NHS National Services Scotland

Requirements for Compliant Endoscope Decontamination

Health Facilities Scotland
Decontamination Services

November 2014

Contents

1. Background

In 2003 the Sterile Services Provision Review Group established that there was a lack of guidance on the provision of endoscope decontamination units (EDUs). As the Glennie Technical Requirements (GTRs[1]) did not cover the decontamination of thermo-labile endoscopes, an interim guidance document 'Endoscope Reprocessing: Guidance on the Requirements for Decontamination Equipment, Facilities and Management', was prepared and made available to the service, on behalf of the Glennie Group, in December 2004 (amended 2007)[2].

A serious decontamination failure incident in Northern Ireland in 2004[3] prompted a detailed survey and report of endoscope decontamination practice within NHSScotland. A review of endoscope decontamination practice in Scotland[4] was produced in 2005, and in 2006 the Chief Medical Officer (CMO)[5] wrote to all practitioners with his recommendations. The requirement for endoscope decontamination premises to be '*fit for purpose*' was listed as one of the priorities for immediate action. However it was also accepted that rectifying all premises would be a long term initiative. Hence, Scottish Health Planning Note (SHPN) 13 part 3[6] was developed and introduced to provide guidance on EDU design, provision and operational policies. The document was published in September 2010.

From February 2010, endoscopy units were visited and assessed for their state of readiness for formal Joint Advisory Group (JAG) accreditation and to validate their self-assessed Global Rating Scale scores. These visits are referred to as pre-JAG visits. Decontamination practice was one of four aspects assessed by the pre-JAG Teams, led by Healthcare Improvement Scotland (HIS). A national framework based on these key areas has been developed to support the Endoscopy Raising Standards and Effectiveness (ENDORSE) Programme which all NHS boards are required to achieve by March 2015.

In order to progress improved endoscope decontamination practice, Health Facilities Scotland (HFS) established a decontamination stakeholder network. This allows users and managers within endoscopy decontamination to share knowledge and address issues. The stakeholder network includes the Endoscope Decontamination Working Group (EDWG). This group's membership consists of a representative from each NHS Board, HFS, HIS, NHS Education for Scotland (NES) and Health Protection Scotland (HPS). The EDWG agreed to recommend the new requirements to achieve compliant EDUs across NHSScotland.

The publication of this document is supported by the HAI National Advisory Group.

2. Scope

The scope of this document covers EDUs exclusively reprocessing flexible, thermo-labile endoscopes and their accessories. These endoscopes are not suitable for steam sterilization and can contain fine lumens requiring manual cleaning and high level chemical disinfection.

3. Purpose and Requirements

The purpose of this document is to specify the technical requirements for compliant EDUs. All EDUs in Scotland should move towards compliance as specified in Table 1 in Appendix 1. The requirements will be used to achieve the national decontamination standards.

4. Staff and patient safety

Flexible endoscopes and their accessories are classified as medical devices under the Medical Devices Directive (93/42/EEC[7] and 2007/47/EEC[8]). The Medical Device Regulations 2002[9] (MDR) implemented the EC Medical Devices Directives into UK law. Manufacturers' instructions for reprocessing should be followed[6].

The patient risks associated with inadequate endoscope decontamination have been documented in many journal articles and "more endoscopes have been associated with hospital-acquired infections than any other device"[10]. The literature reports a large number of cases of outbreaks relating to endoscopic procedures including procedures using upper GI endoscopes[11&12], ERCP[13&14], colonoscopes[15], bronchoscopes[16&17] and laryngoscopes[18]. To inform these requirements a systematic literature review was carried out.

Quality Assurance is a systematic monitoring and evaluation of the various aspects including facilities, equipment, management and process to ensure the delivery of standards of quality reprocessed instruments as per requirements listed in Appendix 1. The user must routinely carry out quality assurance checks at local level.

Appendix 1: Requirements for compliant EDUs

	Requirements for Compliant EDUs
Facilities	For small/medium size units adjacent to clinical units – One, two room or two room with ante rooms EDU as specified in SHPN 13 Part 3[6]. For centralised services - Two room EDU with ante and other support rooms as specified in SHPN 13 Part 3[6]. Ongoing maintenance (provided by an in-house or contracted service).
Equipment	For a one room EDU: Single-ended Endoscope Washer Disinfector (EWD) compliant to EN ISO 15883:1,4[19] and latest guidance [a)]. For all other models as per SHPN13 Part 3[6]: Pass-through EWD compliant to EN ISO 15883:1, 4[19] and latest guidance [a)]. Final rinse water compliant to BS EN ISO 15883-4[19]. HEPA filter endoscope storage cabinets validated as per latest standard and guidance [a&c)]. Installation validation and periodic testing of all equipment as per latest guidance[a)]. Maintenance contracts and operation as per equipment manufacturers' instructions.
Management	Designated roles for management, operation, maintenance, testing, safety and validation as defined in latest guidance[a)]. Compliance with the 'management' section defined in the latest guidance [a)]. Access to an independent Authorising Engineer (Decontamination) AE(D) Service[d)] . Automated electronic device tracking system[e)] to be in place. Decontamination Policy, Procedures and Records[f)] to be in place. Completion of NHS Scotland endoscope decontamination training programme appropriate for the role[g)]. If supplying processed endoscopes to other legal entities the quality management system must be accredited to EN 13485[22] by a notified body.
Process	As per device manufacturer's instructions and compliant with the latest guidance [a&6]. Completion of a satisfactory decontamination process[a)] including leak test, manual cleaning, inspection, cleaning and disinfection in EWD and drying. Transported in a labelled and solid-walled transport system as per latest guidance[a&h)].

Table 1

Note:

a) The current guidance documents are the HPS Endoscope Guidance 2007[2] and SHTM 2030[20]. However, there is a plan to revise the current guidance. Project Initiation Document 2.4 for the revision of the technical requirements and guidance is awaiting approval from the HAI Task Force.

b) NP 143, the National Procurement Contract for decontamination equipment including endoscope washer disinfector and HEPA filter endoscope storage cabinets, is available from January 2014. This Framework should be the first port of call for the Health Boards requiring equipment. However, access to the equipment on the Framework would require relevant Health Boards to carry out a detail product evaluation to meet their particular requirements. Advice from Authorising Engineers (Decontamination) [AE(D)] must be sought.

c) Currently the British Standards Institution is preparing the draft BS EN 16442 - Controlled environment storage cabinet for disinfected thermolabile endoscopes.

d) HFS provides Authorising Engineers (Decontamination) [AE(D)] services for NHS Scotland. A list of UK and Ireland registered AE(D)s can be found on the IHEEM website (www.iheem.org.uk).

e)Consider a GS1 compatible system.

f) Following the publication of the revised guidance, HFS is planning to develop the Endoscope Decontamination Documentation System containing policy, procedures and record forms for EDUs.

g) Staff are required to undertake appropriate decontamination training . Currently NHS Education for Scotland (NES) provides an on-line training programme on endoscope decontamination.

Contact details: http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/healthcare-associated-infections/educational-programmes.aspx

h) Guide to the Carriage of Dangerous Goods Regulations with respect to Used Medical Devices[21].

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