



Department
of Health

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

Engineering, equipment and validation

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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 – ‘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. New bullet point added to paragraph 4.28 on the provision of extract ventilation in continuous tunnel washers to reduce the risk of inhaling hazardous airborne particles.

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1 Introduction and overview of structure for quality inspectors

1.1 This volume details the engineering statutory and regulatory framework for those organisations that process healthcare and adult social care linen. It also contains guidance on incident reporting requirements for NHS organisations and additional good practice notes on design and pre-purchase of washers to be used for processing healthcare and adult social care linen.

1.2 This volume also contains detailed advice regarding validation for those linen processors not proceeding with independently certified adoption of BS EN 14065.

1.3 It is anticipated that those linen processors that do achieve independently certified adoption of BS EN 14065 will already have in place roles, procedures and validation routines that equate to or exceed those

detailed in Chapter 3, 'Incident reporting for NHS-operated laundries or laundries on NHS premises', Chapter 5, 'Functional engineering responsibilities advice for NHS-operated laundries' and Chapter 6, 'Validation and verification for those not adopting independently certified BS EN 14065 systems'. Therefore these sections will not apply in such cases. Those that do not pursue this form of certification should consider the adoption of this detailed guidance as part of their choice framework.

1.4 Additionally, Chapter 3 applies only to NHS (owned or operated) or adult social care organisations.

1.5 Further advice and support on healthcare engineering issues can be found from the Institute of Healthcare Engineering and Estates Management (IHEEM) Technology Platforms.

2 Regulatory framework

Summary for quality inspectors

This chapter outlines the statutory requirements applicable to engineering tasks placed on those operating processes or plant that process health and adult social care linen.

2.1 The chief areas of legislation regarding linen decontamination with which engineering staff should be familiar are health and safety and consumer protection.

Pressure Systems Safety Regulations 2000

2.2 If laundry premises include facilities for the sterilization of medical devices, the Pressure Systems Safety Regulations 2000 will also apply to the sterilizer installation.

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

2.3 The HSE publishes guidance notes on current exposure limits ('Workplace exposure limits').

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

2.5 Guidance on the precautions to be taken when handling microorganisms in a laboratory can be found in the following Health and Safety

Executive (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).
- 'Safe working and the prevention of infection in clinical laboratories and similar facilities' (2003) (compiled by the Health Services Advisory Committee).

2.6 They can be used to determine principles applying to the handling of microbiological hazards in the laundry.

Personal Protective Equipment at Work Regulations 1992 (as amended)

2.7 Managers should assess whether the risks associated with linen processing 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.

Electromagnetic Compatibility Regulations 2005 (as amended)

2.8 The Electromagnetic Compatibility Regulations (EMC) impose requirements concerning the electromagnetic compatibility of most types of electrical and electronic apparatus to be supplied or taken into service.

2.9 Laundry equipment (and any ancillary equipment) is “relevant apparatus” within the terms of the regulations and should meet

standards for emission of, and immunity to, electromagnetic disturbance. It is an offence not only to supply but also to “take into service” laundry equipment that does not conform to the regulations.

2.10 Detailed guidance on the application of the EMC regulations in healthcare premises can be found in Health Technical Memorandum 06-01 – ‘Electrical services and distribution’.

3 Incident reporting for NHS-operated laundries or laundries on NHS premises

Summary for quality inspectors

This chapter details the Department of Health's reporting system that applies to NHS-operated laundries or privately operated laundries on NHS premises.

Introduction

3.1 The general framework for the reporting of adverse incidents and defective equipment in the NHS in England is set out in the Department of Health's DH(2008)01 'Mandatory reporting of defects and failures and disseminating DH Estates and Facilities alerts'.

3.2 Management should designate, for each item of laundry equipment, a responsible person to act as liaison officer for the reporting of incidents.

3.3 The User should be familiar with standard regulatory and statutory reporting requirements; training may be required. Operators and others concerned with the operation of laundry equipment should know what action to take in the event of an incident or failure. The User should ensure that a sufficient supply of the correct reporting forms is available at all times.

For a definition of User and Operator roles, see 'Roles and responsibilities' in the 'Management and provision' volume of this HTM.

3.4 If a serious defect occurs, the item of laundry equipment responsible for disinfection should be withdrawn from service and should not be used until any necessary repairs have been made and a repeat validation (if required) has been carried out. If the defect involves a pressure vessel, an inspection by the Competent Person (Pressure Systems) is required.

