NHS National Services Scotland

NHSScotland Requirements for Compliant Central Decontamination Units (CDUs)

GUID 5014

Version 3 - February 2024

Contents

1. Background

1.1. The first release of this compliance document concerning Central Decontamination Units (CDU) was November 2016 and a subsequent revision was published in May 2019. This latest review in 2023 is required due to the significant changes to legislation, standards, guidance and lessons learned documents that inform this compliance document.

1.2. The changes implemented in this latest revision are outlined at the back of this document (see Appendix B).

2. Scope

2.1. The scope of this document covers:

- processing (see ref 1) Reusable Medical Devices (RMDs) such as surgical instruments used in the acute sector
- outsourcing decontamination of RMDs such as surgical instruments to a third party service provider

2.2. Outwith scope:

- devices that are subject to chemical disinfection
- equipment not regarded as RMDs

2.3. Requirements:

- the requirements of a Service Level Agreement (SLA) when outsourcing the decontamination service to a Central Decontamination Unit (CDU) is specified in Section 6 of this document
- requirements for compliant CDUs are specified in Appendix A

2.4. The requirements in Appendix A cover facilities, equipment, management and process. Each requirement is identified by these subjects for instance, facilities (F), equipment (E), management (M) and process (P).

3. Purpose

3.1. This guidance sets the requirements to be implemented by Central Decontamination Units (CDUs) to improve patient safety, staff safety, to meet regulatory requirements and national policy/ strategy. It is expected that all CDUs should comply with these requirements by December 2024.

4. Staff and patient safety

4.1. Surgical instruments are classified as medical devices under the 2002 medical devices regulations (see ref 2). These regulations being endorsed by the Medicines and Medical Devices Act 2021 (see ref 2). Further secondary legislation was introduced and took effect in July 2023, that being The Medical Devices (amendment) (GB) Regulations 2023 Statutory Instrument 2023 no.627 (see ref 2). Manufacturers' instructions for reprocessing (see ref 1) should be followed.

4.2. The patient risks associated with inadequate decontamination of reusable surgical instruments have been documented (see refs 3 and 4).

4.3. Dancer et. al., (2012) (see ref 3) described an investigation into a sudden increase in the surgical site infection rates following 'clean' surgery. Post-sterilization contamination of sets containing surgical instruments was linked with an increased rate of deep surgical site infections in orthopaedic and ophthalmic patients. Further investigation of surgical packs and inspection of the contracted decontamination unit "*highlighted inadequate maintenance of autoclave components and poor handling practices by staff ... further compounded by lapses in inspection of surgical sets by theatre staff*." (see ref 3).

4.4. The P.M. Southworth (2014) (see ref 4) review reported "*outbreaks and incidents associated with inappropriate, inadequate or unsuccessful decontamination of surgical instruments.*"

4.5. Reported incidents included failures in decontamination. Forty three percent of incidents involved the failed disinfection of surgical instruments which conflicted with national guidelines (see ref 4). Twenty nine percent of reported decontamination failures were found to impact Instruments used in eye surgery. The author (see ref 4) also reported "*there is a relatively low risk of cross-infection through reusable surgical instruments when cleaning/ sterilization procedures are adhered to.*"

4.6. Lessons learned from incidents related to decontamination in Central Decontamination Unit (CDU) that are reported to IRIC are considered (see ref 30).

4.7. CDU staff must ensure compliance with Standard Infection Control Precautions (SICPs) outlined in Chapter 1 (1.2, 1.4, 1.9 to 1.10) of the 2023 National Infection, Prevention and Control Manual (NIPCM) (see ref 39) to ensure staff safety when processing reusable medical devices.

