NHS National Services Scotland

NHSScotland National Decontamination Guidance Management of on Loan Reusable Medical Devices Roles and Responsibilities

Scottish Health Technical Memorandum 01-08

SHTM 01-08

Draft 0.4 March 2025

NHSScotland Assure
Quality in the healthcare environment

Contents

Executive summary

The revision of National Services Scotland (NSS) National Decontamination Guidance 'Management of on Loan Reusable Medical Devices Roles and Responsibilities' is required due to the publication of new UK legislation (see ref 1), regulations (see ref 2) and standards (see ref 3, 4, and 5) as applicable to GB that is England, Scotland and Wales, as a result of the United Kingdom's exit from the European Union. In addition, the title of this document has been changed to Scottish Health Technical Memorandum (SHTM) 01-08 to better align this reusable medical device (RMD) decontamination guidance with other parts of the SHTM 01 series.

This guidance has also considered lessons learned, from a review of reported adverse incidents. Evidence from Safety Action Notices (SANs) and Patient Safety Action Notices (PSAN) published by the NHSScotland Assure Incident Reporting and Investigation Centre (IRIC) and the UK Medicines and Healthcare Products Regulatory Authority (MHRA) (see ref 6, 7, and 8). This evidence shows that effective control of on loan RMDs continues to present challenges to theatres, clinics, Central Decontamination Units (CDUs) as defined in 'Scottish Health Planning Note (SHPN) 13 part 1' (see ref 9), and 'GUID 5014 - NHSScotland Requirements for Compliant Central Decontamination Units' 2024 (see ref 10), manufacturers and suppliers (see ref 11, 12 and 13). Therefore, these devices must be managed in a consistent way to ensure patient and staff safety.

The aim of the guidance is to ensure on loan medical devices are delivered to theatre fit for purpose, on time and returned safely to the supplier. Healthcare facilities for example operating theatres may use on loan RMDs to provide additional inventory for a range of procedures. To minimise the risk of any cross contamination, all Manufacturers and healthcare facilities are obliged to ensure any on loan RMDs have only been used in the treatment of Humans. That is tracking and traceability measures must be in place to prevent Veterinary instruments entering the CDU/ theatres workstream. Evidence should also be available to show that all on loan RMDs have been appropriately processed prior to deliver/ use,

This guidance also includes roles and responsibilities for theatres, CDUs (sometimes referred to as Sterile Service departments) and manufacturers/ suppliers, and covers the on-loan cycle, from the decision to order a on loan RMD, to returning the on loan RMD to the supplier.

Where on loan devices are required frequently, consideration should be given to increasing the buffer stock held by a service. This would help provide devices with a known decontamination history while supporting NHSScotland's climate emergency and sustainability strategy: 2022-2026 Net Zero strategy (see ref 14).

Additional information on a systematic approach to the acquisition, deployment, maintenance, repair and disposal of on loan medical devices and medical device training can be found in Scottish Health Technical Note (SHTN) 00-04 Guidance on Safe

Management of Medical Devices and Equipment in Scotland's Health and Social Care Services V 3.0 published in 2024 (see ref 15).

1. Background

Who is this Guidance for?

1.1. This guidance has been produced to assist those responsible for, or involved with, the distribution, acquisition or decontamination of on loan reusable medical devices (RMDS) within Central Decontamination Units (CDUs). In addition, the title of this document has been changed to Scottish Health Technical Memorandum (SHTM) 01-08 to better align this RMD decontamination guidance with other parts of the SHTM 01 series.

1.2. Version 1.0 of 'NHSScotland National Decontamination Guidance Management of on Loan Reusable Medical Devices - Roles and Responsibilities was developed in 2015. This revision reflects the publication of new UK legislation (see ref 1) regulations (see ref 2) and standards (see ref 3, 4, and 5) as applicable to GB and guidance (see ref 9, 10 and 16).

