

Compliant Dental Local Decontamination Units in Scotland (Primary Care)

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This document is not a comprehensive guide to the legal and policy requirements for local decontamination facilities but sets out what Health Facilities Scotland considers to be the key essential requirements to assist practitioners to comply with the nationally agreed level of service. Practitioners remain responsible for ensuring their own compliance with relevant legislation and/or policy requirements. As such, practitioners should ensure that they are aware of, and take such steps as are necessary to comply with, relevant legislative and/or policy requirements.

1.0 Scope and Purpose

This document clarifies the national requirements for compliant reprocessing of dental devices in Local Decontamination Units (LDUs) (Primary Care) with regard to The Medical Devices Regulations 2002¹ (as amended) (MDR), current best practice guidance and scope of activity. It brings together all elements and revises some elements of previous advice and requirements in relation to the operation of LDUs, including the Glennie Framework⁶, clarifies the circumstances in which devices may be decontaminated by LDUs owned by a different legal entity, and explains how that can be done in a compliant manner.

LDUs reprocess a wide range of instruments used in procedures which involve contact with “low Creutzfeldt–Jakob disease (CJD) transmission risk tissues” in Primary Care dentistry. 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 alert². Also in Scotland endodontic files must be treated as single use in compliance with the Chief Medical Officer’s letter CMO(2007)5³.

When considering compliance issues it can be useful to consider LDUs reprocessing devices as falling into two distinct categories namely:-

Option 1: LDUs reprocessing instruments remaining within **a single legal entity**

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

Option 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), i.e. 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 by an LDU.

An LDU model along the lines of Option 2 can however be managed in a legally compliant way provided there is:

- a) no “transfer of ownership” of any instruments;
 - b) no “placing on the market” of any procedure packs (i.e. there is no broken chain of ownership in relation to the instruments being processed).
- These concepts are explained further in section 3.0.

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

[Appendix 1](#) gives a summary of LDU requirements for both options.

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

- The Medical Devices Regulations 2002¹ (MDR);
 - Re-usable medical devices, their accessories and decontamination equipment (e.g. sterilizer washer disinfectors) are classified as medical devices and regulated under MDR¹. Whilst LDUs may be operated for the benefit of third parties outside of the scope of the MDR¹, 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.
- The National Health Service (General Dental Services) (Scotland) Regulations 2010⁴ came into force in July 2010. These require the contractor to provide proper, sufficient and safe:
 - Premises;
 - Equipment;
 - Instruments;
 - Procedures.
- Current best practice guidance for patient and staff safety;
 - The compliance requirements are also based on best practice guidance⁵⁻¹⁰, a review of current published literature and safety advice and legislation for patients, staff and the public¹¹⁻¹²;
 - The appropriate technical requirements stated in the following sections ([Sections 2.0, 3.0 and 4.0](#)) must be adhered to, so that the risk associated with the transmission of infections via dental devices is minimised and to ensure that the quality and safety of reprocessed dental devices are fit for use on patients.
- The quality assurance requirements which require to be performed routinely by the user as a part of a Dental Practice Inspection by NHS Boards every 3 years. The definition of ‘user’ can be found [in note \(d\) on page 8](#).

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

This section relates to [Option 1](#) (Section 1.0) above – 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 standards⁵⁻¹⁰. LDU owners/managers also have responsibilities under general law (including consumer protection legislation) to ensure the safety of patients, staff and users¹¹⁻¹².

[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 ADR -1(2013) European Agreement Concerning the International Carriage Of Dangerous Goods by Road ¹³.

3.0 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 2](#) (Section 1.0) above – 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 MDR¹. Key to this is ensuring that the MDR 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/standards⁵⁻¹⁰;
- Managing and operating facilities compliant with all legal requirements to ensure the safety of patients, staff and users¹¹⁻¹²;
- 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 1](#), Column 2 ([Appendix 1](#)) highlights the requirements for this LDU model.

4.0 Outsourcing decontamination services to an LDU

Ensuring the appropriate decontamination of devices is the responsibility of the practitioners or NHS Boards who own and use them. If a LDU of 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 [Section 3.0](#) and highlighted in [Table 1](#) Column 2 ([Appendix 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 (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 as per Decontamination Document System (DDS)¹⁵.

Appendix 1

	Column 1	Column 2
	Requirements for a compliant LDU which is only reprocessing devices owned by the same legal entity	Requirements for a compliant LDU reprocessing devices owned by a different legal entity, where the devices are located in the same building
Facilities	Compliant with the design layout of SHPN 13 Part 2 – One room model ⁵	Compliant with the design layout of SHPN 13 Part 2 – One room model ⁵
Equipment	Use of automatic washer disinfectant & sterilizer in compliance with the relevant standards ^a Installation and annual revalidation in accordance with the current guidance ^b Operation, maintenance and testing in accordance with the manufacturer's instructions ^c	Use of automatic washer disinfectant & sterilizer in compliance with the relevant standards ^a Installation and annual revalidation in accordance with the current guidance ^b Operation, maintenance and testing in accordance with the manufacturer's instructions ^c
Management	The role of User, and Operator within the LDU must be defined ^d The User and Operator must have training records appropriate to their needs Completion of NHS Education for Scotland training ^e Appropriate documentation of policy, procedures and records ^f	The role of User, Operator and Management within the LDU must be defined ^d The User, Operator and Manager must have training records appropriate to their needs Completion of NHS Education for Scotland training ^e Appropriate documentation of policy, procedures and records ^f Service Level Agreement (section 4.0) 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 ¹ Production of sterilized product Sterilized devices must be packed in suitable containers to provide protection and to minimise contamination ⁵ When transported off-site ⁹ , contaminated devices must be packed and transported in suitable containers in accordance with the guidance ¹³⁻¹⁴	Decontamination process in accordance with the device manufacturer's instructions ¹ Production of sterilized product Sterilized devices must be packed in suitable containers to provide protection and to minimise contamination ⁵ When transported off-site ⁹ , contaminated devices must be packed and transported in suitable containers in accordance with the guidance ¹³⁻¹⁴

Table 1: Technical requirements for a compliant dental LDU

Note:

- a) The current standard for benchtop sterilizers is BS EN ISO 13060¹⁶, while the current standard for washer disinfectors is BS EN ISO 15883:1,2¹⁷⁻¹⁸. 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.
(<https://www.scotcat.scot.nhs.uk/cdsnet/cdsnet.asp>)
- b) Installation and annual revalidation must follow the current guidance consisting of SHTM 2010¹⁹ for sterilizers and SHTM 2030²⁰ for washer disinfectors or their revision. Confirm with the suppliers who carried out the installation and annual revalidation to ensure their works are in accordance with SHTM 2010 and SHTM 2030. Advice from an Authorising Engineer (Decontamination) regarding validation may be required.
- c) The periodic testing requirements are:
- Minimum frequency of testing decontamination equipment is to follow manufacturer's instructions. In line with CDO letter SGHD/CDO (2010)²¹
 - 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 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 Standards¹⁶⁻¹⁸
- d) SHTM 2010¹⁹ and SHTM 2030²⁰ define the following roles:
- 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, dentist, or other health professional.
- Operator** is defined as any person with the authority to operate a sterilizer/washer disinfectant 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. (<http://www.nes.scot.nhs.uk/education-and-training/by-discipline/dentistry/areas-of-education/decontamination.aspx>)
- f) Policies, procedures and records for all aspects of management of medical devices and decontamination of reusable medical devices must be in place. DDS¹⁵ is an example.
- g) Transport off site means via road which is scoped in the ADR¹³. Guidance regarding transportation of medical devices can be found at HFS website¹⁴
(<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.

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