



Department
of Health

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

Part A: Management and provision

July 2016

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

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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.

Foreword

This guidance has been developed to support health organisations in delivering the required standard of decontamination of surgical instruments and builds on existing good practice to ensure that high standards of infection prevention and control are developed and maintained.

The guidance in this Health Technical Memorandum should inform your local continuous improvement programme on decontamination performance. The major change in this latest revision is taking account of recent changes to the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroup's general principles of decontamination (see [ACDP-TSE's Annex C](#)). This establishes a move towards *in situ* testing for residual proteins on instruments. Residual protein is important because of the continuing risks of transmission of prions (the causative agent of transmissible spongiform encephalopathies such as variant Creutzfeldt-Jakob disease (vCJD)).

This guidance provides information on how sterile services departments (SSDs) can mitigate the patient safety risk from residual protein with a move towards first achieving this $\leq 5 \mu\text{g}$ level and subsequently producing further reductions in protein contamination levels through the optimisation of decontamination processes. The ambition is that all healthcare providers engaged in the management and decontamination of surgical instruments used in acute care will be expected to have implemented this guidance by 1 July 2018. However, providers whose instruments are likely to come into contact with higher risk tissues, for example neurological tissue, are expected to give this guidance higher priority and move to *in situ* protein detection methodologies by 1 July 2017.

Professor Dame Sally Davies
Chief Medical Officer

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 A 2016 supersedes all previous versions of CFPP 01-01 Part A.

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 ≤ 5 μg 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 μg 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 ≤ 5 μg 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 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 to 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 μg 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 2.271–2.277 in HTM 01-01 Part D –‘Validation and verification’). See also Appendix B in this document for example sampling rates.

Priority for cleaning validation and continuous monitoring should be given to instruments that have contact with high-prion-risk tissues as defined by ACDP-TSE (see Table A1 in ACDP-TSE’s guidance [Annex A1](#)).

* 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 ≤ 5 μg of BSA *in situ* on the surface of an instrument. Commercial technologies that can detect the 5 μg limit *in situ* are being developed (see ACDP-TSE’s [Annex C](#)). Methods that do not have protein as their target, such as ATP assays, cannot be used as a substitute for residual protein detection. 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 ≤ 5 μg 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.

Implementation of guidance

The ambition is that all healthcare providers engaged in the management and decontamination of surgical instruments used in acute care will be expected to have updated their local policies and continuous improvement plans in line with this guidance by 1 July 2018. However, providers whose instruments are likely to come into contact with higher risk tissues, for example neurological tissue, are expected to give this guidance higher priority and move to *in situ* protein detection methodologies by 1 July 2017.

List of major changes to Part A

- CFPP 01-01 has reverted to the Health Technical Memorandum title format and now becomes Health Technical Memorandum 01-01.
- New guidance included on how to ensure implementation of the ACDP-TSE's Subgroup's recommendations.
- Chapter 5 on prion diseases updated to reflect the changes to the ACDP-TSE Subgroup's guidance (2015).
- In the section on "Separation of instruments used on high risk tissues for patients born before and after 1 January 1997" in Chapter 6, the management of instruments for the small number of patients born after 1 January 1997 who have already had past high risk tissue surgery using pre-1997 instruments has been amended (see paragraphs 6.8–6.10) in line with both the views of the Society of British Neurological Surgeons and the ACDP-TSE Subgroup.

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Abbreviations

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

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1 Introduction

1.1 This HTM offers best practice guidance on the management and decontamination of surgical instruments used in acute care. The guidance supports the 'Health and Social Care Act 2008: Code of Practice for the prevention and control of infections and related guidance' and has been developed to strengthen local decision making and accountability. This HTM also supports the vision for the NHS as set out in the Health and Social Care Act 2012.

1.2 In order to be registered with the Care Quality Commission (CQC), providers are required to maintain appropriate levels of cleanliness and hygiene in relation to reusable medical devices. The Code of Practice provides guidance on how providers can meet this registration requirement, including key recommendations on the provision of a safe decontamination service that generates a clean and sterile product.

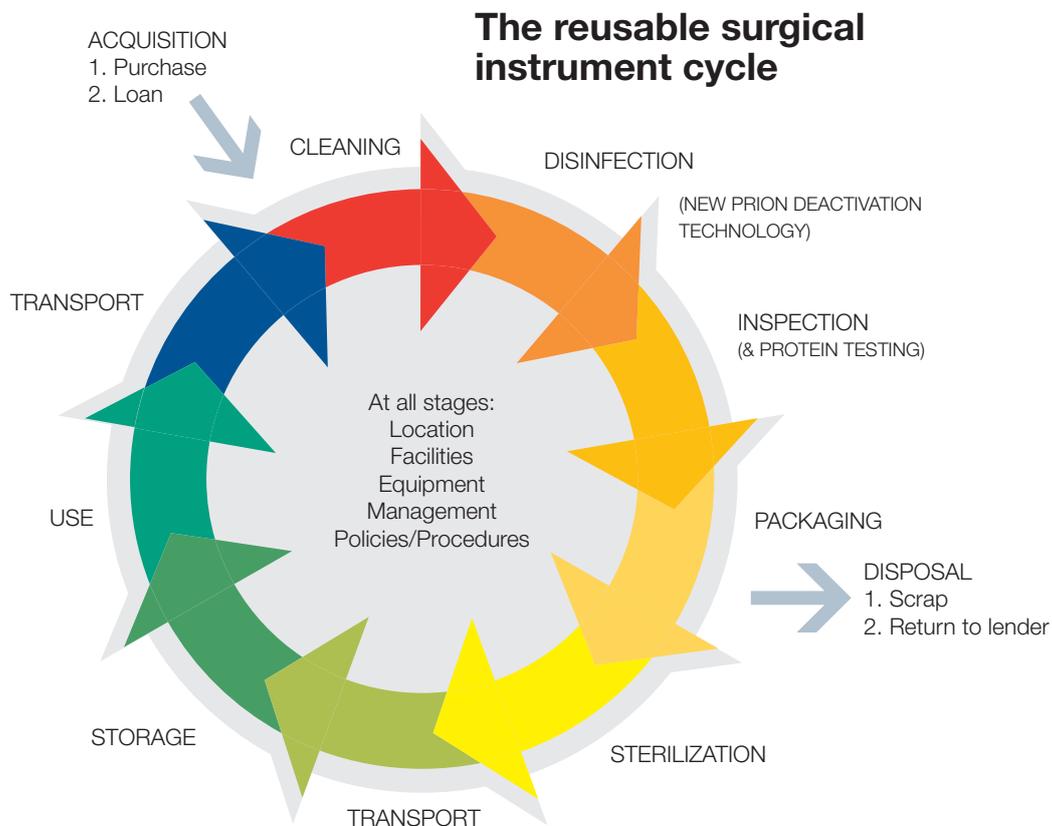
1.3 The Health and Social Care Act 2012 sets out the Government's intention to ensure providers are properly regulated, allowing them to work with clinical commissioners to focus on improving outcomes, be more responsive to patients and innovate.

1.4 The Act also introduces a duty on NHS England (the operating name of the NHS Commissioning Board) and clinical commissioning groups to secure continuous improvement in the quality of outcomes achieved from health services. These outcomes are to focus on the effectiveness, safety and patient experience aspects of healthcare.

1.5 HTM 01-01 supports local decision-making in the commissioning, regulation, management, use and decontamination of surgical instruments used in acute care. The guidance is designed to support continuous improvements in efficiency and outcomes in terms of safety, clinical effectiveness and patient experience by:

- providing guidance on compliance with the ACDP-TSE Subgroup's guidelines;
- guiding care commissioners and regulators in assessing the local policies and practices of a provider in terms of their approach to the management and decontamination of surgical instruments. Clear definitions of Essential Quality Requirements and Best Practice are provided in this HTM, to help with this assessment;
- providing the evidence base and standards for use by providers of care and those decontaminating surgical instruments within the NHS or commercially, to support them in their decision-making process;
- contributing to the effective management of surgical instruments through all parts of the use and reprocessing cycle (see [Figure 1](#)). This includes management practices related to surgical instruments in the theatre environment;
- providing guidance for service-users and patient groups on issues that are relevant to them. This has been written to take account of HealthWatch's future role in

Figure 1 The reusable surgical instrument cycle



- working with providers, commissioners and quality regulators;
- using the experience of previous pilot studies to demonstrate approaches to risk management and to the implementation of the National Institute for Health and Clinical Excellence’s (NICE) interventional procedure guidance 196 – ‘Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures’ (hereafter referred to as NICE IPG 196 (2006)).
- the prevention and control of the risk of transmission of infection through surgical instruments – with specific reference to the theoretical risk of human prion diseases transmission (transmissible spongiform encephalopathies, or TSEs);
- a comprehensive approach to risk control and reduction across instrument management and decontamination;
- assurance over the management of surgical instruments, in terms of availability, quality and suitability;
- the preservation and advance of high-quality engineering through the support of European Norms (ENs), quality systems and standards;
- guidance for optimisation of the environment, equipment and facilities used in surgical decontamination.

Note

Regulators include the CQC, the Medicines and Healthcare products Regulatory Agency (MHRA), and notified bodies.

1.6 With HTM 01-01, the DH is seeking to establish:

1.7 HTM 01-01 refers to NICE IPG 196 (2006) and guidance derived from the Advisory

Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies (ACDP-TSE RM) subgroup throughout. It has drawn on the findings of the National Decontamination Survey (NDS) (2008–2010) to highlight aspects of decontamination management practice that need addressing, and the findings from various NDS pilot studies.

1.8 Management recommendations centre on:

- ensuring maximum efficiency in protein detection and decontamination;
- improving instrument set integrity
- ensuring that a separate pool of new neuroendoscopes and reusable surgical instruments is available for high risk procedures on patients born since 1 January 1997, as it is thought that people born since 1 January 1997 have had lower exposure to prions via the food chain or blood transfusion;
- ensuring contingency for dropped or unavailable instruments;
- ensuring a continuously moist environment for instruments between use and reprocessing;
- having a system in place for surgical instrument management and to cover the quality, condition and suitability of reusable surgical instrument.

1.9 Whether decontamination services are provided by the healthcare provider or from an external source, the requirements of the instrument management and decontamination policy outlined in this guidance should be followed.

1.10 HTM 01-01 Part A supersedes all previous versions of CFPP 01-01 Part A.

Structure of HTM 01-01

1.11 HTM 01-01 Part A covers the policy, management approach and choices available in

the formulation of a locally developed, risk-controlled operational environment.

1.12 The technical concepts are based on European (EN), International (ISO) and British (BS) Standards used alongside policy, broad guidance and research. 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

1.13 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.

1.14 Part C covers standards and guidance on steam sterilization.

1.15 Part D covers standards and guidance on washer-disinfectors.

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

2 Decontamination policy for reusable surgical instruments

2.1 A safe decontamination service contributes to successful clinical outcomes and the wellbeing of patients and staff. Healthcare providers in England are required by law to comply with essential levels of safety and quality which are assessed by the CQC. These levels are set in law through registration requirements, one of which covers cleanliness and infection control. Guidance on meeting this registration requirement is provided by the ‘Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance’. The 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.

2.2 HTM 01-01 draws on DH policy and current advice to provide comprehensive guidance on the management and decontamination of surgical instruments used in acute care. This includes clear definitions of what constitutes Essential Quality Requirements and Best Practice.

2.3 In acute care, precautionary policies in respect of human prion diseases including vCJD also apply.

2.4 This guidance therefore seeks to offer advice across a range of risk types. Specifically, these include:

- The risk of infection via surgical instruments.

- The theoretical but potentially highly significant risk of transmission of human prion diseases including, but not limited to, vCJD.
- The availability, quality and suitability of surgical instruments.
- Interruption to, or abandonment of, surgery where this is due to instrument quality, the absence of key instruments from the surgical set or, in very rare instances, where an instrument has been dropped perioperatively or otherwise has had its sterility compromised during use.

2.5 In this HTM, a number of options are offered for dealing with risks highlighted by the NDS (2008–2010). These options are outlined based on experience gained from pilot studies and guidance, and include information on the observed outcomes. As experience grows, individual reports and findings will be incorporated.

The policy context

2.6 HTM 01-01 is best practice guidance. It forms an integral part of enabling the delivery of the following policy initiatives.

2.7 The Health and Social Care Act 2012 sets out the framework for the government’s vision for modernising the NHS. It gives power to clinicians to make commissioning decisions, and gives more choice and control to patients. It also establishes Monitor as a strong service regulator to act in the interests of patients.

2.8 The NHS Commissioning Board (NHS England) will continue to look to providers to deliver services that enhance patient safety and the patient experience, and that deliver value for money. Part of this is a drive towards constant assurance of correctly selected, clean, sterile and fully functioning surgical instruments at the point of care delivery.

2.9 The management and decontamination of surgical instruments are key components in the delivery of safe interventional care. This guidance advocates a full assessment of the volume and types of surgical service provided, the turnaround times required for decontamination, the prion transmission risks associated with the tissues encountered in each area of service, and the instrument stock required for onsite and offsite decontamination. To gain a full understanding of the risks involved, including the risk of prion disease transmission, see [paragraph 5.1](#).

2.10 In light of this, HTM 01-01 advocates that commissioners, providers and regulators adopt a risk-control approach to the management of single-use instruments and to the management and decontamination processes for reusable surgical instruments, in line with the essential requirements of the Medical Devices Directive (MDD) and the ENs that support them (see [Chapter 4](#)).

Essential Quality Requirements and Best Practice in decontamination

2.11 Essential Quality Requirements, for the purposes of this best practice guidance, is a term that encompasses all existing statutory and regulatory requirements. Essential Quality Requirements incorporate requirements of the current MDD and approved Codes of Practice as well as relevant applicable Standards. They will help to demonstrate that an acute care service provider operates safely with respect to the management and decontamination of instruments.

2.12 Attainment of Essential Quality Requirements should also include a local risk-

assessment for surgical instrument management, encompassing the provision of instruments that are safe to use and the reliable provision of all required instruments.

2.13 Local policy should define how a provider achieves risk control and what plan is in place to work towards Best Practice.