5. CDU scope of activity

5.1. The scope of decontamination activities in a Central Decontamination Unit (CDU) (see ref 5) includes:

- Reusable Medical Devices (RMDs) used within the same and/ or a different legal entity. Example of a legal entity is an NHSScotland Board or a private healthcare organisation. The CDU can supply decontamination of RMDs and procedure packs to other NHSScotland 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
- the legal requirements for CDUs are compliance with the Regulations and Act (see ref 2) on medical devices including registration with Medicines and Healthcare products Regulatory Agency (MHRA). The CDU operation of their Quality Management System (QMS) to Annex V of the 2002 Medical Device Regulation (MDR) (see ref 2) and BS EN ISO 13485 (see ref 6) must be audited by an UK approved body annually and any non-conformities found are dealt with in a timely fashion
- processing a wide range of RMDs (invasive, non-invasive and low/ medium/ high risk potential prion diseases as defined in their QMS to a range of clinical specialities within acute and primary care sectors
- quality assurance involves the systematic monitoring and evaluation of various aspects. This includes facilities, equipment, management and processes to ensure the delivery of quality RMDs as per the standards and requirements listed in Appendix A
- the awareness that a single use medical device (see ref 11 and 38) that is re-sterilized by the board and re-used outwith the manufacturer's instructions for use (see ref 38), is against MHRA advice and would become the responsibility of the board. The board would require to understand the risks and benefits of this approach. When the single use medical device is supplied non sterile, it should be in its original packaging and be processed as per the manufacturer's instruction for use (see ref 38).
- devices that are subjected to thermal disinfection and steam sterilization or low temperature sterilization

The requirements for CDUs are given in Appendix A.

6. Outsourcing decontamination services to a CDU

6.1. Ensuring the appropriate decontamination of reusable medical devices is the responsibility of the practitioners or NHS Boards who own and use them. The healthcare facilities outsourcing their decontamination services must have a procedure and records for the management of medical devices as follows.

6.2. For Central Decontamination Units (CDUs) who provide a decontamination service for a different legal entity a Service Level Agreement (SLA) should be put in place (see ref 2).

6.3. 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 Annex V of the 2002 Medical Device Regulation (MDR) (see ref 2) and BS EN ISO 13485 (see ref 6) and compliance with the CDU requirements as Appendix A
- a right for the customer to undertake audits of the CDU reprocessing their devices. The audit team may include an independent Authorising Engineer (Decontamination) (AE(D))
- practical requirements for wrapping (see refs 7-10), labelling (see ref 11) and transporting devices (see ref 12)
- management of non-conforming products (for example damaged, wet, missing/ lost, incorrect devices in the pack/ tray/ cassette), handling and investigations of complaints (see ref 6)
- financial and liability protection for both parties in the SLA including the supplier's contingency plans

Appendix A Requirements for compliant CDUs

Table A.1 - Requirements for compliant Central Decontamination Units (CDUs)

Subject	Requirement for compliant CDUs
Facilities	F1. Scottish Health Planning Note (SHPN) 13 part 1 (see ref 5) (for upgrades or new builds), noting its duplex requirements for critical plant. F2. Ongoing facility maintenance (including calibration) should ensure compliance to SHPN 13 part 1 (see refs 5, 13-16) (maintenance may be provided by an in-house or a contracted service).
Equipment	E1. Use automated (thermal) Washer Disinfectors (WDs). E2. Pass-through (single or multi chamber) WD models. E3. Installation, validation and periodic testing of the WDs including water quality compliant to the latest standards[a] and guidance[b]. E4. Water supply for WDs via a Reverse Osmosis (RO) water treatment system[b]). E5. Use porous load sterilizers (single or double doors) in compliance with the latest standard[c]). E6. Use (where applicable*) low temperature sterilizers in compliance with the latest standard (see ref 35). *where porous load sterilizers are not compatible with the reusable medical devices an alternative validated sterilization process compliant with the relevant standards[d]) and guidance if available should be used. Hydrogen peroxide sterilization (see ref 35) and Ethylene oxide sterilization is covered in Scottish Health Technical Memorandum (SHTM) 01-01 part E[b]). E7. Installation, validation and periodic testing of porous load sterilizers compliant to the latest standard[c]) and the latest guidance[e]).