Department of Health reporting procedures

3.5 Certain types of defect must be reported to the Department of Health. Reportable defects are those where some central action could be helpful in bringing about necessary improvements in the quality principles of safety, design, construction, performance reliability or economics.

3.6 Section 2 of the Department of Health's 'Mandatory reporting of defects and failures and disseminating DH Estates and Facilities alerts' states that "equipment in laundries, catering departments, workshops and any other plant or equipment used for maintenance or cleaning" falls within the remit of the DH Estates and Facilities reporting system.

3.7 A reportable defect and failure can be classed as:

- any event that gives rise to, or has the potential for, unexpected or unwanted

effects involving the safety of patients, staff or others;

- incidents that arise through incorrect use, inappropriate modifications or adjustments, and inadequate servicing and maintenance procedures;
- deficiencies in the technical performance or economic efficiency of equipment;
- any defects in product or product instructions identified by inspectors from the Health and Safety Executive (HSE) or by inspectors from a local authority;

- failures in critical services (electricity, water, steam, gas, communications etc).

3.8 A report is required for laundry equipment or plant concerning:

- any fatal accident or serious injury;
- RIDDOR incidents (for example equipment that has led to an accident);
- an explosion or sudden fracture of any pressure vessel, pressurised system or steam/high-pressure water main;
- any major electrical explosion (for example transformers or switchgear).

4 Design and pre-purchase considerations

Summary for quality inspectors

The purchase of a washer suitable for disinfecting healthcare linen is discussed together with process monitoring instrumentation necessary to repeatedly measure the parameters needed to produce safe, disinfected linen. Specific additional equipment needed for chemical disinfection and the safe use of those chemicals is discussed. A standard for the chemical and microbial quality of the rinse water used is recommended in addition to the parameters that define disinfection. Finally the chapter details the specific design/safety requirements for continuous tunnel washers (CTWs) processing infectious linen.

Classification of washer types

4.1 Washers may be classified by their construction and the manner in which the load is processed within the machine. This HTM classifies washers into two distinct types.

Washer-extractor

4.2 The washer-extractor is a traditional type of washer used in small healthcare laundries and as a specialist load machine in larger premises. These machines have a single chamber in which the full range of process stages are carried out. They are batch process machines in which all stages of the cycle are completed on the one chamber load before

another load can be processed in that chamber.

4.3 They usually have a single door through which both loading and unloading takes place although double-door machines are available.

Continuous tunnel washer

4.4 Sometimes referred to as continuous batch washers, continuous tunnel washers (CTWs) are specifically designed to handle high-volume heavy loads.

4.5 Loads move through the washer in one direction while water and chemicals are forced through in the other.

4.6 Linen moves through pockets of progressively cleaner water and fresher chemicals. Soiled linen goes into one end of the washer while clean linen moves out of the other. They are usually loaded via a hopper or chute.

Choice of equipment

4.7 When choosing equipment for the disinfection of healthcare linen, all washers should be checked:

- **prior to purchase** to ensure that they have the specified programming ability to meet the disinfection standards required in the 'Management and provision' volume of this HTM;
- **on commissioning** to ensure compliance with the required disinfection standards.

4.8 Consideration should be given to the range of items to be disinfected with specific regard to their heat, chemical compatibility and volumes. (See also the Textile Services Association's 'The Laundry Handbook', which offers advice on processes and design of the wash process.)

4.9 When selecting and operating equipment installed in healthcare organisations, the advice of the Director of Infection Prevention and Control (DIPC) or the Infection Control Practitioner should be sought.

4.10 Commercial-type, purpose-designed washers are preferable to domestic types.

Specification and contract

4.11 This HTM covers only the purchasing requirements of equipment used for the disinfection of healthcare linen, not the general purchasing requirements of laundry equipment.

General

4.12 CTWs should be designed in such a way that the machine and the load are not recontaminated by the simultaneous processing of other loads.

Instrumentation

4.13 All washers should be fitted with accurate heat sensors capable of controlling the disinfection stage to a level that ensures disinfection parameters are met. The sensing elements must be correctly placed to register the true wash temperature (that is, the temperature of the wash water in contact with the load).

4.14 Process-monitoring equipment and instruments should be fitted to the machine to allow monitoring of the key variables listed below:

a. For washer-extractors:

- (i) Programme identification (by relationship with defined cycle

parameters including quantity, type of washing, and detergents, bleaches and disinfectants used).

