



Department
of Health

Health Technical Memorandum 01-04: Decontamination of linen for health and social care

Management and provision

March 2016

Health Technical Memorandum 01-04: Decontamination of linen for health and social 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 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 01-04 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.

Purpose

The purpose of this HTM is to enable local choices to be made regarding the

management, use and decontamination of linen at controlled costs using risk control.

The 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.

Local policy should define how a provider 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 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
- HTM 01-06: Decontamination of flexible endoscopes

Abbreviations

ACDP: Advisory Committee on Dangerous Pathogens

BP: Best Practice

BSI: British Standards Institution

CEN: European Committee for Standardization (comité européen de normalization)

CQC: Care Quality Commission

Cfu: Colony forming units

CTW: Continuous tunnel washer

DIPC: Director of Infection Prevention and Control

EQR: Essential Quality Requirements

GCL: Guild of Cleaners & Launderers

HSE: Health and Safety Executive

IQ: Installation qualification

MDD: Medical Devices Directive

OJEU: Official Journal of the European Union

OQ: Operational qualification

PPE: Personal protective equipment

PQ: Performance qualification

RABC: Risk Analysis and Biocontamination Control

SHLSLM: Society of Hospital Linen Services & Laundry Managers

TSA: Textile Services Association

TVC: Total viable count

UKAS: United Kingdom Accreditation Service

W/E: Washer-extractor

WEL: workplace exposure limitsIntroduction

Executive summary

Health Technical Memorandum (HTM) 01-04 forms part of the HTM 01 Decontamination series. Other parts include:

- HTM 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care.
- HTM 01-05: Decontamination in primary care dental practices.
- HTM 01-06: Reprocessing of flexible endoscopes: management and decontamination.

Aims of the HTM

The purpose of this HTM is to provide a structure that will enable local decision-making regarding the management, use and decontamination of healthcare and social care linen. The guidance is designed to ensure patient safety and enhanced outcomes at controlled cost using risk control.

This best practice guidance will be of direct interest to providers of care and those working in laundry management and linen decontamination. Management and technical information is also provided for care providers and linen services providers.

The guidance provided in this HTM promotes a principle of continuous improvement in linen processing performance at all levels. It provides options that allow laundries, launderette operators and local linen processors (hereafter referred to as “linen processors”) to choose how to meet EQR and how to progress to BP.

Definition of linen

For the purposes of this document, “linen” means all reusable textile items requiring cleaning/disinfection via laundry processing including:

- Bed linen: blankets, counterpanes, cot sheets and blankets, duvets, duvet covers, pillowcases and sheets (woven, knitted, half sheets, draw and slide sheets);
- bibs;
- blankets;
- canvases;
- curtains;
- hoist slings;
- patient clothing (gowns, nightdresses and shirts, pyjama tops and bottoms);
- staff clothing (coats, scrub suits, tabards, uniforms*);
- towels.

* Consideration should be given to the Note under paragraph 1.12.

Status

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

If any laundry installation or premises includes facilities for the sterilization of medical devices,

then the Essential Quality Requirements of HTM 01-01 Part A will also apply to the sterilizer installation. Other existing regulations and industry standards are discussed in the 'Engineering, equipment and validation' volume of this HTM.

Structure

HTM 01-04 is divided into four volumes. The 'Management and provision' volume includes:

- a description of the overall structure of the guidance and the rationale behind the structure;
- Department of Health policy on safe linen decontamination and processing.

The 'Social care' volume gives guidance on how to implement linen decontamination in social care settings.

The 'Guidance for linen processors implementing BS EN 14065' volume gives guidance on ways of complying with HTM 01-04 specifically for those organisations that have implemented or will be implementing the European standard BS EN 14065.

The 'Engineering, equipment and validation' volume covers:

- the standards and regulatory framework;
- roles of key personnel;

- the built environment;
- design and pre-purchase considerations; and
- validation and verification of disinfection performance of washers, washer-extractors and continuous tunnel washers (CTWs).

Each volume contains disinfection-specific information only.

List of changes since the 2013 edition of 01-04

- a. In this 2016 edition, CFPP 01-04 has reverted to the Health Technical Memorandum (HTM) title format. This realigns it with '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. This will also help to align decontamination guidance across the four UK nations.
- b. A definition of "linen" has now been included to clarify the scope of HTM 01-04.
- c. New guidance in Chapter 2 (paragraphs 2.24–2.29) on climate change and the environmental impact of laundry processes.

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1 Policy, essential quality requirements and best practice

Guidance summary

1.1 This section gives an overview of the Department of Health's policy and best practice guidance on the decontamination of linen for health and social care. It outlines the Essential Quality Requirements (EQR) contained in this HTM and explains the choices on how to move upwards to Best Practice (BP).

1.2 This best practice guidance will be of direct interest to providers of care and those working in laundry management and linen decontamination.

1.3 This policy and guidance is designed to help healthcare professionals to procure and deliver the standard of decontamination that our patients have a right to expect, by building on existing good practice.

1.4 In accordance with the 'Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance', commissioning organisations may wish to assure themselves that the services that they commission are meeting expected requirements. This complements the rights for patients under the NHS Constitution.

1.5 Under section 2a of the NHS Constitution, patients have a right to expect care to be provided in a '... clean and safe environment that is fit for purpose, based on national best practice'. This includes the range of support services such as the provision of a linen and

laundry service that reduces the risk of cross-infection and enhances the patient experience.

1.6 Laundry and its products should preserve the patient's dignity, promote the patient's care, and be appropriate to the patient group, gender, clinical status, religion and beliefs. Where appropriate, it should support the use of personal clothing.

1.7 Laundry to be provided and used by care providers should be fit for purpose. It:

- should look visibly clean;
- should be the right material;
- should not be damaged or discoloured.

1.8 If used in clinical areas where surgical procedures are performed, it should have the required amount of impermeability from body fluids (containment), and in some cases be sterile and offer a degree of personal protection.

1.9 Quality inspectors may wish to understand how the laundry process impacts on the above and use this Health Technical Memorandum (HTM) to identify whether the necessary quality requirements are in place within organisations. In doing so, they could consider safety policies, appropriate records and demonstrable evidence of compliance with EQR (such as a summary of any audit outcomes and proof of quality systems such as BS EN 14065).

Introduction

1.10 This HTM provides guidance for all those processing linen used in health and adult social care. This will primarily be laundries, launderette operators and local linen processors (hereafter referred to as “linen processors”).

1.11 The guidance provided in this HTM is aimed at establishing a programme of continuous improvement, where needed, in linen processing performance at all levels.

1.12 Two levels of attainment are presented:

- Essential Quality Requirements (EQR); and
- Best Practice (BP).

Note

The Department of Health’s ‘Uniforms and workwear: an evidence base for developing local policy’ should be taken into consideration when formulating local policy for the implementation of this HTM and applying it to uniform laundering.

The Health Act Code of Practice

1.13 The guidance provided here follows the essential principles given in the ‘Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance’ (the Code). This requires that effective prevention and control of infection be embedded in everyday practice. For this reason, the guidance is written with emphasis on practical and readily-implemented measures.

Essential Quality Requirements (EQR) and Best Practice (BP)

1.14 The Essential Quality Requirements (EQR) and Best Practice (BP) in this section apply to the healthcare sector only. Attainment for the adult social care sector is discussed in the ‘Social care’ volume of this HTM.

EQR

1.15 Essential Quality Requirements (EQR) for the purposes of this best practice guidance is a term that encompasses all existing statutory and regulatory requirements.

1.16 Every healthcare linen processor should be capable of meeting the following EQR and communicate these local provisions to the providers of care such that they may be agreed and incorporated into local policy:

- There is a duty of care to carry out a hazard and risk assessment and to reduce risk to an acceptable level. As part of this, laundry staff should not undertake the pre-sorting of infectious linen.
- Regardless of the technology used, linen should be processed using a disinfection cycle complying with the requirements of [paragraphs 5.45ff ‘Disinfection of linen’](#), thereby achieving at least the defined level of reduction in microorganism contamination.
- Facilities for processing linen should be clearly separate from clinical treatment and publicly accessible areas. A separate facility/room or rooms should be used for the accommodation of linen processing. In these facilities, the room(s) should be used for this purpose only, and access should accordingly be restricted to those staff processing linen.
- All healthcare linen processors should validate their disinfection processes as part of their BS EN 14065 procedures or using the frequencies and methodologies outlined in the ‘Engineering, equipment and validation’ volume of this HTM.
- Linen processors who process infectious linen should undertake a risk analysis of their processes including identifying key areas requiring microbiological control and measuring key factors (critical control points) essential to a safe product. [Paragraph 5.70, ‘Risk analysis and](#)

biocontamination control' provides further explanation.

