NSS Health Facilities Scotland

Requirements for Compliant Central Decontamination Units Version 2 – GUID 5014

May 2019

Content

1. Background

Version 1 of this guidance was published in November 2016. A review of the guidance is required within the routine three year review period due to significant changes to regulations, standards and guidance documents.

The changes (additions/removals) in the reference documentation are detailed in the Changes from version 1 of GUID 5014: 2016 at the rear of this document.

2. Scope

The scope of this document covers:

- processing[1] reusable medical devices such as surgical instruments used in the acute sector;
- outsourcing decontamination of reusable medical devices such as surgical instruments to a third party service provider.

Outwith Scope:

- single use;
- devices that are subject to chemical disinfection;
  - equipment not regarded as reusable medical device.

Requirements:

- the requirements of a service level agreement 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 1.

3. Purpose

This guidance sets the requirements to be implemented by CDUs to improve patient safety, staff safety, to meet regulatory requirements and national policy/strategy. All CDUs should comply with these requirements by 31st December 2019.

4. Staff and patient safety

Surgical instruments are classified as medical devices under the EU regulation 2017/745 on medical devices[2]. The Regulations came into effect in 2017. Manufacturers' instructions for reprocessing should be followed.

The patient risks associated with inadequate decontamination of reusable surgical instruments have been documented[3&4].

Dancer et. al., (2012)[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[3]."

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

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

5. Central Decontamination Unit scope of activity

The scope of decontamination activities in a CDU[5] includes:

- Reusable medical devices used within the same and/or a different legal entity. Example of a legal entity is an NHS Board or a private healthcare organisation. 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;
- The legal requirements for CDUs are compliance with the Regulation[2] on medical devices including registration with MHRA. The CDU operation of their quality management system to EN ISO 13485[6] must be audited by a notified body annually and any non-conformities found are dealt with in a timely fashion;
- Processing a wide range of reusable medical devices (invasive, non-invasive and low/medium/high risk for Creutzfeldt–Jakob Disease (CJD)) transmission as defined in their Quality Management System 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 1;
- CDUs must not reprocess single use devices. When the single use medical device is supplied non sterile, the CDU may process once. Ensure the device is received in its original packaging;
- Devices that are subjected to thermal disinfection and steam sterilization or low temperature sterilization.

The requirements for CDUs are given in Appendix 1.

6. Outsourcing decontamination services to a Central Decontamination Unit

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 listed below.

For CDUs who provide a decontamination service for a different legal entity a Service Level Agreement (SLA) should be put in place[2].

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[6] and compliance with the CDU requirements as Appendix 1;
- A right for the customer to undertake audits of the CDU reprocessing their devices. The audit team may include an independent Authorised Engineer (Decontamination);
- Practical requirements for wrapping[7-10], labelling[11] and transporting devices[12];
- Management of non-conforming products (e.g. damaged, wet, missing/lost, incorrect devices in the pack/tray/cassette), handling and investigations of complaints[6];
- Financial and liability protection for both parties in the SLA including the supplier's contingency plans.

Appendix 1: Requirements for compliant Central Decontamination Units

	Requirements for Compliant CDUs
Facilities	Scottish Health Planning Note (SHPN) 13 Part 1[5] (for upgrades or new builds). Ongoing facility maintenance should ensure compliance to SHPN 13 Part1[5, 13-16] (maintenance may be provided by an in-house or a contracted service).
Equipment	• Use automated (thermal) Washer Disinfectors (WD). • Pass-through (single or multi chamber) WD models. • Installation, validation and periodic testing of the WDs including water quality compliant to the latest standards[a)] and guidance[b)]. • Water supply for WDs via a Reverse Osmosis (RO) water treatment system. --- • Use porous load sterilizers (single or double doors) in compliance with the latest standard[c)]. • Installation, validation and periodic testing of porous load sterilizers compliant to the latest standard[c)] and the latest guidance[d)]. • Steam quality for porous load sterilizers compliant to the latest standard and the latest guidance[e)]. --- Where porous load sterilizers are not compatible with the reusable medical devices an alternative validated sterilization process compliant with the relevant standards[f)] and guidance if available should be used. Hydrogen peroxide sterilization and Ethylene oxide sterilization is covered in SHTM 01-01 part E. --- Installation, validation and periodic testing of other equipment such as a heat sealer[g)], ultrasonic pre-cleaner, trolley washer, lubricator, containment cabinet[h)] or a compressor compliant with the latest standards and SHTM 01-01[19]. Maintenance and operation of equipment as the equipment manufacturers' instructions. Periodic decontamination of transport containers, storage shelf/cabinets and transport vehicles in accordance with the Quality Management System, local Infection control policy and manufacturers' instructions as applicable.