a The latest standards for WDs are BS EN ISO 15883-1 (see ref 17), BS EN ISO 15883-2 (see ref 18) and BS EN ISO 15883-5 (see ref 31).
b The best practice guidance is the SHTM 01-01 series (see ref 19) and an addendum GUID 5019 (See ref 19).
c The latest standards for porous load sterilisers are BS EN 285 (see ref 20) and BS EN ISO 17665-1 (see ref 21).
d The latest standard for low temperature hydrogen peroxide sterilization validation processes is BS ISO 22441 (see ref 34) and for ethylene oxide BS EN ISO 11135-1 (see ref 36).
e The best practice guidance is SHTM 01-01 series (ref 19).

Subject	Requirement for compliant CDUs
	E8. Installation, validation and periodic testing of low temperature sterilizers (if applicable) compliant to the latest standard[f]) and the latest guidance[e]). E9. Steam quality for porous load sterilizers compliant to the latest standard (see ref 20) and the latest guidance[g]). E10. Installation, validation and periodic testing of other equipment such as a heat sealer[h]), ultrasonic pre-cleaner, trolley washer, lubricator, containment cabinet[i]) or a compressor compliant with the latest standards and SHTM 01-01[b]). Trolley Washer is preferred where transport carts are moved in the outside environment and carts to be decontaminated (see ref 33) to the level defined in board's Quality Management System (QMS). E11. Maintenance and operation of equipment as per the equipment manufacturers' instructions. Noting Board liability if changes are made to equipment outwith manufacturer's instructions. E12. Periodic decontamination of transport containers, storage shelf/ cabinets and transport vehicles in accordance with the QMS, local Infection prevention control policy and manufacturers' instructions as applicable. E13. Calibration of all measuring instrumentation fitted to decontamination equipment to be verified annually (see ref 19) using equipment that is calibrated by an accredited laboratory in accordance with BS EN ISO/IEC 17025 (see ref 37).
Management	M1. An operational Quality Management System as per the latest standard[j]).

f The latest standard for low temperature hydrogen peroxide sterilization validation processes is BS ISO 22441 (see ref 34) and for ethylene oxide BS EN ISO 11135-1 (see ref 36).

g The latest best practice guidance on clean steam for sterilization is SHTM 01-01 (see ref 19).

h The latest standard on packaging for terminally sterilized medical devices is BS EN ISO 11607 part 1 (see ref 7) and part 2 (see ref 8) and associated guidance CEN TS 16775 (see ref 9).

i The latest standard on containment cabinets is BS EN ISO 14644-7 (see ref 23). Boards take on liability if making changes to equipment outwith the manufacturer's instructions.

j The latest standard on QMS is BS EN ISO 13485 (see ref 6). A standard operating procedure for managing approved body un-announced audits is required. Non-conformities raised by approved body audits should be addressed in a timely manner. Contingency should consider the scale of the requirements and the impact on the supplier and receiver of the contingency.

Subject	Requirement for compliant CDUs
	M2. The CDU operates and is accredited to clause 14 of the 2002 medical devices regulation (see ref 2) and its amendment regulations (see ref 2). M3. Risk management carried out in accordance with the latest standard[k]). M4. Compliance with the current mandatory requirements of the Scottish Government Health and Social Care Directorate (SGHSCD)[l]). M5. Compliance with SHTM 01-01 (see ref 19) and its addendum GUID 5019 (see ref 19). M6. Compliance with Advisory Committee on Dangerous Pathogens (ACDP) guidance (see ref 19 and 25). M7. Relevant professional body membership for CDU management. M8. Access to an independent Authorising Engineer (Decontamination) AE(D)[m]). M9. All staff complete a decontamination training programme appropriate for their role[n]). Roles/ responsibilities defined in SHTM 01-01 (see ref 19). M10. An automated electronic reusable medical device tracking system, to track through the decontamination process and to the patient is in place[o]). M11. Service Level Agreements (SLA) with customers. M12. Business continuity and contingency arrangements in place. M13. National procurement contracts where they exist[p]).

