

Requirements for Compliant Central Decontamination Units

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1. Background

The Glennie Report published under cover of HDL (2001)66 in August 2001¹ set out a framework specifically related to technical and operational requirements for decontamination of Reusable Medical Devices (RMDs). Glennie¹ has promoted significant improvement in the decontamination of RMDs such as surgical instruments. However, the majority of reference documents stated in the Glennie Technical Requirements (GTRs)¹ have now been superseded or no longer exist. For example Quality Management System standard EN 46002 was replaced by EN 13485² in 2003. Further, the organisation, the Institute of Sterile Services Managers (ISSM) referred to in the GTRs no longer exists. Given that more than ten years have elapsed since the last review¹, the technical requirements should be updated in order to align with changes in standards, guidance, new initiatives and other decontamination sectors not covered by the GTRs. A stakeholder event held July 2012 set priorities for the service. Feedback from the event included the need for risk assessments and a revision of the existing 2001¹GTRs.

2. Scope

The scope of this document covers:

- a) processing³ reusable medical devices such as surgical instruments used in the acute sector;
- b) outsourcing decontamination of reusable medical devices such as surgical instruments to a third party service provider.

Outwith Scope:

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

Requirements

- e) 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;
- f) requirements for compliant CDUs are specified in [Appendix 1](#).

3. Purpose

This document establishes the technical requirements for compliant Central Decontamination Units.

All Theatres and CDUs in Scotland should move towards compliance to the requirements specified in this document deemed to be best practice thus reducing risks to patient safety.

4. Staff and patient safety

Surgical instruments are classified as medical devices under the Medical Devices Directive (93/42/EEC and 2007/47/EEC^{4&5}). The Medical Device Regulations 2002⁶ (MDR) implemented the EC Medical Devices Directives into UK law. Manufacturers' instructions for reprocessing should be followed.

The patient risks associated with inadequate decontamination of reusable surgical instruments have been documented^{7&8}.

Dancer et. al., (2012)⁷ 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 staff⁷.”

More recently the P.M. Southworth (2014)⁸ 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 guidelines⁸. Twenty nine percent of reported decontamination failures were found to impact Instruments used in eye surgery. The author⁸ 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 CDU⁹ includes:

- g) 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;
- h) The legal requirements for CDUs are compliance with the Medical Device Regulations⁶ including registration with MHRA. The CDU operation of their quality management system to EN ISO 13485² must be audited by a notified body annually;
- i) 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;
- j) 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](#);
- k) CDUs must not reprocess single use devices. When the single use medical device is supplied non sterile, the CDU may process once.
- l) 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 place⁵.

Any SLA should include provision for the following as a minimum:

- m) A clear allocation of responsibilities and duties;
- n) The CDU manager must maintain CDU accreditation to EN ISO 13485² and compliance with the CDU requirements as [Appendix 1](#);
- o) A right for the customer to undertake audits of the CDU reprocessing their devices. The audit team must include an independent Authorised Engineer (Decontamination);
- p) Practical requirements for wrapping¹⁰⁻¹³, labelling¹⁴ and transporting devices¹⁵;
- q) Management of non-conforming products (e.g. damaged, wet, missing/lost, incorrect devices in the pack/tray/cassette), handling and investigations of complaints²;
- r) Financial and liability protection for both parties in the SLA.

Appendix 1: Requirements for compliant Central Decontamination Units

	Requirements for Compliant CDUs
Facilities	<p>Scottish Health Planning Note (SHPN) 13 Part 1⁹ (for upgrades or new builds).</p> <p>Ongoing facility maintenance should ensure compliance to SHPN 13 Part 1^{9, 16&17} (maintenance may be provided by an in-house or a contracted service).</p>
Equipment	<ul style="list-style-type: none"> • 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. <hr/> <ul style="list-style-type: none"> • 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)}. <hr/> <p>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.</p> <hr/> <p>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 guidance as applicable.</p> <p>Maintenance and operation of equipment as the equipment manufacturers' instructions.</p> <p>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.</p>
Management	<p>An operational Quality Management system as per the latest standardⁱ⁾.</p> <p>The CDU operates and is accredited to Article 12 or Annex V of the Medical Device Regulations 2002⁶.</p> <p>Risk management carried out in accordance with the latest standard^{j)}.</p> <p>Compliance with the current mandatory requirements of the Scottish Government Health and Social Care Directorate (SGHSCD)^{k)}.</p> <p>Compliance with relevant guidance from the Advisory Dangerous Pathogens Committee (TSE Guidance³⁰).</p> <p>Compliance with NICE guidance IP 196³¹.</p> <p>Relevant professional body membership for CDU management.</p> <p>Access to an independent Authorising Engineer (Decontamination) AE(D)^{l)}.</p>

Management cont'd	<p>All staff complete a decontamination training programme appropriate for their role^{m)}.</p> <p>An automated electronic reusable medical device tracking system, to track through the decontamination process and to the patient is in placeⁿ⁾.</p> <p>Service Level Agreements with customers.</p> <p>Business continuity and contingency arrangements in place.</p> <p>National, regional or local procurement contracts where they exist (including framework arrangements^{o)}).</p>
Process	<p>Satisfactory decontamination process as defined in the QMS compliant with the latest standardⁱ⁾ and certified by a notified body.</p> <p>Production of sterile products compliant with the latest standard^{p)} and the pre-sterilization packaging standards^{10&11}.</p> <p>Validated decontamination processes as per the reusable medical device manufacturer's instructions and compliance with the latest guidance and standards^{q)}.</p> <p>Labelling in accordance with the Medical Device Directive^{4,5&6} and relevant standards.</p> <p>Transportation of the reusable medical devices in a container/transport system in line with the latest guidance¹⁵.</p>

Table 1

References for Table 1(previous page)

- a) *The latest European standards for washer disinfectors are 15883-1¹⁸ and 15883-2¹⁹*
- b) *The best practice guidance is SHTM 2030 parts one to three²⁰⁻²².*
- c) *The latest European standards for porous load sterilisers are EN 285²³ and EN 17665-1²⁴.*
- d) *The best practice guidance is SHTM 2010 parts one to six²⁵.*
- e) *The latest best practice guidance on clean steam for sterilization is SHTM 2031²⁶.*
- f) *The latest European standard for alternative sterilization processes is EN 14937²⁷.*
- g) *The latest European standard on packaging for terminally sterilized medical devices is EN 11607 part 1¹⁰ and part 2¹¹ and associated guidance CEN TS 16775¹².*
- h) *The last European standard on containment cabinets is EN 14644-7²⁸.*
- i) *The latest European standard on Quality Management Systems is EN 13485².*
- j) *The last European standard on risk management is EN 14971²⁹.*
- 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 devices³⁴.*
- n) *Consider 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 556-1³³.*
- q) *The latest European standard on information to be provided by the manufacturer for processing of resterilizable medical devices is EN 17664³.*

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.

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12. **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.
13. **EN ISO 868-3:2009.** Packaging for terminally sterilized medical devices. Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the

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