- Linen processors should put in place the management structure defined in **Chapter 4, 'Functional responsibilities'**, or follow the guidance given in the 'Social care' and 'Guidance for linen processors implementing BS EN 14065' volumes of this HTM, as appropriate to their organisational needs.
- Linen processors should ensure safe systems of work are in place such as to offer protection to staff against exposure to infectious linen received from health and social care facilities to a level that is as low as reasonably practicable (see the Control of Substances Hazardous to Health (COSHH) Regulations).
- Healthcare linen processors should have in place written policies and procedures for the safe operation of all equipment.
- The environment in which linen processing is carried out should be such as to minimise the risk of recontamination of decontaminated linen and by doing so ensure the protection of patients, residents and staff involved in the handling of linen.
- Processed linen should be transported and stored in such a way as to avoid microbiological recontamination as far as is reasonably practicable.
- Storage areas for linen should be dedicated for the purpose and in accordance with **paragraph 5.74, 'Separation of process to prevent recontamination'**.
- Healthcare linen processors should have in place a detailed plan on how the provision and processing of such linen will move towards BP (see paragraph 1.18, 'Best Practice').

1.17 The clauses above should reflect the local policies of the providers served. Mechanisms should be agreed between the parties to allow providers to assure themselves that linen processors have met the requirements of any agreed local policy.

Best Practice

1.18 To demonstrate Best Practice, further risk assessments could be carried out which build upon the EQRs in the areas outlined below. In carrying out these risk assessments, providers may wish to identify whether efficiencies can be achieved while maintaining a progressive approach to linen safety, with particular regard to healthcare-associated infection and safety of laundry staff and other workers.

1.19 For those not adopting independently certified biocontamination control systems in accordance with BS EN 14065, the soiled linen area should be functionally separated from the clean-linen processing areas. Functionally separated is defined in the section on 'Separation of process to prevent recontamination'.

- **Linen processors who process infectious linen should adopt post-wash sorting of linen (for example, after processing through the washing equipment) for production purposes or limit pre-wash sorting to choice of machine type only. (Note that this refers to production/batch sorting and not necessarily to the adoption of option 2 detailed in the 'Classification and sorting options' section.)**
- **Linen processors who process infectious linen should adopt bag handling and opening procedures that:**
 - (i) do not use liquid permeable bags;**

**(ii) minimise manual handling/
opening of infectious linen and**

- **any other exposure of staff to the linen prior to decontamination; -are fully automated for washer loading (once technology has been developed to allow this); and -are capable of being adequately disinfected.**

1.20 It is envisaged, at this time, that easy-emptying impermeable bags combined with step conveyor-type systems could be implemented which may, if installed and operated correctly, achieve this option as an alternative to using water-soluble bags in CTWs.

1.21 Process design should be such as to reasonably ensure that laundry staff:

- (i) do not manually open bags containing infectious linen; and**
- (ii) are protected from infectious agents.**

1.22 Any systems adopted should not expose the laundry staff to any greater risk than that posed by the use of water-soluble bags.

1.23 The microbiological performance of the chemical disinfection process is evaluated using the additional dose strip test described in ‘Microbiological test for disinfection stage’ in the ‘Engineering, equipment and validation’ volume.

Note

For the purposes of this guidance, the following terminology is used:

Impermeable bags are bags that a liquid does not leak or pass through at any time during their use or during the washing process.

Liquid permeable bags are bags that a liquid may leak or pass through at any time. These are not to be confused with water-soluble bags (and bags with water-soluble seams), which only become permeable when processed in a washing machine. The traditional linen-style laundry bags often fall into this category.

Water-soluble bags (sometimes referred to as “alginate” bags) are (1) bags that dissolve or break apart when processed in a washing machine and/or (2) impermeable bags with a water-soluble seam. Throughout this volume, both types are referred to as “water-soluble bags”.

Note

Suppliers of linen decontamination services to the health and social care sector that have achieved independently certified adoption of BS EN 14065 may consider this status to contribute to Best Practice under this guidance.

Progression towards Best Practice

1.24 Not all laundries, small laundry facilities operators and local linen processors will, at present, be in a position to adopt Best Practice. However, all should assess the improvements needed to move towards Best Practice and prepare a plan to implement the necessary changes within the choices offered in this guidance. This plan should realistically outline how they will progress to Best Practice, for example:

- **measures to purchase and incorporate purpose-designed commercial/industrial laundry equipment;**
- **(for those processing large amounts of linen) measures to minimise laundry staff handling and sorting of used linen.**

Training and education

1.25 Training and education in the processes of pathogen control, disinfection and hygiene (including hand hygiene), exposure to blood-borne viruses, health and safety, and infection risk reduction (including waste disposal) should be part of staff induction programmes and should be recorded in staff training records. These are key aspects of safety and service quality.

1.26 Further advice on specific healthcare linen services education can be obtained from the Society of Hospital Linen Service and Laundry Managers.

2 Regulatory framework

Summary for quality inspectors

This chapter outlines the statutory requirements placed on those operating processes or plant that process health and social care linen. It identifies statutory reporting systems that apply to employers in order to satisfy regulatory health and safety requirements.

Statutory requirements

Registration with the Care Quality Commission

2.1 The Care Quality Commission (CQC) regulates all providers of regulated health and adult social care activities in England.

2.2 The CQC's role is to provide assurance that the care people receive meets fundamental standards of quality and safety.

2.3 The registration requirements are set out in the Care Quality Commission (Registration) Regulations 2009 and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and include a requirement relating to safety and suitability of premises. The CQC is responsible for developing and consulting on its methodology for assessing whether providers are meeting the registration requirements (see the CQC's (2015) 'Guidance for providers on meeting the regulations').

2.4 Failure to comply with the requirements is an offence, and under the 2008 Act, CQC has a wide range of enforcement powers that it can

use if the 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.

Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended)

2.5 The Health and Safety Executive (HSE) publishes guidance notes on current exposure limits ('Workplace exposure limits – EH 40').

2.6 Users of laundry equipment should note that "substances hazardous to health" can include microorganisms that create a hazard to the health of any person.

2.7 Guidance on the precautions to be taken when handling microorganisms in a laboratory can be found in the following HSE documents (compiled with the Advisory Committee on Dangerous Pathogens):

- 'The management, design and operation of microbiological containment laboratories' (2001);
- 'Biological agents: managing the risks in the laboratory and healthcare premises' (2005);
- 'The approved list of biological agents' (2004); and
- 'Safe working and the prevention of infection in clinical laboratories and similar facilities' (2003) (compiled by the Health Services Advisory Committee).

2.8 They may be of use in determining principles for applying to handling of microbiological hazards in the laundry.

Personal Protective Equipment at Work Regulations 1992 (as amended)

2.9 Managers should assess whether the risks associated with laundry activities require the use of personal protective equipment (PPE). Some examples include overalls and aprons for use when loading washer-extractors, and protective gloves for use when sorting (further guidance is given at [paragraph 5.77](#), 'Protection of laundry staff').

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (known as the Carriage Regulations)

2.10 Advice on the carriage of dangerous goods and the appointment of dangerous goods safety advisers (DGSA's) can be found in DH's 'Safe management of healthcare waste' guidance.

Application of the Carriage Regulations to used linen

2.11 The majority of used linen that is transported to off-site laundries will not normally be assessed as dangerous for transport. Occasionally, infectious linen will need to be classified as dangerous for transport, such as when a consignment is thought to contain pathogens that pose a significant risk of spreading disease and the load is heavily soiled to the extent that the potential for exposure and infection is high. In such instances, the load should be categorised as infectious, bagged accordingly and packaged as UN 3291 as it is not appropriate for processing in a laundry (see also DH's 'Safe management of healthcare waste' guidance).

The Consumer Protection Act 1987

Consumer Protection Act 1987 (Part 1)

2.12 This legislation imposes strict liability on producers for harm caused by defective products. This means that people who are injured by defective products can sue for compensation without having to prove the producer negligent, provided that they can prove that the product was defective and the defect in the product caused the injury. The legislation applies to all consumer products and products used at a place of work.

Consumer Protection Act 1987 (Part 2)

2.13 Section 11 empowers the Secretary of State to make emergency regulations without consultation to secure the safety of products when public protection is deemed necessary. Regulations made under this procedure lapse after 12 months. However, under normal circumstances, the Act requires prior consultation with interested parties. Safety regulations made under the procedure remain in force indefinitely, unless specifically revoked.

