

**Provision of
Compliant Podiatry
Instruments**

Contents

	<i>Page</i>
1. Background	3
2. Scope and purpose	4
3. Options	5
4. Single use instruments	6
5. Central Decontamination Unit (CDU)	7
6. Local Decontamination Unit (LDU)	8
7. Outsourcing decontamination services to a LDU /CDU	10
Appendix 1 – Requirements for a compliant LDU	11
References	15

Disclaimer

The contents of this document are provided by way of general guidance only at the time of its publication. Any party making any use thereof or placing any reliance thereon shall do so only upon exercise of that party's own judgement as to the adequacy of the contents in the particular circumstances of its use and application. No warranty is given as to the accuracy, relevance or completeness of the contents of this document and Health Facilities Scotland, a Division of NHS National Services Scotland, shall have no responsibility for any errors in or omissions therefrom, or any use made of, or reliance placed upon, any of the contents of this document.

1. Background

The Scottish Government Health & Social Care Directorate (SGHSCD) instructed NHS Boards to ensure decontamination carried out in all Primary Care settings, including podiatry (both directly managed and independent contractors) achieves compliance with the Glennie Technical Requirements (GTR)¹. NHS Boards were asked to submit their action plans as detailed in letter HDL (2006)40² to comply with a December 2009 deadline.

Compliant Dental Local Decontamination Units in Scotland (Primary Care)³ was published in May 2013 to clarify the national requirements for compliant reprocessing of dental devices in Local Decontamination Units (LDUs) (Primary Care). However, there is no clarification or further follow up on the requirements for the provision of podiatry instruments.

This document was developed in conjunction with the Primary Care Decontamination Working Group and the Society of Chiropractors and Podiatrists Scottish Podiatry Managers' Group.

The publication of this document is supported by the HAI National Advisory Group.

2. Scope and purpose

This document clarifies:

- The national requirements for the provision of podiatry instruments;
- The national requirements for compliant reprocessing of podiatry instruments in Local Decontamination Units (LDUs).

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

- The Medical Devices Regulations 2002⁴ (MDR);
 - CDU activity which is regulated under the MDR⁴;
 - Whilst LDUs may be operated for the benefit of third parties outside of the scope of the MDR⁴, 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. It is the responsibility of the owner/manager of the LDU to do so.
- Current best practice guidance for patient and staff safety;
 - The compliance requirements are also based on best practice guidance a review of current published literature and safety advice and legislation for patients, staff and the public^{1,2,5,6,7,8 & 9};
 - That the appropriate technical requirements must be adhered to, ensure the risk associated with the transmission of infections via podiatry instruments is minimised and to ensure that the quality and safety of reprocessed podiatry instruments are fit for use on patients.
- The quality assurance requirements which require to be performed routinely by the user as a part of a NHS Board inspection every 3 years.

3. Options

The order of preference with respect to the provision of podiatry instruments is as follows:

Option 1 - Use of single use instruments.

Option 2 - Outsourcing to an accredited Central Decontamination Unit (CDU).

Option 3 - Use of Local Decontamination Unit (LDU) facilities.

Option 3.1- LDUs reprocessing instruments remaining within **a single legal entity**:

- An onsite LDU (the preferred option of Health Facilities Scotland when using an LDU is where the owner /manager of the LDU is only reprocessing its own instruments);
- An offsite LDU owned /managed by the same entity which owns the instruments.

Option 3.2 - LDUs reprocessing instruments for **different legal entities**; (e.g. an LDU owned by a NHS Board providing decontamination services to a practice owned by an independent contractor located within the same building).

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

Each option will be explained in the subsequent sections.

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 cost of an onsite LDU;
- The availability, quality, storage and cost of single-use instruments.

4. Single use instruments

The expression 'single-use' as defined in the MHRA 'Single-use Medical Devices: Implications and Consequences of Reuse' - DB 2006(04) v2.0¹⁰ states "that the medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed".

All single use podiatry instruments should be purchased from the National Procurement contract for single use podiatry instruments (NP 177) as mandated in CEL 05 (2012) 1st March 2012¹¹ 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".

Consideration should be given to metal recycling of used single use devices. The board's waste management officer should be consulted.

5. Central Decontamination Unit (CDU)

The scope of decontamination activities in a CDU ^{1&12} includes:

- Reusable medical devices used within the same and/or another legal entity. The 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;
- 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;
- The legal requirements for CDUs are compliance with the Medical Device Regulations 2002⁴ including registration with MHRA;
- Operation of a quality management system to EN ISO 13485¹³ which is audited by a notified body.

6. Local Decontamination Unit (LDU)

LDUs reprocess a wide range of instruments used in procedures which involve contact with “low Creutzfeldt–Jakob disease (CJD) transmission risk tissues” in Podiatry. Any instruments which contact “medium or high CJD transmission risk tissues” should be single use. LDUs must not reprocess single use instruments as indicated in the MHRA DB (2006) 04¹⁰.

