NHSScotland Requirements for Compliant Endoscope Decontamination Units (EDUs)

GUID 5013

Draft 2.6 - February 2024

Contents

1. Background

1.1. The publication of version 2.0 of guidance GUID 5013 was supported by the Healthcare Associated Infection (HAI) National Advisory Group in 2014. Revision to version three has been undertaken as a significant number of new or revised standards and best practice guidance have recently been released. For example, the publication of Scottish Health Technical Note (SHTN) 00-04 v3: 2024 (see ref 1) 'Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services' and the first release of Scottish Health Technical Memorandum (SHTM) 01-06 v1: 2023 five-part series on 'Decontamination of thermolabile flexible endoscopes and Transoesophageal echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units' (see refs 2, 3, 4, 5 and 6).

1.2. SHTM 01-06 v1: 2023 replaced SHTM 2030 Part 1, 2 and 3 (see ref 7, 8 and 9) as applicable to Endoscope Washer Disinfectors (EWDs). Validation requirements for a range of decontamination equipment technologies not described in other guidance or standards was also introduced. These included manual cleaning flushing units and packing systems to contain disinfected endoscopes.

1.3. The changes implemented in this latest revision of GUID 5013 are outlined in Appendix B of this document.

1.4. Flexible thermolabile endoscopes and their accessories are classified as medical devices under the 2002 medical devices regulations (see ref 10). These regulations were endorsed by the Medicines and Medical Devices Act 2021 (see ref 11). 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 12)). Manufacturers' instructions for reprocessing should be followed (see refs 13 and 14).

2. Scope

2.1. This document specifies the requirements for compliant Endoscope Decontamination Units (EDUs) as shown in Appendix A. The scope of this document covers:

- EDUs designed and built in line with Scottish Health Planning Note (SHPN) 13 Part 3 (see ref 15) reprocessing (see ref 14) flexible, thermolabile endoscopes and their reusable accessories requiring manual cleaning and automated cleaning and chemical disinfection in an Endoscope Washer Disinfector (EWD)
- Transoesophageal Echocardiograph (TOE) ultrasound probes recommended by the manufacturer as suitable for processing in an EWD

2.2. The following Reusable Medical Devices (RMDs) are outwith the document scope:

- endoscopes suitable for steam sterilization, robotic instruments, single use accessories and equipment not regarded as RMDs
- ultrasound probes other than TOE ultrasound probes

2.3. The requirements in Appendix A cover facilities, equipment, management and process. Each requirement is identified by the following subjects facilities (F), equipment (E), management (M) and process (P).

3. Purpose

3.1. This guidance sets the requirements to be implemented by Endoscope Decontamination Units (EDUs) to improve patient safety, staff safety, to meet regulatory requirements and national policy/ strategy. It is expected that all EDUs should comply with these requirements by March 2025.

4. Staff and patient safety

4.1. The patient risks associated with inadequate endoscope decontamination have been documented in journal articles. For example, in 1993 Spach et.al. (see ref 16) reported "*More endoscopes have been associated with hospital-acquired infections than any other device."*

4.2. In 2004 a serious decontamination failure occurred in Northern Ireland (see ref 17) which resulted in a review of the service in NHSScotland (see ref 18), the publication of the Chief Medical officer (CMO), letter Scottish Executive Health Department (SEHD)/ CMO (2006)04 (see ref 19) and a programme of improvement in endoscope decontamination practices within NHSScotland.

4.3. Despite major improvements in the facilities, management, equipment and decontamination processes, the literature continued to report outbreaks linked to endoscopic procedures (see refs 20 and 21, 22, 23 and 24).

4.4. Recent reviews continue to highlight the risks posed by Duodenoscopes use during Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures (see refs 25, 26 and 27) and outbreaks linked to multi resistant bacterial strains such as Carbapenemase-producing Gram-negative bacteria (see ref 28).

4.5. Recognising the patient risks outlined above and to ensure staff safety during decontamination of thermolabile flexible endoscopes, staff must ensure compliance with Standard Infection Control Precautions (SICPs) outlined in Chapter 1 (sections 1.1, 1.4, 1.9 and 1.10) of the National Infection, Prevention and Control Manual (NIPCM) (2024) (see ref 29).

4.6. In addition, the User (see ref 2) must carry out periodic quality assurance checks at a local level. This should include systematic monitoring and evaluation of the Endoscope Decontamination Unit (EDU) facilities (see ref 7), equipment, management and processes. Local Governance procedures must be in place to ensure lessons are learned from identified risks (see ref 30).

