NHS Scotland Provision of Compliant Podiatry Instruments

GUID 5007

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Contents

1. Background

1.1. This compliance document was developed in conjunction with the Reusable Medical Devices - Decontamination Expert Group (RMD-DEG) and the Scottish Podiatry Leadership Network. It supersedes Version 3 of GUID 5007 - Provision of Compliant Podiatry Instruments published in 2020.

2. Scope and Purpose

2.1. This document clarifies:

- the national requirements for the provision of sterilized podiatry instruments within NHS Scotland and private clinics contracted to NHS Scotland
- the national requirements for compliant reprocessing of podiatry instruments in Primary Care Local Decontamination Units (LDUs)
- the national requirements for outsourcing podiatry instrument decontamination to third party providers

2.2. LDUs reprocess a wide range of instruments used during podiatry treatment which may involve contact with low Creutzfeldt-Jakob Disease (CJD) transmission risk tissues. Any instruments which contact medium or high CJD transmission risk tissues should be single use or outsourced to be reprocessed at a Central Decontamination Unit (CDU) as per Appendix A. Single use instruments must not be reprocessed as indicated in the Medicines and Healthcare Products Regulatory Agency (MHRA) 1[OBJ]).

2.3. As the majority of LDUs in Scotland process instruments within a single legal entity. Thus, the main body of this document focuses on LDUs reprocessing instruments remaining within a single legal entity such as:

- an onsite LDU (the preferred option is where the owner/ manager of the LDU is only reprocessing their own instruments)
- an offsite LDU owned/ managed by the same legal entity which owns the instruments

2.4. Examples of a legal entity are an NHS board or a podiatry practice owned by an independent contractor(s) or a corporate body.

2.5. The processing of podiatry instruments between different legal entities is addressed in Appendix A. Please consult NHS Scotland Assure for further guidance where this option is being considered.

2.6. In defining these technical requirements, the areas requiring consideration were:

- LDU premises, equipment; instruments and procedures
- UK Medical Devices Regulations (MDRs) 2002 as amended by GB MDRs 2023
- re-usable medical devices, their accessories and decontamination equipment (such as sterilizer and washer disinfector) are classified as medical devices and regulated under the UK MDR 2002 as amended (see ref 2)

- current best practice guidance for patient and staff safety:
    - the appropriate technical requirements stated in Section 5.0 for single legal entities must be adhered to, so that the risk associated with the transmission of infections via podiatry instruments is minimised and to ensure that the quality and safety of reprocessed podiatry devices is fit for use on patients
- the quality assurance requirements require to be performed routinely by 'the User' as part of the Combined Practice Inspection by NHS boards every 3 years. Scottish Health Technical Memorandum (SHTM) 01-05 Part A (see ref 3) defines the role of 'User'

3. Options for the provision of sterile/ sterilized podiatry instruments

3.1. There are three options:

- option one - use of single use instruments (see section 4)
- option two - outsourcing to an accredited Central Decontamination Unit (CDU) (see appendix A).
- option three - use of Local Decontamination Unit (LDU) facilities including:
    - LDUs reprocessing instruments in an onsite LDU where the owner or manager of the LDU is only reprocessing its own instruments such as a single legal entity (the preferred option of NHS Scotland Assure)
    - an offsite LDU owned and managed by the same legal entity which owns the instruments (see section 5)
    - LDUs reprocessing instruments for different legal entities (see appendix A)

3.2. An option appraisal must be performed to consider:

- the availability, capacity, location, cost and transport with respect to use of a CDU or offsite LDU
- adequate space, inventory and the cost of operating an onsite LDU
- the availability, quality, storage and cost and environmental impact of single-use instruments

3.3. The LDU owner/ manager is responsible for operating a compliant facility in accordance with all appropriate guidance and standards (see ref 4, 5 and 6). LDU owners/ managers also have responsibilities under general law (including consumer protection legislation) to ensure the safety of patients, staff and users (see refs 7, 8 and 9).

3.4. To ensure the UK Medical Devices Regulations (MDR) (2002) as amended (see ref 2) is not applicable, the LDU owner/ manager must ensure no transfer of ownership of any devices or any “placing on the market” therefore, all devices once decontaminated or reprocessed, must be returned to their original owner. Table 5.1 highlights the requirements for this LDU model.

4. The requirement for the purchase of single use podiatry instruments

4.1. The expression ‘single-use’ as defined in the Medicines and Healthcare products regulatory agency (MHRA) ‘Single-use Medical Devices: Implications and Consequences of Reuse’ v2.3 - (October 2019) states “A device designated as ‘single-use’ must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient”.