6.1 Technical requirements for an LDU reprocessing its own devices and/or procedure packs

This section relates to Option 3.1 – namely where the owner of the LDU is the same legal entity as the owner of all devices (and/or procedure packs) decontaminated/reprocessed within that facility.

The LDU owner/manager is responsible for operating a compliant facility in accordance with all appropriate guidance and standards^{1, 2, 5&6}. LDU owners/managers also have responsibilities under general law (including consumer protection legislation) to ensure the safety of patients, staff and users⁷⁻⁹.

Table 1, Column 1 (Appendix 1) highlights the requirements for this LDU model.

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)¹⁴⁻¹⁵ Act.

6.2 Technical requirements for an LDU reprocessing devices owned by another legal entity where the devices are located within the same building

This section relates to Option 3.2 – namely where the owner of the LDU is not the same legal entity as the owner of all devices (and/or procedure packs) decontaminated/reprocessed within that facility.

The LDU owner/manager is responsible for the following:

- Ensuring that there is no breach of the MDR⁴. Key to this is ensuring that the MDR⁴ do not apply. To achieve this, the LDU owner/manager must ensure no transfer of ownership of any devices or any “placing on the market” of any procedure packs i.e. all devices once decontaminated or processed must be returned to their original owner.
- 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 ^{1,2,5&6}.
- Managing and operating facilities compliant with all legal requirements to ensure the safety of patients, staff and users ⁷⁻⁹.
- 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 (SLA) between it and its “customers”.

Table 1, Column 2 (Appendix 1) highlights the requirements for this LDU model.

7. Outsourcing decontamination services to a LDU /CDU

Ensuring the appropriate decontamination of devices is the responsibility of the practitioners or NHS Boards who own and use them. For CDUs and LDUs who provide a decontamination service for a different legal entity a SLA should be put in place. Any SLA should include provision for the following as a minimum:

- A clear allocation of responsibilities and duties;
- If using a CDU the CDU manager must maintain CDU accreditation to EN ISO 13485¹³ (as specified in Section 5.0);
- If using a LDU the owner/manager of the LDU must comply with the technical requirements as specified in Section 6.0;
- A right for the customer to undertake audits of the LDU/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.

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 as per Quality Management System (QMS) for a CDU or a Decontamination Document System (DDS¹⁶) for a LDU.

Appendix 1 – Requirements for a compliant LDU

	Requirements for a policy compliant podiatry LDU reprocessing own devices.	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 ⁶ – Single room LDU model.	Compliant with the design layout of SHPN 13 Part 2 ⁶ – Single room LDU model.
Equipment	Use automatic washer disinfectant & sterilizer in compliance with the relevant standards ^a . Installation and annual revalidation in accordance with the latest current guidance ^b . Operation, maintenance and testing in accordance with the manufacturer’s instructions ^{4,c} .	Use automatic washer disinfectant & sterilizer in compliance with the relevant standards ^a . Installation and annual revalidation in accordance with the latest current guidance ^b . Operation, maintenance and testing in accordance with the manufacturer’s instructions ^{4,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 .	The role of User, Operator and Management within LDU must be defined see ^d . The User, Operator and Manager must have training record appropriate to the needs of their role. Completion of NHS Education for Scotland training ^e . Service Level Agreement (refer to section 7.0) Appropriate documentation of policy, procedures and records ^f . Method to differentiate instruments between entities e.g. electronic tracking system or colour coded cassette or time slot difference.

<p>Process</p>	<p>Decontamination process in accordance with the device manufacturer's instructions^{4,16}. Production of sterilized product. Sterilized devices must be packed in suitable containers to provide protection and to prevent contamination⁴. When transported off-site⁹, e.g. for domiciliary care contaminated devices must be packed and transported in suitable containers in accordance with the guidance^{14,15}.</p>	<p>Decontamination process in accordance with the device manufacturer's instructions^{4,16}. Production of sterilized product. Sterilized devices must be packed in suitable containers to provide protection and to prevent contamination⁴. When transported off-site⁹, e.g. for domiciliary care, contaminated devices must be packed and transported in suitable containers in accordance with the guidance^{14,15}.</p>
-----------------------	---	--

Table1: technical requirements for a compliant LDU

Note:

a) The current standard for benchtop sterilizers is EN ISO 13060¹⁷ and the current standard for washer disinfectors is EN ISO 15883 Parts 1 and 2¹⁸⁻¹⁹. All equipment in NP 143 is in compliance with the relevant standards and guidance. This is a national procurement contract for benchtop, underbench and freestanding decontamination equipment used in LDUs as well as equipment used in CDUs and EDUs. (<https://scot-ccm.eurodyn.com/ccm/>)

To gain access to view supplier pricing please contact your local procurement department or e mail NSS.NPepandS@nhs.net.

b) Installation and annual revalidation must follow the latest current guidance consisting of the revision of SHTM 2010²⁰ for sterilizers and 2030²¹ for washer disinfectors. Confirm with the suppliers who carried out the installation and annual revalidation to ensure their work was in accordance with SHTM 2010²⁰ and SHTM2030²¹. Advice from an Authorizing Engineer (Decontamination) regarding validation may be required.

c) The periodic testing requirements are:

The minimum frequency of testing decontamination equipment is to follow manufacturer's instructions in line with the MDR⁴.

