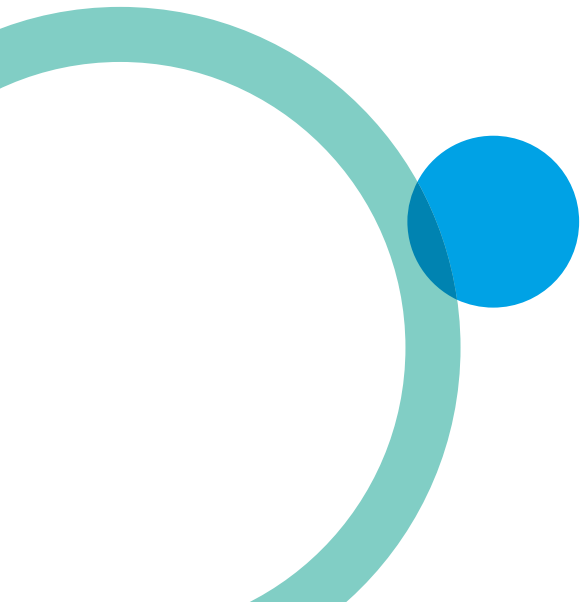
Compliant Dental Local Decontamination Units in Scotland Version 2 – GUID 5005



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1. Scope and Purpose

1.1 This document clarifies the national requirements for compliant reprocessing of dental devices in Local Decontamination Units (LDUs) with regard to The European Union Medical Devices Regulations 2017[1] (EU 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. It supersedes version1 of Compliant Dental Local Decontamination Units in Scotland (Primary Care) published by HFS in 2013.

1.2 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.

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[2]. Also in Scotland endodontic files must be treated as single use in compliance with the Chief Medical Officer's letter CMO(2007)5[3].

1.3 This revised document simplifies the Dental LDU requirements, based on the fact that the majority of Dental LDUs in Scotland process instruments within a 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 dental practice owned by an independent contractor(s) or a corporate body.

The processing of dental 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. *The preferred option is LDUs reprocessing instruments remaining within a single legal entity.*

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

- The EU Medical Devices Regulations 2017[1] (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[1].
  - the National Health Service (General Dental Services) (Scotland) Regulations 2010[4] which came into force in July 2010. These require the LDU 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 standards and best practice guidance[5-10&21], a review of published literature and safety advice and legislation for patients, staff and the public[10-11];
  - the appropriate technical requirements stated in Sections 2.0 for single legal entities must be adhered to, so that the risk associated with the transmission of infections via dental devices is minimized. It is also to ensure that the quality and safety of reprocessed dental devices is fit for use on patients.
- The quality assurance requirements require to be performed routinely by 'the User' as a part of the Combined Practice Inspection by NHS Boards every 3 years. The definition of 'User' can be found in note (d) on page 6.

2. Technical requirements for a Dental LDU reprocessing devices within a single legal entity

2.1 The LDU owner/manager is responsible for operating a compliant facility in accordance with all appropriate guidance and standards[5-10&21]. LDU owners/managers also have responsibilities under general law (including consumer protection legislation[4]) to ensure the safety of patients, staff and users[10-11].

2.2 To ensure the EU MDR[1] 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.

2.3 Table 1 highlights the technical requirements for this LDU model.

	Requirements for a compliant Dental LDU which is only reprocessing devices owned by a single legal entity
Facilities	Compliant with the design layout of SHPN 13 Part 2 – One room model[5].
Equipment	Use of automatic washer disinfector & sterilizer in compliance with the relevant standards[a]. 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].
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].
Process	Decontamination process in accordance with the device manufacturer's instructions[1&8&21]. Production of sterilized product. Sterilized devices must be packed in suitable containers to provide protection and to minimise contamination during transport and storage[5&8]. When transported off-site[g], contaminated devices must be packed and transported in suitable containers in accordance with the guidance on carriage of dangerous goods[12-13].

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

Note:

a) The current standard for benchtop sterilizers is BS EN ISO 13060[15], while the current standard for washer disinfectors is BS EN ISO 15883:1,2[16-17]. All equipment in NP 143 is in compliance with the relevant standards and guidance. NP 143 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[18] for sterilizers and SHTM 2030[19] 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[18] and SHTM 2030[19]. 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[20] 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[15-17].

d) SHTM 2010[18] and SHTM 2030[19] 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. https://www.nes.scot.nhs.uk/education-and-training/by-discipline/dentistry/dental-directorate/resources/decontamination-infection-control-resources.aspx

f) 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[14] is an example.

g) Transport off site means via road which is scoped in the ADR[12]. Guidance, GUID 5006 regarding transportation of medical devices can be found on the HFS website[13].