2.14 Local policy development that takes account of this HTM could result in amended theatre practices, such as improvements to the audit trail for instruments and the provision of instruments sets that do not require the use of supplementary instruments.

2.15 Comparison of local policy statements and quality systems with audit results will confirm attainment of Essential Quality Requirements and progression towards Best Practice. Such assessment could provide a mechanism for differentiating between care providers in commissioning services.

2.16 Best Practice is additional to the Essential Quality Requirements. 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.

2.17 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.

Developing a decontamination policy

2.18 In the context of this HTM, decontamination policy is dependent on the types of surgical procedure undertaken and determined by the staff involved with the management and decontamination of reusable surgical instruments. It is recommended that

staff conduct a local risk assessment, record their local policy, and adopt and develop procedures appropriate to their services. The policies and procedures selected should meet Essential Quality Requirements or exceed them by achieving Best Practice. **Figure 2** illustrates the drivers for improvements and desired outcomes.

2.19 This applies to decontamination facilities on and off healthcare premises and in decontamination services managed by independent healthcare providers.

2.20 For the key elements of a decontamination policy, see **paragraph 2.6 of 'The Health and Social Care Act 2008: Code of Practice'**.

Local determination of Best Practice

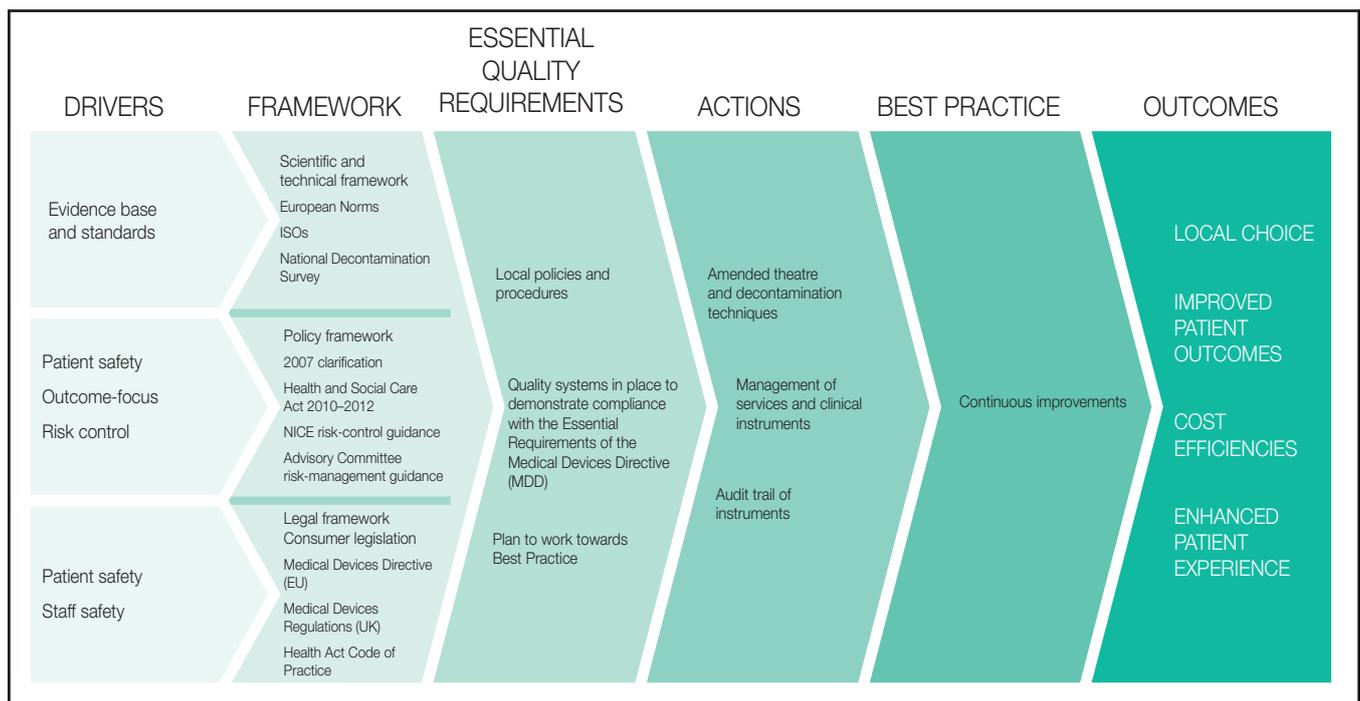
2.21 To assess Best Practice, a local risk assessment group may be set up. This group could assess decontamination option requirements and consider what aspects of Best Practice should be implemented, based on improving patient outcomes, decontamination benefits, efficiencies and risks, including those prion risks as defined by the ACDP-TSE Subgroup.

2.22 A Director of Infection Prevention and Control (DIPC) will have ultimate responsibility for the risk assessments. Others included in the group could be:

- the DIPC's designated appointee;
 - the decontamination lead;
 - the surgical instrument manager;
 - representative(s) from the Infection Control Team;
 - representative(s) from the clinical device users;
 - the User;
 - an Authorising Engineer (Decontamination).
- 2.23** For a brief summary of staffing roles and responsibilities, see **paragraphs 6.30–6.71**.

2.24 Others, such as representatives of decontamination services and estates and facilities, may be members of the group or co-opted at the discretion of the DIPC.

Figure 2 Drivers for quality improvements and desired outcomes



Implementation of HTM 01-01

2.25 This guidance will help providers to achieve a satisfactory level of risk control together with compliance with the essential requirements of the Medical Devices Regulations (MDR).

2.26 This guidance recommends that all providers of surgical care work with their decontamination specialists to achieve Essential Quality Requirements and a locally risk-assessed progression to Best Practice. Not all service providers will be in a position to adopt Best Practice recommendations. However, every service provider will need to:

- assess what Best Practice is appropriate for each of the decontamination settings in their control, based on the surgical procedures undertaken;
- what improvements they need to undertake to move towards these; and
- prepare a plan for progression to Best Practice.

2.27 All units where surgical instruments are used or decontaminated should be working at or above Essential Quality Requirements and have in place local policies and business development programmes that demonstrate progression to Best Practice.

2.28 This guidance has been developed and validated by a series of pilot studies in England and Scotland, which looked primarily at the feasibility and practicality of implementation. Principally these include:

- Maintaining instruments in a moist environment following use and before reprocessing.
- The retention of surgical instruments within their sets by the application of both individual instruments and set level track and trace technologies.
- Revision of set contents in neurosurgery in order to obtain enhanced suitability for purpose and reduced set instrument

leakage when combined with set colour codes.

- Strategies for the purchase, set design and application of instruments used in paediatric high-risk surgery for patients born after 1 January 1997.
- The development and evaluation of protein detection and quantification techniques for use with instruments following washing and disinfection.
- The maximisation of protein removal by the use of suitably optimised washer-disinfector and detergent systems (see paragraphs 2.29–2.38).

ACDP-TSE's recommendations on protein detection

2.29 The ACDP-TSE Subgroup's general principles of decontamination ([Annex C](#)) state:

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 ≤ 5 μg 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 μg 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 ≤ 5 μg 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 Subgroup's recommendations

2.30 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

2.31 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

2.32 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 to 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.

2.33 It is important to continuously monitor the residual protein on reprocessed instruments. SSDs should not view the 5 μg 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 2.271–2.277 in HTM 01-01 Part D –‘Validation and verification’). See also Appendix B in this document for example sampling rates.

2.34 Priority for cleaning validation and continuous monitoring should be given to instruments that have contact with high-priority tissues as defined by the ACDP-TSE Subgroup (see Table A1 in the ACDP-TSE’s guidance [Annex A1](#)).

* 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.

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

Methods for detecting residual protein

2.36 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](#)). Methods that do not have protein as their target, such as ATP assays, cannot be used as a substitute for residual protein detection.

2.37 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

2.38 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). There should also be a specific record that relates to residual protein trend analysis. The ambition is that all healthcare providers engaged in the management and decontamination of surgical instruments used in acute care will be expected to have updated their local policies and continuous improvement plans in line with this guidance by **1 July 2018**. However, providers whose instruments are likely to come into contact with higher risk tissues, for example neurological tissue, are expected to give this guidance higher priority and move to *in situ* protein detection methodologies by **1 July 2017**.

3 Guidance for commissioners, regulators and providers

3.1 The overarching aim of the commissioning function is to ensure the highest levels of patient care and staff safety, in the most cost-effective manner. In commissioning decontamination services for surgical instruments used in acute care, commissioning organisations should aim to deliver:

- sustainable high standards of patient safety;
- improved clinical care outcomes arising from a carefully considered local instrument management strategy;
- an enhanced patient experience through minimising delay and procedure cancellations associated with instrument provision;
- cost efficiencies from instrument provision to the demands of the care given;
- local choice in the means of risk control both through instrument management and in choices with regard to decontamination;
- appropriate quality systems and engineering standards;
- professional work by trained managers and staff throughout the reusable surgical instrument cycle.

See the NHS Operating Framework for further guidance on the new commissioning and management system for the NHS.

3.2 Responsibility for achieving acceptable standards of decontamination rests with commissioning organisations, individual trusts and provider organisations. Reprocessing units in healthcare establishments responsible for the decontamination of medical devices fall into two distinct categories when considering compliance with the MDD:

- Devices transferred between legal entities (for example – reprocessing by one entity followed by use in another).
- Devices remaining within one legal entity (for example – reprocessing and use by the same entity or organisation).

For further information, see [paragraph 4.5, 'Compliance with the Medical Devices Regulations'](#).

3.3 When commissioning surgery, commissioning organisations should require that the healthcare provider is receiving devices, or it has a decontamination service, that meets the essential requirements of the MDR and is able to demonstrate evidence of an appropriate quality management system and audit system.

3.4 Commissioning organisations should also expect the healthcare provider to have a plan in place to achieve Best Practice. This plan should have been developed, having taken account of the risk of surgical procedures (see [paragraph 2.18](#) and [Chapter 5](#)). Commissioning organisations may use this plan to improve the services commissioned from providers for the benefit of patients, and to differentiate between providers.

3.5 They may do this by:

- including the attainments within the service specification element of the standard contract;
- establishing key performance indicators as part of a tendering process; and
- using Best Practice as an incentive to improve provider performance.

3.6 Best Practice could also be used as attainment levels against which improvements can be measured and rewarded, enabling commissioners to encourage evidence-based practices and innovation.

3.7 Providers may refer to [paragraph 2.11](#) in order to assess the quality of their decontamination services and demonstrate quality improvement within their organisation.

3.8 In the event of poor performance, commissioners may discuss the level of performance with their providers and address any issues and concerns before introducing more formal contractual remedies.

3.9 Regulators may use the recorded risk-assessed local policy to check Essential Quality Requirements attainments alongside adherence to regulatory requirements.

Implication for contractual agreements

3.10 The adoption of a risk-control based approach to surgical instrument management should not prejudice current contractual

agreements. While there is sufficient flexibility in current contractual arrangements to accommodate the HTM approach, the development of local policies and procedures may require locally negotiated variations to the contract to accommodate changes to the service specification. There are two routes to vary the contracts let through the National Decontamination Programme: via schedule 11 and schedule 21 of the Decontamination Services Agreement. For other third-party contracts, advice would have to be sought locally on the mechanism for implementing changes.

Implication for third-party providers

3.11 Where decontamination services are provided by a third party, all parties to the service should work together to develop local policies and procedures that are appropriate and can be implemented.

3.12 It should be noted that third-party providers of decontamination services come under the MDD (directive 93/42/EEC has been superseded by directive 2007/47/ EC). They will be using existing British and European Standards to demonstrate compliance with the essential requirements of the MDD and will have a quality system against which they are independently audited. The development and implementation of new local policies and procedures may require a variation to the contract and changes to quality systems to accommodate.

4 Regulatory framework

4.1 This chapter sets out the duty of care for decontamination services in England. The regulatory framework is applicable across all sectors of healthcare (see Figure 3).

European legislation

4.2 There are three EU Directives relating to the manufacture and supply of medical devices:

- MDD 93/42/EEC
- In-vitro Diagnostic Devices Directive 98/79/EEC
- Active Implantable Medical Devices Directive 90/385/EEC.

4.3 These three directives have been transposed into UK law as the Medical Devices Regulations (MDR) 2002, as amended. (For more information about the MDDs and compliance, visit the MHRA's website.)

4.4 Washer-disinfectors and sterilizers – that is, those machines specifically intended for the decontamination of reusable medical devices – can also fall within the scope of the MDR.

Compliance with the Medical Devices Regulations

4.5 Only those units that transfer reusable medical devices are within the scope of the MDD and the MDR.

4.6 Devices decontaminated for reuse are not “placed on the market” and are therefore outside the scope of the regulations.

4.7 Irrespective of this, however, the standards applied to all organisations that provide decontamination services are monitored against the essential requirements of the MDD. This is undertaken either by a notified body, whose activities are monitored by the MHRA if the formal certification route is applied, or by the CQC.

4.8 Figure 4 illustrates the regulatory framework and the compliance routes for reusable medical devices transferred between legal entities and for reusable medical devices remaining within one legal entity.

Compliance with the MDD

4.9 Responsibility for achieving acceptable standards of decontamination rests with commissioners, individual trusts and provider organisations.