- (ii) Disinfection stage time.
- (iii) Disinfection temperature.
- (iv) Disinfection concentration via dosing (if chemical disinfectant used).
- (v) Load weight.
- (vi) Dip level.
- (vii) Liquor ratio.
- (viii) Alkalinity/pH.
- (ix) Water hardness.

b. For CTWs:

- (i) Programme identification (by relationship with defined cycle parameters including quantity, type of washing, detergents, bleached and disinfectants used).
- (ii) Cycle stage time (including soak time).
- (iii) Detergent tank alkalinity/pH.
- (iv) Disinfection temperature.
- (v) Disinfection concentration via dosing (if chemical disinfectant used).
- (vi) Load weight.
- (vii) Water hardness.
- (viii) Water flow rate.

Temperature-indicating systems

4.15 Temperature sensors should be either platinum-resistance types complying with Class B of IEC 60751 or thermocouples complying with one of the international tables specified in Tolerance Class 2 of IEC 60584-1 (or other systems of demonstrated equivalence).

4.16 The temperature-indicating system should:

- be either digital or analogue;

- be graduated in degrees Celsius;
- have a scale which includes the range 5°C to 99°C;
- have an accuracy of at least $\pm 2^\circ\text{C}$ over the scale range 10°C to 99°C;
- for analogue instruments, be graduated in divisions not greater than 1°C;
- for digital instruments, have a resolution of at least 1°C;
- have an ambient temperature error compensation not exceeding 0.08 K/K;
- have means to be adjusted in situ by the use of a special key, code or tool.

Note

It is unlikely that these performance requirements can be met by bi-metallic-type indicating thermometers.

Timing equipment

4.17 Process control timers should have an accuracy and repeatability at least an order of magnitude better than the time intervals that they are intended to measure.

4.18 Time indicators, including chart recorders, should:

- be graduated in seconds or minutes;
- have an accuracy of at least $\pm 2.5\%$;
- be adjustable in situ by means of a special key, code or tool.

Disinfection

Thermal disinfection

4.19 Thermal disinfection of the load should be deemed to have been achieved if, when tested as part of BS EN 14065 procedures or in accordance with this HTM, the specified minimum temperature for the specified minimum (holding) time is achieved on all items

that need to be disinfected. The temperature should be continuously maintained at or above 65°C for not less than ten minutes or 71°C for not less than three minutes.

Chemical disinfection

4.20 Chemical disinfection of the load should be deemed to have been achieved if, when tested in accordance with this HTM:

- all items have been exposed to the specified conditions of chemical disinfectant concentration and temperature for the required contact time; and
- any other parameters deemed necessary for achievement of disinfection as specified by the disinfection system supplier have been met.

4.21 The conditions of time, temperature and chemical disinfectant concentration should be those specified, under the conditions of use, by the disinfectant manufacturer. The entire process (including washing, dilution and disinfection) should be capable of passing the microbiological test specified within this HTM (see the 'Microbiological test for disinfection stage' section, which also specifies a test 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).

4.22 Any chemical disinfection system should, as part of its design qualification, have undergone type tests that prove:

- that adequate disinfection will occur with the levels of organic matter expected in a reasonable worst case within the load in those stages in which chemical disinfectant activity takes place;
- that adequate disinfection will occur at the pH levels of those stages in which chemical disinfectant activity takes place

Chemical disinfection additives

4.23 The User should obtain information from the washer manufacturer, the disinfection system supplier or the chemical supplier, as appropriate, for each specified chemical disinfectant, any requirements for safe handling, data on the maximum permitted residual level on items and the method of detection to be used for determining process residuals. The sampling method and analytical method specified should be capable of determining the presence of the chemical disinfectant at concentrations below that specified as potentially harmful, that is as the maximum acceptable level.

