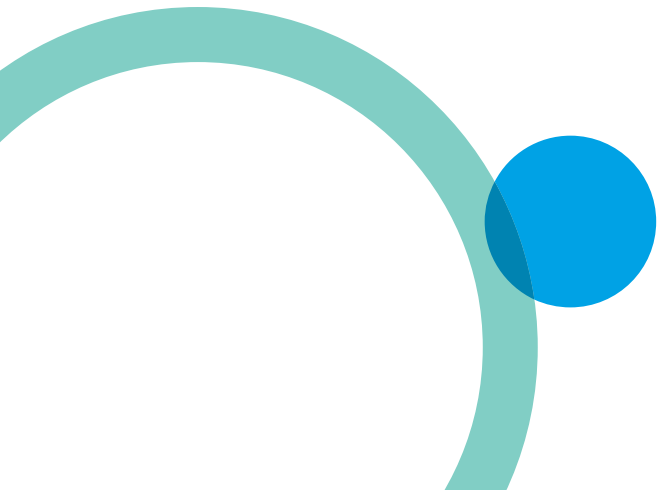
NHS National Services Scotland

Provision of Compliant Podiatry Instruments – GUID 5007 Version 3.0



March 2020

Contents

1. Scope and Purpose

1.1 This compliance document was developed in conjunction with the Reusable Medical Devices Decontamination Operational Group (RMD-DOG) and the College of Podiatry. It supersedes Version 2 of GUID 5007-Provision of Compliant Podiatry Instruments published in 2014. The changes (identified in the last page) were largely reformatting in nature.

1.2 This document clarifies:

- the national requirements for the provision of sterilized podiatry instruments within NHSScotland and private clinics;
- 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.

1.3 LDUs reprocess a wide range of instruments used in procedures which involve contact with low Creutzfeldt–Jakob Disease (CJD) transmission risk tissues during podiatry treatment.

Note: Any instruments which contact medium or high Creutzfeldt–Jakob Disease (CJD) transmission risk tissues should be single use. LDUs must not reprocess single use instruments as indicated in the MHRA alert[1].

1.4 This revised document simplifies the podiatry decontamination requirements, based on the fact that 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 i.e.***

- 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 entity which owns the instruments.

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

The processing of podiatry instruments between <u>different legal entities</u> is addressed in Appendix 1: Please consult Health Facilities Scotland for further guidance where this option is being considered.

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

- LDU premises, equipment; instruments and procedures;
- The EU Medical Devices Regulations 2017[2] (EU MDR);

  - re-usable medical devices, their accessories and decontamination equipment (e.g. sterilizer, washer disinfector) are classified as medical devices and regulated under the EU MDR[2];
- Current best practice guidance for patient and staff safety;
  - a review of current published literature, safety advice and legislation for patients, staff and the public;
  - the appropriate technical requirements stated in Section 2.0 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. The definition of 'User' can be found in Note (d) on page 7.

Options

1.6 The order of preference with respect to the provision of sterile/sterilized podiatry instruments is as follows:

Option 1 - use of single use instruments (see 1.10)

Option 2 - outsourcing to an accredited Central Decontamination Unit (CDU, see appendix 1).

Option 3 - 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 i.e. ***a single legal entity:*** (the preferred option of Health Facilities Scotland);
- *or an offsite LDU owned and managed by the same legal entity which* owns the instruments (see section 2);
- LDUs reprocessing instruments for different legal entities (see appendix 1).

1.7 An option appraisal must be performed to consider:

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

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

1.9 To ensure the EU MDR[2] is not applicable, the LDU owner/manager must ensure no transfer of ownership of any devices or any “placing on the market” i.e. all devices once decontaminated or processed, must be returned to their original owner. Table 1 highlights the requirements for this LDU model.