2.14 Section 12 makes it an offence to supply goods that do not meet safety regulations made under the Act.

2.15 All consumer goods and goods used in the workplace are covered by the Act. A person can sue under the Act for compensation for death, personal injury and damage to private property (provided the amount of loss or damage to property is £275 or more). Medical devices legislation (under review) within the UK is enabled under the Consumer Protection Act.

Statutory reporting procedure (RIDDOR)

2.16 The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995 place responsibilities on employers to report certain incidents and dangerous occurrences to the local office of the HSE. The action to be taken following any incident should

be detailed in the organisation's procedures to ensure compliance with this legal requirement.

2.17 The User (see [paragraph 4.7, 'Roles and responsibilities'](#)) should notify HSE immediately, normally by telephone, following:

- a. any fatal injuries to employees or other people in an accident connected with the operation of the equipment;
- b. any major injuries to employees or other people in an accident connected with the operation of the equipment;
- c. any of the dangerous occurrences listed in the Regulations.

2.18 The User should send a written report to HSE within seven days of any incident including:

- a. any of the notifiable incidents listed above;
- b. any other injury to an employee which results in their absence from work or being unable to do their normal work for more than three days;
- c. any of the cases of ill-health listed in the Regulations.

2.19 A record should be kept of any injury, occurrence or case of disease requiring a report. This should include the date, time and place, personal details of those involved and a brief description of the nature of the event.

2.20 Examples of dangerous occurrences applicable to laundry equipment include:

- the explosion, collapse or bursting of any closed vessel;
- electrical short-circuit or overload causing fire or explosion;
- any explosion or fire resulting in the suspension of normal work for more than 24 hours;

- an uncontrolled or accidental release or escape of any pathogens or substance from any apparatus or equipment;
- any incident where breathing apparatus malfunctions in such a way as to deprive the wearer of oxygen.

2.21 Examples of reportable diseases applicable to laundry equipment include any illness caused by a pathogen.

2.22 Further details can be found in HSE's L73: 'A guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985'.

2.23 Incidents and dangerous occurrences that are reported to HSE should also be reported to the Department of Health, as appropriate, by telephone during the first working day after the incident and then followed by a written report.

Climate change

2.24 The Intergovernmental Panel on Climate Change highlights three major issues:

- that warming in the climate system is unequivocal;
- that the effect of humans on the climate is clear; and
- that climate change mitigation requires significant reduction of greenhouse gas emissions.

2.25 This poses a double challenge for healthcare facilities:

- to reduce their carbon emissions and contribute to the national and NHS targets for climate mitigation, to identify opportunities for adapting to expected climate change and to build resilience to extreme climate events;
- to support resilient communities including planning services for expected changes in health needs and providing high quality

healthcare particularly focusing on needs during adverse climatic conditions.

2.26 Health Technical Memorandum 07-02 – ‘EnCO₂de 2015 - making energy work in healthcare’ sets the foundations for meeting this challenge and for assisting in the delivery of a resilient healthcare estate as detailed in HBN 00-07 – ‘Planning for a resilient healthcare estate’ (published April 2014). It is the primary guidance on energy efficiency in healthcare facilities in England. It has been produced as a guide to all issues relating to the procurement and management of energy in the NHS and energy efficiency in new build and existing buildings.

2.27 The Sustainable Development Unit (SDU) has promoted the development of a sustainable development management plan (SDMP) by all healthcare provider organisations. Further details can be found on the SDU’s website.

Finance Act 2000/Climate Change Agreements (Eligible Facilities) Regulations 2012

2.28 Under the above legislation, industrial sectors that are high users of energy may be eligible for relief from the Climate Change Levy on energy by contracting with government to meet rigorously negotiated and audited energy reduction targets. The TSA administers a successful Umbrella Agreement on behalf of the industrial laundry sector. Reductions in water and chemical usage also accrue from technologies which save energy so the environmental impact of industrial laundering is further reduced.

2.29 Further information for NHS organisations with regard to the Climate Change Levy and the Carbon Reduction Commitment (CRC) Energy Efficiency Scheme are provided in HTM 07-02: EnCO₂de 2015.

3 Standards, quality systems and other guidance

Summary for commissioners and quality inspectors

This HTM advocates a framework of European quality standards for adoption by linen processors. Standards and relevant other guidance that may apply are described in this section.

BS EN 14065 provides an outline of a suitable system that may be adopted by linen processors, and its implementation and external verification is encouraged by the Department of Health.

Commissioners and inspectors should consider that suppliers of laundry services to health and social care who have achieved independently certified adoption of BS EN 14065 are using it to contribute to Best Practice (BP) under this guidance.

Under the Health and Safety at Work etc Act 1974, healthcare organisations have a duty of care to ensure that no risk is posed to staff in the laundering of linen.

The regulators will enforce the duty of care so as to protect the environment and reduce the negative impacts of waste on people's quality of life.

3.1 Compliance with the following European Standards described within this section would assist laundries processing and disinfecting healthcare products to demonstrate that they

are committed to producing goods of an appropriate quality.

BS EN 14065. Textiles. Laundry processed textiles. Biocontamination control system

3.2 This standard describes a system compatible with ISO 9000 for ensuring microbiological quality of linen used in sectors such as healthcare where it is necessary to control biocontamination. It is based upon a Risk Analysis and Biocontamination Control (RABC) system similar to that used within BS EN ISO 14698.

3.3 It sets out requirements for auditable and documented process validation and monitoring procedures that could contribute to the microbiological quality of the processed textiles.

BS EN ISO 9000. Quality management systems. Fundamentals and vocabulary

3.4 For those not processing medical devices, this standard provides a basis for an accredited quality system.

Relevant other guidance

3.5 The following documents offer useful guidance in addition to this HTM although they are not necessarily endorsed by the Department of Health:

- The Textile Services Association's (TSA) 'The Laundry Handbook';
 - TSA's 'Code of practice for the safe operation of continuous tunnel washers';
 - The Society of Hospital Linen Services and Laundry Managers' (SHLSLM) 'Best practice guide for linen services';
 - The Healthcare Laundry Accreditation Council's (HLAC) 'Accreditation standards for processing reusable textiles for use in healthcare facilities USA'.
- 3.6** Further advice and support on healthcare engineering issues can be found from the Institute of Healthcare Engineering and Estates Management (IHEEM) Technology Platforms.

4 Functional responsibilities

Summary for quality inspectors

Training for all staff involved in the decontamination of linen for health and social care is essential. Guidance is given on appropriate staff training and the need to keep up to date with new developments with accompanying records.

Also covered is the need for all staff involved to have clearly defined roles and responsibilities, which are documented.

The role of the User is discussed as they have the responsibility to enact guidance contained in this HTM.

The responsibilities of the Executive Manager (for example the hospital chief executive) are discussed, as they are responsible for operation of the laundry or purchased service. This responsibility should be delegated to key personnel who are listed together with other specialists whose assistance will be required on a regular basis.

off-site centralised laundry to a small local unit with one washing machine.

4.2 Any locally agreed choice in management structure may wish to reflect the principles of this HTM.

For the assignment of these roles in (a) laundries certified to BS EN 14065 and (b) social care settings, the guidance given in the 'Social care' and 'Guidance for linen processors implementing BS EN 14065' volumes of this HTM should be followed.

4.3 The approach taken by this guidance is to identify the distinct functions and the responsibilities that go with them. The titles given are therefore generic; they describe the individual's role, but are not intended to be prescriptive job titles for terms of employment. Indeed, many of the personnel referred to might not be resident staff but employed by outside bodies and those working on contract. Furthermore, in a small setting, many of the roles might be performed by a single person with additional support.

4.4 Health Technical Memorandum 00 provides general advice – for the NHS sector – on these responsibilities along with the experience, qualifications and training required. However, that advice is based on a universal application in complex systems, which are probably inappropriate to many linen processors.

4.5 Linen processors can, therefore, establish their own choice of system concerning staff

Introduction

4.1 There have been profound changes in the management philosophy of both the NHS and adult social care provision, including a move towards self-management (for example, foundation hospitals in England) and for contracting-out of services. It is therefore not appropriate to prescribe a management structure that is universally applicable given the wide range of circumstances in which laundry equipment might be used – that is, from a large

responsibilities, but they should be able to demonstrate the same degree of understanding, competency and management as required by the 'Professional support policy' manual. The following can be used as a guide to these roles. The terminology used in this manual is used for clarity but it is likely that local personnel may have differing titles.