5. EDU scope of activity

5.1. The scope of decontamination activities in an Endoscope Decontamination Unit (EDU) can include:

- decontamination of a range of thermolabile flexible endoscopes, their accessories[a] and Transoesophageal echocardiograph (TOE) ultrasound probes (where advised by the device manufacturer) used within the same legal entity. An example of a legal entity is an NHSScotland health board
- processing thermolabile flexible endoscopes for use in (semi-invasive procedures defined as low/ medium/ risk for Creutzfeldt-Jakob Disease (CJD)) transmission in the Advisory Committee on Dangerous Pathogens (ACDP) - Transmissible Spongiform Encephalopathy (TSE) Subgroup guidance (see ref 31)

a EDUs must not reprocess single use devices SHTM 01-06 part A - Management (see ref 2).

Appendix A Requirement for compliant EDUs

Table A.1 - Requirements for compliant Endoscope Decontamination Units (EDUs)

Subject	Requirements for Compliant EDUs
Facilities	F1. For small/ medium size units adjacent to clinical units. A one room[b], two room or two room with ante rooms Endoscope Decontamination Unit (EDU) as specified in Scottish Health Planning Note (SHPN) 13 Part 3[b] F2. For centralised services - Two room EDU with ante and other support rooms as specified in SHPN 13 Part 3[b] F3. Ongoing facility maintenance (including equipment calibration) should ensure compliance to SHPN 13 part 3
Equipment	E1. For a one room EDU: Single-ended Endoscope Washer Disinfector (EWD) compliant to the washer-disinfector standards BS EN ISO 15883 Part 1, Part 4 and Part 5 (see refs 32, 33, and 34) and latest guidance[c] E2. For all other EDU models (see ref 15) a Pass-through EWD compliant to BS EN ISO 15883 Parts 1, 4 and 5 (see refs 32, 33 and 34) and SHTM 01-06 Part D (see ref 5). E3. Water supply for EWDs via a Reverse Osmosis (RO) water treatment is advised[d] Final rinse water compliant to BS EN ISO 15883 part 4 (see ref 33) and Scottish Health Technical Memorandum (SHTM) 01-06 part D (see ref 5). E4. Storage cabinets compliant with BS EN 16442:2015 (see ref 35) and SHTM 01-06 part E: 2023 v1 (see ref 6). E5. Dry leak testers and wet leak testers compliant with SHTM 01-06 part C: 2023 (see ref 4). E6. Manual clean flushing units compliant with SHTM 01-06: part C: 2023 (see ref 4). E7. Packing systems (vacuum/ positive pressure) compliant with SHTM 01-06 part E: 2023 (see ref 6). E8. Installation validation and periodic testing of all equipment as per latest guidance[c].

b One room model as per SHPN 13 Part 3 (see ref 15) only where other options are not possible.
c The current guidance documents are SHTM 01-06 parts A to E (see refs 2 to 6).
d Where shown to achieve the required quality of water, alternative methods such as 2-micron filtration and UV light may be used (see ref 5 and ref 33).

Subject	Requirements for Compliant EDUs
	E9. Maintenance contracts[e] and operation as per equipment manufacturers' instructions (see refs 13 and 14). Manufacturers' instructions for use and decontamination must be followed at all times[f]. E10. Periodic decontamination of transport containers, storage shelf/ cabinets and transport vehicles in accordance with local Infection prevention control policy[g] and manufacturers' instructions as applicable[f]. E11. Calibration of all measuring instrumentation fitted to decontamination equipment to be verified annually (see refs 2 and 3) using equipment that is calibrated by an accredited organisation (see ref 36)[h].
Management	M1. An operational Quality Management system (QMS) as per SHTM 01-06 Part A (see ref 2). M2. Designated roles for management, operation, maintenance, testing, safety and validation as defined in latest guidance (see ref 2). M3. Access to an independent Authorising Engineer (Decontamination) AE(D) Service)[i]. M4. Decontamination Policy, Procedures and Records to be in place (see ref 2). M5. Completion of an endoscope decontamination training programme appropriate for the role[j]. Staff are required to undertake appropriate decontamination training before performing each task, followed by ongoing assessments. M6. If supplying processed endoscopes to other legal entities the QMS must be certified to BS EN ISO 13485 (see ref 37) by a UK approved body.

e NP 143 is the National Procurement (NP) Contract for decontamination equipment. This Framework should be the first port of call for the Health Boards (HBs) requiring equipment unless validation would be compromised and require to be revisited. Access to the equipment on the Framework requires that relevant HBs 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 contract for consumables.

f Manufacturers' instructions for use must be followed at all times. Failure to follow manufacturers' instructions or if changes are made to equipment out with manufacturer's instructions may result in Board liability (see refs 13 and 14).

g National Infection Prevention and Control Manual (NIPCM) Chapter 4 2024 (see ref 29).

h In accordance with BS EN ISO/IEC 17025: 2017 requirements for calibration laboratories and testing organisations.

i HFS provides AE(D) services for NHSScotland.

j NHS Education for Scotland (NES) provides an on-line training programme on endoscope decontamination.

