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<th>Local Decontamination Unit (LDU) Operational Guidance</th>
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<td>Angela Rooke, Dental Nurse Team Leader (North) Caryn Gray, Acting Podiatry Service Lead</td>
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<tr>
<td>Policy application / Target Audience</td>
<td>Throughout NHS Ayrshire and Arran</td>
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<td>Policy Statement:</td>
<td>Local decontamination of invasive medical devices, including dental instruments, used on NHS patients must be performed in accordance with the Full Technical Requirements of the Glennie Framework (See Appendix 1). This document details how NHS Ayrshire and Arran directly managed services will meet these Standards. Independent Contractors may utilise this guidance to ensure that they are able to meet the required Standards.</td>
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<td>Decontamination Committee</td>
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<td>Electronic approval by:</td>
<td>Bob Wilson</td>
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<td>Infection Control Manager</td>
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1.0 INTRODUCTION

Local decontamination of invasive medical devices, including dental instruments, used on NHS patients must be performed in accordance with the Full Technical Requirements of the Glennie Framework (see Appendix 1). This document details how NHS Ayrshire and Arran directly managed services will meet these standards.

This guidance only applies to instruments that are classified as ‘Low Risk’ for the transmission of Creutzfeldt - Jakob disease (CJD) (see Appendix 2). Instruments classed as medium or high risk for transmission of CJD must be re-processed in an accredited sterilisation unit. The Centralised Decontamination Unit (CDU) responsible for sterilisation within NHS Ayrshire and Arran is based at Ayrshire Central Hospital (ACH).

Endoscopy Decontamination Units are not addressed within this document.

NHS Ayrshire and Arran Local Decontamination Units (LDUs), or those providing instruments for use on NHS patients, must meet the following criteria

- Reprocess devices used in procedures contacting tissues considered low risk for the transmission of CJD
- Sterilise unwrapped items
- The LDU is equipped to process only relatively low volumes of devices with efficient use of decontamination equipment
- Both re-processed and contaminated items may require to be transported to and from the LDU for domiciliary visits or outlying satellite clinics. They must be transported in line with the Guide - Carriage of Dangerous Goods Regulations with respect to Used Medical Devices (December 2013)
- Staff responsible for decontamination may have duties other than decontamination
- An LDU may serve two clinical disciplines i.e. dentistry and podiatry
- The LDU does not supply to a third party

2.0 MANAGEMENT RESPONSIBILITIES

2.1 Directly managed services

Executive Nurse Director

The Executive Nurse Director has overall management responsibility at NHS Board level for decontamination of invasive medical devices within NHS Ayrshire and Arran.
Infection Control Manager (ICM)

The ICM has designated written responsibility and authority to oversee all aspects of the decontamination processes on behalf of the Executive Nurse Director.

Infection Prevention and Control Team (IPCT)

The IPCT is responsible for advising on all infection control aspects of the decontamination process.

Estates Department

The Estates Department will maintain and test equipment in line with Scottish Health Technical Memorandum (SHTM) 2010 and SHTM 2030 on all bench top sterilisers, and ultrasonic cleaners in NHS Ayrshire and Arran LDUs.

Service Managers

Service Managers have operational responsibility for ensuring that their services are fully compliant with regulatory requirements, Scottish Government Health Department (SGHD) Decontamination Guidance and NHS Ayrshire and Arran policies and procedures.

LDU Lead Clinician

Service managers should identify a Lead Clinician for each LDU. This individual will assume the responsibilities of the ‘User’ as detailed in SHTM 2010 and SHTM 2030. The Lead Clinician is responsible for:

- Ensuring implementation of NHS Ayrshire and Arran decontamination policies and procedures within the LDU
- Developing local operational decontamination protocols for each LDU within their remit
- Ensuring all staff involved in local decontamination receive appropriate training
- Undertaking periodic audits of local decontamination within each LDU in their area
- Identifying deficiencies in practice or the environment, reporting these to line management and where appropriate taking corrective action
- Holding all documentation relating to all automated decontamination equipment in the LDU e.g. sterilisers, ultrasonic cleaners and washer disinfectors that is not otherwise held by the Estates Department
- Ensuring that the automated decontamination equipment is subject to periodic testing by estates or a decontamination engineer
- Ensuring that the automated decontamination equipment in the LDU has undergone appropriate testing, maintenance and has been certified ‘fit for use’ by a decontamination engineer
- Identifying the operators (where required)
- Maintaining the production records for all automated decontamination equipment
• Providing quarterly assurance reports to the Decontamination Committee

Operators

Clinical staff working in LDUs are designated as Operators. Their duties include:

• Undertaking local decontamination in compliance with this policy
• Operating decontamination equipment
• Performing and recording daily and weekly tests as required
• Performing routine maintenance such as cleaning decontamination equipment or changing water in sterilisers and ultrasonic cleaners as required by the engineers
• Maintaining all appropriate records including exception reports, operator tests and maintenance activity
• General housekeeping duties within the LDU
• Completing quarterly assurance reports for the LDU Lead Clinician)

3.0 INFECTION CONTROL

Detailed infection control guidance is contained in the Health Protection Scotland National Infection Prevention and Control Manual

3.1 Personal Protective Equipment (PPE)

The correct use of PPE during the decontamination process is essential to protect healthcare workers (HCWs). In most circumstances disposable non-sterile gloves and a disposable plastic apron are all that is required. For procedures where there is a risk of splashing or spraying of body fluids into the mucous membranes, then face and eye protection must be worn.

To ensure that processed instruments are not re-contaminated, it is essential that PPE is changed between the different stages of the decontamination process. The exact timing of the change will depend upon the decontamination equipment used and the layout of the decontamination facilities.

4.0 TRAINING

All staff working within the LDU must have completed induction training in order to operate the decontamination equipment. Competency assessments are required on an annual basis and should be completed by appropriately trained personnel. The documented training scheme requires training records for each individual to be kept, identifying that they have the required competency to carry out their assigned duties.
A departmental/practice skills register must be maintained by the Service Managers.

Staff must be trained in all aspects of reprocessing which are applicable to their role including:
- Cleaning
- Disinfection
- Disposal/return to decontamination
- Environmental cleaning
- Inspection
- Issue for use
- Packing
- PPE
- Sterilising
- Storage
- Transport

5.0 DECONTAMINATION CYCLE

The decontamination and re-use of invasive medical devices is a complex procedure. Action is required at a number of levels in order to ensure that the devices are safely and consistently decontaminated. The process begins with the acquisition of the device either through purchase or loan. The devices then enter the ‘Decontamination Cycle’ (see Figure 1). This cycle will continue until the devices are no longer fit for use and are disposed of by an approved route.

![Figure 1: Decontamination Cycle](image_url)
6.0 ACQUISITION

**Single use** devices (see Appendix 4) should be used whenever practicable and where they do not affect clinical outcome (see Section 7.0). However, if the items are not single use then they **must** be able to be decontaminated by the cleaning and sterilisation processes available within the LDU.

All staff competent and trained in decontamination must ensure all **re-usable** invasive medical devices that they currently have in stock can be decontaminated by the cleaning and sterilisation processes available in the LDU. This should be done by reference to the device manufacturers instructions.

Those responsible for the purchase of new devices must ensure prior to purchase that the devices are compatible with the decontamination processes available in the clinical areas. This information can be achieved by:

- Reviewing the device manufacturers instructions
- Identifying all decontamination processes including pre-sterilisation cleaning and sterilisation available in the relevant LDUs
- Developing a documented specification for the device being purchased

It is also essential that any ancillary materials such as chemicals, packaging and chemical indicators used in the decontamination process are appropriate for their intended use. This may be achieved by:

- Compliance with any relevant BS EN Standards
- Purchase from reputable suppliers
- Review of the decontamination equipment manufacturers instructions for compatibility
- Review of the device manufacturers instructions for compatibility

