



Department  
of Health

# Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care

Part E: Alternatives to steam for the sterilization of reusable medical devices

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reusable medical devices

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# Preface

## Introduction

This HTM supersedes the Choice Framework for local Policy and Procedures (CFPP) series, which was a pilot initiative by the Department of Health.

The CFPP series of documents are reverting to the Health Technical Memorandum title format. This will realign them with HTM 00 – ‘Policies and principles of healthcare engineering’ and ‘HTM 01-05: Decontamination in primary care dental practices’ and the naming convention used for other healthcare estates and facilities related technical guidance documents within England. It will also help to address the recommendation to align decontamination guidance across the four nations.

In 01-01 and 01-06 DH will be retaining the Essential Quality Requirements and Best Practice format, this maintains their alignment with HTM 01-05 and the requirement of ‘The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance’ which requires that “decontamination policy should demonstrate that it complies with guidance establishing essential quality requirements and a plan is in place for progression to best practice”. We are aware that policy within the devolved nations differs on this particular issue but the aim is that the technical content should be consistent and able to be adopted by the devolved nations so that the requirements of the ACDP-TSE Subgroup’s amended guidance can be met.

HTM 01-01 forms a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices.

## Purpose

The purpose of this HTM is to help health organisations to develop policies regarding the management, use and decontamination of reusable medical devices at controlled costs using risk control, which will enable them to comply with Regulations 12(2)(h) and 15 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 .

This HTM is designed to reflect the need to continuously improve outcomes in terms of:

- patient safety;
- clinical effectiveness; and
- patient experience.

## Essential Quality Requirements and Best Practice

The Health Act Code of Practice recommends that healthcare organisations comply with guidance establishing Essential Quality Requirements and demonstrate that a plan is in place for progression to Best Practice.

Essential Quality Requirements (EQR), for the purposes of this best practice guidance, is a term that encompasses all existing statutory and regulatory requirements. EQRs incorporate requirements of the current Medical Devices

Directive and Approved Codes of Practice as well as relevant applicable Standards. They will help to demonstrate that an acute provider operates safely with respect to its decontamination services.

A healthcare provider's policy should define how it achieves risk control and what plan is in place to work towards Best Practice.

Best Practice is additional to EQR. Best Practice as defined in this guidance covers non-mandatory policies and procedures that aim to further minimise risks to patients; deliver better patient outcomes; promote and encourage innovation and choice; and achieve cost efficiencies.

Best Practice should be considered when developing local policies and procedures based on the risk of surgical procedures and available evidence. Best Practice encompasses guidance on the whole of the decontamination cycle, including, for example, improved instrument management, where there is evidence that these procedures will contribute to improved clinical outcomes.

The HTM 01 suite is listed below.

- HTM 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care
- HTM 01-04: Decontamination of linen for health and social care
- HTM 01-05: Decontamination in primary care dental practices [check title]
- HTM 01-06: Decontamination of flexible endoscopes.

### **Note**

This guidance remains a work in progress which will be updated as additional evidence becomes available; each iteration of the guidance is designed to help to incrementally reduce the risk of cross-infection.

# Abbreviations

ACDP-TSE [Subgroup]: Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies [Subgroup]	EN: European norm
ACDST: Advisory Committee on Decontamination Science and Technology	FITC: fluorescein isothiocyanate
AE(D): Authorising Engineer (Decontamination)	ISO: International Standards Organisation
AP(D): Authorised Person (Decontamination)	MDD: Medical Devices Directive
BCH: Birmingham Children’s Hospital	MDR: Medical Devices Regulations
BS: British Standard	MHRA: Medicines and Healthcare products Regulatory Agency
BSE: Bovine Spongiform Encephalopathy	NDS: National Decontamination Survey
CFPP: Choice Framework for local Policy and Procedures	NICE: National Institute for Health and Clinical Excellence
CJD: Creutzfeldt-Jakob disease	NICE IPG 196 (2006): NICE’s (2006) interventional procedure guidance 196 – ‘Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures’
CMO: Chief Medical Officer	OPA/NAC: o-phthalaldehyde/N-acetyl-L-cysteine
CP(D): Competent Person (Decontamination)	PO: posterior ophthalmic
CQC: Care Quality Commission	sCJD: sporadic Creutzfeldt-Jakob disease
DH: Department of Health	SSD: sterile services department
DIPC: Director of Infection Prevention and Control	TSEs: transmissible spongiform encephalopathies
EDIC: episcopic differential interference contrast	UCHL: University College Hospital London
EDIC/EF: episcopic differential interference contrast/epifluorescence	vCJD: variant Creutzfeldt-Jakob disease
EFSCAN: epifluorescent surface scanner	

# Executive summary

Health Technical Memorandum (HTM) 01-01 offers best practice guidance on the whole decontamination cycle including the management and decontamination of surgical instruments used in acute care.