Aim of the guidance

1.3. The aim of the guidance is to ensures on loan RMDs are delivered to theatre fit for purpose, in a timely manner and returned safely to the supplier. Delivering a positive health impact by ensuring that on loan medical devices are:

- safe
- available at the designated time
- managed by staff trained in reprocessing on loan medical devices
- reprocessed, packaged and transported in a manner that complies with the UK Medical Device Regulations (MDR) 2002 (see ref 1) (Amendment) (EU Exit) Regulations 2020)
- reprocessed, packaged and transported in a manner to prevent damage to instruments and risks to staff
- returned to the supplier in a safe and decontaminated state

1.4. The lack of clear on loan RMD guidance could result in delayed and cancelled patient treatment, injury and cross infection. A review of Safety Action Notices (SANs) and Patient Safety Action Notices (PSAN) published by Incident Reporting and Investigation Centre (IRIC) and Medicines and Healthcare Products Regulatory Authority (MHRA) (see ref 6, 7, and 8) identified that some processed instruments have been released for use in an unsterile state, that on loan RMDs have arrived at CDUs dirty or corroded and that some devices previously used by Veterinary services were sent to CDU/ theatres as on loan devices, posing a risk of cross contamination. Therefore, evidence shows that effective control of on loan RMDs continues to present challenges to theatres, clinics, sterile services, manufacturers' and suppliers. Lapses in planning, policies, communications and instructions (see refs 11, 12 and 13) were found to have contributed to the risks associated with on loan RMDs, including:

- patient, staff and supplier safety
- cross infection
- injury from defective on loan RMDs
- damaged or missing on loan RMDs
- cost of replacements
- disputes with suppliers
- cancellation or delay of surgical procedures
- financial burdens to rectify these risks

1.5. This is of particular concern to CDU staff responsible for inspecting, processing, storing, and issuing on loan RMDs to theatres. In addition, on loan RMDs may include many complex instruments which could be new or unfamiliar to CDU staff and require additional time to validate the decontamination process and provide staff training (see ref 9 and 10).

1.6. Where on loan devices RMDs are required frequently, consideration should be given to increasing the buffer stock of these devices held by a service. This would ensure devices with a known decontamination history were in use and support NHSScotland's Net Zero sustainability strategy: 2022-2026 (see ref 14) by reducing the need for transportation to and from suppliers, minimising the use of fossil fuels and their resulting carbon emissions.

Scope

1.7. This guidance is applicable to on loan RMDs from all suppliers. Where on loan RMDs can be configured as:

- Instrument sets in reusable containers or trays
- Individual instruments packaged as sterile
- non sterile instruments requiring processing in an NHS CDU (see ref 9, 10 and 15) or, a contracted sterilization services operating to a quality management System (QMS) accredited to British Standard (BS) EU ISO 13485: 2021 see ref 3).

Out of scope

1.8. Loan endoscopes and Endoscope Decontamination Units (EDUs) are not within the scope of this guidance. Loan devices for use in a dental practice processing in a Local decontamination Unit (LDU) are not covered in this SHTM. Guidance can be found in SHTM 01-06 (see ref 17) and SHTM 01-05 (see ref 18) respectively.

2. Theatre/ clinic roles and responsibilities

Factors to consider before acquisition

2.1. The overall responsibility for management of on loan Reusable Medical Devices (RMDs) resides with the operating theatres requesting the RMD (see ref 19). This covers all stages of the process, from assessing the requirement for on loan RMDs, to returning them to the supplier. Whenever possible the need for on loan RMDs should be identified as soon as possible by theatre teams.

2.2. All RMDs on loan from suppliers or manufacturers should be subject to a Service Level Agreements (SLAs) which defines the on loan RMDs requirements during acquisition, deployment, decontamination and return to the supplier (see ref 10). Any responsibilities or liabilities for maintenance, repair and disposal of RMDs, should also be included.

2.3. Scottish Health Technical Note (SHTN) 00-04 Guidance on Safe Management of Medical Devices and Equipment in Scotland's Health and Social Care Services V3.0 published in 2024 (see ref 15) outlines a systematic approach to the acquisition, deployment, maintenance, repair and disposal of medical devices and medical device training. Medicines and Healthcare Products Regulatory Authority (MHRA) Managing Medical Devices 2021 (see ref 20) also provides guidance for manufacturers and suppliers of RMDs.

Emergency or trauma cases

2.4. Where additional on loan devices are required for emergency or trauma procedures, inform the Central Decontamination Units (CDUs) of the type of device requested and specify that they should be regarded as and a high priority and 'fast tracked' to expedite their supply, checking and processing.