7.0 SINGLE USE DEVICES

Where it does not affect clinical outcome, and whenever practicable, single use invasive medical devices should be used. Factors that will influence the decision to utilise single use devices include:

- Disposal
- Economic considerations
- Instrument quality
- Reusable devices that are impossible or difficult to clean or sterilise
- Storage
- Supply

**Single use devices must not be reprocessed and/or reused under any circumstances.**
8.0 LOCAL DECONTAMINATION UNIT ENVIRONMENTS

The LDU environment is crucial to ensuring that effective decontamination is safely and successfully undertaken. The physical layout of existing premises will be the most significant factor in determining the most appropriate design for the LDU. Each unit must be assessed individually to ensure it meets the required standards. New LDUs must be developed in line with the national requirements. Suggested LDU schematics are contained in Decontamination Facilities – Local Decontamination Units SHPN 13 Part 2.

The design rationale should be to deliver a satisfactory decontamination process for medical devices that has no adverse effect on the clinical environment, patients and staff or on other medical devices.

Consideration should be given to the following:

- All decontamination should take place in a designated controlled area separate from the clinical area. Where this is not possible it should be noted on the risk register
- The passage of all materials and personnel should be controlled. Access to the decontamination area should be restricted to staff who have received appropriate training, and be secured to prevent public access
- There should be separate dedicated storage areas outwith the LDU for sterile and sterilised goods. Storage areas should be fitted with appropriate shelving, be cleanable, dry, well lit and secure
- The staff changing facilities where available should be maintained in a clean and tidy condition
- Cloakrooms and toilets must be separate from the decontamination area

9.0 PRE-STERILISATION CLEANING

Cleaning should completely remove all soiling. Thorough cleaning followed by thermal disinfection minimises the infection risk to staff when handling devices prior to sterilisation and reduces the microbial challenge for the sterilisation process.

9.1 Manual cleaning

Manual cleaning must only be used:

- When required by the manufacturers’ instructions
- When automated cleaning processes are not available
- To remove difficult to remove material e.g. dental cement, prior to automated cleaning

9.1.1 Facilities

Ultrasonic cleaning for pre-cleaning or manual cleaning may be required for some devices (manufacturer’s instructions must be followed). Wash and rinse sinks are required for devices which need to be manually cleaned.
**Equipment**

- Wash hand basin
- PPE storage
- Wall mounted cartridge soap dispenser
- Wall mounted paper towel dispenser
- Hands free clinical waste bin
- Wash and rinse sinks with draining boards – for equipment that cannot be cleaned by an automated process
- Ultrasonic cleaner
- Washer disinfectors
- Dedicated cleaning equipment
- Telephone or intercom
- Computer for administration area

A separate dedicated hand wash sink must be provided in this area. The sink should have the following features:

- No overflow
- No plug
- Elbow or lever operated mixer taps or non touch sensor taps
- The flow of the water from the taps does not discharge directly into the waste (plug hole)
- Remotely sited trap

### 9.1.2 Detergents

Manual cleaning must be carried out using a detergent with a neutral pH designated by the manufacturer for use on invasive medical devices.

### 9.1.3 Brushes

In some instances brushing is not required depending on the detergent used. In situations where brushing is required e.g. difficult to clean instruments, then brushes with soft bristles should be used. Wire brushes and pot scourers must not be used as these will damage the instruments.

Brushes must either be single use or subject to thorough cleaning after use and sterilisation at the end of the session.

### 9.2 Ultrasonic cleaners (Podiatry services only)

Automated cleaning using an ultrasonic cleaner is preferred to manual cleaning, providing the following conditions are met:

- The device manufacturer states that ultrasonic cleaning is an acceptable method of cleaning for that device
- The ultrasonic cleaner is properly installed, maintained and undergoes periodic testing (both by the company providing the device and by the estates department)

This guidance must be used in conjunction with the manufacturer's instructions for the safe operation of the ultrasonic cleaner.
The ultrasonic cleaner may only be operated by staff who have been trained to do so and are deemed as being an approved operator. On completion of the cycle, the operator must sign the print out for that cycle. Local arrangements must be made for the retention and storage of print outs and log books, which is currently 13 years.