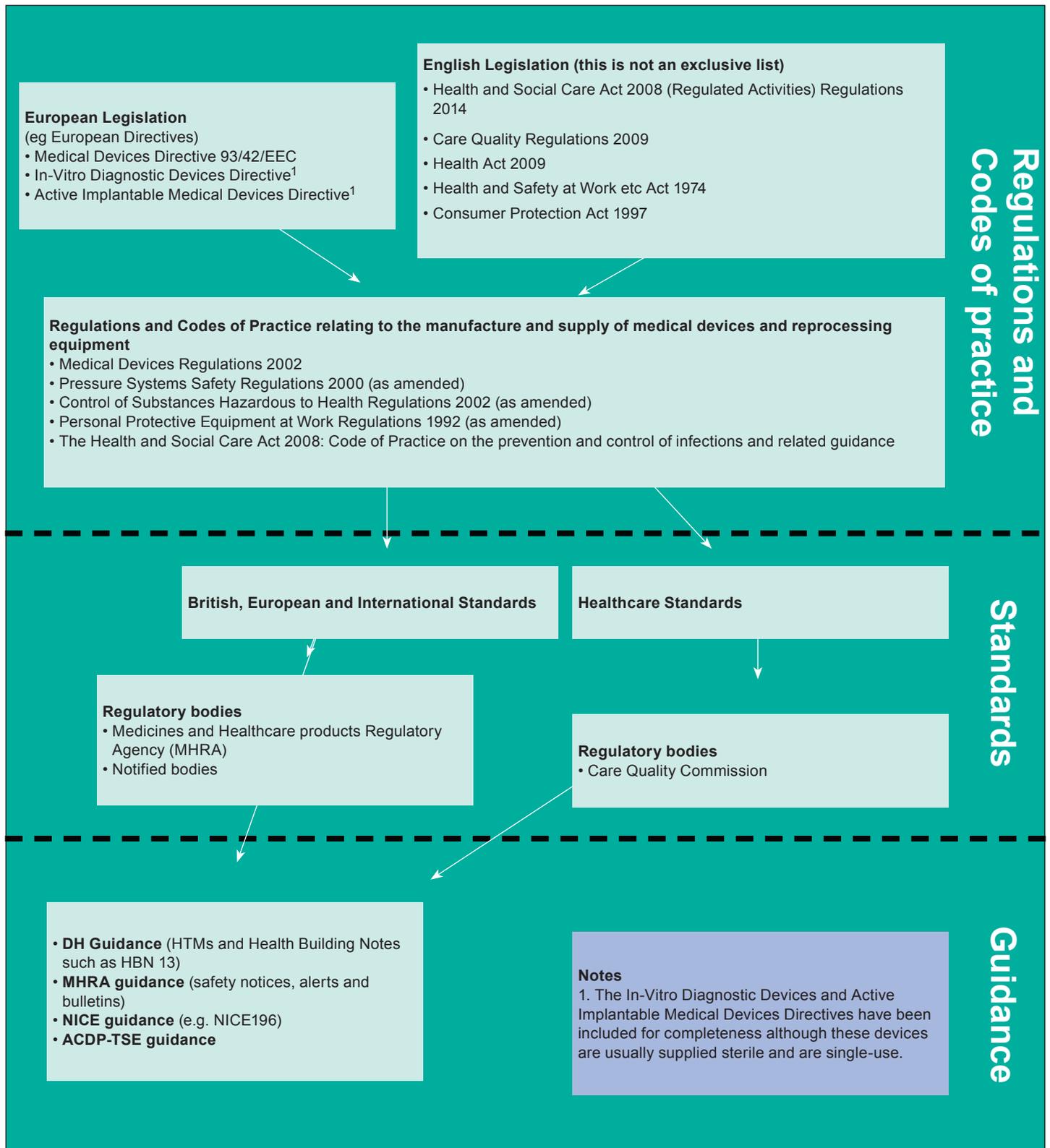
4.10 Healthcare organisations decontaminating reusable medical devices fall into two distinct categories when considering compliance with the MDD:

- reusable medical devices transferred between legal entities
- reusable medical devices remaining within one legal entity.

4.11 The requirement for formal certification of SSDs under the MDD is dependent on whether “product” is “placed on the market”. Providing products to another legal entity is “placing product on the market”.

4.12 The implications of the MDD regulations are that all those organisations that provide

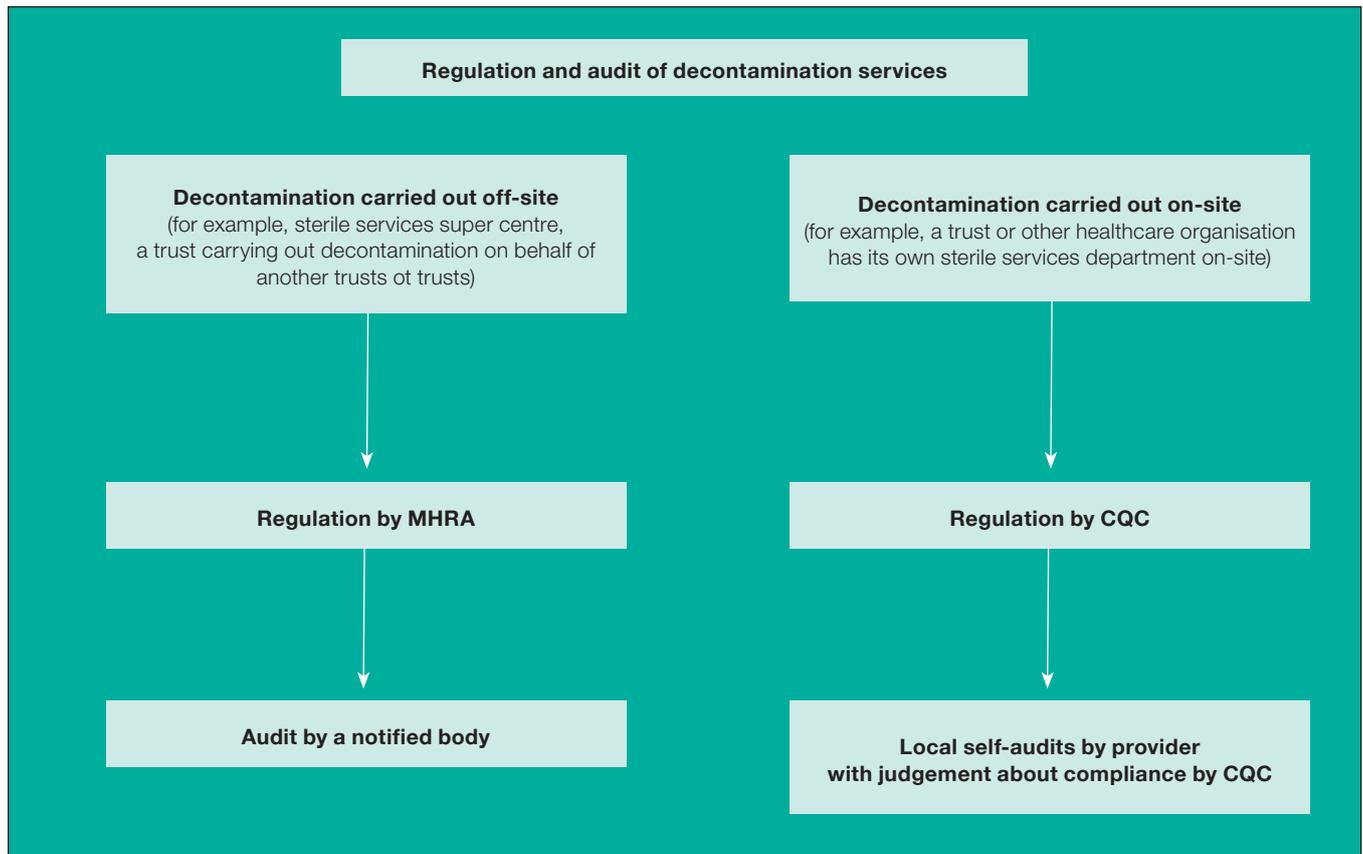
Figure 3 Overview of the interaction between the different structures within the English legislative system



decontamination services and which “place product on the market” are legally required to demonstrate compliance to the harmonised standards contained within the directive. It

provides a standardised approach to decontamination in the UK and across all European countries.

Figure 4 Regulation and audit of decontamination services and the respective responsibilities of MHRA and CQC



4.13 The most commonly used route to demonstrating compliance is to institute a quality management system such as BS EN ISO 13485 across all areas of the decontamination cycle.

4.14 BS EN ISO 13485 specifies requirements for a quality management system that can be used by a healthcare organisation for the design and development, production, installation and servicing of reusable medical devices and the design, development and provision of related services. It can also be used by internal and external parties, including certification bodies, to access the healthcare organisation’s ability to meet customer and regulatory requirements. Its primary objective is to facilitate reusable medical device regulatory requirements for quality management systems.

Reusable medical devices transferred between legal entities

4.15 Healthcare organisations offering the decontamination of reusable medical devices to

another legal entity are subject to the requirements of the MDR. If sterile devices are produced, the intervention of a third-party audit programme must also be undertaken by a recognised notified body.

4.16 A notified body is a certification organisation that the competent authority (MHRA within the UK) designates to carry out one or more of the conformity assessment procedures described in the annexes of the MDD.

4.17 Healthcare organisations “placing product on the market” must also register with the MHRA.

4.18 Commissioners should be provided access, if required, to check that a provider is registered with a notified body and has an appropriate quality system in place.

4.19 Commissioners should be given access to the results of the most recent third-party (notified body) audit and should be able to see any:

- non-conformances picked up in the audit;
- required corrective actions that have been agreed; and
- evidence of corrective actions being implemented.

Reusable medical devices remaining within one legal entity

4.20 If a healthcare organisation only provides decontaminated reusable medical devices for use on, or by, patients of that same entity (that is, there is no "placing on the market"), the MDR do not apply.

4.21 These healthcare organisations do not need to register with the MHRA nor do they need to use a notified body; nevertheless, they are subject to the duty of care imposed under product liability. They must still ensure instruments are safe, fit for purpose and of suitable quality. The CQC will assess the performance of these organisations. Registration with the CQC includes a number of requirements in this area, and providers are required to comply with these requirements.

4.22 Compliance with BS EN ISO 13485 will demonstrate a commitment to producing reusable medical devices of appropriate quality.

Outsourcing

4.23 The options for those healthcare organisations that do not undertake decontamination services include:

- Using a decontamination service that is registered with the MHRA, that is compliant with the MDR, and that uses a notified body as its third-party auditor.
- Using CE-marked single-use medical devices.

4.24 The relative merits of the options should be evident through developing a business case highlighting the options, timescales, cost benefits and reliability assessment.

The Health and Social Care Act 2008: Code of Practice

4.25 The guidance provided here is consistent with the 'Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance 2010 revision' ('the Code'). The Code recommends that effective prevention and control of healthcare-associated infections be embedded in everyday practice. For this reason, the guidance is written with emphasis on practical and readily implemented measures.

4.26 Adhering to this HTM will assist providers in complying with the decontamination guidance set out in the Code and in meeting the CQC registration requirement on hygiene and infection control.

Key Code recommendations

4.27 With a view to minimising the risk of infection, a registered provider should normally ensure that it designates leads for environmental cleaning and decontamination of equipment used for diagnosis and treatment (a single individual may be designated for both areas).

4.28 The decontamination lead should have responsibility for ensuring that policies exist and that they take account of best practice and national guidance for the decontamination of reusable surgical instruments.

4.29 The decontamination policy should demonstrate that:

- it complies with guidance establishing Essential Quality Requirements and a plan is in place for progression to Best Practice;
- decontamination of reusable medical devices takes place in appropriate facilities designed to minimise the risks that are present;
- appropriate procedures are followed for the acquisition, maintenance and validation of decontamination equipment;

- staff are trained in cleaning and decontamination processes and hold appropriate competences for their role; and
- a record-keeping regime is in place to ensure that decontamination processes are fit for purpose and use the required quality systems. (See also Outcome 11, Regulation 16 Safety, availability and suitability of equipment contained in CQC Guidance about compliance.)

Care Quality Commission

4.30 The CQC independently regulates all providers of regulated health and adult social care activities in England. The CQC's (2015) 'Guidance for providers on meeting the regulations' explains how to meet regulations 12(2)(h) (on safe care and treatment) and 15 (safe premises and equipment) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

4.31 Failure to comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the Care Quality Commission (Registration) Regulations (2009) is an offence, and the CQC has a wide range of enforcement powers that it can use if a provider is not compliant. These include the issue of a warning notice that requires improvement within a specified time, prosecution, and the power to cancel a provider's registration, removing its ability to provide regulated activities.

British, European and International Standards

4.32 To support the MDD and to assist manufacturers (including decontamination services) to interpret the essential requirements, the European Commission has published an updated list of harmonised standards. Compliance with all relevant harmonised standards on this list leads to an automatic presumption that the medical devices comply with the requirements of the MDD.

4.33 Although compliance with a mandated standard is not the only way of complying with the directives, it is the simplest.

4.34 The list of standards given in [Appendix A](#) is not exhaustive but includes the key documents that may be used to inform the management of decontamination of reusable medical devices in a healthcare organisation. See also the website of the European Union.

Policy and guidance

4.35 The DH and other professional bodies and advisory committees have published guidance on the decontamination of surgical instruments. The list below is not exhaustive but includes the key resources that may be used to inform the management of decontamination within a health service environment:

- The DH's HTM series.
- For a list of medical device alerts, safety notices, hazard notices and device bulletins relating to decontamination, visit the MHRA's website.

4.36 The DH's policy is that the measures defined in NICE IPG 196 (2006) guidance be incorporated into practice and supplemented by the guidance derived from the ACDP-TSE Subgroup:

- the ACDP-TSE Subgroup provides practical scientifically based advice on the management of risks from TSEs in order to limit or reduce the risks of human exposure to, or transmission of, TSEs in healthcare and other occupational settings.
- NICE IPG 196 (2006) provides guidance on how best to manage the risk of transmission of CJD and vCJD via interventional procedures. This was the subject of CMO Letters recommending the implementation of NICE IPG 196 (2006) and is DH policy.

5 Human prion diseases (including variant CJD and other forms of CJD)

Background

The human prion diseases are a group of rare fatal neurological disorders that occur in sporadic, genetic and acquired forms, the latter occurring by transmission from one individual (or species) to another. These conditions are all associated with the conversion of a normal protein in the body, the prion protein, to an abnormal disease-associated form that accumulates in the brain and results in neuronal degeneration and death. The abnormal prion protein is thought to be the major component of transmissible prion agents.