The requirement for the purchase of single use podiatry instruments

1.10 The expression ‘single-use’ as defined in the 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”.

1.11 For NHSScotland managed podiatry services purchasing single use podiatry instruments should be from the National Procurement contract for single use podiatry instruments (NP 177) as mandated in CEL 05 (2012) 1st March 2012[3] 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”.

1.12 Consideration should be given to metal recycling of used single use devices. The Board’s waste management officer should be consulted.

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

2.1 The technical requirements for a compliant Podiatry LDU reprocessing devices within a single legal entity are specified in table 1.

Requirements for a policy compliant LDU only reprocessing devices owned by a single legal entity.	
Facilities	Compliant with the design layout of SHPN 13 Part 2[4] – Single room model.
Equipment	Use automatic washer disinfector & sterilizer in compliance with the relevant standards[a]. Installation and validation tests in accordance with the latest current guidance[b]. Operation, maintenance, annual revalidation and periodic testing in accordance with the manufacturer's instructions[c].
Management	The role of User and Operator within LDU must be defined[d]. The User and operator must have training record appropriate to the needs of their role. Completion of NHS Education for Scotland training[e]. Appropriate documentation of policy, procedures and records[f].
Process	Decontamination process in accordance with the device manufacturer's instructions[9]. Production of sterilized product. Sterilized devices must be packed in suitable containers to provide protection and to prevent contamination[4]. When contaminated devices are transported off-site[g], e.g. for domiciliary care they must be packed and transported in suitable containers in accordance with the guidance on carriage of dangerous goods[10-11].

Table 1: Technical requirements for compliant Podiatry LDU reprocessing devices within a single legal entity

2.2 When transporting devices, via a public road, outside the building in which the LDU is located, but within the same legal entity, there are additional requirements that include:

- sterilized devices must be packed in a container to provide protection and to minimise contamination during transport and storage.
- the contaminated devices must be transported in compliance with the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR 2013)[11] Act.

Note:

a) The current standard for benchtop sterilizers is BS EN ISO 13060[12], while the current standard for washer disinfectors is BS EN ISO 15883:1,2[13-14]. All equipment in NP 143 is in compliance with the relevant standards and guidance. NP143 is a national procurement contract for benchtop, underbench and free standing decontamination equipment used in LDUs.

b) Installation and validation tests must follow the current guidance consisting of SHTM 2010[15] for sterilizers and SHTM 2030[16] for washer disinfectors or their revision. Confirm with the suppliers who carried out the installation and validation to ensure their works are in accordance with SHTM 2010[15] and SHTM 2030[16]. Advice from an Authorising Engineer (Decontamination) regarding validation may be required.

c) The maintenance, annual revalidation and periodic testing requirements are to be in line with the CDO letter SGHD/CDO (2010)2[17] 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 European Standards[12-14].

d) SHTM 2010[15] and SHTM 2030[16] define the following roles:

User is defined as the person designated by management to be responsible for the sterilizer/washer disinfector. In primary care, this could be a general practitioner, dentist, or other health professional.

Operator is defined as any person with the authority to operate a sterilizer/washer disinfector including the noting of device readings and simple housekeeping duties.

Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the sole operation of its premises.

e) NHS Education for Scotland (NES) provides on-site training on infection control covering decontamination.

f) Policies, procedures and records for all aspects of management of medical devices and decontamination of reusable medical devices must be in place.

g) Transport off site means via road which is scoped in the ADR[11].
Guidance, GUID 5006[10] regarding transportation of medical devices can be found on the HFS website.

Appendix 1 - Technical requirements for LDU/CDU reprocessing devices owned by a different legal entity

LDU reprocessing for different legal entities

Where an LDU is reprocessing instruments for ***different legal entities*** (e.g. 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.

Whilst LDUs may be operated for the benefit of third parties outside of the scope of the EU MDR[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 EU MDR[2].

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 2;
- 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 (e.g. damaged, wet, missing/lost, incorrect devices in the pack/tray/cassette), handling and investigations of complaints;
- financial and liability issues.