4.24 Where chemical disinfection methods are used, the following additional requirements apply to the chemical-disinfectant dosing system:

- Each system should be provided with means to adjust the volume admitted. Access to the means of adjustment should require the use of a special key, code or tool. The means of adjustment should be manual or automatic.
 - The stage(s) in the process cycle at which the chemical-disinfectant dosing system admits chemicals to the washer should be under the control of the automatic controller.
 - Each dosing system should be provided with means to determine, directly or indirectly, that the volume admitted and the time within the operational cycle when the admission occurred were as programmed in the automatic controller.
 - Failure to admit the specified minimum volume should cause a fault to be indicated before or at the end of the cycle. The washer manufacturer (or where appropriate, the disinfection system supplier) should specify the test method to be used to demonstrate compliance.
- The washer manufacturer (or where appropriate, the disinfection system supplier) should specify the accuracy and reproducibility of the control of volume admitted for the each of the chemical-disinfectant dosing systems provided. Compliance should be tested in accordance with this HTM or by a method of demonstrated equivalence specified by the washer manufacturer (or where appropriate, the disinfection system supplier).
 - It should be verified that the required minimum concentration of chemical disinfectant is maintained for the minimum required time at the minimum required temperature in each system in which the chemical disinfectant will be used. This does not necessarily mean the continuous monitoring of the concentration of the chemical disinfectant in the machine. It could be achieved by other indirect verified measurements or by monitoring other parameters that are validated to result in successful disinfection within the machine. The washer or disinfection system should either:
 - (i) be fitted with a means that will indicate when there is (are) insufficient chemical disinfectant(s) available for the next cycle or next stage of the cycle; or
 - (ii) incorporate a monitoring system that will abort the cycle and indicate a failure should there be insufficient chemical disinfectant delivered to satisfy the parameters for chemical disinfection required in this section.

Water quality

4.25 The chemical and microbial quality of the rinse water used after disinfection could have an adverse impact on the quality of the processed linen. However the levels of contamination having such an impact are

significantly different from those identified for washer-disinfectors used in the decontamination of surgical instruments. The specification for final rinse water quality during the disinfection stage should be equivalent to that suggested by the Textile Services Association (see below):

Criterion	Maximum value or range
Essential	
pH	6.5–8.0
Hardness (total Ca ²⁺ /Mg ²⁺)	30 ppm
Turbidity	10 NTU
Colour	No colour
Iron	0.1 ppm
Manganese	0.03 ppm
Copper	0.05 ppm
Surfactant	10 ppm
Bioburden (TVC)	No pathogens and ≤100 CFU/mL
Optional	
Total dissolved solids (TDS)	1200 ppm
Total alkalinity	250 ppm

Notes:

ppm = parts per million NTU = nephelometric turbidity units CFU = colony forming units TVC = total viable count

Source: Textile Services Association’s (2008) “Target specification for recycled water to meet final rinse quality”.

4.26 Where chemical disinfectants are used, care should be taken to ensure that the chemical quality of water as well as physical properties such as hardness do not affect the efficacy of the disinfectant.

Specific design/safety requirements for CTWs

4.27 As stated in the ‘Management and provision’ volume of this HTM, 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.

4.28 Any machine used for the processing of infectious linen needs the following safety measures adopted:

- Any vent pipes associated with machines processing infectious linen should be routed to a safe point of discharge outside the laundry 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 cross-infection. If the machine drains to an open sump or pit immediately below the machine drain valve, the sump or pit should be covered and sealed to reduce the risk of bacteria being spread by the aerosol effect when water is pumped from the machine.
- Validation of the ability of the CTW to process water-soluble bags if used to transport infectious linen must be undertaken.
- When using a CTW to process infectious linen in water soluble bags, consideration should be given to the location of any extract ventilation to ensure any aerosols generated in the loading hopper or first sections of the machine are effectively removed and do not provide a hazard to staff.

For further guidance on trade effluent and discharges to sewer, see DH’s ‘Safe management of healthcare waste’ guidance. Also see Water UK’s ‘[National guidance for healthcare waste water discharges](#)’.

5 Functional engineering responsibilities advice for NHS-operated laundries

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 training for engineering staff 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.

Context

5.1 The installation, maintenance, repair, calibration and testing of the disinfection aspects of washing equipment in NHS laundries is primarily an engineering function. The roles described in this HTM align with other critical engineering services (for example medical gases, high voltage/low voltage electrical systems, and fire safety) as outlined in Health Technical Memorandum 00 – ‘Policies and principles of healthcare engineering’ and provide a framework for future support to the NHS for those choosing to adopt it.

5.2 Roles discussed in this guidance are:

- Senior Operational Manager;
- Maintenance Engineer;
- Manufacturer;
- Contractor;

- Purchaser;
- Competent Person (Pressure Systems).

Senior Operational Manager

5.3 The Senior Operational Manager is technically, professionally and managerially responsible for the engineering aspects of laundry equipment.