9.2.1 Preparation of the ultrasonic cleaner

The ultrasonic cleaner must be prepared and in line with the manufacturer’s instructions.

9.2.2 Changing cleaning solution between sessions and at the end of each day

The ultrasonic cleaner must be drained and rinsed at the end of each session, no longer than every 4 hours and at the end of each day. This must be done in accordance with the manufacturer’s instructions. The waste water must be emptied via the drainage tap into the instrument rinse sink. The hand washing sink must not be used.

9.2.3 Safe operating reminders

▪ Do not operate the bath without liquid in the bath
▪ Always use a basket – the ultrasonic cleaner will be damaged if items are placed directly into the machine
▪ Ensure machine is filled with water to the fill line
▪ Ensure instruments are totally immersed in solution
▪ Use correct detergent
▪ Never put hot water into a cold chamber

9.2.4 Ultrasonic cleaner testing regime

Staff will perform a protein residue test using a ‘Protect Stick’, on a weekly basis in line with the manufacturer’s instructions.

The Estates Department will undertake a foil ablation test on all NHS Ayrshire and Arran ultrasonic cleaners as part of their quarterly maintenance programme.

9.3 Washer disinfectors

Washer disinfectors should be used for the reprocessing and decontamination of medical devices, including dental and podiatry equipment. Washer disinfectors must:

▪ Be fit for their intended purpose
▪ Carry out the processes of cleaning and disinfection consecutively
▪ Be subject to a planned programme of tests to validate their performance
Local Guidelines specific to either dentistry or podiatry must be used in conjunction with the manufacturer’s instructions for the safe operation of washer disinfectors.

Washer disinfectors must only be operated by staff who have been trained to do so and are deemed as being an approved operator. Local arrangements must be made for the retention and storage of print outs. Where digital data loggers are used the information must be downloaded from the memory card to a PC for future reference.

9.3.1 Preparation of the washer disinfector

The washer disinfector must be prepared and in line with the manufacturer’s instructions.

9.3.2 Washer disinfector testing regime

Staff will perform a protein residue test on a weekly basis in line with the manufacturer’s instructions.

Washer disinfectors must have testing completed in line with guidance set out in SHTM 2030.

9.4 Record keeping

National guidance requires that detailed records are kept for all parts of the decontamination process, including cleaning.

At present NHS Ayrshire and Arran operates an exception reporting system. A standard template is contained in Appendix 5. This should be completed each time there is a failure in the decontamination process.

10.0 PRE-STERILISATION INSPECTION

Staff must put on clean disposable non-sterile examination gloves and a clean plastic apron prior to inspecting the rinsed instruments.

In order to guarantee the sterilisation process, devices must be free of all physical contaminants, including organic matter and other debris e.g. dental cement. In addition, the instruments must be free from damage. Careful inspection of the instruments is required following the cleaning process.

The area designated for the post cleaning inspection must be well lit. This may require the provision of lighting specifically for the inspection task. For small intricate instruments magnification may be required to check the instruments.

As well as inspecting for functionality, staff must ensure that the device is assembled correctly (if required) and that it functions as intended. Staff require to be trained in the assembly of devices, where necessary, and the functioning of the instruments.
National guidance states that, wherever possible, post cleaning inspection should be undertaken by a member of staff who did not perform the pre-sterilisation cleaning process. It is recognised in many LDUs that this will not be possible.

Where an instrument is found to be physically soiled, then it should be returned for reprocessing through the appropriate cleaning process.

Instruments found to be damaged must be assessed to establish whether they may be repaired. Instruments that require maintenance, service or repair should be prepared in line with the guidance contained in the Health Protection Scotland National Infection Prevention and Control Manual. Instruments that are not suitable for maintenance, service or repair should be discarded in line with the Waste Management Policy.

If instruments require further decontamination prior to dispatch for maintenance, service, repair or disposal they should be processed separately from instruments that are to be used on patients.