Staff education and training

2.5. Ensure staff have a full understanding of on loan RMD policies and procedures and recognise that additional time that may be required for processing on loan RMDs that are unfamiliar to theatre or CDU staff. Co-ordinate with all interested parties to enable the supplier's trainer to deliver training and update as required. Ensure the manual handling regulations (see ref 21) are included in any training, and that all Infection Prevention and Control (IP&C) measures are implemented as required by the National Infection Prevention and Control Manual (NIPCM) (see ref 22).

Ordering on loan RMDs

2.6. As soon as staff become aware there is a need to procure an on loan RMD theatre staff should inform the supplier and CDU.

2.7. Staff responsible for sourcing on loan RMDs should discuss the requirements with the surgeon prior to ordering. If the device is new or unknown to staff, where possible their supply should be organised at least one week prior to surgery. On ordering the on loan RMD:

- request the Manufacturer's Instructions and forward to the CDU for approval before the order is placed, to confirm that they can be processed by the CDU
- specify quantities and time of delivery
- inform CDU when the order has been confirmed
- arrange for CDU to receive the sets 48 hours prior to planned procedure time
- raise purchase order

Pre operative checks

2.8. On arrival of the on loan RMD from the supplier and before opening any protective packaging check that:

- all requested RMDs sets are present and of the correct specification
- there are no signs of staining or damage

2.9. Where an on loan RMD was requested as 'sterile', check any protective packaging is intact and that labelling is consistent with the requirements for 'sterile' product, as stated in the relevant British standards (see ref 3, 4, and 5).

2.10. Where an RMD is supplied nonsterile it should be accompanied by a decontamination certificate from the previous user stating the level and type of decontamination undertaken.

2.11. Prior to sending to the CDU for reprocessing also ensure the following documents are available:

- indemnity certificate
- instruction for use (IFU) (including any validated decontamination process)
- list of tray contents or images of each device with name for each tray

2.12. Advise the supplier of any discrepancies immediately.

2.13. When introducing on loan medical devices onto the theatre register or electronic tracking system (preferred) for traceability:

- identify and tag the RMDs as: 'On Loan'
- track on loan RMDs details to the patient
- prevent on loan RMD set migration in theatre

Post operative checks

2.14. Where on loan RMDs provided sterile were not opened during the procedure they can be retained by theatre, ready to return to the supplier. The CDU should be informed.

2.15. Prior to returning any RMD to the CDU for reprocessing after use:

- ensure all opened devices and sets are intact and no migration of instruments has occurred
- all devices are returned to the CDU post use
- that on loan RMDs and documents are complete and in order
- allow the CDU at least 48 hours to process and issue decontamination certificates

Returning on loan RMDs to a supplier

2.16. Before returning on loan RMDs to the supplier:

- ensure protective packaging is intact and sterility has not been compromised, and the package has been labelled as **sterile** upon delivery from CDU
- the RMD is packaged appropriately, to prevent damage on return to supplier
- agreed tracking and traceability information is included
- arrange uplift by supplier as agreed and sign off in the theatre tracking system

Note 1 Where the device cannot be steam sterilised, decontaminate as agreed with the manufacturer or supplier and in line with the IFUs. Complete a decontamination certificate stating the type and level of decontamination carried out post use, for example manual cleaning or disinfection.

Reporting non-conformances, complaints and incidents

2.17. Report non-conformances or other complaints to the relevant parties (theatre manager, CDU manager and/ or supplier) within 48 hours.

2.18. In the event of an incident/ defect, immediately complete any local reporting system and notify:

- the manufacturer/ supplier
- theatre and CDU managers
- the Infection Prevention and Control team,
- Incident Reporting and Investigation Centre (IRIC)

2.19. Where a complaint is received from the CDU or supplier:

- acknowledge within one working day
- agree a plan of corrective actions
- complete actions within the agreed timescale with the complainant

- retain all communications, and electronic records. Maintain and archived as per local policy

Additional responsibilities for 'high risk' potential Creutzfeldt Jakob disease (CJD)/ Variant Creutzfeldt-Jakob disease (vCJD) patients

2.20. Prior to any request for on loan RMD which may be required for 'High Risk Procedures' as listed in National Institute for Health and Social Care Excellence (NICE) Interventional procedures guidance (IPC) 666 Appendix D, 2020 (see ref 23), theatre staff should follow the Advisory Committee on Dangerous Pathogens (ACDP) Transmissible Spongiform Encephalopathy (TSE) subgroup guidance - Annex J: 2014' (See ref 24) on identifying patients who have been "notified that they are at increased risk" of Creutzfeldt-Jakob disease (CJD/ vCJD).