4.6 Further advice on the engineering roles is detailed in the 'Engineering, equipment and validation' volume of this HTM.

Roles and responsibilities

For the assignment of these roles in (a) laundries certified to BS EN 14065 and (b) social care settings, the guidance given in the 'Social care' and 'Guidance for linen processors implementing BS EN 14065' volumes of this HTM should be followed.

4.7 This section describes the roles and responsibilities of key personnel involved in the operation and use of decontamination processes in laundries.

4.8 Local choice may dictate that some staff will have other responsibilities unconnected with decontamination in laundries, and in some cases the same individual may take on more than one role.

4.9 In every case, however, it is possible to identify a User (see below) who is responsible for the day-to-day management of decontamination processes (including equipment) in laundries. The philosophy of this guidance is to invest the User with the responsibility for ensuring that the equipment is operated safely and efficiently.

Note

Other topics in the HTM series recommend the use of an Authorised Person (Decontamination) and Authorising Engineer (Decontamination). Currently, their involvement is not widespread within the laundry sector. However, healthcare organisations that wish to implement these roles within this setting should consult Health Technical Memorandum 01-01 Part A for further guidance. It should however be noted that linen decontamination does not currently form part of the syllabus of training for Authorised Persons (Decontamination) and Authorising Engineers (Decontamination). The IHEEM Technology Platform also offers advice in this area.

Authorising Engineers (Decontamination) may also be able to provide independent sign-off and audit of validation results, if required.

Management – definition

4.10 Management is defined as the owner, occupier, employer, general manager, chief executive or other person of similar authority who is ultimately accountable for the safe operation of the premises. In some cases this might be the laundry manager or care home manager.

Key personnel

4.11 In this HTM, the following are key personnel who have specific responsibilities within decontamination in laundries:

- Executive Manager (for example, chief executive);
- NHS/Organisation Decontamination Lead (this person may also act as the Designated Person if locally agreed);
- Designated Person;
- User (for example, a linen services manager or a laundry manager);

- NHS Director of Infection Prevention and Control, or Infection Prevention and Control Lead
- Infection Control Practitioner;
- Microbiologist (Decontamination);
- Operator.

4.12 Roles discussed in the 'Engineering, equipment and validation' volume are:

- Senior Operational Manager;
- Maintenance Engineer;
- Manufacturer;
- Contractor;
- Purchaser;
- Competent Person (Pressure Systems).

Executive Manager

4.13 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 laundry equipment is installed.

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

NHS/Organisation Decontamination Lead

4.15 Every health and adult social care organisation should have a nominated Decontamination Lead with responsibility for decontamination. Further guidance is given in the Code and Health Technical Memorandum 01-01 Part A.

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

Designated Person

4.16 This role is the interface between the linen processor and support services supplied internally or externally, including service, maintenance and testing. This could be the maintenance manager of the laundry or a care home manager. The Decontamination Lead could also act as the Designated Person.

User

4.17 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 as defined below.

4.18 In the acute sector, the User could be a linen services manager. Alternatively, in primary or social care, this person could be a general practitioner, home manager or other health professional.

4.19 The principal responsibilities of the User, within local policy, are as follows:

- a. to certify that the laundry equipment is fit for use from a decontamination perspective;
- b. to hold all documentation relating to the laundry equipment, including the names of other key personnel;
- c. to ensure that laundry equipment from a decontamination perspective is subject to periodic testing and maintenance;
- d. to appoint operators where required and ensure that they are adequately trained;
- e. to maintain production records;
- f. to establish procedures for product release in line with the quality management system;
- g. 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.

Note

The User may seek the advice of infection control teams, which may consist of a Director of Infection Prevention and Control, Infection Control Practitioner or Microbiologist (Decontamination).

For larger linen processors (not primary care or care home settings), the Executive Manager should consider appointing a User with appropriate qualifications, for example:

- evidence of attendance on an approved course in laundry technology;
- a minimum of two years' experience in the management and provision of linen services;
- membership of an appropriate professional body with experience in the subject of laundry management (SHLSLM, TSA, Guild of Cleaners & Launderers (GCL) etc).

NHS Director of Infection Prevention and Control, or Infection Prevention and Control Lead

4.20 A Director of Infection Prevention and Control (DIPC) or Infection Prevention and Control Lead should be designated in each organisation. The lead reports directly to the chief executive and the Board and not through any other officer. The lead oversees local infection control policies and their implementation. If the person has a degree in microbiology, he/she may also fulfil the role of the Microbiologist (Decontamination). If the person has a degree or equivalent qualification in microbiology, he/she may also fulfil the role of the Microbiologist (Decontamination).

Infection Control Practitioner

4.21 This person is designated by Management to be responsible for advising the User on all infection control aspects (see also the 'Social care' and 'Guidance for linen processors implementing BS EN 14065' volumes of this HTM).

Microbiologist (Decontamination)

4.22 The Microbiologist (Decontamination) is defined as a person designated by Management to be responsible for advising the User on the microbiological aspects of the disinfection and recontamination of linen.

4.23 The Microbiologist (Decontamination) should have a relevant degree (for example microbiology or medicine).

4.24 The principal responsibilities of the Microbiologist (Decontamination) are:

- a. to advise the User on the microbiological aspects of decontamination procedures for linen;
- b. to audit the documentation from all decontamination equipment that has been tested by microbiological methods.

4.25 In some organisations, the Microbiologist (Decontamination) and Infection Control Practitioner may be the same person.

Operator

4.26 The Operator is defined as any person with the authority to operate a washer-extractor, CTW and any other laundry equipment, including the noting of instrument readings and simple housekeeping duties.

5 Decontamination arrangements for linen used in health and adult social care sectors

Summary for commissioners and quality inspectors

This chapter details the way in which used linen should be sorted and classified. It discusses disinfection methods and sets a benchmark for chemo-thermal or chemical processes. Transport and storage arrangements are also discussed including bag colour coding and labelling. Importantly it describes the Department of Health's approach to laundry processes and their effectiveness against *Clostridium difficile*.

Commissioners will wish to assure themselves that adequate sorting and disinfection arrangements are in place and that these arrangements are agreed between both linen processors and users. Quality inspectors may wish to review how such arrangements are documented and look to satisfy themselves that organisations are dealing with the risks associated to both staff and patients regarding infectious linen.

However, it is not the intention that quality inspectors replicate any independently-certified audit processes.

Introduction

5.1 The microbiological quality required of textiles should be determined by their intended use. In certain cases where very high microbiological quality is required (for example in operating theatres), processing may need to be completed by sterilization.

5.2 For general healthcare and care-home linen, the prime task of linen processing is to kill or remove microbial contamination derived from the previous user. Once the linen is decontaminated, recontamination with microbes from used linen should be avoided.

5.3 As a minimum, all linen processors who process infectious linen should undertake a risk analysis of their processes including:

- identifying areas requiring microbiological control; and
- setting and measuring critical control points as defined in [paragraph 5.70, 'Risk Analysis and Biocontamination Control'](#).

5.4 Those processing large amounts of linen may wish to consider the implementation of BS EN 14065.

5.5 Health and adult social care providers should give consideration to the correct use, selection and validation of any local laundering arrangements such that the requirements of the above paragraph and the Code can be met.

5.6 When selecting and operating locally installed equipment, the advice of the infection control team should be sought. A risk-based approach should be adopted.

5.7 Commercial, purpose-designed solutions are preferable to domestic solutions. Some physiotherapy departments and neonatal care units install domestic-type washing machines for local processing. Before any such similar areas are designed and installed, a full options appraisal and risk evaluation should be undertaken to demonstrate why existing centralised options (such as the use of the organisation's main provider of linen processing services) are not suitable.

Classification of linen

History

5.8 The publication of Health Service Guideline 'Hospital laundry arrangements for used and infected linen' (commonly known as HSG(95)18) in 1995 recommended the classification of linen into two groups: "used (soiled and fouled)" and "infected".

5.9 At the time the HSG was written, limitations in the design of CTWs (called batch washers within the HSG) meant that restrictions were placed on high throughput machines that processed infectious linen (because of the risks associated with staff entering the machine to deal with breakdowns and maintenance, and the requirement to sort and handle linen before it was processed). This further encouraged the principle of linen classification.

Approach to classification sorting and processing

5.10 CTWs and procedures have advanced over the last few years. This has opened the possibility of processing all types of work through these machines with the right control measures in place. With current trends in laundry development, this flexibility may improve further.