The commonest human prion disease is the sporadic form of Creutzfeldt-Jakob disease (sCJD), with an annual incidence worldwide of one-to-two cases per million of the population. In the UK, there are between 50 and 90 cases annually, with a peak incidence in the 60–70-year age group. This disease presents with rapidly progressive dementia and a range of other neurological signs and symptoms, with death occurring in around three-to-six months of disease onset. The genetic forms of human prion disease account for around 10% of total cases, while acquired cases account for around 1%, including iatrogenic CJD (iCJD) in human growth hormone and dura mater graft recipients, and variant CJD (vCJD). Incubation periods in acquired human prion diseases can vary from two to over 40 years, depending on the route of exposure. vCJD was first reported as a novel human prion disease in 1996, acquired from infection by the bovine spongiform encephalopathy (BSE) agent, most likely via the oral route. Patients with sCJD and vCJD have differences in the distribution of prion infectivity around the body. In sCJD (and also in some cases of genetic prion diseases and iCJD), abnormal prion protein appears to be restricted to the central nervous system (CNS), whereas in vCJD it has also been detected in lymphoid tissues, including tonsils, spleen and gastrointestinal lymphoid tissue. Abnormal prion protein has been detected in the lymphoid tissues of a few individuals infected with vCJD before the onset of clinical signs and symptoms of the illness, indicating asymptomatic vCJD infection.

vCJD is distinguishable from non-vCJD in a number of ways:

- It tends to affect younger people with an average (median) age of onset of around 26 years (median age at death 28 years).
- The predominant initial clinical symptom is of psychiatric or sensory problems, with coordination problems, dementia and muscle-twitching occurring later.
- The illness usually lasts about 14 months (range 6–84 months) before death.

A definitive diagnosis of vCJD can only be confirmed by examining brain tissue, usually at post-mortem, and requires the exclusion of other forms of human prion disease, particularly sCJD.

In the UK, as of 2016, there have been 177 deaths from definite or probable cases of vCJD, three of which appear to have been acquired by packed red blood cell transfusion from infected donors. The peak year of deaths was 2000, since when numbers of cases have fallen progressively with no new cases reported since 2012. However, given the long incubation periods previously seen for acquired CJD, and with evidence from tissue-based prevalence studies in the general population, the potential for further cases to emerge or for potential asymptomatic abnormal prion carriage within the general population has yet to be ruled out.

While three vCJD cases may have been transmitted by blood transfusion, there are no known cases of vCJD being transmitted by surgical instruments or endoscopes. However, it may be possible because:

- sCJD has been transmitted by neurosurgical instruments used on the brain;
- abnormal prion protein binds avidly to steel surfaces and can be very difficult to remove from surgical instruments; and
- prion infectivity has been found in a range of tissues (brain, spleen, tonsils etc) of patients who have developed symptomatic vCJD

Guidance from the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy (ACDP-TSE) Subgroup, formerly the TSE Working Group, details precautions to be taken when dealing with known or suspected cases and those at increased risk of human prion disease.

What is the relevance of decontamination to human prion diseases?

While there is still a good deal of scientific uncertainty about human prion diseases, the DH continues to take a precautionary approach and adapt policy as new evidence emerges. To maintain effective risk management, it is important to combine improved recognition of potentially infected individuals who are at increased risk of human prion disease with the most effective methods for surgical instrument decontamination.

Introduction

5.1 The human prion diseases (including sCJD and vCJD) are a group of rare invariably fatal neurological disorders. In these diseases the normal human prion protein in the body undergoes misfolding to become an abnormal disease-associated protein, which is the major component of the transmissible agents in prion diseases.

5.2 Abnormal prion protein is heat-stable, exceptionally resistant to enzymatic digestion and, once dried onto surfaces of surgical instruments, is very difficult to remove or

inactivate by conventional decontamination processes.

5.3 Abnormal prion protein may accumulate to very high levels in the CNS of all patients with a human prion disease (including sCJD and vCJD). For this reason, the CNS is considered as a high infectivity tissue in all forms of human prion disease.

5.4 In vCJD, abnormal prion protein also accumulates at lower levels in lymphoid tissues (for example tonsils, spleen, lymph nodes and Peyer's patches in the gastrointestinal system). This accumulation appears to begin before the onset of clinical symptoms of vCJD and may therefore indicate asymptomatic vCJD infection.

Lymphoid tissues are considered medium infectivity tissues in vCJD (but not in sCJD and most other human prion diseases).

5.5 This HTM supports commissioners and providers in implementing appropriate and effective decontamination measures to reduce the risks of transmission of human prion diseases. Owing to the difficulty of inactivating or removing human prion proteins from surgical instruments, special measures are required to prevent their potential transmission between patients.

5.6 Guidance on the relative risk of different body tissues can be found in the [ACDP-TSE Subgroup's Annex A1](#). Patient risk assessment and procedures can be found in [Annex J](#). See also [Public Health England's CJD section](#).

Patients with CJD, suspected CJD or an increased risk of developing CJD

5.7 The ACDP-TSE Subgroup's guidance on minimising the transmission of CJD and vCJD in healthcare settings provides advice on the use and management of surgical instruments for procedures where there may be a risk of surgical transmission.

5.8 This advice applies to:

- patients with probable or confirmed CJD;
- those for whom CJD is being considered as a differential diagnosis; and
- around 5000 people who:
 - have an increased risk of CJD because of an operation or medical treatment in the past, or
 - are at risk of inherited prion disease.

Detailed descriptions and definitions of these risk groups can be found in paragraph 4.17 ("Patient categorization") of the ACDP-TSE's [Part 4 – 'Infection control of CJD, vCJD and other human prion diseases in healthcare and community settings'](#).

5.9 Part 4 also describes:

- The range of tissues for which surgical instrument precautions should be taken ("Tissue infectivity", paragraph 4.12).
- Recommendations for single use instruments; handling of reusable instruments; and instrument disposal ("Surgical procedures and instrument management", paragraph 4.46). Advice is set out separately for patients at risk of sCJD, iCJD and inherited prion disease and those at risk of vCJD due to the larger range of tissues involved in vCJD (tables 4c and 4d).
- Advice on the procedures to be followed for quarantining surgical instruments is given in [Annex E](#) of the guidance. Under no circumstances should quarantined instrument sets be used on other patients unless the diagnosis of CJD or vCJD has been positively excluded.

5.10 All instruments should be kept moist prior to being sent for reprocessing. There are a variety of methods, for example gels, sprays and use of wet towels, that could be applied to keep instruments moist; the choice of the exact method used rests with the decontamination manager, Decontamination Lead or local Infection Control Team following risk assessment.

5.11 The instrument set should be reprocessed through the SSD in the usual manner. No special precautions are necessary as proteins lifted by detergent action from the surface of a contaminated instrument will not deposit on other surfaces in the washer-disinfector. The possibility of residual abnormal prion on the instruments is of far greater concern than the possibility of contamination of instruments in other sets processed in the washer-disinfector either concurrently or subsequently.

5.12 A traceability system for equipment especially where used on patients with, or at increased risk of, human prion disease is very important. Also subsequent storage (including

quarantine if indicated) or use of instruments must be recorded and where appropriate specialist advice obtained from the local Health Protection Team.

5.13 For details about action required following invasive procedures on a patient with definite or probable vCJD or presumed infected cases, see also Public Health England's '[CJD: public health action following report of new case or person at increased risk](#)'.

Protein removal and detection

5.14 Guidance on protein removal and detection is given in paragraphs 2.29–2.38.

Note

This remains a work in progress which will be updated as additional evidence becomes available.

Prion-specific decontamination technologies

5.15 There are technologies that may offer future potential to enhance the existing decontamination process to reduce protein, including prion protein contamination of instruments.

5.16 In addition to activity against abnormal prions, prion decontamination technologies must also:

- a. be compatible with the existing decontamination processes;
- b. remove protein;
- c. have good stability;
- d. have acceptable environmental and operator safety;
- e. be compatible with instruments and EWDs.

6 Management of surgical instruments

Introduction

6.1 This chapter aims to provide further guidance on the management of surgical instruments to support further risk reduction and improvements to patient outcomes.

6.2 Management of surgical instruments in HTM 01-01 relates to those used in acute care. In this context, management of surgical instruments should make sure that risks associated with surgical procedures are minimised.

6.3 The following management choices have been identified:

- keeping instruments moist;
- separation of instruments used on high risk tissues for patients born before and after 1 January 1997;
- instrument audit and tracking.

6.4 Other management choices covered in this guidance include:

- loan sets;
- loan sets used in high-risk surgical procedures;
- repairs;
- instrument audit and tracking policy;
- single-use instrument tracking and records;
- decontamination of surgical instruments that have been dropped perioperatively.

Keeping instruments moist between use and reprocessing

6.5 Prions are hydrophobic proteins. The attachment of hydrophobic proteins to surfaces becomes less reversible if they are allowed to dry fully. Keeping the environment around soiled instruments at or near saturation humidities (moist) prevents full attachment of hydrophobic proteins such that they are more efficiently removed by cleaning.

6.6 A number of means are available to generate moist conditions, including the use of enclosed containers/bagged trays used with single-use moist pads, gels, foams, water sprays or other methods as determined locally.

6.7 However, whatever method is used, care should be taken to ensure that all parts or surfaces of the surgical instruments are constantly exposed to the moist environment.

Separation of instruments used on high risk tissues for patients born before and after 1 January 1997

6.8 It is thought that people born since 1 January 1997 have had lower exposure to prions via the food chain. These people form a group at lower risk of prion diseases and thus at a lower risk of contaminating surgical instruments with prions. The NICE IPG 196 (2006) risk-reduction strategy requires that separate pools of instruments be used for high-risk tissue surgery, dependent on the patient's birth date. This differentiates between patients who were either born before 1 January 1997, or who were born on or after 1 January 1997, and

requires that separate pools of instruments be used for each stream.

6.9 There will be a small number of patients born after 1 January 1997 who were operated on using pre-1997 instruments before the 2006 NICE guidance was issued. For these patients, further high-risk tissue surgery should use either:

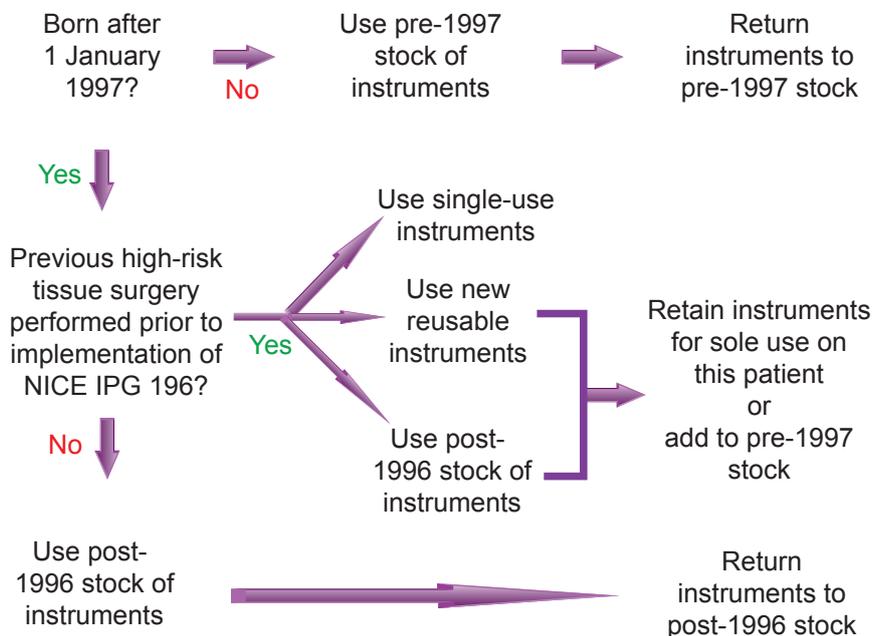
- single-use instruments, provided these are available and of satisfactory quality; or
- new reusable instruments, or post-1996 instruments and either:
 - retain them for sole use on this patient; or
 - afterwards add to the pre-1997 stock¹.

6.10 If instruments from the reserved post-1996 stock are used deliberately or by mistake in a patient born before 1997, they should not be returned to the post-1996 stock, but may continue to be used as part of the pre-1997 stock (see Figure 5). The same age separation should be applied to loan sets.

Loan sets

6.11 Instrument sets that are supplied from an external source, used for that procedure only and then returned are known as loan sets. This practice increases the risks associated with the decontamination and reprocessing of such instruments, because the organisation may not be familiar with them. Organisations have also expressed concern over the decontamination status of such instruments and the lack of track and traceability, including potential for instrument migration. It is a requirement of the

Figure 5 Instrument stock identification for high-risk tissue surgery



¹ This reflects guidance by the Society of British Neurological Surgeons and the ACDP-TSE Subgroup in preparation at the time of publication of this HTM.

Code of Practice that reusable medical devices should be decontaminated in accordance with manufacturers' instructions. Therefore, loan sets should be provided with decontamination instructions so that staff can ensure their compatibility with local decontamination processes. It should be ensured that when equipment is supplied to a healthcare provider, adequate time is allowed for cleaning, sterilization and return of the equipment to the theatres, both prior to and after use (see the AfPP's (2010) guidance 'Loan set management principles between suppliers/manufacturers, theatres & sterile service departments' and MHRA's 'Managing medical devices').

6.12 Set integrity needs to be maintained to minimise instrument migration and enable traceability to the patient. This extends to the control of individual instruments within loaned sets, to audit their removal and replacement.

Loan sets used in high-risk surgical procedures

6.13 Particularly for high risk surgical procedures (see Chapter 5), healthcare providers using loan sets should ensure that records of such sets are maintained within their control. These records should be available for independent review and should, at a minimum, make it possible to ascertain the details of the instruments contained within the set and the surgical units within which the set has been used. Dates and session times for each use should also be recorded. The identity of patients with whom the sets have been used should be traceable from the record but, for patient confidentiality, maintained within the secure environment of the clinical service providers concerned.

6.14 Instruments within loan sets shall be subject to quality system and control measures at least equal to those normally applied in the surgical centres where they are used. This applies equally when surgeons or other team members are the sponsor of any loan arrangement.

6.15 Theatre staff and SSDs should take special care to ensure integrity of loan sets and, for instruments used on high risk tissues, their membership of pre or post 1 January 1997 instrument groups from receipt to dispatch.

Repairs

6.16 Any instrument used on high risk tissues that are removed for repair should be returned to the instrument set from which it was removed.

Instrument audit and tracking

6.17 There is a need to track and trace reusable surgical instruments throughout their use and reprocessing. This is to avoid instrument migration and is an essential requirement of the MDR and the Code of Practice.

