination Working Group to the Corporate Governance Sub-Committee.

The remit of the Decontamination Working Group is: -

- In accordance with Controls Assurance Standards seek assurance that the Trust has a robust framework for the management of decontamination of reusable Medical Devices including Endoscopes.
- Bi-annually review the Trust's Decontamination Policy to ensure that it reflects best practice and current legislation pertaining to decontamination.

- Audit compliance with the Trust's Decontamination Policy and act on outcomes.
- Review compliance with external ISO 13485:2016 Medical Devices quality audits and ensure action on recommendations.
- Provide assurance that there are good systems in place for the training of staff involved in the decontamination of reusable Medical Devices including Endoscopes.
- Review all decontamination related incidents, safety notices and guidance, recommending appropriate action to ensure continued compliance.
- Review and prioritise decontamination risks, making recommendations as necessary. Ensure all risks are registered on the appropriate Risk Register.
- Liaise where appropriate with local and national agencies in decontamination related matters.
- Provide guidance to the Trust on the procurement, upgrading or replacement of decontamination equipment.
- Provide quarterly briefing papers on all decontamination related matters to the Trust's Corporate Governance Sub-Committee.
- Provide annual ISO audit reports to the Quality and Standards Committee
- Escalate any decontamination related matters of concern to the Trust's Corporate Management Team.

The Decontamination Working Group's Terms of Reference including membership is outlined in Appendix 1 and the Working Group's position with the Trust's Governance Assurance Framework and Reporting Sub-Committee Working Groups is outlined in Appendix 2.

7.0 DECONTAMINATION OF SURGICAL INSTRUMENTS

Within the Trust all reusable surgical instruments including those used for minor procedures i.e. dental and podiatry must be decontaminated within the Hospital Sterilisation Disinfection Unit at Altnagelvin Hospital or OH&PCC. All instruments must be cleaned, disinfected, inspected, packaged and sterilised using validated automated processes and in accordance with manufacturers' instructions.

The Northern Ireland regional strategy for decontamination recommends that decontamination of invasive medical devices is carried out in a centralised Sterile Service Department with full accreditation against Medical Devices Regulation 2017 All equipment used in the decontamination process must be fit for purpose and be subject to an appropriate planned validation and testing schedule according to Health Technical Memorandum 0101 2016. The environment and facilities where decontamination takes place must meet with Health Building Note 13 Sterile Services Departments (HBN 13).

Both the Hospital Sterilisation Disinfection Unit at Altnagelvin Hospital and OH&PCC must maintain full accreditation against Medical Devices Regulations 2017 and ISO 13485:2016 Quality Management System for Medical Devices. Both facilities must meet HBN 13 and include clean rooms that are regularly validated to Class 8 ISO

14644 for environmental cleanliness. All decontamination equipment must be subject to scheduled testing, validation and maintenance programmes. All departmental procedures must be in accordance with national and regional decontamination standards and regulations and must be audited to ISO 13485 2016.

The most recent guidance for Northern Ireland is Health Technical Memorandum 01-01 Management and Decontamination of Surgical Instruments (Medical Devices) used in Acute Care July 2016 accessed via https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care

8.0 DECONTAMINATION OF FLEXIBLE ENDOSCOPES AND TOE PROBES

Within the Trust all flexible endoscopes including ENT, Urology and Transesophageal flexible probes must be processed within the Endoscopy Decontamination Units at Altnagelvin, OH&PCC and SWAH. In accordance with manufacturers guidance all flexible endoscopes are manually cleaned and disinfected using liquid chemical disinfectant in an EWD.

Decontamination of endoscopes including the TOE probe should take place in a centralised Endoscopy Decontamination Unit with full accreditation against Medical Devices Regulations 2017 and ISO 13485:2016 Quality Management Systems for Medical Devices. Facilities should separate dirty and clean areas with a Class 8 clean room for storage and packing of endoscopes.

All endoscope decontamination within the Trust must take place within centralised Endoscopic Decontamination Units at either Altnagelvin, OH&PCC or SWAH. All units must maintain full accreditation against Medical Devices Regulations 2017 and ISO 13485:2016 Quality Management System for Medical Devices. All endoscopy decontamination equipment must be subject to scheduled testing, validation and maintenance programmes and departmental procedures must be in accordance with national and regional decontamination standards and regulations.