5.11 This HTM recommends a risk-based approach to classification and allows the service-user and provider to agree the most suitable methods of, and procedures for, classification and sorting.

5.12 The advantages of increased throughput achieved by using CTWs for all linen classifications are difficult to ignore. These benefits should be evaluated by service-users and providers when agreeing the operating mode of any service. However, consideration should also be given to the maintenance, repair, health and safety, and environmental implications of such a decision. This will mean undertaking a full risk assessment of the options.

Linen classifications

5.13 The following definitions apply specifically to the healthcare setting. Further guidance on applying definitions and classifications to the social care setting are discussed in HTM 01-04 'Social care'.

Used (soiled and fouled) linen

5.14 This definition applies to all used linen, irrespective of state, but on occasions contaminated by body fluids or blood. It does not apply to:

- linen from infectious patients;
- those suspected of being infectious; and
- other linen covered by the following paragraph on "infectious linen".

Infectious linen

5.15 This definition applies to:

- linen from patients with diarrhoea;
- linen contaminated with blood or body fluids from patients with blood-borne viruses;
- other conditions as specified by local policy (for example, varicella zoster and measles).

5.16 To ensure that only infectious linen is classified as such, service-users need to use the classification system correctly and accurately. (Some linen processors use a dedicated process for infectious linen, which could be overwhelmed by misclassification, leading to delays in the return of linen.)

5.17 Linen from patients infected with, or at high risk of having, hazard group 4 organisms (haemorrhagic fever viruses such as Lassa Fever) should not be returned to a laundry. See the Advisory Committee on Dangerous Pathogens' (ACDP) guidance.

Heat-labile items

5.18 This category includes fabrics damaged by the normal heat disinfection process and those likely to be damaged at thermal disinfection temperatures. These fabrics should be washed at the highest temperature possible for the item; disinfection may be achieved by chemical disinfection, if required. Service-users should agree local policies regarding purchase of heat-labile items in accordance with available methods of disinfection and linen processing.

Items contaminated with radiation

5.19 For any items that are, or have been, contaminated with radiation (such as items contaminated with vomit following ingestion of radioactive iodine), the disposal guidance given in DH's 'Safe management of healthcare waste' guidance should be followed.

Classification and sorting options

5.20 Sorting fabrics into different drying types is an essential economic part of linen processing. Sheets, for example, require far less energy to dry them than would towels. In some linen processes/facilities, progression from the washing to the drying phases is automatic; therefore, fabrics have to be sorted before washing ("pre-wash sorting"). Some processes will allow sorting between washing and drying

("post-wash sorting"). All washer-extractor processes allow pre- or post-wash sorting.

5.21 This HTM considers two differing scenarios on which any classification and sorting agreement can be based.

Option 1: Infectious linen is segregated by the service-users

5.22 Categorisation of linen should be done at local level with the appropriate colour-coded bags.

5.23 Infectious linen in this category should not be sorted, but should be sealed in a water-soluble¹ bag, which should then be placed in an impermeable bag immediately on removal from the bed or before leaving a clinical department.

5.24 Water-soluble bags are also recommended for heavily fouled linen if capable of being processed by the washer and if agreed with the linen processor.

5.25 Soiled and fouled linen should be placed in an impermeable bag immediately on removal from the bed or before leaving a clinical department.

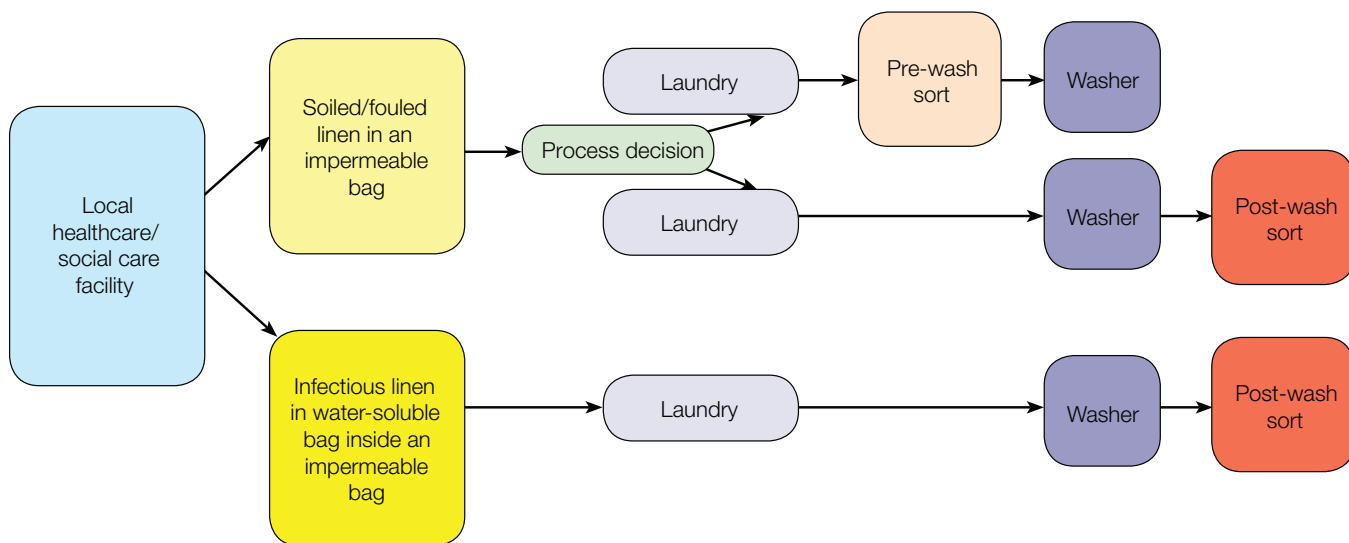
5.26 Water-soluble bags should be transferred to the designated washer without opening, followed by any washable, reusable laundry outer bag, which should be washed in a similar fashion. If a CTW is used, it should be validated to determine its ability to process and breakdown adequately the water-soluble bag.

Option 2: Standard precautions by the user with no segregation of linen

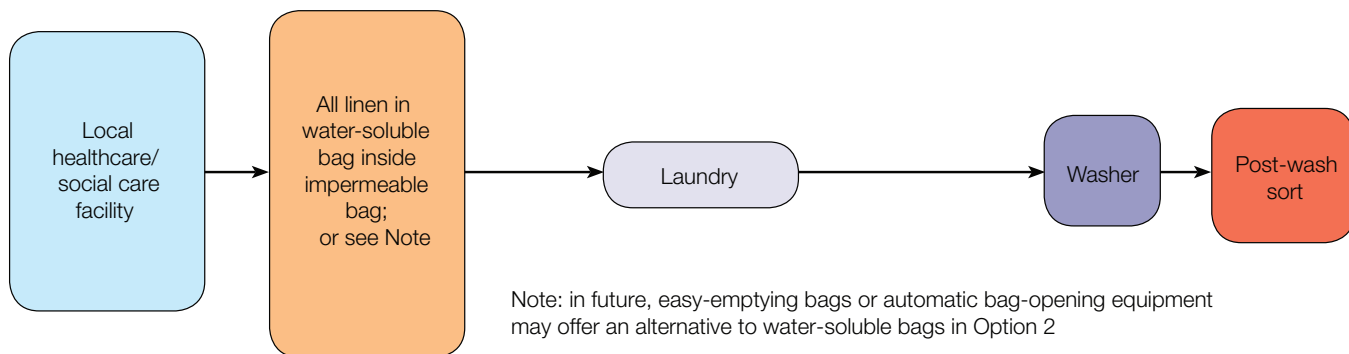
5.27 Linen is not segregated at the local level (subject to the laundry being able to meet processing guidelines), and all linen is presumed to be infectious.

¹ Bags with water-soluble seams are also included within this term but should only be used with the linen processor's agreement in order to prevent damage to tumbler-drying equipment.

