



Department
of Health

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

Guidance for linen processors implementing
BS EN 14065

March 2016

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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 in HTM 01-04 Part A – ‘Management and provision’.

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. A note has been added after paragraph 3.1 which gives clarification on certification to BS EN 14065 and the status of certification bodies.

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1 Summary for quality inspectors

1.1 BS EN 14065 describes a management system for assuring the microbiological quality of processed textiles used in specifically defined sectors in which it is necessary to control microbiological contamination. The Department of Health encourages the adoption of this standard for those operating laundries both in a commercial setting and within the NHS. This section describes for quality inspectors the standard and its relationship with Essential Quality Requirements (EQR).

1.2 The 'Management and provision' volume contains a section detailing functional

responsibilities for those involved in the provision of linen decontamination. However, it is written from the starting premise of public-sector organisations that operate dedicated laundries and not those who may only be responsible for commercial laundries in the private sector. This section also offers advice on how the roles described in clause 6.1.2 of BS EN 14065 on the constitution of the Risk Analysis and Biocontamination Control (RABC) team cross-match against the roles identified in 'Management and provision'.

2 Introduction

2.1 The European Standard BS EN 14065 describes a management system for assuring the microbiological quality of processed linen used in specifically defined sectors in which it is necessary to control microbiological contamination. It describes a Risk Analysis and Biocontamination Control (RABC) system designed to enable linen processors to continuously assure the microbiological quality of the processed linen.

2.2 It applies to textiles processed in laundries and used in specific sectors such as pharmaceuticals, medical devices, food, healthcare and cosmetics, but excludes those aspects relating to worker safety and sterility of the final product.

2.3 As a prerequisite to implementing the standard, a linen processor should follow good manufacturing practices; BS EN 14065 will also dovetail with any existing BS EN ISO 9001-based quality management system.

2.4 BS EN 14065 requires that a formal system be established, implemented and maintained to assess and control risks that can affect the microbiological quality of the process and product. In this system, specific microbiological hazards need to be identified. The control measures and their effectiveness should be determined, analysed and documented.

2.5 The principles of an RABC system are:

- Principle 1. List of microbiological hazards and list of control measures:
 - (i) identification of the microbiological hazard(s) associated with each step of the process, with the product or with staff;
 - (ii) assessment and classification of levels of risk(s) of the microbiological contamination of textiles at each step of the process as a consequence of the hazard;
 - (iii) identification of control measures to eliminate or reduce the risk(s) of the microbiological contamination of textiles to reach the agreed microbiological quality for the end-use of the textiles.
- Principle 2. Determination of the control points: Determination of the points/steps/ environmental conditions that can be controlled (control points) to eliminate or reduce the risk(s).
- Principle 3. Target levels and limits – tolerances: Establishment of limits at each control point, which should not be exceeded in order to assure microbiological quality of textiles.
- Principle 4. Monitoring system: Establishment of scheduled testing or observation to monitor the control points.
- Principle 5. Corrective actions: Establishment of corrective actions to be taken when monitoring indicates that a particular point/procedure/operational step/ environmental condition is not under control.

- Principle 6. RABC system checking procedures: Establishment of procedures to verify that the system is working effectively.
- Principle 7. Documentation: Establishment and maintenance of appropriate documentation.

2.6 If correctly implemented, the BS EN 14065 standard builds on this foundation, providing users with an RABC approach to assure consistently effective disinfection of linen and

reliable protection thereafter from recontamination. The standard fully describes the RABC approach, but it cannot provide for every laundry/market variable and leaves specification of process and product performance to local jurisdictions and/or industries.

2.7 The Textile Services Association's 'Implementation of Risk Analysis and Biocontamination Control (RABC) in laundries' is a guide to implementing BS EN 14065.

3 BS EN 14065, Essential Quality Requirements (EQR) and Best Practice (BP)

3.1 There is no requirement in this HTM for linen processors to adopt BS EN 14065. However, those linen processors that do obtain independent certification of their BS EN 14065 system may consider this status to contribute to

Best Practice (BP) and to satisfy all Essential Quality Requirements of this HTM. See the 'Management and provision' volume of this HTM.

Certification to BS EN 14065

It is the practice in UK for compliance with British, European and International Standards to be certified by certifiers who have been accredited by the UK Accreditation Service (UKAS), recognised by government. Accreditation allows customers to identify and select, by informed choice, certifiers with proven competence in operating to quality management systems that successfully meet the requirements of international accreditation standards.

UKAS offers accreditation to laboratories, test houses, equipment and instrument calibration services and certification bodies, all of which are relevant to HTM 01-04.

It is an EU requirement that all member states recognise certifiers who have been accredited by their own national accreditation bodies. Consequently organisations are free to use any nationally accredited certifier from any member state. Examples of accredited organisations include BSI, SGS and Intertek (accredited by UKAS), and from Ireland, NSAI, which is accredited by the Irish National Accreditation Board (INAB).