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

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. Examples could include the use of an electronic tracking system, the use of colour coded cassettes (with different colours being used for different customers), or the use of different/distinct time slots, whereby devices provided for processing by different parties are processed at different times. The aim of each system being to ensure that the risk of devices transferring between parties is removed;
- 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 operating compliant decontamination practices and processes, and incorporating these practices and processes within a Service Level Agreement between it and its "customers". Table 2 highlights the technical requirements for this LDU model.

	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 SHPN 13 Part 2 – One room model[4].
Equipment	Use of automatic washer disinfector & sterilizer in compliance with the relevant standards[h]. Installation and validation tests in accordance with the current guidance[i]. Operation, maintenance, annual revalidation and periodic testing in accordance with the manufacturer's instructions[j].
Management	The role of User, Operator and Management within the LDU must be defined[k]. The User, Operator and Manager must have training records appropriate to their needs. Completion of NHS Education for Scotland training[l]. Appropriate documentation of policy, procedures and records[m]. Service Level Agreement. Method to differentiate devices owned by different legal entities e.g. electronic tracking system, or colour coded cassette or a time slot allocation.
Process	Decontamination process in accordance with the device manufacturer's instructions[9]. Production of sterilized product. Sterilized devices must be packed in suitable containers to provide protection and to minimise contamination[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[n], contaminated devices must be packed and transported in suitable containers in accordance with the guidance[10&11].

Table 2: Technical requirements for compliant Podiatry LDU reprocessing devices owned by a different legal entity

Note:

h) The current standard for benchtop sterilizers is BS EN ISO 13060[12], while the current standard for washer disinfectors is BS EN ISO 15883:1,2[13&14]. All equipment in NP 143 is in compliance with the relevant standards and guidance. NP143 is a national procurement contract for benchtop, underbench and free standing decontamination equipment used in LDUs.

i) Installation and validation tests must follow the current guidance consisting of SHTM 2010[15] for sterilizers and SHTM 2030[16] for washer disinfectors or their revision. Confirm with the suppliers who carried out the installation and validation to ensure their works are in accordance with SHTM 2010[15] and SHTM 2030[16]. Advice from an Authorising Engineer (Decontamination) regarding validation may be required.

j) The maintenance, annual revalidation and periodic testing requirements are follow manufacturer's instructions in line with CDO letter SGHD/CDO (2010)2[17]. 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 the 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 European Standards[12-14].

k) SHTM 2010[15] and SHTM 2030[16] define the following roles:

User is defined as the person designated by management to be responsible for the sterilizer/washer disinfector. In primary care this could be a general practitioner, dentist, or other health professional.

Operator is defined as any person with the authority to operate a sterilizer/washer disinfector including the noting of device readings and simple housekeeping duties.

Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the sole operation of its premises.

l) NHS Education for Scotland (NES) provides on-site training on infection control covering decontamination.

m) Policies, procedures and records for all aspects of management of medical devices and decontamination of reusable medical devices must be in place. The Practice Support Manual is an example.

n) Transport off site means via road which is scoped in the ADR[11]. Guidance regarding transportation of medical devices can be found at HFS website (http://www.hfs.scot.nhs.uk/home). 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.

Outsourcing decontamination services to a Central Decontamination Unit (CDU)

Ensuring the appropriate decontamination of devices is the responsibility of the practitioners or NHS Boards who own and use them. A CDU can supply decontamination of reusable medical devices and procedure packs to other NHS Boards, third party organisations or practitioners, both NHS and independent, for use on both NHS and (in the case of independent practices) non-NHS patients. Although practices outsourcing their decontamination requirements do not physically undertake the decontamination process, they must nonetheless have a procedure for the management of contaminated devices and maintain a record regarding their sub-contracting.

A CDU can process a wide range of reusable medical devices (invasive, non-invasive, low/medium/high risk Creutzfeldt–Jakob Disease (CJD)) transmission as defined in their QMS) to a range of clinical specialities within acute and primary care sectors.