k The latest standard on risk management is BS EN ISO 14971 (see ref 24).
l Government letters concerning decontamination are available on the SHOW website.
m HFS provides AE(D) services for NHSScotland.
n Staff are required to undertake appropriate decontamination training. Consult the NES Framework to support staff development in the decontamination of reusable medical devices (see ref 27). Training on the importance of maintaining cleanroom integrity is required. The ICD/ Microbiologist role is under review.
o A GS1 compatible system. A national scan for safety program has been established by government thus clarifying there is a national consideration for tracking as well as an individual board requirement.
p NP 143 is the National Procurement Contract for decontamination equipment. This Framework should be the first port of call for the Health Boards requiring equipment unless validation would be compromised and require to be revisited. Access to the equipment on the Framework requires that relevant Health Boards carry out a detailed product evaluation to meet their particular requirements. Advice from an AE(D) may be sought. In the absence of national contracts, regional/ local can be considered. Group requests can be beneficial in costs. NP 187 is the National Procurement Contract for maintenance and consumables.

Subject	Requirement for compliant CDUs
Process	P1. Satisfactory decontamination process as defined in the QMS compliant with the latest standard[j]) and certified by an approved body. P2. Production of sterile products compliant with the latest standard[q]) and the pre-sterilization packaging standards (see ref 7, 8, 9 and10). P3. Validated decontamination processes as per the reusable medical device manufacturer's instructions and compliance with the latest guidance (see ref 19) and standards[r]). P4. Labelling in accordance with the regulations on medical devices (see ref 2) and relevant standards (see ref 11). P5. Transportation of the reusable medical devices in a container/ transport system in line with the latest guidance (see ref 12).

q The latest standard on designating medical devices as 'Sterile' is BS EN 556-1 (see ref 26).
r The standard on information to be provided by the manufacturer for processing of health care products is BS EN ISO 17664-1 (See ref 1) and bioburden testing is BS EN ISO 11737-1 (see ref 28).

Appendix B Changes to GUID 5014

B.1 The following table details the updates in references in the latest revision

Table B.1 - Changes from version 2 to version 3 of GUID 5014

References removed	References/ content added
Regulation (EU) 2017/745	• Medical Devices Regulations (MDR) 2002 • Medicines and Medical Device Act 2021 • The Medical Devices (amendment) (GB) regulations 2023. SI 2023 no.627.
Notified body	Approved body
EN 17664: 2017	BS EN ISO 17664-1: 2021
EN 11607 Parts 1 & 2: 2017	BS EN ISO 11607 Parts 1 & 2: 2020
EN 15223: 2016	BS EN ISO 15223-1: 2021
EN 11135-1: 2014	BS EN ISO 11135-1: 2014+A1: 2019
EN ISO 11737-1: 2018	BS EN ISO 11737-1: 2018+A1: 2021
EN ISO 14971: 2012	• BS EN ISO 14971: 2019+A11: 2021 • BS EN ISO 15883-5: 2021 (first release)
14644-4: 2001	14644-4: 2022
CEN ISO/TS 16775: 2014	• PD CEN ISO/TS 16775: 2021 • BS ISO 22441: 2022 (first release) • GUID 5019: 2022

B.2 The following details are introduced into this latest revision:

- GUID 5019v1: 2022 [addendum to Scottish Health Technical Memorandum (SHTM) 01-01 v1: 2018 series]
- BS EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer
- BS EN ISO/IEC 17025: 2017
- BS EN ISO 15883-6: 2015
- Lessons learned & recommendations report on Cowlairs Central Decontamination Units (CDU) incident Nov 2018 published HFS Oct 2019 (see ref 30)
- Section 4 - Standard Infection Control Precautions (SICPs) and the National Infection Prevention and Control Manual (NIPCM) added
- Section 6 - Amend “the audit team must include” to the audit team may include an independent Authorising Engineer (Decontamination) (AE(D))”
- F2 - added mention of calibration