Accredited certifiers receive accreditation for a specific schedule of standards for each of which an accreditation charge is made. As commercial organisations, certifiers cannot justify accreditation for standards which will not give a return on their investment. Currently in the UK the business generated by certification to BS EN 14065 is small and no accredited certifier includes it on its accreditation schedule. Nevertheless, it is still of great value to be certified by an accredited certifier because certification will still be administered via a quality management system audited to the same international accreditation standards.

4 Implementation of functional responsibilities

4.1 The 'Management and provision' volume contains a section detailing functional responsibilities for those involved in the provision of linen decontamination. However, it is written from the starting premise of public-sector organisations that operate dedicated laundries and not those who may only be responsible for commercial laundries in the private sector.

4.2 Although it is based on a structure that is in place in the NHS already, it has some equivalence with alternative functional structures in the private sector, which follow clause 6.1.2 of BS EN 14065 on the constitution of the RABC team.

4.3 Clause 6.1.2 of BS EN 14065 gives an equivalent list of personnel who should comprise the RABC team and fulfil the same responsibilities. Team members, in addition to their normal duties, have specific responsibilities within the laundry for decontamination/recontamination control:

- Laundry Unit Manager/Production Manager;
- Laundry Workshop Manager/Senior Engineer;
- representation from each department of the laundry – supervisors, senior operatives;
- representative of the hygiene department;
- representative of the cleaning and maintenance department;
- Quality Manager – for BS EN ISO 9000 and BS EN 14065;
- Qualified Microbiologist.

4.4 The following sections below provide further guidance on implementing the roles and show which of the BS EN 14065 roles are equivalent. The 'Management and provision' volume of this HTM should be referred to for the full definitions.

Executive Manager

4.5 The Executive Manager is defined as the person with ultimate management responsibility, including allocation of resources and the appointment of laundry staff.

4.6 Depending on the nature of the organisation, this role may be filled by the general manager, laundry manager or chief executive, or in BS EN 14065 terms, the Laundry Unit Manager.

NHS/Organisation Decontamination Lead

4.7 Every health and adult social care organisation should have a nominated Decontamination Lead with responsibility for decontamination. This person should either be at board level or have line management responsibility to a senior responsible person at that level.

4.8 There is no requirement for private-sector linen processors to have a Decontamination Lead although they should be aware of the role within their customer organisations and may benefit from identifying someone in the organisation who has responsibility for decontamination.

Designated Person

4.9 This role acts as the interface between the linen processor and support services, supplied internally or externally, and will include servicing, maintenance and testing. This is likely to be the maintenance manager of the laundry (Laundry Workshop Manager/Senior Engineer in BS EN 14065 terms). The role will form part of his/her usual engineering management duties.

User (Operator)

4.10 For this role, the terminology used in BS EN 14065 may be difficult to reconcile with that used in other organisations. The term User is used within other HTMs while industry will often refer to this as the laundry operator. If the term Operator is used in this context, the term Operatives should be used in place of Operator below.

4.11 Regardless of terminology, this 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 (Operatives) as defined below.

4.12 This role is likely to be fulfilled by the Laundry Unit Manager or Production Manager and be a member of an appropriate professional body with experience in the subject of laundry management (for example, Society of Hospital Linen Services & Laundry Managers (SHLS&LM), Textile Services Association (TSA), Guild of Cleaners & Launderers (GCL) etc).

NHS Director of Infection Prevention and Control, or Social Care Organisation Lead for Infection Prevention and Control

4.13 This role is not directly comparable with any role within a commercial private-sector linen processor, as the role is not required in a commercial laundry organisation. However, NHS customers of any healthcare linen

processor would have their own appointed lead and this person could liaise with the laundry.

Infection Control Practitioner

4.14 The Infection Control Practitioner is defined as a person designated by Management to be responsible for advising the User (Operator) on all infection control aspects in a healthcare organisation. Such a direct role within a commercial laundry does not exist; however, a similar role could be subcontracted as and when needed or be provided by one of the laundry's healthcare customers. Alternatively, the Qualified Microbiologist may fulfil this role for a commercial laundry, should their experience and training be appropriate.

The Microbiologist (Decontamination) or Qualified Microbiologist

4.15 The Microbiologist (Decontamination) is defined as a person designated by Management to be responsible for advising the User (Operator) on microbiological aspects of disinfecting linen and textiles. He/she should also be defined as the person responsible for advising the User on the microbiological aspects of disinfecting and recontamination of linen.

4.16 This could be a subcontracted role brought in as and when needed or, in the case of larger organisations, a full-time role. In BS EN 14065 terms, this person is known as the Qualified Microbiologist.

Operator/Operative

4.17 The Operator (Operative in BS EN 14065 terms) is defined as any person with the authority to operate a washer-extractor, continuous tunnel washer (CTW) and any other laundry equipment, including the noting of instrument readings and simple housekeeping duties.

References

BS EN 14065.

BS EN ISO 9001.

'Implementation of Risk Analysis and Biocontamination Control (RABC) in laundries'.
Textiles Services Association.

BS EN ISO 9000.