Figure 1 Classification and sorting flowchart

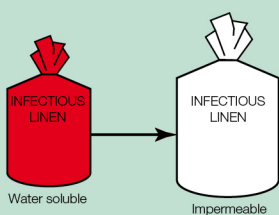
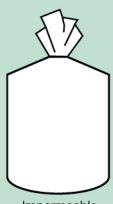


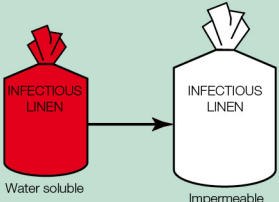
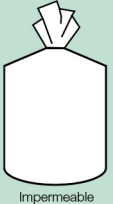
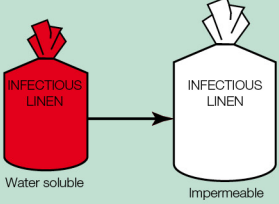
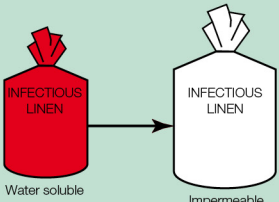

Option 1 – Local policy requires that infectious linen be segregated by the service users



Note: in future, easy-emptying bags or automatic bag-opening equipment may offer an alternative to water-soluble bags in Option 2

Option 2 – Local policy requires standard precautions by the user with no segregation of linen

Option and processing plant available	Category	Bag/container (see paragraph 5.41, 'Colour coding of linen bags')	Production sort system
Option 1 with CTW for soiled/fouled, and dedicated W/E for infectious	Infectious (W/E)	Water-soluble bag inside impermeable outer: 	Post
	Soiled or fouled (CTW)	Impermeable: 	Pre or post

Option and processing plant available	Category	Bag/container (see paragraph 5.41, 'Colour coding of linen')	Production sort system
Option 1 with CTW for all categories	Infectious	Water-soluble bag inside impermeable outer: 	Post
	Soiled or fouled	Impermeable: 	Pre or post depending on delivery mechanism to CTW
Option 2 with W/E for all categories		Water-soluble bag inside impermeable outer: 	Post
Option 2 with CTW for all categories		Water-soluble bag inside impermeable outer: 	Post
		or reusable impermeable (not plastic disposable) using easy-emptying and step conveyor (see note below) 	

Notes:
 Green shading refers to options for meeting EQR
 Blue shading relates to BP progression

Note: In future, easy-emptying bags or automatic bag opening equipment may offer an alternative to water-soluble bags in Option 2.

5.28 Immediately on removal from the bed or before leaving a clinical department, linen should be either:

- sealed in a water-soluble bag, which should then be placed in an impermeable bag; or
- sealed in an impermeable reusable bag having the infectious-linen colour code in accordance with the 'Colour coding of linen bags' section, and labelled, if considered necessary locally.

5.29 If a water-soluble bag is used, the inner bag should be transferred to the designated washer without opening.

5.30 CTWs are not designed to operate solely on loads involving water-soluble bags and should be validated to determine their ability to process and breakdown adequately the water-soluble bags in sufficient quantities. Before adopting option 2, consideration needs to be given to the total mix of all the laundry's work including that from other healthcare customers. The utilisation of options 2 depends on the percentage of healthcare customers, the availability of washer-extractors and the total percentage of work going through the the CTW that will be in water-soluble bags.

5.31 In future, easy-emptying bags or automatic bag opening equipment may offer an alternative to water-soluble bags in Option 2.

If easy-emptying bags or an automated procedure is adopted, a bag handling procedure should be used that:

- minimises manipulation of the bag and prevents exposure of staff to the infectious linen prior to decontamination;
- is fully automated for washer loading;
- incorporates equipment that is capable of being adequately disinfected; and
- requires any outer bag to be decontaminated before disposal or reuse.

5.32 It is not acceptable for staff to manually open bags containing infectious linen.

Note

Laundry equipment providers are encouraged to consider developing products that could assist with satisfying this aim.

5.33 Any systems adopted should not expose the laundry staff to any greater risk than that posed by option 1 above, where water-soluble bags are used.

5.34 Further consideration should also be given to disinfection of hoppers and loading chutes.

5.35 Whichever classification option is chosen, for those seeking to achieve BP, permeable outer bags should not be used.

5.36 Linen is then sorted for further processing on exit of the process.

5.37 Whichever option is chosen, post-wash sorting of linen for production purposes (production batch sorting) is encouraged and would count as BP. If any form of pre-wash sorting for operational or performance reasons is required within the laundry, option 1 above should be adopted. It is not appropriate for laundry staff to undertake sorting of infectious linen.

5.38 The health and safety of personnel operating washers is important, especially where a CTW is used for processing infectious linen. A documented risk assessment should be undertaken describing how the risk will be dealt with, how the process will be undertaken and what documented procedures will be implemented. It should form part of any quality management, safety or risk analysis system operated by the laundry.

5.39 When a machine is used for the processing of infectious linen, the following safety measures need to be adopted. The ability to undertake these measures needs

consideration when choosing either option mentioned above:

- Any vent pipes associated with machines processing infectious linen should be routed to a safe point of discharge outside the building and away from any windows or ventilation plant inlets.
- Effluent from the drains of such machines must be sealed (closed piped) from the machine to the manhole and situated outside the laundry to prevent infection. If the machine drains to an open sump or pit immediately below the machine drain valve, the sump or pit should be covered to reduce the risk of bacteria being spread by aerosol when water is pumped from the machine.

5.40 Validation of the ability of the washer to process water-soluble bags should be undertaken if these bag types are being used.

Colour coding of linen bags

Soiled and fouled linen

5.41 Linen not identified as infectious should be placed in a **white** impermeable bag for despatch to the laundry. A risk assessment should be taken at local level to be assured the containment of soiled and fouled linen is not compromised. All staff at local level should be trained in the correct coding and bagging procedures to ensure that sharps, clinical waste and non-clinical waste do not return to the laundry.

Infectious linen

5.42 All linen identified as infectious should be placed in a red water-soluble bag (with an optional bold legend stating “infectious linen”), which should then be placed inside a white impermeable bag which is identified as “infectious linen”.

Note

If sorting and classification option 2 (see [paragraph 5.8, ‘Classification of linen’](#)) is adopted without the use of water-soluble bags (for example, with impermeable reusable bags using easy-emptying and step conveyors), a red impermeable bag should be used and labelled “infectious linen”.

Heat-labile linen

5.43 All heat-labile linen should be placed inside an impermeable bag, the colour of which should be agreed with the laundry.

5.44 If option 1 or pre-wash sorting is adopted, infectious red-bagged linen and soiled/ fouled linen should not be mixed within the same outer bag.

Disinfection of linen

5.45 Traditionally, linen has been disinfected using heat. One of the advantages of this method is that time–temperature relationships can easily be set and monitored. However, disinfection by heat may not be suitable for some materials, either because they cannot tolerate high temperatures or because specialised coatings may be damaged by a thermal process. Whichever process is selected, effectiveness at decontaminating items contaminated with heat-resistant organisms such as *Clostridium difficile* or enterococci may need to be considered.

5.46 Temperatures other than those specifically recommended in the ‘Disinfection by heat’ section, when maintained for an appropriate time, are acceptable and will also be capable of producing a disinfected product. For a thermal disinfection process, a particular time at a particular temperature can be expected to have a predictable lethal effect against a standardised population of organisms.

5.47 Energy and environmental impact should also be considered when selecting an appropriate process.

5.48 Others processes use a combination of raised temperature (but less than 65°C) and chemical disinfection. These processes, often termed “chemo-thermal” disinfection, are gaining popularity and are constantly being developed into more sophisticated processes. The term “chemical disinfection” is used throughout this HTM and includes such processes as well as any chemical processes operating at ambient temperature.

5.49 An additional pre-wash cycle may be necessary for heavily-soiled/infectious linen processed in washer-extractors. The use of this additional stage should be recorded in the local policy.

Disinfection by heat

5.50 The washing process should have a disinfection cycle in which the temperature of the load is either maintained at 65°C for not less than ten minutes or 71°C for not less than three minutes when thermal disinfection is used. Alternative time– temperature relationships may be used as long as the efficacy of the process chosen is equal to or exceeds that of the 65° or 71°C processes. With all these options, mixing time should be added to ensure heat penetration and assure disinfection. For conventionally-designed machines and those with a low degree of loading (less than 0.056 kg/L), four minutes should be added to these times to allow for adequate mixing time. For a heavy degree of loading (that is, above 0.056 kg/L), it is necessary to add eight minutes.

5.51 The routine validation of achievement of the above parameters is important. The adoption of recommendations in the ‘Engineering, equipment and validation’ volume of this HTM could assist in demonstrating compliance.

Note

The Department of Health’s ‘Uniforms and workwear: guidance on uniform and workwear policies for NHS employers’ offers advice on home-laundering of uniforms in domestic facilities, but states “wash uniforms ... at the hottest temperature suitable for the fabric”. It then recommends a ten-minute wash at 60°C. The time–temperature relationship discussed in this section is not applied to the domestic laundering setting. The level of soiling (due to the use of PPE), direct contact time with the service-user and therefore overall risk is less for uniforms and workwear than it is for other types of linen such as sheets and drapes.