The LDU owners 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 instruments 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 standards¹⁷⁻¹⁹.

d) SHTM 2010²⁰ and 2030²¹ defines the following roles.

The user is defined as the person designated by management to be responsible for the sterilizer/washer disinfectant. In primary care he or she could be a general practitioner, podiatrist or other health professional.

An operator is defined as any person with the authority to operate a sterilizer/washer disinfectant including the noting of instrument 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-line training on decontamination.

(http://www.decontamination.scot.nhs.uk/lms/nhs_splash/nhs_splash.asp). This programme is currently under review.

- f) Policies and procedures for all aspects of management of medical devices and decontamination of reusable medical devices must be in place. DDS¹⁶ is an example.
- g) Transport off site means via road, rail or sea as scoped in ADR, European Agreement Concerning the International Carriage Of Dangerous Goods by Road¹⁴. Guidance regarding transportation of podiatry instruments can be found at HFS website¹⁵ (<http://www.hfs.scot.nhs.uk/home>). LDUs reprocessing instruments owned by a different legal entity must be located within the same building; therefore transport off site is only for domiciliary purposes.

ARCHIVED (Mar 2020)

References

1. Scottish Executive Health Department, NHSScotland: Sterile Services Provision Review Group: 1st Report – The Glennie Framework (2001). (<http://www.sehd.scot.nhs.uk/publications/sspr/sspr.pdf>)
2. Scottish Executive Health Department, NHS HDL (2006) 40, Decontamination – Updated Compliance in Primary Care, July 2006. (http://www.sehd.scot.nhs.uk/mels/HDL2006_40.pdf)
3. Health Facilities Scotland, Compliant Dental Local Decontamination Units in Scotland (Primary Care), May 2013. (<http://www.hfs.scot.nhs.uk/services/decontamination-services/guidance/>)
4. The Medical Devices Regulations 2002, SI 2002 No 618. (<http://www.legislation.gov.uk/uksi/2002/618/contents/made>)
5. Health Protection Scotland, Local Decontamination Units: Guidance on the Requirements for Equipment, Facilities and Management, Version 1.2, October 2005 (Amended August 2007). (<http://www.documents.hps.scot.nhs.uk/hai/decontamination/publications/ldu-001-02-v1-2.pdf>)
6. Health Facilities Scotland, Scottish Health Planning Note 13 Part 2 Decontamination Facilities: Local Decontamination Units (2008).
7. Consumer Protection Act 1987, TSO. (<http://www.legislation.gov.uk/ukpga/1987/43/contents>)
8. Health and Safety at Work etc. Act 1974, SI 1974 c 37, (<http://www.legislation.gov.uk/ukpga/1974/37>)
9. Management of Health and Safety at Work Regulations 1999, SI 1999 No. 3242 (<http://www.legislation.gov.uk/uksi/1999/3242/contents/made>)
10. Medicines and Healthcare products regulatory agency (MHRA) DB (2006) 04 v 2.0 'Single-use Medical Devices: Implications and Consequences of Reuse'. (<http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/C ON2024995>)
11. SGHD CEL 05 (2012) Key Procurement Principles, 1ST March 2012 (http://www.sehd.scot.nhs.uk/mels/CEL2012_05.pdf)
12. Health Facilities Scotland, Scottish Health Planning Note 13 Part 1 Decontamination Facilities: Central Decontamination Unit 2011

(<http://www.hfs.scot.nhs.uk/online-services/publications/decontamination/>)

13. EN ISO13485: 2012. Medical Devices. Quality Management System. Requirements for Regulatory Purposes. CEN.
14. 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
[http://www.unece.org.unecedevelcoiway.ch/trans/danger/publi/adr/adr2013/13contentse.html](http://www.unece.org/unecedevelcoiway.ch/trans/danger/publi/adr/adr2013/13contentse.html)
15. Health Facilities Scotland, NHS Scotland Guide to the Carriage of Dangerous Goods Regulations with respect to used medical devices, December 2013. (<http://www.hfs.scot.nhs.uk/publications>)
16. Decontamination Documentation System.
(<http://www.pcdds.scot.nhs.uk/>)
17. EN 13060 + A2 2010 Small steam sterilizers, 2010. CEN.
18. EN ISO 15883-1:2009 Washer-disinfectors. General requirements, terms and definitions and tests, October 2009. CEN.
19. 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.
20. SHTM 2010 (Parts 1 - 6) – Sterilization, Health Facilities Scotland, 2001.
21. SHTM 2030: Washer Disinfectors, 2001, Health Facilities Scotland.