Part A covers the policy, management approach and choices available in the formulation of a locally developed, risk-controlled operational environment. The technical concepts are based on European (EN), International (ISO) and British (BS) Standards used alongside policy and broad guidance. In addition to the prevention of transmission of conventional pathogens, precautionary policies in respect of human prion diseases including variant Creutzfeldt-Jakob disease (vCJD) are clearly stated. Advice is also given on surgical instrument management related to surgical care efficiencies and contingency against perioperative non-availability of instruments.

Part B covers common elements that apply to all methods of surgical instrument reprocessing such as:

- test equipment and materials
- design and pre-purchase considerations
- validation and verification.

Part C covers standards and guidance on steam sterilization.

Part D covers standards and guidance on washer-disinfectors.

Part E covers low temperature (non-steam) sterilization processes (such as the use of vapourised hydrogen peroxide gas plasmas and ethylene oxide exposure).

HTM 01-01 Part E 2016 supersedes all previous versions of CFPP 01-01 Part E.

## Why has the guidance been updated?

HTM 01-01 has been updated to take account of recent changes to the ACDP TSE Subgroup's general principles of decontamination ([Annex C](#)). In relation to the decontamination of surgical instruments, this principally relates to paragraphs C21 and C22:

### Protein detection

C21. Work commissioned by the Department of Health indicates the upper limit of acceptable protein contamination after processing is 5µg BSA equivalent per instrument side. A lower level is necessary for neurosurgical instruments.

C22. It is necessary to use protein detection methods to check for the efficient removal of protein from surgical instruments after processing. Protein levels are used as an indication of the amount of prion protein contamination. Ninhydrin swab kits are commonly used for this purpose, but recent evidence shows that ninhydrin is insensitive. Furthermore, proteins are poorly desorbed from instruments by swabbing. Other commonly used methods have also been shown to be insensitive.

The ACDP TSE subgroup's guidance requires that there should be  $\leq 5$   $\mu\text{g}$  of protein *in situ* on the side of any instrument tested. The rationale for each of these elements is as follows:

- The figure of 5  $\mu\text{g}$  of protein has been shown to be achievable by effective cleaning processes. There is currently no definitive evidence base to link this with the absence of prion transmission risk, which is why lower levels for instruments making contact with high risk tissues (see ACDP TSE's [Annex J](#)) is necessary.
- The measurement is per side of instrument rather than per unit area of an instrument. Prion proteins have been shown to be infectious by contact (Kirby et al 2012). Infection transmission would be related to the total area of an instrument that makes contact with patient tissues. Thus, while not a perfect relationship, the assessment of protein levels per side of an instrument is likely to be a greater predictor of risk control than an assessment based on a unit area of an instrument.
- Protein levels on an instrument should be measured directly on the surface rather than by swabbing or elution (see the ACDP-TSE Subgroup's [Annex C](#) paragraph C23), as detection of proteins on the surface of an instrument gives a more appropriate indication of cleaning efficacy related to prion risk (see Table C2 in ACDP TSE's [Annex C](#)). As technologies become available that are able to detect residual protein *in situ* to  $\leq 5$   $\mu\text{g}$  per instrument side, they should be adopted. Prion proteins are very hydrophobic and will, once dry, adhere strongly to surfaces and resist removal by swabbing or elution for the purpose of protein detection.

## What SSDs can do to ensure implementation of the ACDP TSE's Subgroup's recommendations

Because of the risks of prion transmission, there is a need to optimise the whole of the decontamination pathway of surgical instruments.

### Reducing the time from close of procedure to reprocessing

Prions are easier to remove if they have not dried on the surface of an instrument. To enable efficient prion removal, theatre and SSD staff should ensure that instruments are transported to the SSD immediately after the close of the procedure, for cleaning and reprocessing as soon as practically possible. This will make the cleaning process more effective, hence reducing the risks to the patients and staff handling the devices. If devices cannot be returned in a timely manner, it is important that the instruments are kept moist using appropriate methods approved and verified by the SSD.

### Cleaning validation and continuous monitoring

Traditionally, cleaning validation has been about removing visible soiling. Now the emphasis is on removing highly adherent proteins to very low levels. To be able have a greater chance of removing these sticky proteins, there needs to be as efficient a cleaning process as possible – therefore SSDs need to both optimise the cleaning performance of washer-disinfectors and remain within the validation parameters.