- E10 - trolley washer and manual cleaning of carts included
- New - E13 added
- M9 - roles/ responsibilities added and referenced to SHTM 01-01. Noted that ICD role is under review
- National perspective to tracking included in item n) of the references for Table 1. Inclusion of validation considerations in item o) of the references for Table 1.
- 4.7 added CDU to read as CDU staff for clarity purposes
- 5 - added that single use non sterile devices should be received in original packaging and processed in line with manufacturer's instructions for use. Also added it is the board's responsibility if not following the medical device manufacturer's instructions for use
- 5.1 removed reference to CJD and replaced with prion diseases
- Table A.1 added reference to SHTM 01-01 series in P3
- Added NP187 contract to footnote P on page 10

B.3 The following table details the updates made in version 2 of this guidance.

Table B.2 - Changes from version 1: 2016 to version 2: 2019 of GUID 5014

References removed	References/ content added
MDR 2002 & MDD 93/42/EEC	• Regulation (EU) 2017/745
17664: 2004	• EN 17664: 2017
SHTM 2010 SHTM 2030 SHTM 2031	• SHTM 01-01 series 2018
EN 11607 Parts 1& 2: 2014	• EN 11607 Parts 1& 2: 2017
EN 15223: 2012	• EN 15223: 2016
Health Department Letter (HDL (2001)66	• GUID 5010: 2014
EN 863-3: 2009	• EN 11135-1: 2014
EN 15223: 2012	• EN 11138-1: 2017

B.4 The following standards were introduced in version 2:

- EN ISO 11737-1: 2018
- EN ISO 11139: 2018

References

These references were current at the time this document was produced. Anyone using this document should ensure that they refer to the current version of these references.

1. BS EN ISO 17664-1: 2021. Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices, BSI.
2. The Medical Devices Regulations 2002 (statutory instrument 2002 No.618 Consumer Protection), Medicines & Medical Device Act 2021 and The Medical Devices (amendment)(GB) Regulations 2023 (statutory instrument 2023 no. 627).
3. Dancer et. al., (2012) Surgical site infections linked to contaminated surgical instruments, Journal of Hosp Infection Vol 81 Issue 4 Pages 231-238 August 2012.
4. P.M. Southworth (2014) Infections and exposures: reported incidents associated with unsuccessful decontamination of reusable surgical instruments: Health Protection Scotland: Journal of Hospital Infection 88 pp127-131 (2014).
5. Scottish Health Planning Note 13 Part 1: 2010 Decontamination Facilities: Central Decontamination Unit. Health Facilities Scotland (HFS), 2010. [revision conducted in 2023 for publication 2024]
6. BS EN ISO 13485: 2021 Medical Devices. Quality management systems. Requirements for regulatory purposes. BSI.
7. BS EN ISO 11607 -1: 2020 Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems. BSI.
8. BS EN ISO 11607-2: 2020 Packaging for terminally sterilized medical devices. BSI.
9. PD CEN ISO/TS 16775: 2021 - Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 (ISO/TS 16775:2014). BSI.
10. BS EN ISO 868-3: 2017. Packaging for terminally sterilized medical devices. Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) Requirements and test methods. CEN.
11. BS EN ISO 15223-1: 2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements. BSI.
12. GUID 5006 v1 Guide to the Carriage of Dangerous Goods Regulations with respect to Used Medical Devices, Health Facilities Scotland, 2013.
13. BS EN ISO 14644-4: 2022 Cleanrooms and associated controlled environments. Design, construction and start-up. BSI.

14. BS EN ISO 14644-2: 2015 Cleanrooms and associated controlled environments. Specifications for testing and monitoring to prove continued compliance with ISO 14644-1. CEN.