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

Where an LDU is 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), 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[13].

Whilst LDUs may be operated for the benefit of third parties outside of the scope of the EU MDR[1], 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[1].

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 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 such as the Practice Support Manaual[14].

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[5-10];
- managing and operating facilities compliant with all legal requirements to ensure the safety of patients, staff and users[10-11];
- 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 compliant Dental LDU which is reprocessing devices owned by a different legal entity (where the devices are located within the same building).
Facilities	Compliant with the design layout of SHPN 13 Part 2 – One room model[5].
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[1&21]. Production of sterilized product. Sterilized devices must be packed in suitable containers to provide protection and to minimise contamination[5]. 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[12-13].

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

Note:

h) The current standard for benchtop sterilizers is BS EN ISO 13060[15], while the current standard for washer disinfectors is BS EN ISO 15883:1,2[16-17]. All equipment in NP 143 is in compliance with the relevant standards and guidance. NP 143 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[18] for sterilizers and SHTM 2030[19] 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[18] and SHTM 2030[19]. Advice from an Authorising Engineer (Decontamination) regarding validation may be required.

j) The maintenance, annual revalidation and periodic testing requirements are to follow manufacturer's instructions in line with CDO letter SGHD/CDO (2010)2[20]. 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[15-17].

k) SHTM 2010[18] and SHTM 2030[19] 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. https://www.nes.scot.nhs.uk/education-and-training/by-discipline/dentistry/dental-directorate/resources/decontamination-infection-control-resources.aspx

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[12]. Guidance regarding transportation of medical devices can be found at HFS website[13] (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.

When transporting contaminated devices, via a public road, outside the building in which the LDU is located, 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[12].

Guidance regarding transportation of medical devices can be found at the HFS website[13].

References

1. 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

2. DB (2006) 04 'Single-use Medical Devices: Implications and Consequences of Reuse', Medicines and Healthcare products regulatory agency (MHRA) version 2.0

3. SEHD/CMO (2007) 5, Important Advice for Dentists on Re-use of Endodontic Devices and Variant Creutzfeldt-Jacob Disease (vCJD), Scottish Executive Health Department 19 April 2007

4. The National Health Service (General Dental Services) (Scotland) Regulations 2010, SSI 2010 No 208, 2 July 2010

5. Scottish Health Planning Note 13 Part 2 Decontamination Facilities: Local Decontamination Units (2008), Health Facilities Scotland

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

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

8. Scottish Dental Clinical Effectiveness Programme - Decontamination into Practice – Dental Clinical Guidance 2016

9. SGHD/CDO(2009)1 Decontamination of Dental Devices in Primary Care –Timescales for Compliance, 5 November 2009

10. Health and Safety at Work etc. Act 1974, SI 1974 c 37

11. Management of Health and Safety at Work Regulations 1999, SI 1999 No. 3242 (Amendment Regulations 2006)

12. 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

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

14. Practice Support Manual, Scottish Dental Clinical Effectiveness Programme www.psm.sdcep.org.uk

15. BS EN 13060:2014 + A1 2018 Small steam sterilizers, BSI**,** 2014

16. BS EN ISO 15883-1:2009 + A1 2014 Washer-disinfectors. General requirements, terms and definitions and tests, BSI

17. BS EN ISO 15883-2:2009 Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical devices, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc., BSI

18. SHTM 2010 (Parts 1 – 6) – Sterilization, Health Facilities Scotland**,** 2001

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

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

21. BS EN 17664:2017 Processing of healthcare products – Information to be provided by the medical device manufacturer for the processing of medical devices, BSI

Changes to version 1 of GUID 5005: 2013

Change of title from

"Compliant Dental Local Decontamination Units in Scotland (Primary Care) 2013" to

Compliant Dental Local Decontamination Units in Scotland Version 2 GUID 5005".

Change of document structure – Section 3 -The technical requirements for an LDU reprocessing devices owned by another legal entity and Section 4 on outsourcing was moved into appendix 1.

removed	added
Another legal entity	Different legal entity
UK Medical Devices Regulation 2002	EU regulation on medical devices 2017/745
DDS	Practice Support Manual – published by SDCEP
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 – 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].