**Dental hand pieces will require lubrication prior to sterilisation. This should be performed in such a way as to minimise environmental contamination.**

### 11.0 STERILISATION

Local decontamination may be carried out using 2 types of steriliser:

- Non-vacuum (bowl and instrument)
- Vacuum (porous load)

All local decontamination in primary care podiatry and dental services is undertaken using non-vacuum sterilisers. Each steriliser must be covered by Pressure Vessel Insurance and undergo annual inspection by the insurance provider. This is a legal requirement and any steriliser not insured must not be used under any circumstances.

### 11.1 Steriliser testing and maintenance

All benchtop steam sterilisers must undergo routine testing and maintenance in line with SHTM 2010 (see Appendix 1).

### 11.2 Non-vacuum sterilisers

The following criteria must be met for the use of non-vacuum sterilisers:

- Process unwrapped instruments only
- Process instruments without lumens or other constructional detail that would inhibit air removal (dental hand pieces can be processed in a non-vacuum autoclave)
• Instrument trays must have sufficient perforations to allow free passage of steam and air. Solid bottom containers must not be used.

11.3 Sterilisation process

Following inspection, instruments must be laid out on appropriate steriliser trays in a way that does not hinder the sterilisation process. Ensure that:

• Instruments do not touch each other
• Hinged instruments must be opened
• Instruments do not touch the chamber of the steriliser

Place the instruments in the steriliser. Remove PPE and apply alcohol hand rub to hands. Close steriliser door and commence chosen cycle.

11.4 Sterilisation verification

Each sterilisation cycle must be reviewed and formally accepted as satisfactory before devices from that cycle are released as sterilised and ready for use. The following criteria must be met before a product is issued for use or storage pending use:

• All maintenance and test records are up to date and satisfactory (check at beginning of session)
• The automated decontamination equipment automatic controller indicates a satisfactory (pass) cycle
• The temperature, pressure and cycle times were within the satisfactory limits:
  - Temperature 134°C - 137°C
  - Time > 3 minutes
  - Pressure 2.25 bar
• The load was correct for the steriliser

Any failure should be noted and a “Failure of Decontamination – Exception Reporting” form completed (see Appendix 5).

11.5 Post sterilisation storage

On completion of the sterilisation process the instruments must be handled and stored in a manner that does not lead to re-contamination from staff or the environment.

11.5.1 Unwrapped instruments

Unwrapped instruments must not be left in the steriliser overnight as they will remain wet, resulting in an increased risk of corrosion both to the instruments and the steriliser.

The opening of the steriliser door equates to the opening of a sterile pack. Sterility is no longer guaranteed. Instruments should be used as soon as possible on removal from the steriliser. Instruments laid out for use should be placed in an area designated for the placement of sterilised devices. They
must not be placed in areas where contaminated instruments are placed or be exposed to potential recontamination from the decontamination process.

Instruments that are not to be used immediately must be placed in pouches. These instruments are sterilised - they cannot be considered sterile. If the instruments are wet on removal from the steriliser then they should be dried with a clean disposable lint free cloth before placing in the pouches. The sterilised packs should be date stamped and stored in designated drawers or cupboards in clean dry conditions. They must be stored separately from sterile and single use instruments.

If this process is followed, the sterilised instruments can be stored for up to one year in a designated area until they are required for use. There is no requirement to re-sterilise the stored sterilised equipment prior to use unless the packaging is damaged.

11.5.2 Stock control

Storage of sterile, sterilised and single use instruments must ensure proper stock control and operate on a “first in, first out” (FIFO) principal to ensure that storage is not unnecessarily prolonged.

12.0 TRANSPORTATION

Instruments require to be transported between the different stages of the decontamination process. The layout of the local decontamination unit is the most important factor in determining the transportation procedures.