Maintenance Engineer

5.4 The Maintenance Engineer is provided either in-house or under a service level agreement or contract, and is certified by the healthcare organisation, service agent or equipment manufacturer to be competent to service and/or test specified laundry equipment.

Manufacturer

5.5 The Manufacturer is defined as a person or organisation responsible for the manufacture of laundry equipment.

Contractor

5.6 The Contractor (or supplier) is defined as a person or organisation designated by Management to be responsible for the supply and installation of the washer, and for the conduct of the installation checks and tests. The Contractor (or supplier) may also be the manufacturer of the machine.

Purchaser

5.7 The Purchaser is defined as the person or organisation that orders the washer and is responsible for paying for it.

Competent Person (Pressure Systems)

5.8 This is a chartered engineer responsible for drawing up a written scheme of examination for the system.

5.9 The United Kingdom Accreditation Service (UKAS) maintains a list of inspection organisations accredited to BS EN ISO/IEC 17020 that can undertake the drawing up of a written scheme of examination.

Training

5.10 Staff at all levels should have a sound general knowledge of the principles, design and functions of the equipment used in the disinfection of linen. They should be trained on those types and models of equipment with which they are concerned. They should have some knowledge of the basic elements of microbiology in order to ensure personal safety and the safety of others. Training given to individuals should be recorded and reviewed regularly.

Notes

a. 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 HTM 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 Decontamination 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.

b. In HTM 01-01 Part A (see (a) above), the role of Competent Person (Decontamination) is discussed. All NHS-operated laundries will likely be providing engineering support and maintenance functions using either in-house or subcontracted Maintenance Engineers. However, equipment used in the disinfection of linen does not currently form part of the syllabus of training for Competent Person (Decontamination) and therefore at this current time there is no requirement within this volume to require technicians and craftsmen to be classified as Competent Persons (Decontamination). Hence the term Maintenance Engineer is used here.

In future, subject to the inclusion of appropriate training within the syllabus, it may be appropriate for quarterly and annual tests to be undertaken only by Competent Persons (Decontamination).

6 Validation and verification for those not adopting independently certified BS EN 14065 systems

Summary for quality inspectors

It is envisaged that those organisations adopting independently certified BS EN 14065 systems will already have in place appropriate validation and verification routines that satisfy the Essential Quality requirements (EQR) in this HTM. The procedures described in this section are therefore designed to provide a validation and verification regime that allows those not adopting BS EN 14065 to demonstrate an equivalent level of process assurance for the disinfection stage of the washing process. Furthermore, it may also be used by those who are adopting the European Standard as a set of tests to assist them in obtaining independent certification of their processes. The use of a validated process is recommended. This section also includes discussion on the role of works tests, type tests, installation tests, operational tests and performance qualification tests.

The use of portable test equipment is discussed together with sources of error and calibration. The measurement of temperature, liquid flow, volume and chemical use are included.

Commissioning tests (IQ and OQ) are tabulated in this section, but type and factory tests (although discussed) are not detailed, as the washer manufacturer will determine these. Each model may well have a different set of tests. The role of PQ tests is discussed. Also included is a suggested order for carrying out the tests and a table of periodic tests as a guide to which tests should be carried out and when.

Test equipment and materials

6.1 This chapter reviews the key items of portable test equipment necessary to carry out the test procedures described in this HTM so that the attainment of disinfection parameters is demonstrated for equipment used in the disinfection of linen. Specifications for instruments fitted permanently to laundry equipment are given in the relevant British, European and International Standards.

6.2 Instrumentation technology continues to advance rapidly, making it increasingly difficult and undesirable to provide detailed specifications for the equipment to be used in testing equipment. There is a clear trend towards computer-controlled data-loggers with software that enables the system to verify attainment of the required conditions and then to produce a detailed written report accompanied by tabulated or graphed data. Although these new systems may offer advantages in clarity of presentation as well as reduced operator time, traditional instruments such as chart recorders remain equally acceptable. Data-loggers and chart recorders should be equipped with memory devices that enable data to be retrieved at any later date.

6.3 The objectives of this section are both to ensure that traditional measurement methods are supported adequately and to define clearly the essential requirements that apply to the test equipment whether it be a traditional system or the latest technology.

6.4 As this HTM recommends using UKAS-laboratory-certified reference calibration equipment and supplies, accreditation and certification methods are not detailed.