Subject	Requirements for Compliant EDUs
	M7. An automated electronic reusable medical device tracking system, to track through the decontamination process and to the patient is in place[k]. M8. Procurement of equipment and services via national procurement contracts where they exist[e].
Process	P1. Validated decontamination processes as per the reusable medical device manufacturer's instructions and compliance with the latest guidance[c] and standards[l]. P2. In accordance with a QMS, completion of a satisfactory decontamination process (see refs 2 to 6) including leak test, manual cleaning, inspection, cleaning and disinfection in an EWD, and use of storage cabinets or packing systems where in use. P3. Transport in a labelled and solid-walled transport system as per latest guidance[m] (see ref 38)

k A national scan for safety program has been established by government clarifying requirements for tracking and traceability systems. Consider a GS1 compatible system.

l The standard on information to be provided by the manufacturer for processing of health care products is BS EN ISO 17664-1 (see ref 14) and BS ISO 20417: 2021 Medical devices - Information to be supplied by the manufacturer (see ref 13).

m GUID 5006 Guide to the Carriage of Dangerous Goods Regulations with respect to Used Medical Devices.

Appendix B Changes to GUID 5013 v2.0

Amendments made to GUID 5013 v2 are given in the table B.1

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

Table B.1 - Changes made to References in version 2 of GUID 5013

References removed	References/ content added
GUID 5013 v2	• GUID 5013 V3
"the audit team **must** include an independent Authorising Engineer (Decontamination) (AE(D))".	• Section 6 - Amended "the audit team **may** include an independent Authorising Engineer (Decontamination) (AE(D))".
Regulation (European Union (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.
Appendix A. Table 1 item F2	• added mention of calibration.
Appendix A. Table 1 equipment items	• added items E6 to E11.
Appendix A. Table 1 management items	• M9 - roles/ responsibilities added and referenced to Scottish Health Technical Memorandum (SHTM) 01-06. • National perspective to tracking included of the references for Table 1. • Inclusion of validation considerations[36]) of the references for Table 1.
Notified body	Approved body
EN 17664: 2017	BS EN ISO 17664-1: 2021
EN 15223: 2016	BS EN ISO 15223-1: 2021
EN ISO 14971: 2012	BS EN ISO 14971: 2019+A11: 2021
ISO/TS 15883-5:2005	BS EN ISO 15883-5: 2021 (first release)
BS EN 1041:2008+A1:2013: Medical devices - Information to be supplied by the manufacturer	BS EN ISO 20417: 2021 Medical devices - Information to be supplied by the manufacturer

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

- Section 4 updated reference to - Standard Infection Control Precautions (SICPs) and the NIPCM added.
- BS EN ISO/IEC 17025: 2017

Abbreviations

ACDP: Advisory Committee on Dangerous Pathogens

AE(D): Authorising Engineer (Decontamination)

BS: British Standard

CJD: Creutzfeldt Jakob Disease

CMO: Chief Medical Officer

EDU: Endoscope Decontamination Unit

ERCP: Endoscopic Retrograde Cholangiopancreatography

EU: European Union

EWD: Endoscope Washer Disinfector

HAI: Healthcare Associated Infection

HB: Health Board

HFS: Health Facilities Scotland

IPCT: Infection, Prevention and Control Team

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

SEHD Scottish Executive Health Department

SHPN: Scottish Health Planning Note

SHTM: Scottish Health Technical Memorandum

SICPs: Standard Infection Control Precautions

SLA: Service Level Agreement

TOE: Transoesophageal echocardiograph

TSE: Transmissible Spongiform Encephalopathy

vCJD: variant Creutzfeldt Jakob Disease

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 Scottish Health Technical Note (SHTN) 00-04 v3 Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services. HFS 2024.

2 Scottish Health Technical Memorandum (SHTM) 01-06 Part A - Management Decontamination of thermolabile flexible endoscopes and Transoesophageal echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units. HFS 2023.

3 SHTM 01-06 Part B - General requirements for decontamination equipment and test equipment provision - Decontamination of thermolabile flexible endoscopes and Transoesophageal echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units. HFS 2023.

4 SHTM 01-06 Part C - Dry and wet leak testers, and manual clean flushing unit equipment - Decontamination of thermolabile flexible endoscopes and Transoesophageal echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units. HFS 2023.