For CDUs who provide decontamination service for a different legal entity an SLA should be put in place. Any SLA should include provision for the following as a minimum:

- A clear allocation of responsibilities and duties;
- The CDU manager must maintain CDU accreditation to EN ISO 13485[18];
- A right for the customer to undertake audits of the CDU which is reprocessing their devices;
- Practical requirements for wrapping, labelling and transporting devices;
- Management of non-conforming products (e.g. damaged, wet, missing/lost, incorrect devices in the pack/tray/cassette), handling and investigations of complaints;
- Financial and liability issues.

Technical requirements for a Central Decontamination Unit

The technical requirements for CDUs are specified in GUID 5014[19] published by HFS in 2019.

References

1. Medicines and Healthcare products regulatory agency (MHRA) DB (2018) v 2.3 'Single-use Medical Devices: Implications and Consequences of Reuse'.

2. The Medical Devices Regulations 2017, Regulation (EU) 2017/745 of the European parliament and Council of the 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

3. SGHD CEL 05 (2012) Key Procurement Principles, 1st March 2012. http://www.sehd.scot.nhs.uk/mels/CEL2012_05.pdf

4. Health Facilities Scotland, Scottish Health Planning Note 13 Part 2 Decontamination Facilities: Local Decontamination Unit 2008.

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

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

7. Consumer Protection Act 1987, TSO. 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 17664:2017 Processing of healthcare products – Information to be provided by the medical device manufacturer for the processing of medical devices, BSI.

10. GUID 5006 - NHSScotland Guide to the Carriage of Dangerous Goods Regulations with respect to used medical devices, Health Facilities Scotland, December 2013.

11. ADR, European Agreement Concerning the International Carriage of Dangerous Goods by Road, Volume 1, ECE/TRANS/225(Vol.1), Applicable as from 1 January 2013, Economic Commission for Europe Committee on Inland Transport, United Nations, New York and Geneva, 2012

12. EN 13060:2014 + A1:2018 Small steam sterilizers, CEN.

13. EN ISO 15883-1:2009 +A1:2012 Washer-disinfectors. General requirements, terms and definitions and tests, CEN.

14. EN ISO 15883-2:2009 Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments,

anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc., October 2009. CEN.

15. SHTM 2010 (Parts 1 - 6) – Sterilization, Health Facilities Scotland, 2001.

16. SHTM 2030: Washer Disinfectors, 2001, Health Facilities Scotland.

17. Primary and Community Care Directorate SGHD/CDO (2010)2, Decontamination-Testing, Maintenance and Revalidation of Equipment, Scottish Government Health Department.

18. EN ISO 13485: 2016. Medical Devices. Quality Management System. Requirements for Regulatory Purposes. CEN.

19. GUID 5014 version 2: 2019 Requirements for compliant Central Decontamination Units, HFS.

Changes to Version 2.0 of GUID 5007: 2014

Change of document structure – The number of sections was reduced. Background Section 1 was moved into Scope and Purpose Section 1. Section 6.2 (on the technical requirements for an LDU reprocessing devices owned by another legal entity) was moved into Appendix 1. The technical requirements for a single legal entity was moved from Appendix 1 into Section 2.

removed	added
Another legal entity	Different legal entity
UK Medical Devices Regulation 2002	EU regulation on medical devices 2017/745
DDS	Practice Support Manual
n/a	BS EN 17664: 2017
BS EN 13060+A2 2010	BS EN 13060: 2014 + A1 2018
Table 1 – Equipment - Installation and annual revalidation in accordance with the current guidance[b]. Operation, maintenance and testing in accordance with the manufacturer's instructions[c].	Table 1&2 – Equipment - Installation and validation tests in accordance with the current guidance[b]. Operation, maintenance, annual revalidation and periodic testing in accordance with the manufacturer's instructions[c].