Chemical disinfection including chemo-thermal processes

5.52 This process is essential for some heat-labile items. A variety of processes using a range of chemical agents are available, and the exact process should be chosen in discussion and agreement with the infection control team for a care provider and with the appointed Microbiologist (Decontamination).

5.53 It is important that the chemical does not damage fire-retardant or other specialist coatings. Hypochlorite should not be used on fabrics treated for fire retardance.

5.54 Chemical disinfection processes also need to be validated, but traditional time–temperature relationships are not applicable. The entire process (including washing, dilution and disinfection) should be capable of passing the microbiological tests specified within this HTM, including the ability to process a sterile swatch and leave it free of viable microorganisms (see ‘Microbiological test for disinfection stage’ in the ‘Engineering, equipment and validation’ volume). In addition, a method for proving a disinfecting efficacy equal to or exceeding that of the 65° or 71°C thermal disinfection processes using semi-permeable dose strips is specified in this HTM

(see 'Microbiological test for disinfection stage' in the 'Engineering, equipment and validation' volume).

Clostridium difficile contamination and potential infection

5.55 The Department of Health has undertaken a series of three studies in collaboration with University College London and the laundry industry concerning an assessment of the risk of possible presence and persistence of *Clostridium difficile* spores after the completion of linen decontamination processes.

5.56 The studies focused on:

- the potential for contamination in the use of linen with particular reference to bed sheets;
- the effectiveness of small washers in the removal of such contamination, and similar studies involving industrial-scale processes with CTWs;
- the potential for any residual *Clostridium difficile* contamination to be released from linen when in the sustained presence of a patient's saliva (acting as a continuous contaminant).

5.57 The studies show that *Clostridium difficile* contamination occurs from colonised and/or infected patients at significant levels. This contamination is not necessarily linked to the presence of visible soil on the linen concerned.

5.58 A standard washer-extractor is highly effective in reducing the extent of contamination present at the end of the linen decontamination process provided that the quality requirements match those offered under EQR within this guidance (see [paragraph 1.14](#), 'Essential Quality Requirements (EQR) and Best Practice (BP)').

5.59 Additional tests have shown that CTWs are more effective than standard washer-extractors. However, low-level contamination of linen will persist if the initial level of *Clostridium difficile* spore contamination is high, irrespective of which type of machine/process is used.

5.60 DH concludes, subject to future review, that the guidance offered in this HTM when properly applied as part of a quality system does give adequate and reliable safeguard against the spread of this form of contamination/infection for the purpose of general hospital care.

5.61 In the case of highly immunosuppressed or compromised patients, the advice of a clinical microbiologist should be sought. It may be appropriate to consider the use of disposable single-use products.

Note

A review by Creamer and Humphreys (2008) did not identify any outbreaks of *Clostridium difficile* infection that were linked to contaminated linen (although it included a list of published outbreaks linked to bed components).

However, there have been two published reports linking *Bacillus cereus* contamination of linen with hospital infection (Barrie *et al* 1994 and Sasahara *et al* 2011).

Continuous tunnel washers – disinfection

5.62 All CTWs should be fitted with the necessary controls and interlocks to ensure work being processed is not recontaminated during the rinsing stages of the wash process. To achieve this, rinse sections should be disinfected before production starts each working day.

5.63 The apparatus used to disinfect rinse sections of the CTW should be interlocked with the normal running control of the machine. This is to prevent the machine being set to work before the disinfection of these stages has been satisfactorily completed. The requirements are as follows:

- For machines using thermal disinfection, all sections of the machines that follow

the high temperature sections which do not reach a minimum temperature of 65°C should receive a thermal disinfection cycle. The disinfection cycle will be considered satisfactory when the water temperature has been raised to 65°C and held at this temperature for a period of not less than ten minutes or at a temperature of 71°C for a period of not less than three minutes. During thermal disinfection of the rinse stages, the machine cage/drum should rotate to ensure that all surfaces are in contact with high-temperature liquids. The disinfection process should be controlled by a timer.

- For machines using chemical disinfection, all sections of the machines that follow the disinfection section which do not normally receive disinfection should receive a disinfection cycle. The disinfection cycle will be considered satisfactory when the requirements given in [paragraph 5.52, 'Chemical disinfection including chemo-thermal processes'](#) are achieved. During disinfection of the rinse stages, all surfaces should be in contact with the disinfectant.
- A machine using chemical disinfection for its main linen disinfection process can use thermal disinfection for its rinse- and cool-stage disinfection process if needed.
- A timer should be incorporated into the control system to override the need to proceed through the disinfection of the cool stages if the machine is stopped for short periods during the day. This timer, however, should be interconnected such that if the machine is shut down for a period of three hours or more, the cool stage disinfection cycle will proceed and simultaneously lock out the washing controls. The lock out should include any mechanical devices, interlocked with the washing cycle or not, for feeding work into the machine.

- The cool stage disinfection cycle should be initiated by a single button. The cycling of any steam and/or water control valves necessary to raise the temperature of these stages to that required for thermal disinfection or the admittance and control of any chemical disinfectant should be automatic. The incorporation of hand-operated valves in this system is not acceptable.

5.64 For washing machines without thermal interlocks, all linen should be run out at the end of the day to avoid recontamination, should normal machine disinfection processes not be enough to prevent this (otherwise bacterial growth may occur overnight).

Other disinfection considerations

5.65 Adequate disinfection procedures should be in place for the tanks that are used to collect water for reuse within the CTW.

5.66 If the installation of a heat exchanger in the recovered water system is envisaged, special consideration to thermal disinfection needs should be given.

5.67 Machinery should be kept clean and free from algae and biofilm (for example, any slime layers).

5.68 All conveyor belting and surfaces used to transfer clean processed work from the press/ extraction device to tumblers should be regularly cleaned and disinfected.

Continuous tunnel washers – safe operation

5.69 The Textile Services Association's 'Code of practice for the safe operation of continuous tunnel washers' should be adopted as the minimum standard for safe operation by all organisations using CTWs.

Risk Analysis and Biocontamination Control (including critical control points and recontamination)

5.70 All linen processors who process infectious linen should undertake a risk analysis of their processes including identifying areas requiring microbiological control and setting and measuring critical control points.

5.71 Particular attention should be paid to those areas or transmission routes where recontamination of linen can occur (with special regard to potential recontamination from unprocessed healthcare linen); but all steps of the process should be considered within the analysis. BS EN 14065 provides an outline of a suitable system that may be adopted by linen processors and its implementation and external verification is encouraged by the Department of Health. It describes an RABC system designed to enable laundries to continuously assure the microbiological quality of processed textiles.

5.72 The following diagram used within the Textiles Services Association's 'Guide to BS EN 14065' shows a schematic illustration of decontamination status during processing.

5.73 Further information is given in the 'Guidance for linen processors implementing BS EN 14065' volume of this HTM.

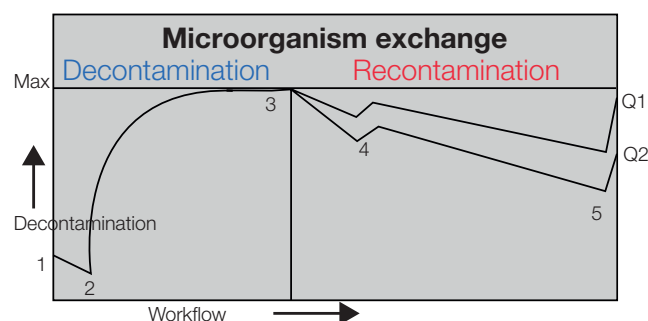
Separation of process to prevent recontamination

5.74 For those not adopting independently certified biocontamination control systems in accordance with BS EN 14065, to achieve BP the soiled linen area should be functionally separated from the clean linen processing areas. This is not required for attainment of EQR.

5.75 Examples of how functional separation may be obtained are:

- a. physical barrier;
- b. negative air pressure in the soiled linen area; and/or
- c. positive air flow from the clean textiles area through the soiled textiles area with venting directly to the outside.

5.76 Achievement of functional separation may be expensive or impractical in some environments. Therefore, before embarking on satisfying this aspect of BP, a risk assessment should be undertaken. The attainment of independently certified BS EN 14065 may be a more achievable route for progressing to BP.