15. BS EN ISO 14698-1: 2003 Cleanrooms and associated controlled environments — Biocontamination control - Part 1: General principles and methods. CEN. [superseded by BS EN 17141: 2020]

16. BS EN 17141: 2020 Cleanrooms and associated controlled environments- Biocontamination Control. BSI.

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

18. BS 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. (ISO 15883-2:2006) CEN.

19. Scottish Health Technical Memorandum 01-01 series Decontamination of medical devices in a Central Decontamination Unit, HFS, v1: 2018 including supplement GUID 5017 and GUID 5019 Addendum to Scottish Health Technical Memorandum (SHTM) 01-01 in relation to the change of NICE IPG 196. HFS v1: 2022.

20. BS EN 285:2015+A1: 2021 Sterilization. Steam sterilizers. Large sterilizers. BSI.

21. BS EN ISO 17665-1: 2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. CEN.

22. BS EN ISO 14937: 2009 Sterilization of health care products. General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices. CEN.

23. BS EN ISO 14644-7:2004 Cleanrooms and associated controlled environments. Separative devices (clean air hoods, gloveboxes, isolators and mini-environments). CEN.

24. BS EN ISO 14971: 2019+A1: 2021 Medical devices - Application of risk management to medical devices. BSI.

25. Transmissible Spongiform Encephalopathy (TSE) Guidance - Prevention of CJD and vCJD by Advisory Committee on Dangerous Pathogens' (ACDP) ACDP TSE Subgroup published by DoH 2016.

26. BS EN 556-1: 2001 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices. CEN.

27. Framework to Support Staff Development in the Decontamination of Re-usable Medical Devices v2, NHS Education for Scotland (NES) 2022.

28. BS EN ISO 11737-1: 2018+A1: 2021 Sterilization of health care products - Microbiological methods. Part 1: Determination of a population of microorganisms on products. BSI.

29. BS EN ISO 11139: 2018 Sterilization of health care products - Vocabulary - Terms used in sterilization and related equipment and process standards. CEN.

30. Lessons learned & recommendations report on Cowlairs Central Decontamination Units (CDU) incident Nov 2018 published HFS Oct 2019.

31. BS EN ISO 15883-5: 2021 Washer-disinfectors Performance requirements and test method criteria for demonstrating cleaning efficacy. BSI.

32. DD CEN ISO/TS 17665-2:2009 Sterilization of health care products. Moist heat. Guidance on the application of ISO 17665-1. CEN.

33. BS EN ISO 15883-6: 2015 Washer-disinfectors Part 6: Requirements and tests for washer disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment. CEN.

34. BS ISO 22441: 2022 Sterilization of health care products. Low temperature vaporized hydrogen peroxide. Requirements for the development, validation and routine control of a sterilization process for medical devices. BSI.

35. BS EN 17180: 2023 consultation draft. Sterilizers for medical purposes. Low temperature vapourized hydrogen peroxide sterilizers. Requirements and testing. BSI.

36. BS EN ISO 11135:2014+A1:2019 Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical device. BSI.

37. BS EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. BSI.

38. BS EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer. BSI.

39. National Infection Prevention and Control Manual, NSS 2023.

Abbreviations

ACDP: Advisory Committee on Dangerous Pathogens

AE(D): Authorising Engineer (Decontamination)

CDU: Central Decontamination Unit

CJD: Creutzfeldt Jakob Disease

EU: European Union

HDL: Health Department Letter

HFS: Health Facilities Scotland

MDR: Medical Devices Regulations

MHRA: Medicines & Healthcare products Regulatory Agency

NES: NHS Education for Scotland

NIPCM: National Infection Prevention and Control Manual

NP: National Procurement

QMS: Quality Management System

RMD: Reusable Medical Device

RO: Reverse Osmosis

SGHSCD: Scottish Government Health and Social Care Directorate

SHPN: Scottish Health Planning Note

SHTM: Scottish Health Technical Memorandum

SICPs: Standard Infection Control Precautions

SLA: Service Level Agreement

TSE: Transmissible Spongiform Encephalopathy

vCJD: variant Creutzfeldt Jakob Disease

WD: Washer Disinfector