6.18 Records should be maintained for all the instrument sets (and supplementaries for high-risk procedures) identifying:

- the cleaning and sterilization method used
- a record of the decontamination equipment and cycle
- the identity of the person(s) undertaking decontamination at each stage of the cycle
- the patients on whom they have been used and details of the procedures involved.

6.19 This information is required so that instrument sets (and supplementaries for high-risk procedures) and the patients they have been used on can be traced and the instrument sets and supplementaries recalled when necessary.

6.20 The reunification of instruments with their sets following repair or replacement benefits from accurate instrument identification. Tracking is likely to mitigate other factors, including those associated with operative failure due to the absence of key instruments or arising from poor

adherence to scheduled instrument maintenance – particularly those which have electrical components.

6.21 For those instruments, including delicate components such as electronic devices or imaging related markers, the use of single instrument identification may be of special value. When marking is combined with properly managed decontamination procedures the individual instrument may be correctly identified as requiring a non-standard approach to washing, disinfection or sterilization.

6.22 Individual instruments may have warranties associated with them which carry a guarantee. However if the individual warranted instrument cannot be reliably identified to a standard which is satisfactory to the supplier, then it is unlikely that the warranty can be evoked. A similar argument applies to instruments such as arthroscopy scissors, which are limited in terms of the number of use cycles, authorised by the manufacturer under CE marking.

6.23 NICE IPG 196 (2006) guidance requires that high-risk tissue instrument sets used with patients born since 1 January 1997 form a pool within which instruments must be retained and from which other instruments must be excluded. This is challenging when supplementary instruments are used. Teams are likely to find effective streaming of non-marked instruments difficult. The use of larger sets which include supplementary instruments will partly mitigate this risk, particularly when combined with instrument marking, tracking and audit techniques.

Single-use instrument tracking and records

6.24 When single-use surgical instruments are used, they must be separated from reusable surgical instruments and disposed of at the end of the procedure. It is important that the single-use instruments are not allowed to enter reusable instrument sets.

Decontamination of surgical instruments that have been dropped perioperatively

6.25 Instruments dropped or which otherwise have their sterility compromised during use should be replaced. There should, where standard sets are being used, always be at least one readily accessible spare set so this can happen with minimal delay. The local policy to ensure this occurs efficiently should be established with the theatre users, the theatre manager and the DIPC (or their nominee). This may on rare occasions not be possible, for example if use of loan sets does not allow this.

6.26 On these occasions, a local risk assessment by the operating team should assess the relative risks of the options available, for example: the continuation of the procedure without that item; the abandonment of surgery; the return of that item to the SSD for full decontamination.

6.27 Current DH policy remains to reduce inappropriate local reprocessing such as the use of non-compliant, non-validated bench top sterilizers. Development of local policies and procedures needs to consider benefits, risk and cost of the options available.

6.28 Where benchtop sterilizers are still available, these should be a last resort, and instruments should be subject to local manual cleaning to an agreed procedure. The unwrapped item should be processed in a downward displacement steam sterilizer maintained and validated including undertaking the necessary daily automatic control tests

6.29 There should be measures in place to audit each use of this sterilizer and identify which cycles are for the sterilizer's routine validation and which are for surgical instrument decontamination. This audit should ensure that the sterilizer is only used for instrument decontamination in the exceptional circumstances outlined above. It should be appreciated that this should be a last resort and should be reported through the hospital's adverse incident report system.

Staff roles and responsibilities

Note:

One of the recommendations arising from a survey of decontamination services in England undertaken by the Department of Health in 2000 was that “all staff, including managers, directly or indirectly involved in decontamination of surgical instruments to be competent on the basis of appropriate education, training, skills and experience.”

Furthermore, the Health and Social Care Act Code of Practice on the prevention and control of infections states that decontamination policies should demonstrate that “staff are trained in cleaning and decontamination processes and hold appropriate competencies for their role”.

The ACDP-TSE Subgroup therefore recommends that decontamination staff should undertake appropriate formal training: for example, the training package offered by the Institute of Decontamination Sciences (IDSc) in conjunction with Anglia Ruskin University, or other equivalents such as the training programmes being developed under the Modernising Scientific Careers initiative. It also suggests that, although there is no current professional registration of decontamination personnel, it would be best practice for senior SSD staff (for example the User) to be members of a relevant professional body such as the IDSc.

All medical device decontamination sciences staff are aligned to the [national profiles for healthcare science](#). Implementing the generic job descriptions (JDs) for medical device decontamination sciences staff will improve patient safety and staffing structures within medical device decontamination sciences departments – example generic JDs are available on the [IDSc website](#).

6.30 Staff undertaking decontamination and management of decontamination should be able to demonstrate their competencies and training in this area through individual training records, detailing the appropriate core competencies and any other supplementary training. These records should be updated at least annually. Line or training managers should be responsible for maintaining these records.

6.31 The approach adopted in this HTM is to identify the distinct functions that need to be exercised and the responsibilities that go with them. The titles given are therefore generic; they describe the individual’s role in connection with decontamination but are not intended to be prescriptive job titles for terms of employment. Indeed, many of the personnel referred to may not be resident staff but employed by outside bodies and working on contract. Some of them will have other responsibilities unconnected with decontamination and in some cases the same individual may take on more than one role.

6.32 Whatever model of operational management is chosen, the roles and responsibilities of the individuals involved should be clearly defined and documented. In every case, however, it should be possible to identify a User who is responsible for the day-to-day management of the decontamination of reusable surgical instruments. The philosophy of this HTM is to invest the User with the responsibility for seeing that the decontamination process is operated safely and efficiently.

6.33 The following personnel are referred to in this HTM.

Management – definition

6.34 Management of a healthcare organisation performing decontamination is defined as the owner, chief executive or other person of similar authority who is ultimately accountable for the safe operation of the premises, including decontamination.

- Executive Manager (for example, chief executive);
- Decontamination Lead (this person may also act as the Designated Person if locally agreed);
- Designated Person
- Surgical Instruments Manager
- Senior Operational Manager (for example, estates manager);
- User (for example, sterile services manager);
- Authorising Engineer (Decontamination);
- Authorised Person (Decontamination);
- Competent Person (Decontamination);
- Director of Infection Prevention and Control (in England);
- Infection Control Doctor;
- Microbiologist (Decontamination);
- Operator;
- Manufacturer;
- Contractor;
- Purchaser;
- Competent Person (Pressure Systems).

Executive Manager

6.35 The Executive Manager is defined as the person with ultimate management responsibility, including allocation of resources and the appointment of personnel, for the organisation in which the decontamination equipment is installed.

6.36 Depending on the nature of the organisation, this role may be filled by the general manager, chief executive or other person of similar authority.

Decontamination Lead

6.37 Every healthcare provider should have a nominated Decontamination Lead with

responsibility for decontamination, either at board level or who has line management responsibility to a senior responsible person at that level.

6.38 The Decontamination Lead should report directly to the Executive Manager.

6.39 The Decontamination Lead is organisationally responsible for the effective, and technically compliant, provision of decontamination services.

6.40 The Decontamination Lead is responsible for the implementation of operational policies for decontamination and should ensure specific operational policies are in place for the decontamination of all medical devices. He/she should ensure that the operational policy clearly defines the roles and responsibilities of all personnel who may be involved in the use, installation and maintenance of decontamination equipment. The Decontamination Lead is also responsible for monitoring the implementation of the policy and should have a competent understanding of the decontamination of medical devices, guidance, legislation and standards.

6.41 The Decontamination Lead may delegate specific responsibilities to key personnel; the extent of such delegation should be clearly set out in the operational policy together with the arrangements for liaison and monitoring.

6.42 The Decontamination Lead may also act as the Designated Person.

Designated Person

6.43 This person provides the essential senior management link between the organisation and professional support.

6.44 The Designated Person should also provide an informed position at board level.

6.45 The Designated Person should work closely with the Senior Operational Manager to ensure that provision is made to adequately support the decontamination system.

Surgical Instrument Manager/coordinator

Note:

This role can be fulfilled by the User.

6.46 The decontamination manager of surgical instruments (medical devices) or other designated person should be assigned by the Decontamination Lead to take responsibility for coordinating activity between the theatre, decontamination and supply/purchase teams. The person fulfilling that role should also ensure that the inventory of surgical instruments is proactively reviewed and managed in accordance with this guidance, clinical requirements and industry best practice.

6.47 Specifically, this officer will:

- make judgements on the suitability of reusable instruments in consultation with surgical teams and those responsible for decontamination. This work will be assisted by the formation of a working group for ongoing collaboration;
- determine appropriate instrument-set structures designed to assist in the prevention of leakage of instruments between sets (including preventing the movement of supplementary instruments between sets) in consultation with clinical specialists and decontamination teams;
- ensure that guidance on tracking and traceability is appropriately applied to all instruments (this includes loan sets) and collaborate with those responsible for patient records to ensure any patient with whom they are used can be identified and linked to the sets or individual instruments used;
- ensure that missing or damaged surgical instruments are replaced preserving the appropriate set structure;
- oversee the monitoring of condition and suitability for surgical instruments;
- oversee the audit process for instrument sets from procurement through use, decontamination and final disposal;
- ensure instrument sets never used are reviewed and/or disposed of;
- oversee actions to provide a mechanism for routinely revalidating instrument-set content (for example, annual sign off of the tray checklist by surgical teams);
- ensure the leakage of surgical instruments between sets is minimized by effective process mapping using recommended audit procedures, post-operative checks, the signing of tray checklists by theatre sister, and decontamination facility processing techniques (that is, specific instrument set contents are kept together throughout the decontamination cycle);
- ensure instrument sets with observed missing or damaged content are updated through targeted investment ensure the healthcare organisation has documented policies in place for the operational management of its instrument-set inventory; these should include policies on (as a minimum);
- manage the loaning of instrument sets to and from external suppliers using the audit techniques given in this guidance;
- purchase new instrument and sets (including, as a minimum, the documented approval of the theatre team, decontamination specialists and Control of Infection lead);
- ensure repaired instruments are returned to the original instrument set;
- oversee a standardised approach to instrument nomenclature throughout the healthcare organisation;
- ensure all Instrument sets have an accurate version-controlled checklist validated by the surgical team (preferably in an electronic format);
- determine that all Instrument stores (including wards and departments) are

audited on a regular basis, and all redundant items removed from circulation;

- ensure a mechanism is in place for addressing instrument set usage non-conformities such as wet packs, torn tray wrap etc.;
- provide and oversee mechanisms to ensure all instruments in the healthcare organisation's inventory are fit for purpose (for example regular review of appropriate records);
- ensure the healthcare organisation holds an accurate database of its instrument-set inventory including tray type, location of use and stock level;
- ensure all instruments sets which are critical in stock levels are risk assessed, to maximize patient safety and inform instrument set investment.

Senior Operational Manager

6.48 The Senior Operational Manager is technically, professionally and managerially responsible (and accountable to the Decontamination Lead) for the engineering aspects of decontamination (for example, decontamination equipment and the environment).

User

6.49 The User is defined as the person designated by Management to be responsible for the management of the process. The User is also responsible for the Operators.

6.50 In the acute sector, the User could be a sterile services manager.

6.51 The principal responsibilities of the User are as follows:

- to certify that the decontamination equipment is fit for use;
- to hold all documentation relating to the decontamination equipment, including the names of other key personnel;

- to ensure that decontamination equipment is subject to periodic testing and maintenance;
- to appoint operators where required and ensure that they are adequately trained;
- to maintain production records;
- to establish procedures for product release in line with the quality management system;
- to ensure that procedures for production, quality control and safe working are documented and adhered to in the light of statutory requirements and accepted best practice.

6.52 The User may seek the advice of infection control teams, which may consist of a DIPC, Infection Control Doctor or Microbiologist (Decontamination).

Authorising Engineer (Decontamination) (AE(D))

6.53 The role of the AE(D) should be fully independent of the healthcare facilities' structure for maintenance, testing and management of the decontamination equipment.

6.54 The AE(D) is defined as a person designated by Management to provide independent auditing and technical advice on decontamination procedures, washer-disinfectors, sterilizers and sterilization and to review and witness documentation on validation.

6.55 The AE(D) is required to liaise closely with other professionals in various disciplines and, consequently, the appointment should be made known in writing to all interested parties.

6.56 The AE(D) should assist healthcare organisations in the appointments and interviews of the AP(D)s and their consequent annual assessments.

- The AE(D) should have a reporting route to the Decontamination Lead and should

provide professional and technical advice to the AP(D)s, CP(D)s, Users and other key personnel involved in the control of decontamination processes in all healthcare facilities.

Responsibilities

6.57 The principal responsibilities of the AE(D) are as follows:

- to provide to Management and others, general and impartial advice on all matters concerned with decontamination;
- to advise Management and others on programmes of validation and testing;
- to audit reports on validation, revalidation and yearly tests submitted by the AP(D);
- to advise Management and others on programmes of periodic tests and periodic maintenance;
- to advise Management and others on operational procedures for routine production;
- to advise Management on the appointment of the AP(D);
- to provide technical advice on purchasing and selection of decontamination equipment for the users;
- to provide technical advice on the relevant guidance on decontamination equipment and procedures.

6.58 Each appointed AE(D) is independent in the advice and roles of the decontamination procedures and responsibilities for the effective management of the guidance and safety as recommended by the DH and regional administrations of Scotland, Wales and Northern Ireland.

The Institute of Healthcare Engineering and Estate Management (IHEEM) supports and operates the DTP (Decontamination Technology Platform) which is made up of IHEEM-registered AE(D)S (see link in the References section).

Authorised Person (Decontamination) (AP(D))

6.59 See 'Responsibilities' in HTM 01-01 Part B.

Competent Person (Decontamination) (CP(D))

6.60 See 'Responsibilities' in HTM 01-01 Part B.

Director of Infection Prevention and Control (DIPC)

6.61 The DIPC in England is defined as the person responsible for the infection control aspects of decontamination. The designated person is accountable directly to the Chief Executive and to the Board. If the person has a degree or equivalent qualification in microbiology, he/she may also fulfill the role of the Microbiologist (Decontamination).