5 SHTM 01-06 Part D - Automated endoscope washer disinfectors - Decontamination of thermolabile flexible endoscopes and Transoesophageal echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units. HFS 2023.

6 SHTM 01-06 Part E - Storage cabinets and packing systems for containment of disinfected endoscopes - Decontamination of thermolabile flexible endoscopes and Transoesophageal echocardiograph (TOE) ultrasound probes in Endoscope Decontamination Units. HFS 2023.

7 SHTM 2030 Part 1 v2 - Design considerations - Washer-disinfectors: 2001.

8 SHTM 2030 Part 2 v2 - Operational management - Washer-disinfectors: 2001.

9 SHTM 2030 Part 3 v2 - Validation and verification - Washer-disinfectors: 2001.

10 The Medical Devices Regulations 2002 (statutory instrument 2002 No.618 Consumer Protection).

11 Medicines and Medical Devices Act 2021. The National Archive - legislation.gov.uk.

12 Medical Devices (Amendment) (Great Britain) Regulations 2023 (statutory instrument 2023 no. 627). The National Archive - legislation.gov.uk.

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

14 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. CEN.24.

15 Scottish Health Planning Note (SHPN) 13. Part 3 - Decontamination Facilities: Endoscope Decontamination Units, HFS 2010.

16 Spach, D.H., F.E. Silverstein, and W.E. Stamm, Transmission of infection by gastrointestinal endoscopy and bronchoscopy. [Review] [133 refs]. Annals of Internal Medicine, 1993. 118(2): p. 117-28.

17 The Report of an Independent Review of Endoscope Decontamination Northern Ireland. Department of Health, Social Services and Public Safety published by the Department of Health, Social Services and public Safety, Northern Ireland(2005).

18 Review of Endoscope Decontamination Practice in Scotland: November 2004 to May 2005. SEHD(2006).

19 Important Information for all Practitioners Engaged in Endoscopy and Decontamination of Endoscopes. Chief Medical officer, SEHD/CMO(2006)04.

20 Seoane-Vazquez, E., et al., Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: Clinical and economic burden. Current Medical Research and Opinion, 2007. 22(10): p. 2007-2021.

21 Nelson, D.B., Infectious disease complications of GI endoscopy: part II, exogenous infections. [Review] [128 refs]. Gastrointestinal Endoscopy, 2003. 57(6): p. 695-711.

22 Culver, D.A., S.M. Gordon, and A.C. Mehta, Infection control in the bronchoscopy suite: A review of outbreaks and guidelines for prevention. American Journal of Respiratory and Critical Care Medicine, 2003. 167(8): p. 1050-1056.

23 Weber, D.J. and W.A. Rutala, Lessons from outbreaks associated with bronchoscopy. Infection Control and Hospital Epidemiology, 2001. 22(7): p. 403-408.

24 Cullen, M.M., et al., Serratia marcescens outbreak in a neonatal intensive care unit prompting review of decontamination of laryngoscopes. Journal of Hospital Infection, 2005. 59(1): p. 68-70.

25 Kovaleva,J., - Infectious complications in gastrointestinal endoscopy and their prevention - Best Practice & Research Clinical Gastroenterology, 30 (2016).

26 'Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication August 4, 2015 Safety Communications > Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication

27 Peiqi Wang1,2, Tim Xu3, Saowanee Ngamruengphong1, et. al - Rates of infection after colonoscopy and esophagogastroduodenoscopy in ambulatory surgery centres in the USA.- GUT volume 67, issue 9 - BMJ journals, 2017.

28 Thornhill, G., Endoscope-associated infections: A microbiologist's perspective on current technologies Techniques in Gastrointestinal Endoscopy Volume 21, issue 4, October 2019

29 National Infection Prevention and Control Manual (2024)

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

31 Transmissible Spongiform Encephalopathy (TSE) Guidance - Prevention of CJD and variant Creutzfeldt Jakob Disease (vCJD) by the Advisory Committee on Dangerous Pathogens (ACDP) - TSE Subgroup. Published by DoH 2016.

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

33 BS EN ISO 15883-4: 2018 Washer-disinfectors. Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes. CEN.

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

35 BS EN 16442: 2015 Controlled environment storage cabinet for processed thermolabile endoscopes. CEN.

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

37 BS EN ISO 13485: 2021 Medical Devices. Quality management systems. Requirements for regulatory purposes. CEN

38 GUID 5006 v1 Guide to the Carriage of Dangerous Goods Regulations with respect to Used Medical Devices, Health Facilities Scotland, 2013.