The most recent guidance for Northern Ireland is HTM 01-06 Decontamination of Flexible Endoscopes July 2016 accessed via https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/553303/HTM01-06_PartE.pdf

9.0 DECONTAMINATION OF INSTRUMENTS REQUIRING ETHYLENE OXIDE STERILISATION

Some instruments may require specialised sterilisation i.e. Ethylene Oxide (EO) due to the material or status of sterility e.g. Choledochoscope. Any instrument or scope that requires EO must be first decontaminated within the HSDU Alt or OH&PCC. They will be processed and wrapped in accordance with departmental procedures and transported to the HSDU in the Belfast Health and Social Care Trust to be sent

to Anderson Caledonia Ltd in Scotland. All procedures for processing, labelling, transporting to and receiving back from the BHSCT must be followed. A Standard Level Agreement with the WHSCT and the BHSCT for EO sterilisation will be reviewed periodically.

10.0 TRAINING

All staff involved in the decontamination of reusable medical devices must have completed training and receive regular updates. All Hospital Sterilisation Disinfection Unit staff within the Trust must complete Hospital Sterilisation Disinfection Unit department induction training including a competency assessment programme within both the Hospital Sterilisation Disinfection Unit and Endoscopy Decontamination Unit. All training must be recorded, be available for inspection and include the following: -

- Operational procedures
- Quality procedures
- Environmental procedures
- Operation of equipment including identification of parameters
- Record keeping and traceability
- Quality Management System and Decontamination Standards
- Auditing
- Non-conformance and adverse incidents.
- Risk Management

Having completed competency training all staff within the Hospital Sterilisation Disinfection Unit must commence the Diploma in Healthcare Support Services Decontamination Level 3 and this will be supported by internal A1 assessors and the Trust's vocational training team. Trust mandatory training will also be given in: -

- Infection Control
- Manual Handling
- Fire Safety
- Control of Substances Hazardous to Health (COSHH)
- Information Governance
- Equality Good Relations Human Rights

11.0 TRACKING AND TRACEABILITY

It is important to be able to trace products through the decontamination processes to which they have been subjected and also to the patient on whom they have been used. The ability to track and trace surgical instruments and endoscopes through the decontamination process enables corrective action to be taken in the unlikely event of a process failure when products can then be recalled. Within the Trust all surgical instruments and endoscopes must be barcoded with unique barcode numbers and traced through each stage of the decontamination process by the Fingerprint IT Traceability System. This barcoding scanning system must be used

within the Hospital Sterilisation Disinfection Unit and Endoscopy Decontamination Units.

HSS (MD) 4/01 – Decontamination of Reusable Medical Devices states: -

> *"It is important that systems are in place to allow sets of surgical instruments to be tracked through decontamination processes in order to ensure that the processes have been carried out effectively. Systems should also be implemented to enable the identification of patients on whom the instrument sets have been used. This is important so that the relevant patients can be identified in the event of exposure to potential risk, and is relevant to both the primary and secondary care sectors. This requirement for traceability of instruments is in addition to the measures for identification and tracking of flexible endoscopes set out in HSS (MD) 15/99."*

It is important that instruments including endoscopes and their accessories are tracked through the decontamination process so that corrective action can be taken when necessary or in the event of an adverse incident. Records must be maintained identifying: -

- the cleaning, disinfection and sterilisation method used
- the name of the person undertaking the decontamination and date and time
- details of the item and User identification
- type of equipment used and recorded parameters

Records relating to the management of decontamination equipment must be maintained by the Trust for a minimum of 10 years plus the current year. If children are involved records must be kept until the child's 25th birthday. Records maintained will include: -

- Commissioning reports
- Daily, weekly, quarterly and annual validation reports
- Maintenance records and service reports
- Independent validation and batch reports

12.0 MONITORING

On-going monitoring for decontamination within the Trust must take place both internally and externally and provide assurance to the Trust of compliance against guidance, standards and legislation and reassurance of efficacy of decontamination processes.

External audit for the Hospital Sterilisation Disinfection Units at Altnagelvin & OHPCC and the Endoscopy Decontamination Units, Altnagelvin, OH&PCC and SWAH will be provided by British Standards Institute. All external audits will be measured against Medical Devices Regulations 2017 and ISO 13485:2016 Quality Management System. Findings from all external audits must be reported to the Trust's Quality and Standards Sub Committee and Decontamination Working Group.

All adverse incidents relating to decontamination must be reported as per the Trust's Incident Reporting Policy and reviewed by the Decontamination Working Group. Other decontamination risks will be recorded as per the Trust's Risk Management Strategy. An annual report on the efficacy of the decontamination process must be submitted to the Trust's Corporate Governance Sub Committee.