Management	An operational Quality Management system as per the latest standard[i)]. The CDU operates and is accredited to Article 22 of the Regulation 2017/745[2] on medical devices. Risk management carried out in accordance with the latest standard[i)]. Compliance with the current mandatory requirements of the Scottish Government Health and Social Care Directorate (SGHSCD)[k)]. Compliance with SHTM 01-01[19]. Compliance with ACDP guidance[25]. Relevant professional body membership for CDU management. Access to an independent Authorising Engineer (Decontamination) AE(D)[l)]. All staff complete a decontamination training programme appropriate for their role[m)]. An automated electronic reusable medical device tracking system, to track through the decontamination process and to the patient is in place[n)]. Service Level Agreements with customers. Business continuity and contingency arrangements in place. National, regional or local procurement contracts where they exist (including framework arrangements[o)]).
Process	Satisfactory decontamination process as defined in the QMS compliant with the latest standard[i)] and certified by a notified body. Production of sterile products compliant with the latest standard[p)] and the pre-sterilization packaging standards[7-11]. Validated decontamination processes as per the reusable medical device manufacturer's instructions and compliance with the latest guidance and standards[q)]. Labeling in accordance with the EU Regulation 2017/745[2] on medical devices and relevant standards[11]. Transportation of the reusable medical devices in a container/transport system in line with the latest guidance[12].

Table 1

References for Table 1(previous page)

a) The latest European standards for Washer Disinfectors (WD) are 15883-1[17] and 15883-2[18].

b) The best practice guidance (applicable to WD) is SHTM 01-01[19]. This guidance is effective from December 2019.

c) The latest European standards for porous load sterilisers are EN 285[20] and EN 17665-1[21].

d) The best practice guidance (applicable to porous load sterilizers) is SHTM 01-01[19].

e) The latest best practice guidance on clean steam for sterilization is SHTM 01-01[19].

f) The latest European standard for low temperature Hydrogen peroxide sterilization validation processes is EN 14937[22] and EN 11135-1[30] for Ethylene oxide.

g) The latest European standard on packaging for terminally sterilized medical devices is EN 11607 part 1[7] and part 2[8]and associated guidance CEN TS 16775[9]. Product bioburden testing should be carried out in line with EN 11737-1[28].

h) The last European standard on containment cabinets is EN 14644-7[23].

i) The latest standard on Quality Management Systems is EN 13485[6]. An SOP for managing notified body un-announced audits is required. Non-conformities raised by Notified 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.

j) The last European standard on risk management is EN 14971[24].

k) Government letters concerning decontamination are available on the SHOW website.

l) HFS provides Authorising Engineers (Decontamination) [AE(D)] services for NHSScotland.

m) Staff are required to undertake appropriate decontamination training. Consult the NES Framework to support staff development in the decontamination of reusable medical devices[27]. Training on the importance of maintaining cleanroom integrity is required.

n) A GS1 compatible system.

o) 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. Access to the equipment on the Framework requires that relevant Health Boards carry out a detail product evaluation to meet their particular requirements. Advice from an AE(D) must be sought.

p) The last European standard on designating medical devices as ‘Sterile’ is EN 556-1[26].

q) The standard on information to be provided by the manufacturer for processing of health care products is EN 17664[1].

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. **EN ISO 17664: 2017 processing of health care products –** Information to be provided by the medical device manufacturer for the processing of medical devices. CEN.

2. **Regulation (EU) 2017/745 on medical devices May 2017.** OJEU.

3. **Dancer et. al., (2012)** Surgical site infections linked to contaminated surgical instruments, Journal of Hosp Infection Vol 81 Iss 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. HFS, 2010.

6. **EN 13485: 2016 Medical Devices**. Quality management systems. Requirements for regulatory purposes. CEN.

7. **EN ISO 11607 -1: 2017** Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems. CEN.

8. **EN ISO 11607-2: 2017** Packaging for terminally sterilized medical devices. CEN.

9. **CEN ISO/TS 16775: 2014** - Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 (ISO/TS 16775:2014). CEN.

10. **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. **EN ISO 15223-1: 2016** Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements. CEN.

12. **Guide to the Carriage of Dangerous Goods Regulations** with respect to Used Medical Devices, Health Facilities Scotland, 2013. www.hfs.scot.nhs.uk

13. **EN ISO 14644-4: 2001 Cleanrooms and associated controlled environments**. Design, construction and start-up. CEN.

14. **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. **EN ISO 14698: 2003 Cleanrooms and associated controlled environments**- Biocontamination Control. CEN.

16. **prEN 17141: 2018 Cleanrooms and associated controlled environments**- Biocontamination Control. CEN.

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

18. **EN ISO 15883-2: 2009 Washer-disinfectors**. CEN.

19. **Scottish Health Technical Memorandum 01-01 series, Decontamination of medical devices in a Central Decontamination Unit,** HFS, 2018.

20. **EN 285:2006+A2:2015** Sterilization. Steam sterilizers. Large sterilizers. CEN.

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

24. **EN ISO 14971: 2012 Medical devices** — Application of risk management to medical devices. CEN.

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

26. **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**, NES 2016.

28. **EN ISO 11737-1: 2018 Sterilization of health care products** – Microbiological methods. Part 1: Determination of a population of microorganisms on products. CEN.

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

30. **EN ISO 11135: 2014 Sterilization of health care products-** Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices. CEN.

Changes from version 1 of GUID 5014:2016

References removed	References 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
EN 868-3: 2009	EN 868-3: 2017
HDL (2001)66	GUID 5010: 2014
	EN 11135-1: 2014
	EN 11138-1: 2017
	EN ISO 11737-1: 2018
	EN ISO 11139: 2018
	prEN 17141: 2018