Transportation is required:
- From use to the pre-sterilisation cleaning area
- From the pre-sterilisation cleaning area to the sterilisation area
- From the sterilisation area to the storage area or point of use
- To domiciliary and outlying/satellite clinic setting
- From domiciliary and outlying/satellite clinic setting

12.1 Transportation for cleaning

12.1.1 Cleaning in treatment room

Wherever possible, cleaning of contaminated instruments must not take place in the treatment room. However, it is recognised that due to space constraints some clinics/treatment rooms where local decontamination is carried out currently will not be able to accommodate a separate decontamination room.

Where instruments can only be cleaned in the treatment room following use, they must be removed immediately following treatment to a designated area (workspace or sink) to await reprocessing.
12.1.2 Cleaning outwith treatment room

Used devices must be transported safely from the clinical area where used to the LDU. They should be transported in solid walled, leak proof and lidded containers. When transported through public access areas the containers should be secure. Container labels should indicate that the contents are used medical devices and if they are transported off the premises the label should give details of the sender and the intended recipient.

12.2 Transportation for sterilisation

12.2.1 Sterilisation in same room as cleaning activity

Following cleaning, drying and inspection instruments must be placed immediately into the steriliser for processing. Instruments must follow a one way flow and must not be re-contaminated by any other part of the decontamination process or the environment.

12.2.2 Sterilisation in different room from cleaning processes

Instruments that have been cleaned remain contaminated until they undergo sterilisation. They must be transported in a safe and secure manner to the area for sterilisation.

In two room LDUs with pass through washer disinfectors it is only possible to remove cleaned and disinfected instruments from the washer disinfectors in the sterilisation room. Items which cannot be processed in the washer disinfector can be transferred to the sterilisation room via the pass through hatch.

If the sterilisation room directly adjoins the cleaning room then the instruments should be placed on steriliser trays for transportation to the steriliser.

Used devices must be transported safely from the clinical area where used to the LDU. They should be transported in solid walled, leak proof and lidded containers. When transported through public access areas the containers should be secure. If the contents are to be transported or handled by a person other than that who packaged them, then container labels should indicate that the contents are used medical devices and give details of the sender and the intended recipient.

12.3 Transportation for use post sterilisation

12.3.1 Clinical activity in same room as sterilisation process

Where sterilisation takes place in the treatment room and the instruments are intended for immediate use then they should be removed from the steriliser and used direct from the steriliser tray.

If the instruments are not required to be sterile and are to be stored for later use then they should be packaged as detailed in section 11.5.1.
12.3.2 Clinical activity in different room, from sterilisation process

Sterilised devices must be transported safely from the LDU back to the clinical/storage area. They should be transported in solid walled, leak proof and lidded containers. When transported through public access areas the containers should be secure. If the contents are to be transported or handled by a person other than that who packaged them, then container labels should indicate that the contents are sterilised medical devices and give details of the sender and the intended recipient.

12.4 Domiciliary and outlying/satellite clinic visits

Instruments must be transported to and from domiciliary and outlying /satellite clinic visits in a manner that protects sterilised instruments from contamination and prevents contaminated instruments presenting a risk to people, other instruments or the environment.

12.4.1 Transportation of sterilised Instruments to domiciliary and outlying /satellite clinic visits

Sterilised instruments intended for use in domiciliary and outlying /satellite clinic visits should be placed in sterilisation pouches immediately following sterilisation. They should be placed in a suitable rigid, lidded container indicating sterilised instruments. This container must not be used for contaminated instrument stock.

12.4.2 Transportation of contaminated instruments from domiciliary and outlying /satellite clinic visits

Used instruments should be placed into a clear polythene bag and then placed into a UN approved container for transport to LDU. This container must not be used for sterile or sterilised instrument stock. It must be clearly marked ‘USED MEDICAL DEVICES’.

The container should be transported in the boot of the Clinician's car and returned for reprocessing at an appropriate LDU as soon as practicable after completion of the domiciliary visits or outlying satellite clinic visits. Used Medical Devices and Sterilised Medical Devices should be transported in the vehicle in a manner that prevents cross contamination.

Other local arrangements may be in place for the transportation of contaminated and sterilised instruments by staff other than the clinician.