Calibration and sources of error

6.5 Errors of measurement occur for a number of reasons. These include inherent factors such as the design of the measuring equipment, common problems with sensors (such as loose or imperfect connections), damaged insulation and broken conductors, combined with changes in the environmental temperature around the instrument.

6.6 Variations in the sensors themselves, the method of introducing the sensors into the machine and their location within the load may add to the error in temperature measurement. Changes in conditions other than the one being sensed may also lead to errors; for example, temperature fluctuations within pressure-sensing elements may lead to errors in pressure measurement.

6.7 Careful attention to detail including the location of the test instruments, effective maintenance and the skill of personnel trained in the application, handling and use of the instruments are required to eliminate or minimise these errors. Systematic errors can be reduced by careful calibration.

6.8 Instruments should be subject to a planned maintenance and calibration programme, at least annually, in accordance with the instrument manufacturer's recommendations. Each instrument should be labelled with a calibration date and a reference from which its current calibration status may be traced.

6.9 The calibration of all test instruments should be verified annually by using reference instruments with a valid certificate of calibration traceable to a national standard. The calibration should include a temperature within the disinfection temperature range used. A full history record, including all maintenance and

calibration details, should be kept for each instrument.

6.10 In use, all electronic test instruments should be located in a position protected from draughts and not subjected to rapid temperature variations.

6.11 Test instruments should be allowed a period of time to stabilise within the environment of the test site. The manufacturer's instructions should be followed.

Recorders

6.12 Test recorders may be required to measure temperature in many types of washer (if self-contained data-loggers are not used) and may also be required for the measurement of pressure, flow rates, humidity and other critical parameters. They should be designed for use with the appropriate sensors, independent of those fitted to the machine.

6.13 Four temperature channels are sufficient for all the tests in this guidance. Additional channels may be required for measuring pressure of the flow rate.

6.14 Analogue recorders should comply with the display requirements of BS 3693. Recorders using a potentiometric system should comply with BS 5164.

6.15 Digital recorders (data-loggers) have many advantages over traditional pen recorders. Data may be presented graphically, as a listing of numerical values or as a combination of both. In many cases, parts of the operating cycle can be expanded and replotted for closer examination.

6.16 Digital recorders should have the facility to record data immediately onto magnetic or optical media that can then be removed for secure storage. Alternatively, the recorder may be connected to a central computer and the data recorded to the hard drive. Software used with digital recorders should be developed and

validated under a recognised quality system (such as BS EN ISO 9001).

6.17 The detailed specification for a test recorder will depend upon the range of equipment with which it is to be used. The measurement system (recorder and sensors) should be capable of measuring cycle variables to an accuracy equal to, or greater than, the instruments fitted to the machine.

6.18 The accuracy with which a variable can be read from the recorder will be affected not only by the sources of error discussed above but also by the precision of the calibration, the scale range, the integration time, the sampling interval and the intrinsic accuracy of the recorder. Digital instruments might display measured values with a greater level of discrimination than the accuracy of the system as a whole: care needs to be taken with the configuration of outputs and the interpretation of the measured values.

6.19 The accuracies quoted by recorder manufacturers are measured under controlled reference conditions and do not include the errors from connected sensors. Temperature measurement errors due to ambient temperature changes should not exceed 0.04 K/K rise.

6.20 The scale ranges should include the expected maximum and minimum values of the cycle variables throughout the operating cycle, with sufficient leeway to accommodate any deviations resulting from a malfunctioning washer.

6.21 The most critical stage of the operating cycle is the disinfection period. During this period, the load becomes exposed to the disinfection conditions: the values of the cycle variables are at their most critical. The recorder should therefore be capable of measuring these values to sufficient accuracy to confirm that the disinfection conditions have been attained. The criteria are as follows:

- a. For digital recorders, the sampling interval should be short enough for the disinfection time to contain at least 72 independent measurements in each recording channel. For pen recorders, the chart speed should be fast enough to allow fluctuations on that scale to be clearly resolved. The duration of the disinfection time should be measurable to within 1%.
- b. The integration time of the recorder (the response time) should be short enough to enable the output to follow significant fluctuations in the cycle variables and to ensure that successive measurements are independent of each other. It should not be longer than the sampling interval.
- c. While there is no defined temperature band for the disinfection temperatures recommended within the 'Management and provision' volume of this HTM, the recorder must be accurate enough to demonstrate that the measured temperatures are above the minimum temperature required, especially where equipment is operating at the lower limits of the required temperature. For temperature measurements, the repeatability of the recorder should be ± 0.5 K or better, and the limit of error of the complete measurement system (including sensors) should be no more than 1.0°C when tested in an ambient temperature of $20 \pm 3^{\circ}\text{C}$.
- d. For pressure measurement, the limit of error should be no more than 1% of the absolute pressure.