Infection Control Doctor

6.62 The Infection Control Doctor is defined as a person designated by Management to be responsible for advising the User on all infection control aspects.

Microbiologist (Decontamination)

6.63 The Microbiologist (Decontamination) is designated by Management to be responsible for advising the User and that Management on microbiological and infection prevention aspects of the decontamination of reusable surgical instruments.

6.64 The Microbiologist (Decontamination) should have a relevant degree or equivalent qualification (for example, microbiology or

medicine) together with relevant experience. In some organisations, the Microbiologist (Decontamination) and Infection Control Doctor may be the same person.

Operator

6.65 The Operator is defined as any person with the authority to operate decontamination equipment, including the noting of instrument readings and simple housekeeping duties.

6.66 Operators should have their tasks defined in their job description. Operators should also have documented training records to demonstrate that they are competent at undertaking their assigned tasks.

Manufacturer

6.67 See 'Responsibilities' in HTM 01-01 Part B.

Contractor

6.68 See 'Responsibilities' in HTM 01-01 Part B.

Purchaser

6.69 See 'Responsibilities' in HTM 01-01 Part B.

Competent Person (Pressure Systems)

6.70 The Competent Person as defined in the Pressure Systems Safety Regulations 2000 is not the same person as the Competent Person (Decontamination) defined in this HTM. The former is a chartered engineer responsible for drawing up a written scheme of examination for the system. The latter is the person who carries out maintenance, validation and periodic testing of washer-disinfectors and sterilizers.

6.71 Most insurance companies maintain a technical division able to advise on appointing a CP(PS). The AE(D) should also be able to provide advice.

Appendix A: Standards relevant to decontamination

Standards relevant to decontamination processes and equipment

BS EN ISO 11737-1. Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products.

BS EN ISO 11737-2. Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

BS EN ISO 14937. 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.

BS EN ISO 17665-1. Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices. (This includes porous load and fluid sterilizers (except where used for medicinal products), and sterilizers for unwrapped instruments and utensils.)

BS EN 285. Sterilization. Steam sterilizers. Large sterilizers.

BS EN 13060. Small steam sterilizers.

BS EN 1422. Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods.

BS EN 14180:2003+A2. Sterilizers for medical purposes. Low temperature steam and formaldehyde sterilizers. Requirements and testing.

BS EN ISO 15883-1. Washer-disinfectors. General requirements, terms and definitions and tests.

BS EN ISO 15883-2. Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

BS EN ISO 13485. Medical devices. Quality management systems. Requirements for regulatory purposes.

Standards relevant to decontamination management

BS EN ISO 13485. Medical devices. Quality management systems. Requirements for regulatory purposes.

Standards relevant to safety requirements for decontamination equipment

BS EN 61010-2-040. Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for sterilizers and washer- disinfectors used to treat medical materials.

BS EN ISO 13849-2. Safety machinery. Safety-related parts of control systems. Validation.

Standards relevant to medical devices

BS EN 556-1. Sterilization of medical devices. Requirements for medical devices to be designated 'STERILE'. Requirements for terminally sterilized medical devices.

BS EN 556-2. Sterilization of medical devices. Requirements for medical devices to be

designated 'STERILE'. Requirements for aseptically processed medical devices.

BS EN 1041:2008+A1. Information supplied by the manufacturer of medical devices.

BS EN ISO 14971. Application of risk management to medical devices.

BS EN ISO 17664. Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices.

Appendix B: Example sampling strategy

This Appendix contains guidance on how routine measurement of residual protein on surgical instruments can be implemented. New technologies that quantify residual proteins on washed instruments are being developed, but there is no pre-existing experience of assessing and analysing protein levels on reprocessed surgical instruments. This suggested approach to sampling may be adapted in future guidance as the knowledge base increases.

The use of these technologies opens up the possibility to assess the impact of changes to decontamination parameters (for example, changes in detergents, wash times, wash temperatures). However, this guidance considers only the monitoring of the totality of those parameters associated with protein removal (this may include the time between instrument use and cleaning as well as the cleaning parameters themselves). This can be considered as general guidance in the establishment of an internal quality assurance scheme (IQAS).

The proportion of surgical instruments where residual protein exceeds the 5 µg threshold is expected to be very low. The use of these technologies to attempt to either identify types of instrument or estimate the percentage of reprocessed instruments within an SSD exceeding this threshold is extremely challenging.

The ability to make definitive statements would require an extremely large number of measurements to be made, which would be prohibitive in terms of disruption to the availability of instrument sets.

However, it is possible to design an IQAS with the aim of monitoring, over time, the efficiency

of the cleaning process setting a benchmark derived from earlier observations with the expectation of sequential reductions in that benchmark being possible as the cleaning process is refined. It may also demonstrate inter-instrument variation, much of which is likely to arise due to inherent instrument features such as box joints.

It is likely that measurements made across several instrument types follow a positively skewed distribution (that is, a small number of high measurements when compared with the majority). This could best be seen in a histogram of results.

Determining the baseline

The first step is for an SSD to measure reprocessed surgical instruments representing the full range of their workload to provide the basis upon which a monitoring system can be developed. The measurement scale can be considered as continuous. If a single measurement is to be made at each time point, an individual and moving range (I-MR) chart can be used. If it is considered more appropriate to group instruments into batches (for example, five instruments per week), it may be appropriate to use an Xbar and range (Xbar-R) chart (Xbar = plotting the average of batches; range = plotting the maximum minus the minimum of each batch). Either method constructs two charts: one monitoring the process average, the other monitoring process variation.

As it is likely that the distribution of the residual protein across all instrument types is positively skewed, a logarithmic transformation may provide a more suitable measurement for monitoring. Estimates of the process average

measurement and the variation between measurements are required to construct statistical process control charts used for monitoring future measurements. A total of 20 measurements should suffice initially from

which parameters of the process can be estimated, although these should be periodically re-estimated from a set of measurements made when the process is considered to be “in control”.

Example

Consider that each working day a single reprocessed instrument is measured, and the measurements in µg are entered into an Excel worksheet. This data will be used to demonstrate how to set up both an I-MR and an Xbar-R chart.

	A	B	D	E
1	Day of Week	Date	Measurement (µg)	
2	Monday	14/03/2016	1.02	
3	Tuesday	15/03/2016	0.91	
4	Wednesday	16/03/2016	0.46	
5	Thursday	17/03/2016	1.17	
6	Friday	18/03/2016	5.96	
7	Monday	21/03/2016	0.22	
8	Tuesday	22/03/2016	0.89	
9	Wednesday	23/03/2016	1.36	
10	Thursday	24/03/2016	0.57	
11	Friday	25/03/2016	0.40	
12	Monday	28/03/2016	3.24	
13	Tuesday	29/03/2016	0.50	
14	Wednesday	30/03/2016	0.42	
15	Thursday	31/03/2016	1.02	
16	Friday	01/04/2016	7.73	
17	Monday	04/04/2016	0.98	
18	Tuesday	05/04/2016	1.39	
19	Wednesday	06/04/2016	1.88	
20	Thursday	07/04/2016	0.57	
21	Friday	08/04/2016	0.55	
22				

I-MR Chart

Once the first 20 measurements have been obtained, these are inspected to assess their distribution. The simplest approach is to calculate the average and standard deviation, which in Excel can be achieved using the AVERAGE() and STDEV() functions, respectively, putting the cell range into the parentheses. For example, the average of the measurements in cells D2 to D21 (inclusive) is calculated using the formula =AVERAGE(D2:D21).

In this example the average is 1.56 and the standard deviation is 1.95. If, as in this example, the standard deviation is larger than three-quarters of the average, this indicates that the distribution of the measurements is not symmetric. It is therefore advisable to use the logarithms of the measurement rather than the measurements themselves. Excel has a number of logarithmic functions depending on which base is chosen. In this example, logarithms to the base 10 are used, but it is also acceptable to use natural logarithms.

SUM				
=STDEV(D2:D21)				
	A	B	D	E
1	Day of Week	Date	Measurement (μg)	
2	Monday	14/03/2016	1.02	
3	Tuesday	15/03/2016	0.91	
4	Wednesday	16/03/2016	0.46	
5	Thursday	17/03/2016	1.17	
6	Friday	18/03/2016	5.96	
7	Monday	21/03/2016	0.22	
8	Tuesday	22/03/2016	0.89	
9	Wednesday	23/03/2016	1.36	
10	Thursday	24/03/2016	0.57	
11	Friday	25/03/2016	0.40	
12	Monday	28/03/2016	3.24	
13	Tuesday	29/03/2016	0.50	
14	Wednesday	30/03/2016	0.42	
15	Thursday	31/03/2016	1.02	
16	Friday	01/04/2016	7.73	
17	Monday	04/04/2016	0.98	
18	Tuesday	05/04/2016	1.39	
19	Wednesday	06/04/2016	1.88	
20	Thursday	07/04/2016	0.57	
21	Friday	08/04/2016	0.55	
22				
23		Average	1.56	
24		Std. Deviation	=STDEV(D2:D21)	
25			STDEV(number1, [number2], ...)	

The Excel function for base 10 logarithms is LOG10(), where the parentheses contain the cell to be transformed. For example, in cell F2

enter the function =LOG10(D2) to put the logarithm to the base 10 of D2 into cell F2.

SUM					
=LOG10(D2)					
	A	B	D	E	F
1	Day of Week	Date	Measurement (μg)		log10
2	Monday	14/03/2016	1.02		=LOG10(D2)
3	Tuesday	15/03/2016	0.91		
4	Wednesday	16/03/2016	0.46		
5	Thursday	17/03/2016	1.17		

This formula can be copied down cells F3 to F21 by clicking and holding the bottom right corner of the cell and dragging the cursor to cell F21.

	A	B	D	E	F
1	Day of Week	Date	Measurement (µg)		log10
2	Monday	14/03/2016	1.02		0.009746
3	Tuesday	15/03/2016	0.91		-0.04104
4	Wednesday	16/03/2016	0.46		-0.33787
5	Thursday	17/03/2016	1.17		0.06848
6	Friday	18/03/2016	5.96		0.77491
7	Monday	21/03/2016	0.22		-0.66533
8	Tuesday	22/03/2016	0.09		-0.04944
9	Wednesday	23/03/2016	1.36		0.131952
10	Thursday	24/03/2016	0.57		-0.24632
11	Friday	25/03/2016	0.40		-0.39895
12	Monday	28/03/2016	3.24		0.511181
13	Tuesday	29/03/2016	0.50		-0.29758
14	Wednesday	30/03/2016	0.42		-0.38183
15	Thursday	31/03/2016	1.02		0.009741
16	Friday	01/04/2016	7.73		0.888054
17	Monday	04/04/2016	0.98		-0.00948
18	Tuesday	05/04/2016	1.39		0.141478
19	Wednesday	06/04/2016	1.88		0.273368
20	Thursday	07/04/2016	0.57		-0.24361
21	Friday	08/04/2016	0.55		-0.2629
22					

The absolute value of the difference between subsequent measurements now has to be calculated – that is, the magnitude of the measurement in row k minus the measurement in row $k - 1$. For example, to enter the difference between cells F3 and F2 in cell G3, enter into cell G3 the formula =ABS(F3-F2) and press the return key.

G3		fx		=ABS(F3-F2)			
	A	B	D	E	F	G	H
1	Day of Week	Date	Measurement (µg)		log10	Absolute Difference	
2	Monday	14/03/2016	1.02		0.009746		
3	Tuesday	15/03/2016	0.91		-0.04104	0.05	
4	Wednesday	16/03/2016	0.46		-0.33787		
5	Thursday	17/03/2016	1.17		0.06848		

This formula can be copied as described previously to obtain a column with 19 differences.

The centre line and control limits for the I-MR charts are estimated from the 20 measurements and 19 absolute differences. For the individuals chart the centre line is the average (\bar{x} or \bar{X}) of the 20 \log_{10} (measurements) in column F.

F	G	H	I	J
log10	Absolute Difference			
0.009746				
-0.04104	0.05		Individuals Chart	
-0.33787	0.30		Centre Line (Xbar)	-0.00627
0.06348	0.41		Lower Control Limit (LCL)	
0.77491	0.71		Upper Control Limit (UCL)	
-0.66533	1.44			
-0.04344	0.62		Moving Range Chart	
n 131352	n 18		Centre Line (MRbar)	n 47
-0.24332	0.38		Lower Control Limit (LCL)	
-0.39395	0.15		Upper Control Limit (UCL)	
0.511181	0.91			

The lower and upper control limits (LCL, UCL) are calculated using the formula:

$$\bar{x} \pm k \frac{\overline{MR}}{1.128}$$

where \overline{MR} (also written as MRbar) is the average of the 19 absolute differences.

The quantity of $\overline{MR}/1.128$ provides an estimate of the standard deviation. It is conventional to use 3 for the value of k , this providing limits of plus and minus three standard deviations. If k is set to 3 then the above formula simplifies to $\bar{x} \pm 2.66 \times \overline{MR}$. For the example, the formula $=J4-2.66*J9$ and $=J4+2.66*J9$ are used for the LCL and UCL, respectively.

J6 $f_x = J4+2.66*J9$

	A	B	D	E	F	G	H	I	J
1	Day of Week	Date	Measurement (µg)		log10	Absolute Difference			
2	Monday	14/03/2016	1.02		0.009746				
3	Tuesday	15/03/2016	0.91		-0.04104	0.05		Individuals Chart	
4	Wednesday	16/03/2016	0.46		-0.33787	0.30		Centre Line (Xbar)	-0.00627
5	Thursday	17/03/2016	1.17		0.06848	0.41		Lower Control Limit (LCL)	-1.26886
6	Friday	18/03/2016	5.96		0.77491	0.71		Upper Control Limit (UCL)	1.256316
7	Monday	21/03/2016	0.22		-0.66533	1.44			
8	Tuesday	22/03/2016	0.89		-0.04944	0.62		Moving Range Chart	
9	Wednesday	23/03/2016	1.36		0.131952	0.18		Centre Line (MRbar)	0.47
10	Thursday	24/03/2016	0.57		-0.24632	0.38		Lower Control Limit (LCL)	
11	Friday	25/03/2016	0.40		-0.39895	0.15		Upper Control Limit (UCL)	
12	Monday	28/03/2016	3.24		0.511181	0.91			

For the MR chart, the centre line of the chart is \overline{MR} , the average absolute differences.