2.21. If the patient, family member or representative cannot provide a definitive answer regarding CJD/ vCJD status, then the procedure should proceed. The RMDs should be cleaned as per ACDP TSE guidance Annex E (see ref 25) sent to the CDU for processing as normal, then quarantined until the patient's status is confirmed.

2.22. All electronic and paper records should be maintained and archived in line with local policy and the Scottish Government Records Management: NHS Code of Practice (Scotland) (see ref 26).

3. CDU roles and responsibilities

3.1. Prior to agreeing to process on loan reusable medical devices (RMDs), the Central Decontamination Units (CDU) should ensure that all on loan RMDs are compatible with their existing decontamination processes. The CDU should consider on loan RMDs as contaminated upon delivery and appropriate personal protective equipment (PPE) should be worn throughout any inspection and decontamination (see ref 9, 10, 16 and 22).

Staff education and training

3.2. On notification of the need to process on loan RMD sets, ensure a full understanding of the supplier's reprocessing instructions. When unfamiliar on loan RMDs are received, additional training and processing time may be required. Advise theatre when on-site training is required.

3.3. Upon arrival of the on loan RMDs confirm and check:

- that the device has only ever been used in the treatment of humans
- that all requested on loan medical devices and documents are present
- disassemble in line with 'Manufacturers' Instructions for Use' (IFU) and inspect for contamination, corrosion and assess if the device is considered difficult to clean

3.4. If a discrepancy occurs notify theatre as soon as possible (preferably within an hour of receipt). Quarantine and arrange for theatre supplier and/ or manufacturer to inspect.

Tracking on loan devices

3.5. All on loan RMDs must be tracked through the CDU decontamination process. On arrival at the CDU enter the device details onto CDU tracking system to prevent tray migration of on loan RMDs throughout process.

3.6. Decontaminate using CDU validated procedures and in accordance with written manufacturer's processing instructions.

3.7. Send appropriately packaged sterile RMDs to theatre, accompanied with a list of the contents of each set.

3.8. After use on loan RMDs should be cleaned, disinfected and sterilized in line with the manufacturer's instructions and any Service Level Agreement (SLA), prior to returning to theatres for reuse or return to the suppliers.

In emergency or trauma cases

3.9. Where theatre request processing of on loan RMDs due to an emergency or trauma surgery, where possible:

- expedite the checking, processing and delivery of on loan RMDs
- regard devices as a priority
- notify theatres of any issues or delays as soon as possible

Reporting non-conformances, and incidents

3.10. In the event of an incident/ defect, immediately notify:

- the manufacturer/ suppliers
- theatres and any local reporting system
- Infection Prevention and control team
- The Incident Investigation and Reporting Centre (IRIC)

3.11. Raise complaints and non-conformities with the relevant parties (theatres, supplier and/ or manufacturer) within 48 hours and:

- record the event in the CDU quality system as a non-conformance
- undertake a corrective action and preventative action plan (CAPA) within the Quality Management System (QMS) (See ref 3) and monitor trends
- report at decontamination governance meetings

Receiving a complaint

Where a complaint is received from the device supplier or theatre:

- acknowledge within one working day
- propose corrective actions with the complainant
- complete actions within the agreed timescale

3.12. Maintain and archive paper and electronic records in accordance with British Standard (BS) EN ISO 13485 quality management system (See ref 3).

4. Supplier roles and responsibilities

Service level agreement

4.1. Where a Service Level Agreement (SLA) is in place suppliers are responsible for providing safe, fit for purpose and traceable on loan reusable medical devices (RMDs) to agreed timescales.

4.2. Provide on loan RMDs meeting the required standard and quality as follows:

- ensure only devices intended for use on humans are selected
- the cleanliness, functionality and completeness of on loan RMDs
- package appropriately
- ensure compliance with the facility's handling policy
- on loan medical RMDs should be **CE** or **UKCA** marked unless exempt, for example custom made devices (see ref 1 and 2)

Staff education and training

4.3. Ensure training in the handling, use and reprocessing of unfamiliar devices, is provided for Central Decontamination Unit (CDU)/ theatre staff and for other on loan RMDs as requested. Provide full supporting documentation including:

- reprocessing instructions conforming to British Standard (BS) EN ISO 17664 (see ref 4)
- a decontamination certificate where the device is not sterile
- a detailed tray lists for the on loan RMDs
- product codes and photographic documentation as necessary
- a delivery note

4.4. Ensure weight of the on loan RMDs do not present a manual handling risk.

4.5. Ensure on loan RMDs are controlled on a robust tracking system.

Rectifying supply discrepancies

4.6. Where a signed indemnity agreement is in place, follow the master terms and conditions. Ensure an immediate supply of a replacement device or, inform theatre and CDU of the length of any delay where anticipated.