6.22 A recorder chosen to meet these criteria for the disinfection period will have more than enough performance for the preceding and following stages of the operating cycle.

Temperature measurement

Temperature sensors

6.23 Temperature sensors should be used to sense the temperature in locations specified in the tests described in this HTM. The sensors should be either:

- platinum-resistance elements that comply with IEC 751 Class A; or
- thermocouples that comply with the relevant international table specified in IEC 584 Tolerance Class 1.

6.24 The environment (for example pressure, hot detergent solution etc) in which the temperature sensor is placed should not adversely affect its performance characteristics. To avoid undue disturbance of the system being measured, the major diameter of the temperature sensors and their connecting leads, which will be located within the machine, should not exceed 2 mm.

6.25 Before and after each series of tests on a washer, the temperature-recording system should be verified by comparison with an independent temperature reference source at the disinfection temperature. The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known within $\pm 0.1^\circ\text{C}$ and within the disinfection temperature band should not differ by more than 0.5°C after calibration.

Thermometric recording instrument(s)

6.26 One or more thermometric recording instruments should be used with the temperature sensors to record the temperatures measured in the locations given in the tests described in this HTM (see [paragraph 6.84, 'General test methods'](#)). They may also be used to verify the readings obtained from instruments fitted to the machine.

6.27 The recording instrument(s) should record the temperature from a minimum of three

temperature sensors. The channels may be multiplexed or independent of one another. The data-recording rate for each channel should not exceed 2.5 s. All data sampled should be used for the interpretation of results.

6.28 The scale range should include the expected maximum and minimum values of the cycle variables throughout the operating cycle with sufficient allowance for any deviations resulting from a malfunctioning machine. This should normally include at least the range 10°C to 110°C .

6.29 For analogue instruments, the minor mark interval should not exceed 1 K and the chart speed should be not less than 10 mm per minute. The resolution should be not less than 0.5 K. Digital instruments should register and record in increments of not more than 0.1 K.

6.30 The sensors may often be placed in positions where they are submerged for most of the cycle. Under these conditions, water may migrate along the wire between the cores and the outer insulation sheath. To prevent damage to the recorder, the outer sheath should either be punctured or stripped back a few centimetres from the end connected to the recorder to allow droplets of water to fall clear of the recorder.

6.31 If sensors are used to monitor the temperature of load items, they should be held securely in good thermal contact with the region to be monitored.

Self-contained systems

6.32 Thermometric recording instruments involving the use of leads from the sensing point within the machine to an external measuring instrument may be difficult or impractical to use within several designs of CTWs.

6.33 A number of different designs of small self-contained single-channel data-loggers for the measurement of temperature are commercially available. They are independently powered,

may be programmed to take readings at the required rate for the required duration and are downloaded onto a personal computer on completion of the data-logging period. Those housed in protective cases rated at IP68 are suitable for inclusion in washers. Care needs to be taken in selecting units capable of withstanding the high temperature that may be found during the disinfection stage of the cycle, since many of these devices are powered by batteries that will not withstand temperatures above approximately 75°C.

6.34 Data-loggers with an external probe may be housed in an insulated waterproof container through which the lead to the sensor passes by means of a leak-tight gland. A 25 mm thick layer of mineral wool insulation on all surfaces of a data-logger contained within a 1000 mL screw top polypropylene jar has proved suitable.

6.35 The accuracy obtainable from these units is rarely to the standard specified for conventional temperature recorders but the limit of error should not exceed $\pm 0.8^\circ\text{C}$ when tested over the range 0°C to 100°C at an ambient temperature of $20^\circ\text{C} \pm 3^\circ\text{C}$. The additional error due to changes in environmental temperature should not exceed 0.04 K/K. Instruments should register and record in increments of not more than 1 K.

6.36 The device should be capable of recording the sensed temperature at least every 2.5 s and should be capable of storing not less than 1800 records.