Key:
 1 – soiled receipt
 2 – delay before washing
 3 – end point of main wash process, before rinsing
 4 – end point of drying process
 5 – completion of packaging
 Q1 and Q2 – different quality (microbial) levels, from variation in process and product

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Protection of laundry staff

5.77 Managers should assess whether the risks associated with linen decontamination require the use of personal protective equipment (PPE).

5.78 Although pre-wash sorting is not considered BP, where it does occur, staff in sorting areas must wear PPE (for example, waterproof coverage of chest and forearm areas, gloves, and possibly visors, face-masks or hats, depending on the task being undertaken).

5.79 Any exposed lesion should always be covered with a waterproof dressing. Hand-washing and changing facilities must be provided in accordance with current legislation. Clean overalls should be available to staff at each new shift or work-period change.

5.80 Staff need to discard and replace PPE between work tasks and especially when moving from dirty to clean areas. Staff should not wear their own home clothes, but should be provided with appropriate workwear.

5.81 Staff should be fully trained in all operations involving linen processing. Guidelines setting out cleaning and operational procedures for plant, equipment and laundry buildings should be made available and adhered to. Detailed policy on the occupational health supervision of laundry staff should be determined locally. Common issues identified that may require specific measures include:

- maintenance of laundry cages;
- upper limb disorders;
- manual handling;
- slips and trips;
- safe maintenance of automated systems.

5.82 Immunisation (vaccination) is available against hepatitis B virus but not other blood-borne viruses. The need for laundry staff and other staff handling linen to be immunised should be determined by risk assessment. It

should only be seen as a supplement to reinforce other control measures.

5.83 Employers should make vaccines available free of charge to employees if they are needed. It is recommended that a vaccination record is kept.

5.84 Further information on immunisation can be found in publications by the Advisory Committee on Dangerous Pathogens and the Department of Health.

5.85 Advice on undertaking the risk assessment can be found in the HSE publication 'Blood-borne viruses in the workplace'.

Transport of linen

5.86 Bags should not be overfilled. They should be of an acceptable weight and should be securely fastened before being sent to the laundry. Care should be taken to prevent linen or foul seepage (body fluids or blood) escaping from laundry bags and contaminating other items or staff.

5.87 If used to transport clean linen after transporting used or infectious linen, all reusable transport containers, cages and the inside hold area of transport vehicles should be decontaminated daily and between uses in order to ensure that the condition and decontaminated status of the linen is not compromised. This should be undertaken according to a documented procedure and the process validated. The use of easy-to-clean impervious smooth surfaces will aid this process.

5.88 There should be a physical barrier between clean and used or infectious linen when carried on a vehicle at the same time. Linen bags that are not securely fastened should not be placed in a vehicle.

5.89 Trolleys for clean linen in transit should be covered with a washable or disposable cover. If fully enclosed and sealed containers with

lockable doors are used, these covers are not required.

5.90 See also paragraph 2.11, 'Application of the Carriage Regulations to used linen'.

Clean linen storage and prevention of recontamination

5.91 Storage areas should be dedicated for the purpose and not used for other activities. The storage area should be appropriately designed to prevent damage to linen and to allow for the rotation of stocks.

5.92 Laundry rooms, central linen rooms, linen rooms, linen cupboards and mobile storage

units should be equipped with shelving that can be easily cleaned and allow the free movement of air around the stored linen. Linen should be stored above floor level away from direct sunlight and water in a secure, dry and cool environment.

5.93 Cleaning frequencies should be agreed locally but should be at least quarterly.

5.94 Linen stocks should be removed temporarily to facilitate thorough cleaning of the storage area and shelving.

5.95 Clean linen should be transported around wards on a clean trolley and handled with clean hands.

6 Options for the provision of linen processing services

Summary for quality inspectors

It is recognised that organisations can determine the most suitable means of providing linen processing services. However in doing so, those organisations may wish to pay due regard to the Essential Quality Requirements outlined at [paragraph 1.14](#). This section provides an overview for quality inspectors of the issues that are likely to be considered by organisations when deciding upon the most suitable method of providing a linen processing service.

6.1 Organisations can determine the most suitable means of providing linen processing services by undertaking an options appraisal, whereby they quantify and (where possible) value the costs, benefits, risks and uncertainties associated with each of the following options:

- a. procure a new build;
- b. upgrade existing facilities;
- c. obtain services from a third party;
- d. maintain existing compliant services.

6.2 Issues to consider include:

- Do existing laundry facilities have equipment of adequate capacity to cope with an increased demand according to organisation growth forecasts?
- Can other equipment be utilised for infectious linen to mitigate the effects of growth in demand?
- In particular for healthcare settings, are other laundry-stream demands expected to decrease because of a reduction of other clinical work in the hospital; and has

this been considered in balancing demand?

- Have relationships with other organisations/laundries been established to develop contingency arrangements for support in terms of laundry capacity?

6.3 If looking to outsource provision, the scope of service required needs consideration. Options include:

- wash and return only;
- linen hire;
- total linen management;
- hire of CE-marked reusable barrier theatre textiles;
- combinations of the above.

6.4 If choosing a new build, the following issues may be taken into consideration when determining the location of the laundry:

- availability of site/premises;
- distance from main users;
- revenue and capital costs;
- transport requirements/constraints;
- textile inventory;
- quality and quantity of engineering services;
- personnel issues;
- security issues;
- planning permission requirement;
- health/social care providers' strategies; and
- geographical and environmental constraints.

7 Procurement of medical device textiles and processing instructions

Summary for quality inspectors

Organisations must have a clear understanding of the relevant Essential Requirements of the Medical Devices Directive, BS EN ISO 13485 and BS EN 13795 in order to develop a purchasing policy for Class 1 textile medical devices. This should include a consultation process to ensure that all those involved in the purchase, decontamination and use of the device are given the opportunity to discuss the suitability of an item before a purchase is made.

This understanding, policy and consultation will ensure that textile medical devices that have been purchased may be adequately decontaminated by processes available to the organisation.

7.1 When considering the purchase of textiles and specifically those that are medical devices, the following issues should be taken into account:

- Does the textile have a limited life? Is this specified by the manufacturer?

- What method of linen processing does the manufacturer recommend, and is this process available within the organisation?
- Is the textile heat-labile, and is an alternative available that will withstand higher wash temperatures?
- What processing agents are recommended? Do these comply with local infection control policies, COSHH and health and safety requirements?
- If the textile needs to be sterilized, is the preferred method of steam sterilization (134°C for a minimum of three minutes) recommended? If another method of sterilization is recommended, is this available within the organisation?
- Has a risk assessment been undertaken to determine whether a single-use or a reusable product is more appropriate for the circumstances?

7.2 Manufacturers of reusable medical devices are required to supply information on the appropriate decontamination process to allow reuse, including washing, disinfection and where appropriate the method of sterilization.

References

- BS EN 14065.
- Health Act Code of Practice.
- The NHS Constitution.
- ‘Uniforms and workwear: an evidence base for developing local policy’.
- COSHH Regulations.
- Society of Hospital Linen Service and Laundry Managers.
- Care Quality Commission (Registration) Regulations 2009
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.
- ‘Guidance for providers on meeting the regulations’.
- Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended).
- Workplace exposure limits.
- ‘The management, design and operation of microbiological containment laboratories’.
- ‘Biological agents: managing the risks in the laboratory and healthcare premises’.
- ‘The approved list of biological agents’.
- ‘Safe working and the prevention of infection in clinical laboratories and similar facilities’.
- Personal Protective Equipment at Work Regulations 1992 (as amended).
- Health Technical Memorandum 07-01 – ‘Safe management of healthcare waste’.
- Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.
- Consumer Protection Act 1987.
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).
- A guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995.
- Health and Safety at Work etc Act 1974.
- BS EN ISO 14698.
- ‘The Laundry Handbook’. The Textile Services Association (TSA).
- ‘Code of practice for the safe operation of continuous tunnel washers’. The Textile Services Association (TSA).
- ‘Best practice guide for linen services’. The Society of Hospital Linen Services and Laundry Managers (SHLSLM).
- ‘Accreditation standards for processing reusable textiles for use in healthcare facilities USA’. The Healthcare Laundry Accreditation Council (HLAC).
- Institute of Healthcare Engineering and Estates Management (IHEE) Technology Platforms.
- Health building Note 00-07. Planning for a resilient healthcare estate.

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ACDP guidance: (1) Biological agents: managing the risks in laboratories and healthcare premises.

ACDP guidance: (2) The management and control of viral haemorrhagic fevers.

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Blood-borne viruses in the workplace.

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BS EN ISO 13485.

BS EN 13795.