12.5 Decontamination of transit containers

Transit containers must be decontaminated at least daily. They should be washed with detergent and water or detergent wipes and rinsed and dried. Any leakage of body fluids into the container must be disinfected in line with the Health Protection Scotland National Infection Prevention and Control Manual.
13.0 TRACEABILITY

Traceability of instruments through the decontamination process and onto each patient is extremely difficult to achieve when instruments are reprocessed in a LDU in the primary care setting.

13.1 Traceability through the process

Due to the volume of individual instruments and the lack of individual identification of these instruments it is extremely difficult to have a robust system that will track each instrument through the local decontamination process. However, it is important that any failures in the decontamination process are clearly identified along with the remedial action taken to rectify the problem. Where failures occur then “Failure of Decontamination - Exception Reporting” form should be completed (see Appendix 5).

13.2 Traceability to patients

The problems identified in section 13.1 also make it difficult to employ traceability to patients.

14.0 ENVIRONMENTAL CLEANING

National guidance sets out requirements for cleaning the LDU environment. Independent Contractors should consult this guidance and assess the most practicable way of implementing the standards. NHS Ayrshire and Arran premises will be cleaned in line with “Specifications and Frequencies” that reflect the national guidance.

14.1 Floors

Floors should be cleaned daily using a free rinsing neutral detergent and hot water. Routine use of disinfectants is not required. Where there is no dedicated cleaning equipment for clean and dirty areas then clean areas e.g. sterilisation and treatment areas, should be cleaned before dirty areas, manual washing facilities.

14.2 Work surfaces

All surfaces should be washed with a free rinsing detergent and hot water and then dried on a daily basis.

14.3 Spillages

All spillages and environmental contamination of blood or other body fluids must be decontaminated in line with the guidance contained in the Health Protection Scotland National Infection Prevention and Control Manual.
14.4 Monitoring

Regular monitoring of cleaning is undertaken in all directly managed NHS Ayrshire and Arran premises. Independent contractors should ensure that routine documented inspection of cleaning is undertaken in their local decontamination units.

15.0 REFERENCES


4. NSS Compliant Dental Local Decontamination Units in Scotland (Primary Care (May 2013) Available at: http://www.hfs.scot.nhs.uk/services/decontamination-services/guidance/ (Last accessed 04/09/2017).

## APPENDIX 1 GLENNIE FRAMEWORK

### GLENNIE FRAMEWORK TECHNICAL REQUIREMENTS

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<th>Risk Category</th>
<th>Function</th>
<th>Interim Requirements</th>
<th>Full Requirements</th>
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| **LOW**       | Equipment | ▪ Ability to demonstrate that washer disinfectors are fit for purpose, operating effectively, maintained adequately, and tested and validated in line with current guidance.  
▪ Compliance with SHTM 2010 (sterilisers).  
▪ Compliance with the protocol on the local decontamination of surgical instruments (manual cleaning) if neither a washer disinfector nor ultrasonic cleaner reasonably practical. | Interim Requirements plus compliance with:  
SHTM 2030 (if use of washer disinfector not reasonably practicable then utilization of ultrasonic washer indicated). |
|               | Facilities | ▪ Effective separation of clean and dirty processes in accord with the protocol on the local Decontamination of Surgical Instruments. | As interim requirements. |
|               | Staff | ▪ All personnel carrying out decontamination processes have documented training needs assessment and record of training received. | Training needs and records as part of formal quality assurance system. |
|               | Management | ▪ Senior member of staff with documented responsibility for decontamination processes and capable of assessing and treating risks associated with ineffective decontamination processes.  
▪ Senior manager with overview in accord with HDL 2001(10) if decontamination taking place in NHS Trust. | Interim Requirements plus compliance with:  
▪ MDA Device Bulletin DB 9801 Medical Devices and Equipment Management for Hospital and Community based organisations. |