4.7. Prior to uplift check that the on loan RMD has been processed and labelled as sterile. Where a device is not suitable for sterilization ensure that a decontamination certificate has been provided and shows the agreed decontamination method has been carried out.

4.8. Sign off request, as agreed with customer (theatres or CDU as relevant).

Reporting non-conformances, complaints and incidents

4.9. In case of a defect, or where a non-conformity is discovered on return of the on loan RMD report and raise complaints directly to the relevant parties (Theatres and/ or CDU) within 48 hours.

Receiving complaints

4.10. Where a complaint is received from the CDU or theatre:

- acknowledge within one working day
- propose corrective actions
- agree corrective action with the complainant and complete within the agreed timescale

Where an incident has occurred:

- inform the National Services Scotland (NSS), Incident Investigation and Reporting Centre (IRIC) and Medicines & Healthcare products Regulatory Agency (MHRA)
- maintained communication with all parties until the issues have been satisfactorily resolved
- maintain and archive paper and electronic records in accordance with BS EN ISO 13485: 2021 quality management system (See ref 3)

Abbreviations

ACDP: Advisory Committee on Dangerous Pathogens

BS: British Standard

CAPA: Corrective Action and Preventative Action Plan

CDU: Central Decontamination Unit scope of decontamination activities

CJD: Creutzfeldt Jakob disease

EDU: Endoscope Decontamination Unit

IFU: instruction for use

IP&C: Infection Prevention and Control

IPC: Interventional Procedures Guidance

IRIC: Incident Reporting and Investigation Centre

LDU: Local decontamination Unit

MDR: Medical Device Regulations

MHRA: Medicines & Healthcare products Regulatory Agency

NIPCM: National Infection Prevention and Control Manual

NICE: National Institute for Healthcare Excellence

NSS: National Services Scotland

PPE: Personal Protective Equipment

PSAN: Patient Safety Action Notices

QMS: Quality Management System

RMD: Reusable Medical Devices

SAN: Safety Action Notice

SHPN: Scottish Health Planning Note

SHTM: Scottish Health Technical Memorandum

SHTN: Scottish Health Technical Note

SLA: Service Level Agreement

TSE: Transmissible Spongiform Encephalopathy

vCJD: Variant Creutzfeldt-Jakob disease

Glossary

Complaint - written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices.

Corrective action - action to eliminate the cause of a nonconformity and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

[SOURCE: ISO 9000:2015, 3.12.2, modified - Note 3 to entry has been deleted

Disinfection - process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose IFU portion of the accompanying information that is essential for the safe and effective intended use of a medical device or accessory directed to the user of the medical device

Note 1 to entry: The instructions for use (IFU), or portions thereof, can be located on the display of a medical device or its accessory.

[SOURCE: ISO 20417:2021, 3.11, modified]

Labelling - label, IFU, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping document [SOURCE: EN ISO 13485: 2021 section 3 definitions]

Life-cycle - all phases in the life of a medical device, from the initial conception to final decommissioning and disposal [SOURCE: EN ISO 13485: 2021

Manual cleaning - removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process [SOURCE: ISO 11139:2018, 3.46, modified]

Medical device - material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury
- investigation, replacement, modification, or support of the anatomy, or of a physiological process
- supporting or sustaining life
- control of conception

- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions, but not in others include:

- items specifically intended for cleaning or sterilization of medical devices
- pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization
- disinfection substances
- aids for persons with disabilities
- devices incorporating animal and/ or human tissues
- devices for in vitro fertilization or assisted reproduction technologies

[SOURCE: ISO 13485:2016, 3.11, modified - The first two list items in Note 1 to entry have been added.