4.2. For NHS Scotland managed podiatry services single use podiatry instruments should be purchased from the National Procurement (NP) contract for single use podiatry instruments (NP 177) as mandated in Chief Executive Letter (CEL) 05 (2012) 1 March 2012 (see ref 10) other than “in exceptional circumstances and only with the authority of the Board's Lead Procurement Manager or the Director of Finance, based on existing schemes of delegation”.

5. Technical requirements for LDU reprocessing podiatry instruments within a single legal entity

5.1. The technical requirements for a compliant Podiatry Local Decontamination Units (LDU) reprocessing devices within a single legal entity are specified in Table 5.1.

Table 5.1 - Technical requirements for complaint Podiatry LDU reprocessing devices within a single legal entity

Subject	Requirements for a policy compliant LDU only reprocessing devices owned by a single legal entity
Facilities	Compliant with the design layout of Scottish Health Planning Note (SHPN) 13 Part 2 (see ref 4) - One room model.
Equipment	Use automatic washer-disinfector and sterilizer in compliance with the relevant standards* (see refs 11, 12 and 13). Installation and validation tests should be in accordance with the latest current guidance (see ref 3). Operation, maintenance, annual revalidation and periodic testing in accordance with the manufacturer's instructions** (see refs 11, 12, 13 and 14).
Management	The role of User and Operator within LDU must be defined (see ref 3). The User and operator must have training record appropriate to the needs of their role. Completion of NHS Education for Scotland (NES) training on-site training on infection control covering decontamination. Appropriate documentation of policy, procedures and records for all aspects of management of medical devices and decontamination of reusable medical devices (RMDs) must be in place.

* All equipment in National Procurement (NP) 143 is in compliance with the relevant standards and guidance. NP143 is a NP contract for benchtop, under bench and free standing decontamination equipment used in LDUs.

** The maintenance, annual revalidation and periodic testing requirements are to be in line with the Chief Dental Officer (CDO) letter - Scottish Government Health Directorate (SGHD)/ CDO (2010) (see ref 14) requiring that the manufacturers' instructions are followed. LDU owners/ managers have the responsibility to risk assess the suitability of the manufacturer's instructions for their decontamination equipment to ensure they meet the required quality standard and are compatible with the devices and decontamination process. In the absence of manufacturer's instructions or where there is inadequate or unclear manufacturer instructions, the frequency, methods and outcomes of tests must follow current guidance and the appropriate Standards (see refs 11, 12 and 13).

Subject	Requirements for a policy compliant LDU only reprocessing devices owned by a single legal entity
Process	Decontamination process in accordance with the device manufacturer's instructions (see ref 9 and 15). Production of sterilized product. Sterilized devices must be packed in suitable containers to provide protection and to prevent environmental contamination (see ref 4). When contaminated devices are transported off-site[a], for example for domiciliary care they must be packed and transported in suitable containers in accordance with the guidance on carriage of dangerous goods (see ref 16 and 17).

[a] Transport off site means via road which is scoped in the ADR (see ref 17). SHTM 01-03 (see ref 16) regarding transportation of medical devices can be found on the NSS website.

Appendix A Technical requirements for LDU/ CDU reprocessing devices owned by a different legal entity

LDU reprocessing for different legal entities

A.1 Where a Local Decontamination Unit (LDU) is reprocessing instruments for different legal entities (for example an LDU owned by an NHS board providing decontamination services to a practice owned by an independent contractor located within the same building), it is a requirement of the Scottish Government Health and Social Care Directorate that instruments are not transported outside of the building in which they are used, for decontamination in an LDU.

A.2 Whilst LDUs may be operated for the benefit of third parties outside of the scope of the UK and GB Medical Devices Regulations (MDRs) (see ref 1 and 2), doing so requires the implementation of, and adherence to procedures and arrangements (possibly including contractual arrangements) which ensure there is no 'transfer of ownership' or 'placing on the market' of any devices. That is, all devices once decontaminated must be returned to their original owner. It is the responsibility of the owner/ manager of the LDU to ensure there is no breach of the UK and GB MDRs (see refs 1 and 2).

A.3 Ensuring the appropriate decontamination of devices is the responsibility of the practitioners or NHS boards who own and use them. If an LDU of a different legal entity is to be engaged to provide decontamination services, then a Service Level Agreement (SLA) should be put in place. Any SLA should include provision for the following as a minimum:

- a clear allocation of responsibilities and duties
- an obligation on the owner/ manager of the LDU to comply with the technical requirements as specified in Table A.1
- a right for the customer to undertake audits of the LDU which is reprocessing their devices
- practical requirements for wrapping, labelling and transporting devices
- management of non-conforming products (such as contaminated, damaged, wet, missing/ lost, incorrect devices in the pack/ tray/ cassette), handling and investigations of complaints
- financial and liability issues

A.4 Although practices outsourcing their decontamination requirements do not physically undertake the decontamination process, they must nonetheless have a procedure and maintain a record regarding their sub-contracting and management of medical devices.