13.0 SINGLE USE EQUIPMENT

Single use medical devices used for invasive procedures and endoscopy must not be processed for reuse. Any medical devices with the single use symbol as below must be disposed of after use.

14.0 HANDLING, COLLECTION AND TRANSPORTATION OF CONTAMINATED INSTRUMENTS AND ENDOSCOPES

All reusable instruments, endoscopes and TOE probes must be handled, collected and delivered in a manner that reduces the risk of contamination to the patient, staff and any area of the healthcare facility. All devices must be transferred to the decontamination area as soon as possible after they have been used. All instruments and endoscopes must be placed in a container or transfer trolley that is leak-proof, rigid, easy to clean and secure. Personnel should be trained to handle contaminated devices including procedures to follow when dealing with a spill.

All contaminated endoscopes and used within endoscopy units must be transferred to the Endoscopy Decontamination Units in dedicated basket trays. All contaminated endoscopes and TOE probes used external to the endoscopy unit must be transferred in dedicated containers and covered with a clear bag that is marked with a contaminated symbol.

Contaminated instruments from the community must be transported in a dedicated van and transport staff must be trained in accordance with regulations laid out in The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Act (NI) 2010.

15.0 HANDLING OF INSTRUMENTS ON LOAN FROM ANOTHER ORGANISATION

On occasion instruments are brought into the Trust on loan from a manufacturer or company. This may occur as part of assessment or tendering process prior to purchase or as a one off occasion to perform surgery that is exceptional. Instruments may also be brought in on loan where equipment has to go for repair.

This practice has the potential to increase the risks associated with instrumentation decontamination in regard to the use of appropriate processes and ensuring adequate traceability. Departments and / or clinical staff intending to accept the loan of instruments must notify HSDU in advance.

The Hospital Sterilisation Disinfection Unit Manager will ensure the following: -

- Instruments on loan must be subject to an indemnity and acceptance procedure in line with Trust Policy for the Management of Medical Devices
- Instruments on loan must arrive in the Hospital Sterilisation Disinfection Unit at least 48hrs before intended use
- If arriving in a sterile wrap all instrumentation must be opened and processed through the Hospital Sterilisation Disinfection Unit at Altnagelvin or OH&PCC
- Instruments must be recorded onto the IT barcoding system as being on loan and issued an individual barcode for traceability
- Instruments must be decontaminated after use but not wrapped
- A Hospital Sterilisation Disinfection Unit decontamination certificate must be filled in and accompany the instruments leaving the hospital facility.

Departments' trialling or borrowing instrumentation will also need to follow the steps below: -

- Ensure that the instrumentation is suitable for intended use in line with a manufacturer's instructions.
- Ensure that full decontamination instructions are available including any dismantling or handling instructions
- Ensure the availability of a detailed itemised list of contents including special instructions for sterilisation
- Ensure that the instrumentation is checked and a detailed list is correct preferably by clinical staff and a representative of the loaning company.

16.0 HANDLING AND USE OF INSTRUMENTATION AND ENDOSCOPES USED ON PATIENTS FALLING WITHIN ANY CATEGORY OF CJD

Prion disease is fortunately very rare but represents a huge challenge to conventional methods of decontamination. Transmissible Spongiform Encephalopathy agents are particularly resistant to standard physical and chemical methods of inactivation and decontamination. In most routine clinical contact, no additional precautions are needed for the care of patients in the risk groups. However, when certain invasive interventions are performed there is the potential for exposure. When considering measures to prevent transmission of CJD to patients or staff it is important to make a distinction between patient risk groups. It is useful to make a distinction between 'symptomatic' patients i.e. those who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD and 'at increased risk' patients i.e. those with no clinical symptoms, but who are at risk of increased risk of developing CJD or vCJD because of their medical or family history.

Guidance on the handling and use of instruments and endoscopes used on patients falling within any of the patient risk groups of CJD as defined above is clearly laid out

within the Trust's Policy for the Control of Transmissible Spongiform Encephalopathy. The policy provides advice on safe working practices with the aim of preventing the transmission of CJD, vCJD and other human prion disease in hospital and community care. There are continuous updates to this policy therefore it is strongly advised to access the most recent on line copy.