Medical device manufacturer - natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: This “natural or legal person” has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction

Processing - preparation of medical device, accessory - activity to prepare a new or used medical device or accessory for its intended use

Protective packaging - configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use

Reusable medical device - medical device (3.5) designated or intended by the medical device manufacturer (3.6) as suitable for processing (3.8) and reuse

Note 1 to entry: This is not a medical device that is designated or intended by the manufacturer for single use only. [SOURCE: ISO 11139:2018+ A1: 2024,

Sterile - free from viable microorganisms

References

These references were current at the time this document was produced. Anyone using this document should ensure that they refer to the current version of these references.

1 **The Medicines and Medical devices Act: 2021.** Medicines and Medical Device Act 2021 UK GOV

2 **The Medical Device Regulations:** The Medical Devices Regulations 2002 (statutory instrument 2002 No.618 Consumer Protection) and The Medical Devices (amendment)(GB) Regulations 2023 (statutory instrument 2023 no. 627).as amended 2023. MHRA

3 **BS EN ISO 13485: 2016+A11:2021** - Medical devices - Quality management systems - Requirements for regulatory purposes: 2016+A11:2021

4 **BS EN ISO 17664 - Part 1 -** Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical device: 2021. BSI

5 **BS EN ISO 20417:2021 Medical devices** - Information to be supplied by the manufacturer: 2021 BSI

6 **Safety Action Notice (SAN) 2306 - Issued: 24 November 2023 Review Date: 24 November 2024** - Medical devices intended for use in a sterile state: review of systems and procedures. MHRA

7 **SAN(SC)00/30 -** Handling of Surgical Instruments on Loan from another Organization

8 **SAN(SC)02/19 -** Management of medical devices, equipment and accessories on loan (copy also attached) MHRA

9 **Scottish Health Planning Note (SHPN) 13 Part 1 -** Decontamination Facilities: Central Decontamination Unit. Health Facilities Scotland v2.0, 2024 HFS

10 **NHSScotland Requirements for Compliant Central Decontamination Units (CDUs)** - GUID 5014: v3.0 2024

11 **MHRA DB2003(06) -** Community Equipment Loan Stores - Guidance on Decontamination (copy also attached) 30 OCT 2000

12 **Costa, Dayane de Melo, et al: 2022 -** Management of surgical instruments at loaner companies in upper-middle and high-income countries: The other side of the coin. Infection Disease and Health vol 27, Issue 4 November 2022.

13 **Costa, Dayane de Melo, et al: 2018** - Reprocessing safety issues associated with complex-design orthopaedic loaned surgical instruments and implants - Injury Volume 49, Issue 11 November 2018

14 **NHS Scotland climate emergency and sustainability strategy: 2022-2026** Scottish Government 2022

15 **Scottish Health Technical Note (SHTN) 00-04** - Guidance on Safe Management of Medical Devices and Equipment in Scotland's Health and Social Care Servicesv3 NSS 2024.

16 **Scottish Health Technical Memorandum (SHTM) 01-01** - Decontamination of medical devices in a Central Decontamination Unit: Part A - Management: v1: 2018

17 **SHTM 01-06** - Decontamination of flexible thermolabile endoscopes and Transoesophageal Echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units v1: March 2023 HFS

18 **SHTM 01-05** - Decontamination of medical devices in Local Dental decontamination Units v1.0 SDCEP and HFS 2024

19 **Association for Perioperative Practice (AfPP)** - Loan Set Management Principles between Suppliers/Manufacturers, Theatres & Sterile Service Departments:2010

20 **Managing Medical Devices :2021** MHRA

21 **Manual handling - Manual Handling Operations Regulations 1992**, as amended by the Health and Safety (Miscellaneous Amendments) Regulations 2002.Health and Safety Executive.

22 **National Infection Prevention and Control Manual** (NIPCM) - NHS NSS 2023

23 **NICE IPC 666 - Interventional procedures guidance** - Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues. Published: 22 January 2020

24 **The Advisory Committee on Dangerous Pathogens'** Transmissible Spongiform Encephalopathy (ACDP TSE) subgroup - Prevention of CJD and vCJD Annex J: 2012

25 **The Advisory Committee on Dangerous Pathogens'** Transmissible Spongiform Encephalopathy (ACDP TSE) subgroup. Prevention of CJD and vCJD Annex E - the Quarantining of surgical instruments Previous revision date: January 2011as amended 2016.

26 **Scottish Government Records Management:** NHS Code of Practice (Scotland) Version 2.1 January 2012