Responsibilities of LDU management

A.5 The LDU owner/ manager is responsible for the following:

- applying a system to ensure there is no mix up of different parties' devices, and as such that no 'transfer of ownership' of any devices or any 'placing on the market' of any procedure packs occurs. For example, the use of an electronic tracking system, colour coded cassettes (different colours used for different customers), or different/ distinct time slots whereby each customers devices are reprocessed at different times
- managing and operating compliant facilities in accordance with guidance/ standards
- managing and operating facilities compliant with all legal requirements to ensure the safety of patients, staff and users
- demonstrating that a designated manager is responsible for developing and implementing compliant decontamination practices and processes, and incorporating them within a SLA between the LDU and its 'customer'. Table A.1 highlights the technical requirements for this LDU model

Table A.1 - Technical requirements for compliant Podiatry LDU reprocessing devices owned by a different legal entity

Subject	Requirements for a policy compliant Podiatry LDU supplying a different legal entity which is located within the same building
Facilities	Compliant with the design layout of Scottish Health Planning Note (SHPN) 13 Part 2 - One room model (see ref 4).
Equipment	Use of automatic washer-disinfector and sterilizer in compliance with the relevant standards*** (see refs 11, 12 and 13). Installation and validation tests in accordance with the current guidance (see ref 3). Operation, maintenance, annual revalidation and periodic testing in accordance with the manufacturer's instructions****.

*** NP143 is a NP contract for benchtop, underbench and free-standing decontamination equipment used in LDUs.

**** The maintenance, annual revalidation and periodic testing requirements are to follow manufacturer's instructions in line with CDO letter SGHD/CDO (2010)2. LDU owners/ managers have the responsibility to risk assess the suitability of the manufacturer instructions for their decontamination equipment to ensure they meet the required quality standard and are compatible with their devices and decontamination process. In the absence of manufacturer's instructions or where there is inadequate or unclear manufacturer instruction, the frequency, methods and outcomes of tests must follow current guidance and the appropriate British Standards (See refs 11, 12 and 13).

Subject	Requirements for a policy compliant Podiatry LDU supplying a different legal entity which is located within the same building
Management	The role of User, Operator and Management within the LDU must be defined. The User, Operator and Manager must have training records appropriate to their needs. Completion of NHS Education for Scotland (NES) training for example, on-site training on infection control covering decontamination. Appropriate documentation of policy, procedures and records, for all aspects of management of medical devices and decontamination of Reusable Medical Devices (RMDs) must be in place. The Practice Support Manual is an example. Service Level Agreement Method to differentiate devices owned by different legal entities such as electronic tracking system, or colour coded cassette or a time slot allocation.
Process	Decontamination process in accordance with the device manufacturer's instructions (see ref 9 and 15). Production of sterilized product. Sterilized devices must be packed in suitable containers to provide protection and to minimise environmental contamination (see ref 4). LDUs reprocessing devices owned by a different legal entity must be located within the same building; therefore transport off site is only for domiciliary purposes. When transported off-site*****, contaminated devices must be packed and transported in suitable containers in accordance with the guidance (see refs 16 and 17).

***** Transport off site means via road which is scoped in the ADR (see ref 17). LDUs reprocessing devices owned by a different legal entity must be located within the same building. Therefore, transport off site is only for domiciliary purposes.

Abbreviations

AE(D): Authorising Engineer (Decontamination)

BS: British Standard

BSI: British Standards Institute

CDO: Chief Dental Officer

CDU: Central Decontamination Unit

CEL: Chief Executive Letter

CJD: Creutzfeldt-Jakob Disease

DEG: Decontamination Expert Group

LDU: Local Decontamination Unit

MDR: Medical Devices Regulations

MHRA: Medicines and Healthcare Products Regulatory Agency

NES: NHS Education for Scotland

NP: National Procurement

RMD: Reusable Medical Device

SEHD: Scottish Executive Health Department

SGHD: Scottish Government Health Directorate

SHPN: Scottish Health Planning Note

SHTM: Scottish Health Technical Memorandum

SLA: Service Level Agreement

Glossary

ADR - l'Accord européen relatif au transport international des marchandises Dangereuses par Route. The European agreement concerning the carriage of dangerous goods by road.

Clean - visually free of soil and below specified levels of analytes. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Cleaning - removal of contaminants to the extent necessary for further processing or for intended use. Note 1 to entry: Cleaning consists of the removal of adherent soil (such as blood, protein substances and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated process that prepares the items for safe handling and/or further processing. [SOURCE: BS EN ISO 17664-1: 2021 section 3 definitions]

Decontamination - refer to definitions for “processing” and “reprocessing”.