## APPENDIX 2 CATEGORISATION

### CATEGORISATION OF CLINICAL PROCEDURES BY RISK OF TRANSMISSION OF CREUTZFELDT-JACOB DISEASE (CJD)

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<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tr>
<td>High Risk</td>
<td>- All procedures that involve piercing the dura, or contact with the trigeminal and dorsal root ganglia, or the pineal and pituitary glands.</td>
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<td>- Procedures involving the optic nerve and retina.</td>
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<tr>
<td>Medium Risk</td>
<td>- Other procedures involving the eye, including conjunctiva, cornea, sclera and iris.</td>
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<td></td>
<td>- Procedures involving contact with lymphoreticular system (LRS).</td>
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<tr>
<td></td>
<td>- Anaesthetic procedures that involve contact with LRS during tonsil surgery (for example laryngeal masks).</td>
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<tr>
<td></td>
<td>- Procedures in which biopsy forceps come into contact with LRS tissue.</td>
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<tr>
<td></td>
<td>- Procedures that involve contact with olfactory epithelium.</td>
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<tr>
<td>Low Risk</td>
<td>- All other invasive procedures including anaesthetic procedures and procedures involving contact with the cerebral fluid.</td>
</tr>
</tbody>
</table>

## APPENDIX 3 CORRECT USE OF PPE

### CORRECT USE OF PERSONAL PROTECTIVE EQUIPMENT

<table>
<thead>
<tr>
<th>Manual Cleaning</th>
<th>Ultrasonic Cleaning</th>
<th>Washer Disinfector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Put on PPE</td>
<td>Put on PPE</td>
<td>Put on PPE</td>
</tr>
</tbody>
</table>

#### Handling contaminated equipment
- Place in U/S
- Remove & dispose of PPE
- Hand Hygiene
- Switch on U/S
- Switch on WD
- Remove & dispose of PPE
- Hand Hygiene

#### Cleaning process
- Put on PPE
- Remove & dispose of PPE
- Hand Hygiene
- Put on PPE
- Remove from U/S
- Remove & dispose of PPE
- Hand Hygiene
- Put on PPE
- Remove from rinse sink & place on drainer
- Remove & dispose of PPE
- Hand Hygiene
- Put on PPE
- Remove from rinse sink & place on drainer
- Remove & dispose of PPE
- Hand Hygiene
- Put on PPE

#### Drying
- Hand hygiene
- Put on PPE

#### Inspection
- Remove from WD

#### Packaging (if appropriate)
- Place in steriliser
- Remove & dispose of PPE
- Hand Hygiene
- Place in steriliser
- Remove & dispose of PPE
- Hand Hygiene
- Place in steriliser
- Remove & dispose of PPE
- Hand Hygiene

#### Sterilisation
- Commence sterilisation
- Commence sterilisation
- Commence sterilisation
APPENDIX 4 SYMBOLS USED IN MEDICAL PACKAGING

- **BATCH CODE**
  - **LOT** ABC 1234
  - Synonyms for this are:
    - Lot number
    - Batch number

- **DATE OF MANUFACTURE**
  - 1999-12

- **DO NOT REUSE**
  - Synonyms for this are:
    - Single-use
    - Use only once

- **USE BY DATE**
  - 2002-06-30

- **SERIAL NUMBER**
  - SN ABC123

- **CATALOGUE NUMBER**
  - REF ABC123

- **ATTENTION, SEE INSTRUCTIONS FOR USE**

- **STERILE**
  - **STERILE EO** Method of sterilization: ethylene oxide
  - **STERILE R** Method of sterilization: radiation
  - **STERILE T** Method of sterilization: steam or dry heat

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## APPENDIX 5 FAILURE OF DECONTAMINATION

### FAILURE OF DECONTAMINATION – EXCEPTION REPORTING

<table>
<thead>
<tr>
<th>CLINIC LOCATION</th>
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</table>

<table>
<thead>
<tr>
<th>Date &amp; Time</th>
<th>Type of Equipment &amp; Serial Number</th>
<th>Cycle Number</th>
<th>Failure Code and Reason</th>
<th>Action Taken</th>
<th>Outcome</th>
<th>Signature</th>
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