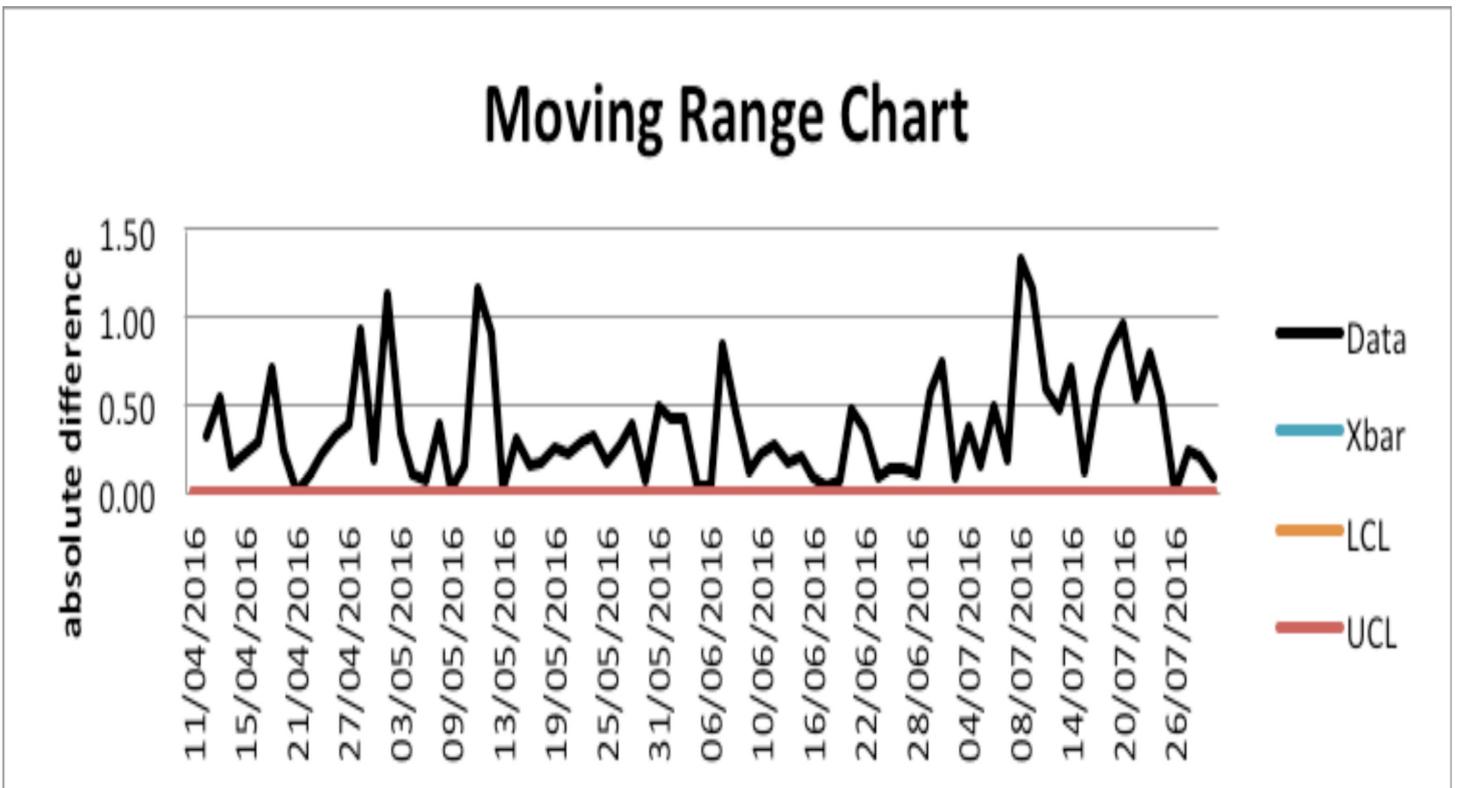
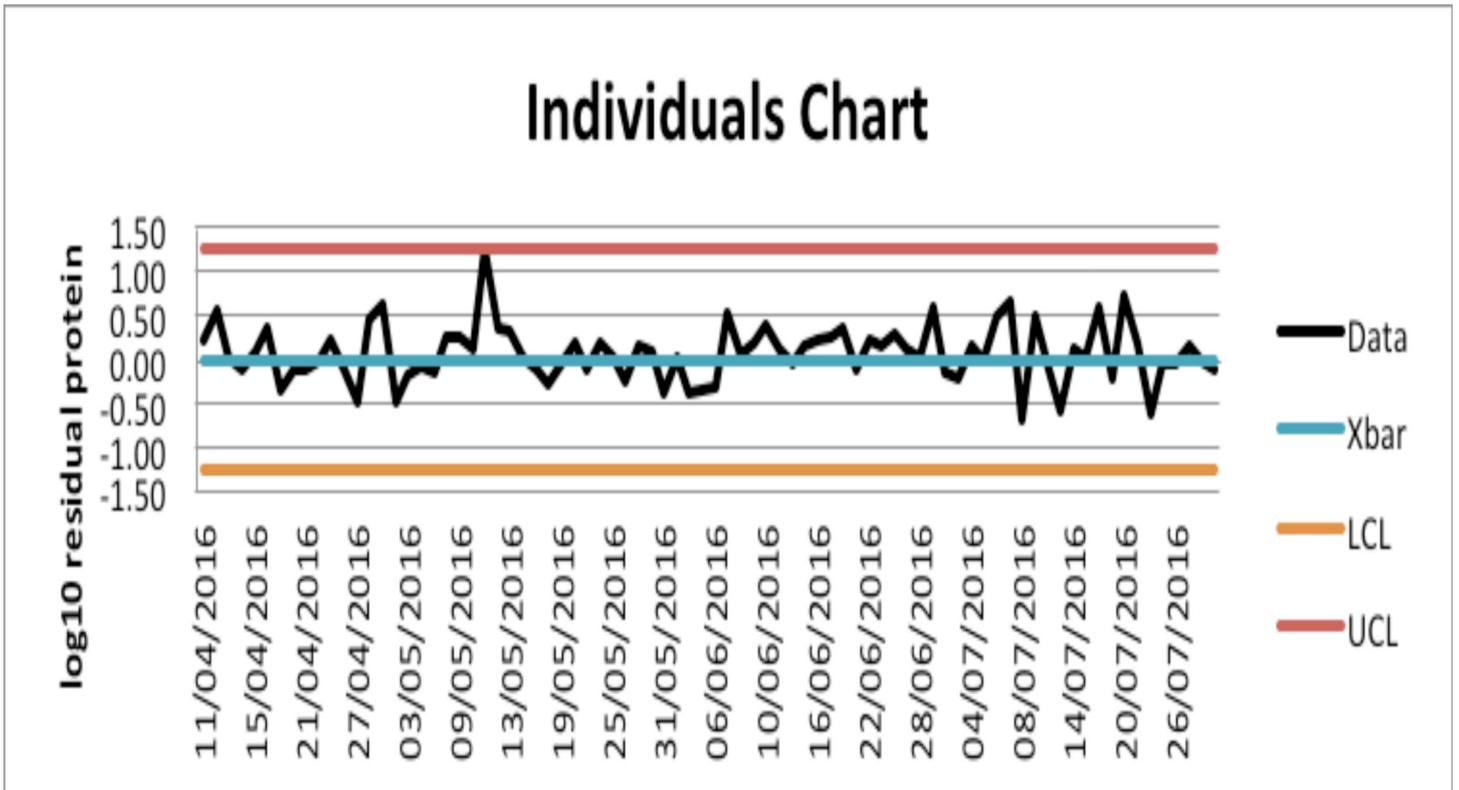
$f_3 = 3.267 \times 19$		D	E	F	G	H	I	J
	Measurement (μg)			log10	Absolute Difference			
6	1.02			0.009746				
6	0.91			-0.04104	0.05		Individuals Chart	
6	0.46			-0.33787	0.30		Centre Line (Xbar)	-0.00627
6	1.17			0.06848	0.41		Lower Control Limit (LCL)	-1.26886
6	5.96			0.77491	0.71		Upper Control Limit (UCL)	1.256316
6	0.22			-0.66533	1.44			
6	0.89			-0.04944	0.62		Moving Range Chart	
6	1.36			0.131952	0.18		Centre Line (MRbar)	0.47
6	0.57			-0.24632	0.38		Lower Control Limit (LCL)	0
6	0.40			-0.39895	0.15		Upper Control Limit (UCL)	1.550705
6	3.24			0.511181	0.91			

A similar approach to that above – subtracting and adding three standard deviations – is used to obtain the control limits, but these simplify to a multiple of \overline{MR} . These limits are obtained by the formulae $LCL = 0$ and $UCL = 3.267 \times \overline{MR}$. The limits obtained are then used in tables or charts to monitor future measurements.

	A	B	D	E	F	G	H	I	J	K	L	M	N	O
25					Individuals Chart				MR Chart					
26	Date				Data	Xbar	LCL	UCL		Data	Xbar	LCL	UCL	
27	Monday	11/04/2016	1.74		0.24	-0.01	-1.27	1.26			0.47	0.00	1.55	
28	Tuesday	12/04/2016	3.68		0.57	-0.01	-1.27	1.26	0.32	0.47	0.00	1.55		
29	Wednesday	13/04/2016	1.07		0.03	-0.01	-1.27	1.26	0.53	0.47	0.00	1.55		
30	Thursday	14/04/2016	0.75		-0.12	-0.01	-1.27	1.26	0.15	0.47	0.00	1.55		
31	Friday	15/04/2016	1.22		0.09	-0.01	-1.27	1.26	0.21	0.47	0.00	1.55		
32	Monday	18/04/2016	2.33		0.37	-0.01	-1.27	1.26	0.26	0.47	0.00	1.55		
33	Tuesday	19/04/2016	0.47		-0.33	-0.01	-1.27	1.26	0.70	0.47	0.00	1.55		
34	Wednesday	20/04/2016	0.81		-0.09	-0.01	-1.27	1.26	0.24	0.47	0.00	1.55		
35	Thursday	21/04/2016	0.80		-0.10	-0.01	-1.27	1.26	0.00	0.47	0.00	1.55		
36	Friday	22/04/2016	1.00		0.00	-0.01	-1.27	1.26	0.10	0.47	0.00	1.55		
37	Monday	25/04/2016	1.88		0.22	-0.01	-1.27	1.26	0.22	0.47	0.00	1.55		
38	Tuesday	26/04/2016	0.80		-0.10	-0.01	-1.27	1.26	0.32	0.47	0.00	1.55		
39	Wednesday	27/04/2016	0.34		-0.47	-0.01	-1.27	1.26	0.38	0.47	0.00	1.55		
40	Thursday	28/04/2016	2.83		0.45	-0.01	-1.27	1.26	0.93	0.47	0.00	1.55		
41	Friday	29/04/2016	4.34		0.64	-0.01	-1.27	1.26	0.19	0.47	0.00	1.55		
42	Monday	02/05/2016	0.32		-0.49	-0.01	-1.27	1.26	1.13	0.47	0.00	1.55		
43	Tuesday	03/05/2016	0.69		-0.16	-0.01	-1.27	1.26	0.33	0.47	0.00	1.55		
44	Wednesday	04/05/2016	0.85		-0.07	-0.01	-1.27	1.26	0.09	0.47	0.00	1.55		
45	Thursday	05/05/2016	0.74		-0.13	-0.01	-1.27	1.26	0.06	0.47	0.00	1.55		
46	Friday	08/05/2016	1.81		0.26	-0.01	-1.27	1.26	0.39	0.47	0.00	1.55		
47	Monday	09/05/2016	1.84		0.27	-0.01	-1.27	1.26	0.01	0.47	0.00	1.55		
48	Tuesday	10/05/2016	1.30		0.11	-0.01	-1.27	1.26	0.15	0.47	0.00	1.55		
49	Wednesday	11/05/2016	18.63		1.27	-0.01	-1.27	1.26	1.16	0.47	0.00	1.55		
50	Thursday	12/05/2016	2.27		0.36	-0.01	-1.27	1.26	0.91	0.47	0.00	1.55		
51	Friday	13/05/2016	2.16		0.34	-0.01	-1.27	1.26	0.02	0.47	0.00	1.55		

In the example above, only one measurement made on 11/05/2016 of 18.63 μg falls above the UCL. Measurements that fall outside of the control limits are an indication that the process is no longer in control. This may warrant an investigation to detect and eliminate any underlying causes. However, it may be expected to observe these occasionally due purely to chance.

It is important to realise that even if all measurements fall within the LCL and the UCL, this does not necessarily mean that the process is in control. What is important is whether there appears to be any systematic behaviour in sequential measurements. For example, if there were ten successive measurements all above the centre line, then this might indicate that a systematic change to the process has occurred, since we would expect half of these measurements to fall either



side of the centre line when the process is in control. To aid interpretation of statistical process control charts, a series of situations that may indicate an “out of control” process have been suggested. Thus, situations such as eight consecutive measurements above or

below the centre line, six consecutive measurements where there is a monotonic trend (all increasing or decreasing), or 14 consecutive measurements where there is an alternating pattern would all suggest an “out of control” process.

Xbar-R chart

These charts are best used when measurements naturally fall into groups, for example per week, where the same number of reprocessed instruments are measured. These groups would normally consist of between two and ten instruments. In each group the average and the range (maximum–minimum) of the set

of measurements are calculated. To construct the Xbar-R chart, the average of both the group average and range from a small number of groups is required. A minimum of 20 measurements is likely to be sufficient to set an initial benchmark, that is, four weekly groups each of five measurements. The group averages are calculated using the AVERAGE() function:

5 fx =AVERAGE(F17:F21)

	A	B	D	E	F	G	H	I	J
1	Day of Week	Date	Measurement (µg)		log10		Batch	Average	Range
2	Monday	14/03/2016	1.02		0.009746		1	0.094846	
3	Tuesday	15/03/2016	0.91		-0.04104		2	-0.245618	
4	Wednesday	16/03/2016	0.46		-0.33787		3	0.145915	
5	Thursday	17/03/2016	1.17		0.06848		4	-0.02023	
6	Friday	18/03/2016	5.96		0.77491				
7	Monday	21/03/2016	0.22		-0.66533				
8	Tuesday	22/03/2016	0.89		-0.04944				
9	Wednesday	23/03/2016	1.36		0.131952				
10	Thursday	24/03/2016	0.57		-0.24632				
11	Friday	25/03/2016	0.40		-0.39895				
12	Monday	28/03/2016	3.24		0.511181				
13	Tuesday	29/03/2016	0.50		-0.29758				

The range within each group is obtained using the MAX() and MIN() functions. For example, =MAX(F2:F6) – MIN(F2:F6) will calculate the range in the first batch.