Labelling - label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents. [SOURCE: BS EN ISO 13485: 2016: +A11:2021 section 3 definitions]

Manual cleaning - 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: BS EN ISO 17664-1: 2021 section 3 definitions]

Medical device - 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, prediction, prognosis, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state
- providing 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

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception
- products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. [SOURCE: Regulation (EU) 2017/745 article 2 - (1)

Reusable medical device (RMD) - medical device designated or intended by the manufacturer as suitable for processing and reuse. [SOURCE: BS EN ISO 17664-1:2021 section 3 definitions]. The UK MDR (2002) as amended (see ref 2), is the legislation applicable in the UK for medical devices and is applicable in Great Britain (England, Wales and Scotland).

Single-use device - a device that is intended to be used on one individual during a single procedure. [SOURCE: Regulation (EU) 2017/745 article 2 - (8)]

Sterile - free from viable microorganisms. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Sterilized – condition of a product that has been exposed to a sterilization process in its sterilized barrier system [SOURCE: BS EN ISO 11139: 2018 section 3 definitions]

Sterile medical device - medical device intended to meet the requirements for sterility. [SOURCE: BS EN ISO 13485: 2016+A11:2021 section 3 definitions]

Sterilization - process used to render product free from viable microorganisms.

Small steam sterilizer - steam sterilizer which has a chamber volume of less than 60 litres and is unable to accommodate a sterilization module. [SOURCE: BS EN 13060: 2014 + A1:2018 section 3 Terms and definitions]

Validation - is the documented procedure required for obtaining, recording, and interpreting the results needed to show that a process will consistently yield a product complying with a predetermined specification.

Washing - removal of adherent contamination from surfaces to be cleaned by means of an aqueous medium, with or without process chemicals, as necessary [SOURCE: BS EN ISO 15883-1 :2009 + A1 2014, section 3 definitions].

Washer-disinfector - equipment designed to clean and disinfect product. [SOURCE: EN ISO 11139: 2018 section 3 definitions] Washer-disinfector (WD) - equipment designed to clean and disinfect product. [SOURCE: BS EN ISO 11139: 2018 section 3 definitions

References

1 **Single-use Medical Devices: Implications and Consequences of Reuse** - Medicines and Healthcare Products Regulatory Agency (MHRA) DB (2021) v 2.4

2 **The Medical Devices Regulations 2002, SI and the Medical Devices (amendments) (GB) Regulation 2023** S.I. 2023 No.627 and the Medicines and Medical Devices Act 2021.

3 **Scottish Health Technical Memorandum (SHTM) 01-05, Management, equipment, and process of the decontamination of dental instruments in a Local Decontamination Unit (LDU) in NHS Scotland**, V1, 2024.

4 **Scottish Health Planning Note (SHPN) 13 Part 2** Decontamination Facilities: Local Decontamination Unit 2008

5 **Decontamination - Compliance in Primary Care**, Scottish Executive Health Department (SEHD) - NHS Health Department Letter (HDL) (2005) 1, 11 January 2005.

6 **Decontamination - Updated guidance on compliance in primary care** - NHS Health Department Letter (HDL) (2006) 40, Scottish Executive Health Department (SEHD), July 2006.

7 **Consumer Protection Act 1987**, (TSO) The Stationary Office. Health and Safety at Work etc. Act 1974, SI 1974 c 37.

8 **Management of Health and Safety at Work Regulations 1999**, SI 1999 No.3242.

9 **BS EN ISO 17664-1:2021** - TC Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices - Critical and semi-critical medical devices. British Standards Institute (BSI).

10 **Scottish Government Health Directorate (SGHD) Chief Executive Letter (CEL) 05 (2012) Key Procurement Principles**, 1 March 2012.

11 **BS EN 13060:2025** - TC: Sterilizers for medical purposes. Small steam sterilizers. Requirements and testing, BSI.

12 **BS EN ISO 15883-1:2025** - TC: Washer-disinfectors. General requirements, terms and definitions and tests, BSI.

13 **BS EN ISO 15883-2:2025** - TC: Washer-disinfectors - Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices, BSI.

14 **Decontamination-Testing, Maintenance and Revalidation of Equipment**, Primary and Community Care Directorate Scottish Government Health Directorate (SGHD)/ Chief Dental Officer (CDO) (2010)2.

15 **BS EN ISO 17664-2:2021** - Processing of healthcare products - Information to be provided by the medical device manufacturer for the processing of medical devices - non-critical medical devices. BSI.

16 **SHTM 01-03**, NHS Scotland Guide to the Carriage of Dangerous Goods Regulations with respect to Used Medical Devices, V2, 2025.

17 **ADR 2023** - Agreement concerning the International Carriage of Dangerous Goods by Road. ADR applicable as from 1 January 2023 United Nations Economic Commission for Europe (UNECE).