The following topics within the CJD policy are of particular relevance to decontamination: -

- Decontamination of instruments
- Decontamination of endoscopes
- Handling of instruments following use on patients with or at increased risk of CJD/vCJD
- Quarantining of surgical instruments and endoscopes following use on patients with possible CJD/vCJD

Further guidance on the handling and use of instrumentation and endoscopes used on patients falling within any category of CJD can be accessed via https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group#history

17.0 REFERENCES

Health Technical Memorandum 01-01 Management and Decontamination of Surgical Instruments (Medical Devices) used in Acute Care July 2016 accessed via https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care

Health Technical Memorandum 01-06 Decontamination of Flexible Endoscopes July 2016 accessed via https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes

BSEN 16442 Controlled Environment Storage Cabinets for Processed Thermolabile Endoscopes 2015 March accessed via https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/530419/HTM_0106_PartD.pdf

BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy November 2017 https://www.bsg.org.uk/clinical-resource/guidance-on-decontamination-of-equipment-for-gastrointestinal-endoscopy-2017-edition/

Medical Devices Regulations 2017. https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

Western Health and Social Care Trust

Appendix 1

Decontamination Working Group – Terms of Reference

Core Purpose

The overall aim of the Decontamination Working Group is to ensure compliance with guidance and standards on the decontamination of reusable Medical Devices including Endoscopes throughout the Western Health and Social Care Trust.

The Working Group's remit will include the following: -

1. In accordance with Controls Assurance Standards seek assurance that the Trust has a robust framework for the management of decontamination of reusable Medical Devices including Endoscopes.
2. Bi-annually review the Trust's Decontamination Policy to ensure that it reflects best practice and current legislation pertaining to decontamination.
3. Audit compliance with the Trust's Decontamination Policy and act on outcomes.
4. Review compliance with external ISO 13485:2016 Medical Devices quality audits and ensure action on recommendations.
5. Provide assurance that there are good systems in place for the training of staff involved in the decontamination of reusable Medical Devices including Endoscopes.
6. Review all decontamination related incidents, safety notices and guidance, recommending appropriate action to ensure continued compliance.
7. Review and prioritise decontamination risks, making recommendations as necessary. Ensure all risks are registered on the appropriate Risk Register.
8. Liaise where appropriate with local and national agencies in decontamination related matters.
9. Provide guidance to the Trust on the procurement, upgrading or replacement of decontamination equipment.
10. Provide quarterly briefing papers on all decontamination related matters to the Trust's Corporate Governance Sub-Committee.
11. Provide annual ISO audit reports to the Quality and Standards Committee
12. Escalate any decontamination related matters of concern to the Trust's Corporate Management Team.

Membership

- Decontamination Lead Director (Chair)
- Decontamination Manager (Vice Chair)
- Endoscopy Unit Manager
- Senior Dental Nurse
- Decontamination Engineer - Authorised Person (Decontamination) Alt & OHPCC
- Authorised Person (Decontamination) - SWAH
- Authorising Engineer (Decontamination Assurance) – Department of Health
- Head of Infection Prevention & Control
- Consultant Microbiologist

- Assistant Director of Nursing – Workforce Planning & Modernisation
- Theatre Manager
- Assistant Director of Acute Services – Nursing (Altnagelvin Hospital)
- Assistant Director of Acute Services – Nursing (Omagh & SWAH)
- Head of Podiatry Services
- Corporate Risk Manager
- Head of Gynaecology, Maternity & NNICU Services
- Logistics Manager – Procurement and Logistics Services
- Head of Patient & Client Support Services *{co-opted and attends as necessary}*

Quorum

A quorum will be achieved if the following members of the Working Group are present: -

- Chair or Vice Chair plus one representative from:-
  - Decontamination Engineer Group
  - Infection Control
  - Nursing

Administrative Arrangements

- Meetings will take place on a quarterly basis except in the case of urgent issues. In this case a sub-committee may be formed if required.
- The notes of each meeting shall be formally recorded by the Chairperson and circulated to all members as soon as possible after each meeting.
- All agenda items must be agreed with the Chair prior to each meeting. The agenda will close four working days prior to the meeting.
- Papers will be circulated at least three working days prior to the meeting. All late papers must be sent out by the member to the remaining members of the group once the agenda has closed and meeting papers issued.
- The Chair's PA must be informed of all apologies.
- Members must nominate a deputy to attend in their absence to provide an update on relevant agenda items.
- Each member must submit a written update for relevant agenda items if they do not nominate a deputy to attend on their behalf. Written updates must be forwarded to the Chair's PA at least two working days in advance of the circulation of meeting papers.

Review

The Working Group will review the terms of reference on a bi-annual basis and if necessary more frequently to ensure that they continue to reflect the Trust's obligations in respect of decontamination of reusable Medical Devices.

Western Health and Social Care Trust

Appendix 2 – Governance Assurance Framework Reporting Sub Committee Working Groups