It is important to continuously monitor the residual protein on reprocessed instruments. SSDs should not view the 5  $\mu\text{g}$  limit as a single pass or fail, but rather use it as a way of working towards and below this value, that is, as part of trend analysis and a quality assurance system whose aim is to monitor not just the cleaning efficacy of washer-disinfectors but also the instrument journey leading up to that stage – in other words, ensuring results are



being monitored and actions are being taken based on these results. SSDs should include:

- daily testing using process challenge devices\* (along with the standard periodic tests);
- quarterly residual protein testing (see paragraphs 2.271–2.278 in HTM 01-01 Part D –‘Validation and verification’). See also Appendix B in HTM 01-01 Part A for example sampling rates.

Priority should be given to instruments used on high-prion-risk tissues as defined by ACDP (see ACDP TSE’s [Annex J](#)).

\* Commercial process challenge devices are being developed whose challenge simulates the attachment of prion protein to instruments and whose analysis is quantitative. When these become available and have been validated, SSDs are advised to consider their use in addition to process challenge devices based on soils in BS EN 15883-5 Annex N.

Results from the quarterly residual protein test should be used to analyse trends and act on that analysis.

### Methods for detecting residual protein

SSDs should no longer rely on elution or swabbing to detect residual protein on an instrument. The method should be validated as being able to detect protein equivalent to  $\leq 5 \mu\text{g}$  of BSA *in situ* on the surface of an instrument. Commercial technologies that can detect the  $5 \mu\text{g}$  limit *in situ* are being developed (see ACDP TSE’s [Annex C](#)). Devices to detect residual protein must be CE-marked as an accessory to a medical device (see the MHRA’s ‘Managing medical devices: guidance for healthcare and social services organisations’ and also ‘Medical devices: conformity assessment and the CE mark’).

Residual protein detection devices should be intended by their manufacturer to be used as an accessory to a surgical instrument that has undergone a cycle through a washer-disinfector validated to BS EN ISO 15883 Parts 1 and 2 for washing and disinfecting of surgical invasive devices and be capable of measuring and detecting residual protein *in situ* to levels of  $\leq 5 \mu\text{g}$  per side of used, washed surgical instruments. The manufacturer will need to have CE-marked the product under the Medical Devices Regulations and issued a declaration of conformity to demonstrate that the device has met all relevant essential requirements for the medical device and that they have followed an appropriate conformity assessment route.

**Until such time as these are available as medical devices, residual protein control relies mainly on controlling the decontamination process rather than on protein detection from instruments – that is, process control makes more of a contribution than product control. When high resolution methods of detecting residual protein *in situ* are available, then product control should be used to inform process control.**

### Continuous improvement plans

SSDs should have in place a plan of continuous process improvement. This plan should be carried out as part of a risk management plan (see BS EN ISO 14971 on medical device risk management). There should also be a specific record that relates to residual protein trend analysis.

### Major change to Part E since the 2013 edition

- CFPP 01-01 has reverted to the Health Technical Memorandum title format and now becomes Health Technical Memorandum 01-01.

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# 1 Introduction

**1.1** Steam sterilization is well-defined and has been used safely with the majority of medical devices for many years.

**1.2** For some specialist instrumentation and devices, steam sterilization has a number of limitations particularly in regard to the reprocessing of medical devices that may be damaged by steam at high temperatures.

**1.3** Non-steam sterilization is becoming increasingly required for the reprocessing of thermolabile new technology medical devices. In addition, some non-steam sterilization

technologies may provide more significant inactivation of prions; this is the subject of current research.

**1.4** Many alternatives to steam sterilization are available for use in sterile services departments (SSDs) and other environments.

**1.5** Current sterilization technologies include ethylene oxide, gaseous hydrogen peroxide and ozone. Future potential technologies include low temperature electronic gas plasmas.

## 2 Guidance for commissioners

**2.1** Commissioners should ensure that local policies for instrument management and decontamination are in place within provider institutions.

**2.2** The use of specialist surgical instrumentation may extend the range of surgical care available from a provider or may advance the quality of care and improve clinical outcomes.

**2.3** In considering such service improvement, commissioners are advised to consult with their providers on the availability and capability of decontamination services in respect of new instrumentation and technologies and the ability to ensure adequate and validated decontamination and sterilization. More specifically: are viable cleaning and sterilization methods in place and, where applicable, can validated sterilization be provided?

## 3 Guidance for regulators

**3.1** A quality framework based on a systems approach is not currently provided within the European Norms (ENs) or BSI standards for alternative sterilization methods. Accordingly, policy guidance follows the broad outline of EN 14937, with significant adaptations to suit the technologies under consideration.