These are then used to calculate the centre lines, LCLs, and UCLs of the Xbar and R charts.

J5 fx =MAX(F17:F21)-MIN(F17:F21)

	A	B	D	E	F	G	H	I	J	K
1	Day of Week	Date	Measurement (µg)		log10		Batch	Average	Range	
2	Monday	14/03/2016	1.02		0.009746		1	0.094846	1.11278	
3	Tuesday	15/03/2016	0.91		-0.04104		2	-0.245618	0.797281	
4	Wednesday	16/03/2016	0.46		-0.33787		3	0.145915	1.269879	
5	Thursday	17/03/2016	1.17		0.06848		4	-0.02023	0.536272	
6	Friday	18/03/2016	5.96		0.77491					
7	Monday	21/03/2016	0.22		-0.66533					
8	Tuesday	22/03/2016	0.89		-0.04944					

For the Xbar chart, the average of the group averages ($\bar{\bar{x}}$) provides the centre line. The LCL and UCL are obtained from the formula:

$$\bar{\bar{x}} \pm A_2 \bar{R}$$

where A_2 is a multiplier depended only on the number of measurements in each group (n), and \bar{R} is the average of the group ranges. For group sizes (n) of 5, A_2 is 0.577.

M6		fx =M4+0.577*M9										
	A	B	D	E	F	G	H	I	J	K	L	M
1	Day of Week	Date	Measurement (µg)		log10		Batch	Average	Range			
2	Monday	14/03/2016	1.02		0.009746		1	0.094846	1.11278			
3	Tuesday	15/03/2016	0.91		-0.04104		2	-0.245618	0.797281		Xbar Chart	
4	Wednesday	16/03/2016	0.46		-0.33787		3	0.145915	1.269879		Centre Lin	-0.00627
5	Thursday	17/03/2016	1.17		0.06848		4	-0.02023	0.536272		Lower Cor	-0.54234
6	Friday	18/03/2016	5.96		0.77491						Upper Cor	0.529792
7	Monday	21/03/2016	0.22		-0.66533							
8	Tuesday	22/03/2016	0.89		-0.04944						Moving Range Chart	
9	Wednesday	23/03/2016	1.36		0.131952						Centre Lin	0.93

For the R chart the average of the group ranges (\bar{R}) provides the centre line. The LCL and UCL are obtained from the formulae $D_3\bar{R}$ and $D_4\bar{R}$, where both D_3 and D_4 are multipliers depended only upon the number of measurements in each group (n). For group sizes (n) of 5, D_3 is 0, and D_4 is 2.115.

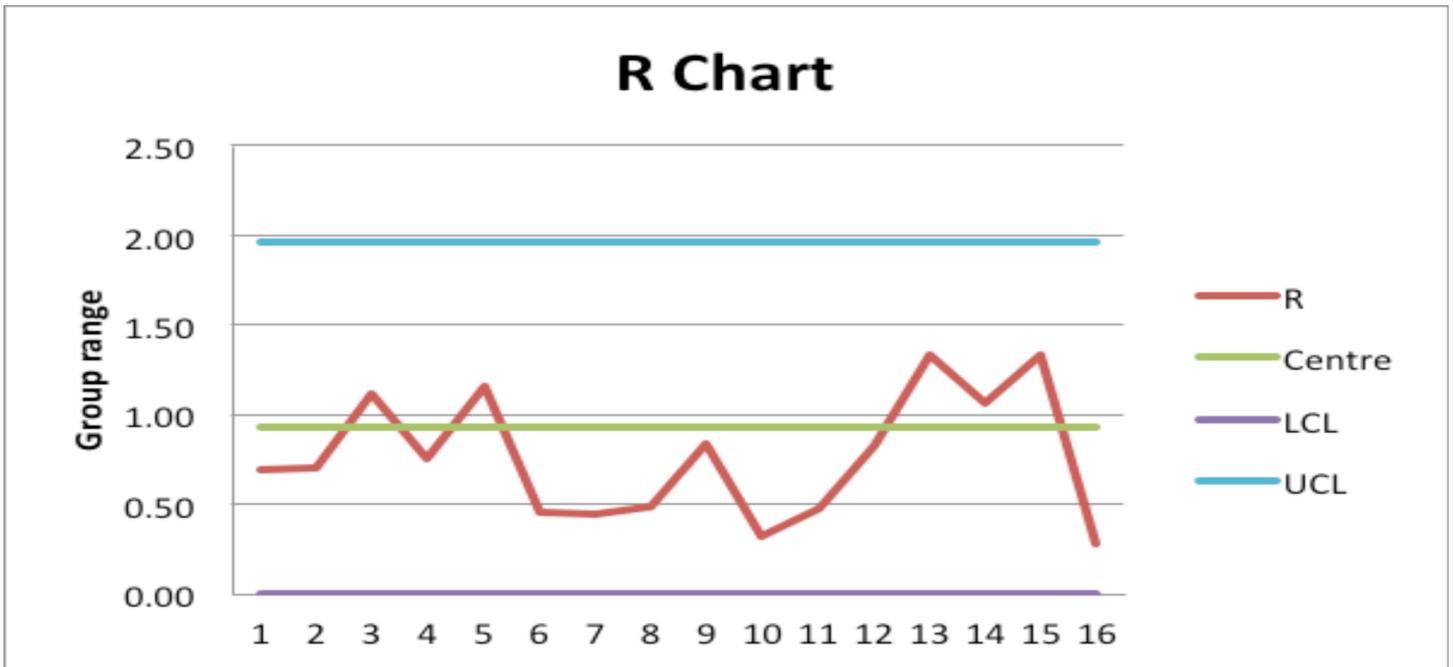
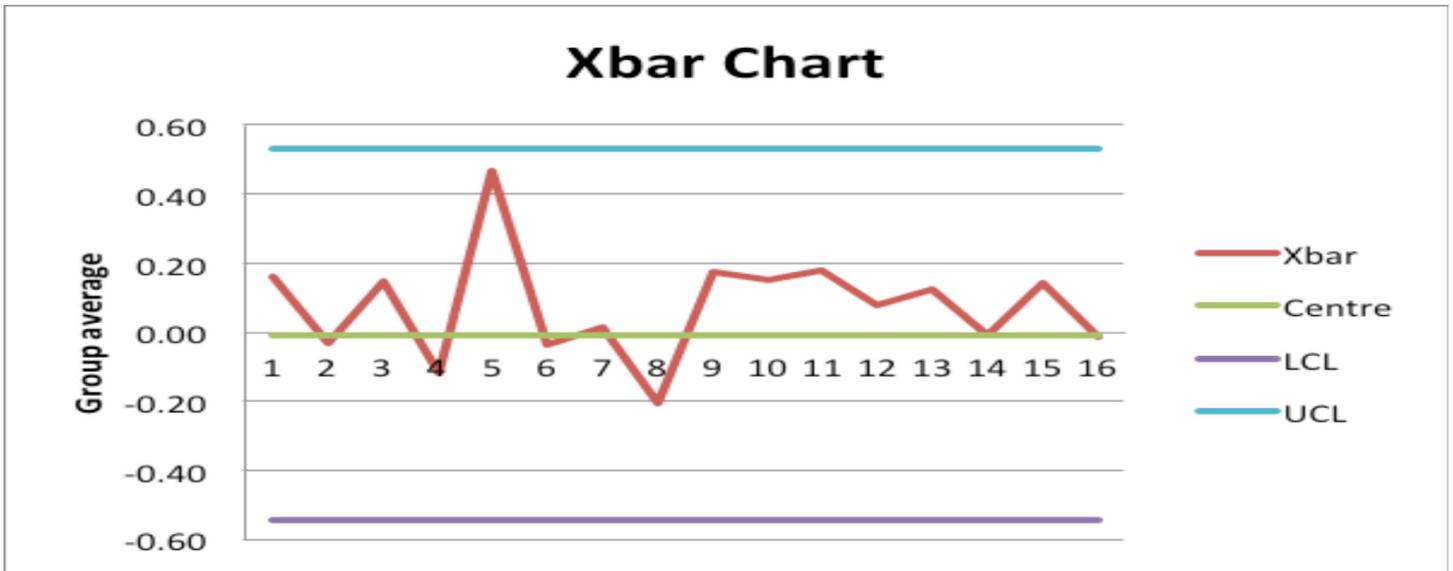
	A	B	D	E	F	G	H	I	J	K	L	M	N
1	Day of Week	Date	Measurement (µg)		log10		Batch	Average	Range				
2	Monday	14/03/2016	1.02		0.009746		1	0.094846	1.11278				
3	Tuesday	15/03/2016	0.91		-0.04104		2	-0.245618	0.797281		Xbar Chart		
4	Wednesday	16/03/2016	0.46		-0.33787		3	0.145915	1.269879		Centre Lin	-0.00627	
5	Thursday	17/03/2016	1.17		0.06848		4	-0.02023	0.536272		Lower Cor	-0.54234	
6	Friday	18/03/2016	5.96		0.77491						Upper Cor	0.529792	
7	Monday	21/03/2016	0.22		-0.66533								
8	Tuesday	22/03/2016	0.89		-0.04944						Moving Range Chart		
9	Wednesday	23/03/2016	1.36		0.131952						Centre Lin	0.93	
10	Thursday	24/03/2016	0.57		-0.24632						Lower Cor	0	
11	Friday	25/03/2016	0.40		-0.39895						Upper Cor	1.964947	
12	Monday	28/03/2016	3.24		0.511181								

The values of these multipliers are tabulated below for group sizes between 2 and 10, inclusive.

Group size		Multiplier		
n	A_2	D_3	D_4	
2	1.880	0	3.267	
3	1.023	0	2.575	
4	0.729	0	2.282	
5	0.577	0	2.115	
6	0.483	0	2.004	
7	0.419	0.076	1.924	
8	0.373	0.136	1.864	
9	0.337	0.184	1.816	
10	0.308	0.223	1.777	

For the next 16 weeks of groups of five measurements, the data required for the Xbar and R charts are calculated and charts produced.

	A	B	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
25																
26		Date			Data	Batch	Xbar Chart					MR Chart				
27	Monday	11/04/2016	1.74		0.24	1	Xbar	Centre	LCL	UCL		R	Centre	LCL	UCL	
28	Tuesday	12/04/2016	3.68		0.57	2	-0.03	-0.01	-0.54	0.53		0.69	0.93	0.00	1.96	
29	Wednesday	13/04/2016	1.07		0.03	3	-0.15	-0.01	-0.54	0.53		1.11	0.93	0.00	1.96	
30	Thursday	14/04/2016	0.75		-0.12	4	-0.12	-0.01	-0.54	0.53		0.75	0.93	0.00	1.96	
31	Friday	15/04/2016	1.22		0.09	5	0.47	-0.01	-0.54	0.53		1.16	0.93	0.00	1.96	
32	Monday	18/04/2016	2.33		0.37	6	-0.04	-0.01	-0.54	0.53		0.45	0.93	0.00	1.96	
33	Tuesday	19/04/2016	0.47		-0.33	7	0.01	-0.01	-0.54	0.53		0.44	0.93	0.00	1.96	
34	Wednesday	20/04/2016	0.81		-0.09	8	-0.20	-0.01	-0.54	0.53		0.48	0.93	0.00	1.96	
35	Thursday	21/04/2016	0.80		-0.10	9	0.17	-0.01	-0.54	0.53		0.84	0.93	0.00	1.96	
36	Friday	22/04/2016	1.00		0.00	0	0.15	-0.01	-0.54	0.53		0.31	0.93	0.00	1.96	
37	Monday	25/04/2016	1.68		0.22	1	0.18	-0.01	-0.54	0.53		0.47	0.93	0.00	1.96	
38	Tuesday	26/04/2016	0.80		-0.10	2	0.08	-0.01	-0.54	0.53		0.82	0.93	0.00	1.96	
39	Wednesday	27/04/2016	0.34		-0.47	3	0.12	-0.01	-0.54	0.53		1.33	0.93	0.00	1.96	
40	Thursday	28/04/2016	2.83		0.45	4	-0.01	-0.01	-0.54	0.53		1.06	0.93	0.00	1.96	
41	Friday	29/04/2016	4.34		0.64	5	0.14	-0.01	-0.54	0.53		1.33	0.93	0.00	1.96	
42	Monday	02/05/2016	0.32		-0.49	6	-0.01	-0.01	-0.54	0.53		0.28	0.93	0.00	1.96	
43	Tuesday	03/05/2016	0.69		-0.16											
44	Wednesday	04/05/2016	0.85		-0.07											



Ongoing monitoring

Monitoring reprocessing of instruments by the use of statistical control charts provides assurance that the process is working as anticipated, and the residual protein on instruments is within the range expected.

A chart for each wash chamber/WD should be set up. The number and types of instruments should be tested as follows:

50 instruments per wash chamber/WD, at least every three months, chosen from difficult-to-clean instruments (for example, box joints, serrations, hinges, graters and reamers and complex retractors) where used. Other difficult-to-clean instruments should be identified and included in this testing.

The instruments stated above should reflect those used to develop the benchmark. This process is thought to provide the best balance between generating informative data and the inevitable disruption such testing will cause.

Further technical details on statistical process control charts are available in Chapter 6 “Monitor” of the *NIST/SEMATECH e-Handbook of Statistical Methods* (see References).

Note:

This test is not expected to be carried out as part of the periodic quarterly tests, but will be performed as an ongoing intermittent series throughout a three-month cycle.

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