**3.2** This guidance recommends that providers of non-steam sterilization and decontamination services use the HTM risk assessment approach (see HTM 01-01 Part A), along with manufacturers' recommendations (both those of the instrument manufacturer and from the manufacturer of the sterilization system).

**3.3** Providers should seek to minimise risks to the operator, patient and environment from the use of these technologies while promoting satisfactory clinical service outcomes.

**3.4** Ensuring effective sterilization is considered to be a key outcome. Validation,

being defined as achieving an effective, reproducible sterilization outcome, needs to be conducted to ensure that sterilization has been achieved.

**3.5** The validation process should be carried out in agreement to the users, manufacturers and AE(D) and be supported by an audit trail.

**3.6** The operational responsibility for ensuring that these key objectives are addressed should be with the Decontamination Lead and possibly the Surgical Instrument Manager, working to the local policies agreed by the risk assessment group.

**3.7** Regulators should ensure that such policies are in place and that operational protocols are appropriately employed. These structures should assure that an adequate validation system is in place and that auditable records exist.

## 4 Role of non-steam sterilization techniques

**4.1** Any non-steam sterilization technology should fit in with the broad approach to instrument management and decontamination given in HTM 01-01 Part B.

**4.2** The installation of the technology needs to work in an environment well-integrated with the local SSD and surgical facilities. The flow of work and items from dirty to clean needs to have the same characteristics as for any other process element within an SSD or external facility.

**4.3** The risk of recontamination should be minimised. These considerations apply whether the reprocessing is done locally or by an external decontamination provider.

**4.4** The compatibility of any alternative sterilization technology with the instruments for which it is intended is a key consideration. The advice of both the technology and instrument manufacturers should be sought when considering non-steam sterilization methods; it should be ensured that the requirements of both the technology and the instrument manufacturers can be reconciled.

# 5 Quality and safety standards for non-steam sterilization

**5.1** In current practice, policy and procedures governing the use of non-steam sterilization methods rely on local risk analysis and manufacturers' advice and instruction. This approach is compatible with the HTM approach. However, a framework is offered within this guidance in order to strengthen the background and provide guidance in decision-making.

**5.2** There is a lack of definition for test methods and protocols together with associated validation across this area. This makes assessment of sterile status and assurance potentially more difficult compared to steam sterilization. However, a quality assurance process should be used with a plan on how the technology and sterilization process fits into the overall quality assurance audit process. The reports and processes generated should be transparent and open for assessment and inspection.

**5.3** Safety when using non-steam sterilization methods must take into account:

- safety of the patient, in particular that no toxic residuals remain or are formed on the device following the process and that sterility is reliably obtained;
- safety of staff using the process present during this time, including physical, ergonomic and chemical considerations;
- safety of the devices, to ensure that they are not damaged by the process;
- safety for the environment.

**5.4** Workplace exposure limits are published by the Health and Safety Executive (HSE) for some of the chemicals involved in non-steam sterilization (for example ethylene oxide, ozone, hydrogen peroxide), and the use of sterilization systems must adhere to these limits.

**5.5** Care should be taken regarding instrument package degassing after sterilization, where process chemicals may be retained in the processed device pack and eluted afterwards. This should form part of any local risk assessment.



## 6 Guidance on safety risk assessment

**6.1** Factors to be considered in local risk assessment include but are not limited to the following:

- a. consideration of environmental and workplace exposure limits for the chemical agents used and any secondary products generated;
- b. appropriate application of environmental and personal monitoring. This is selectively referred to for some sterilization agents. However, it is advised that consideration should be given whenever toxic gases or vapours are employed. In some instances, equipment may contain monitoring devices. The assessment should include the possible use of non-machine-integrated monitors and alarms;
- c. consideration to degassing associated hazards and the environments used in processing and storage;
- d. containment and ventilation associated with the work environment;
- e. constraint of splash and aerosol hazards from liquid agents in use, including hydrogen peroxide;
- f. the use of secondary containment combined with negative pressure exhaust ventilation should be considered and may be an HSE requirement for some of the technologies.

**6.2** Safety risk assessment should be applied to all decontamination technologies, regardless of type or status.

## 7 Surgical instrument and other device compatibility

**7.1** It is the responsibility of reprocessable medical device suppliers to inform users of compatible decontamination processes. However, guidance regarding specific incompatibilities of other processes is not always provided.

**7.2** Before any decontamination technology is used (whether steam or otherwise), it must be determined as compatible by consultation with the reprocessable device supplier.

## References

EH40/2005 Workplace Exposure Limits (HSE Books, 2011).