Pressure measurement

6.37 Pressure may be required to be measured over the range from atmospheric to 10 bar (for example for the water supply pressure). Differential pressure of 1–100 hectoPascals may be required to be measured (for example for the determination of the pressure drop across filters) for fault-finding purposes. The recorder for pressure measurement should have an overall limit of error no more than 1% of the maximum specified operating pressure.

Transducers

6.38 Transducers for use with pressure recorders should conform with BS 6447, be suitable for the purpose and be of an accuracy equal to, or better than, the gauges specified below. The natural frequency of the sensor and connected tubing should be not less than 10 Hz and the time constant for rising pressure (0–63%) should be not greater than 0.04 s.

Gauges

6.39 Pressure gauges may be required when the pressure recorder is unsuitable.

6.40 Pressure gauges should be temperature-compensated and, except for any differential pressure gauge, be Bourdon-tube gauges (conforming to BS EN 837-1) of nominal size 150 mm and accuracy class 0.25 (that is, the air should not exceed 0.25% of full scale deflection).

6.41 Gauges should be tested yearly by a recognised testing laboratory as described in BS EN 837-1.

Flow measurement

Water

6.42 The volume of water admitted to a particular stage of the cycle may be measured using a water meter complying with ISO 4064-1 Class A.

6.43 The meter should be designed to operate at temperatures up to 90°C with a supply pressure up to 16 bar. The meter should have a minimum scale division of 0.1 L or less and be designed to measure flow rates over the range 1 to 25 L/min. A single jet-turbine system is sufficiently accurate for the purpose. Other systems such as multi-jet turbine or semi-positive displacement systems complying with ISO 4064-1 (Class B or Class C) or BS EN 14154 may also be used.

6.44 The calibration of the meter should be verified by determining the indicated volume flowing to a collecting vessel and comparing

this with the collected volume determined by gravimetric or volumetric measurement.

Liquid chemical additives

6.45 The volume of liquid chemical additive used for each stage of the operating cycle may be measured using a flow meter. Flow sensors designed to monitor flows in the range 0 to 2 L/min are suitable for interfacing to a recorder or data-logger.

6.46 The sensor should be suitable for use with fluids having viscosity in the range 0.8 to 20 centistokes and should be calibrated for the viscosity of the fluid to be measured. The sensor should be designed to operate at temperatures up to 70°C with a supply pressure up to 10 bar.

6.47 The meter/recorder should have a minimum scale division of 10 mL or less and be designed to measure flow rates over the range 50 to 1500 mL/min.

6.48 The system should have an accuracy of $\pm 2.5\%$ of full scale deflection or better.

6.49 The calibration of the meter should be verified by determining the indicated volume flowing to a collecting vessel and comparing this with the collected volume determined by gravimetric or volumetric measurement.

Note

A meter of the rotating-vane type calibrated using water at 20°C as the flowing medium and then subsequently used to measure the flow of a detergent solution with a viscosity of 30 centistokes would have an error of 15 to 20% if no correction was applied.

Other instruments

6.50 Where chemical-disinfectant methods are used, the dose of the disinfectant and its dilution can substantially affect the efficacy of the process. In these cases, volume of water

and additives admitted may require validation to prove reproducible processes.

Volume measurement

6.51 The volume of chemical additives and the volume of water can be critical variables in the control of chemical disinfection.

6.52 The volume of any liquids used may be measured directly by collection in a graduated vessel of appropriate size. Alternatively, for liquids of known density, the volume may be determined by collection in an appropriate size vessel of known mass (empty), determination of the mass of the vessel and contents, calculation of the mass of the liquid and hence (by dividing this volume by the density) calculating the volume of liquid. For gaseous additives, the manufacturer of the disinfectant should specify a method for determining reproducibility of the volume admitted.

6.53 Whichever method is used, the accuracy should be such that the error is less than $\pm 2\%$.

6.54 Volumetric-measuring containers complying with BS 5898, ISO 384 are suitable.

Chemical additives

6.55 Many of the chemical additives used in linen processing and associated ancillary equipment (for example water treatment plant) are corrosive, toxic or hazardous and require special provision for their storage and use.

6.56 Some of the substances that may be used in washers, in particular those employing chemical disinfection, have workplace exposure limits (WEL) set out by the Health and Safety Executive. These limits are statutory maxima but should not be regarded as representing a safe working exposure. Employers have a legal obligation to ensure that exposure is reduced as far as reasonably practicable including during any validation procedures.

Testing of washers used in the laundry

6.57 There is no simple method to verify by inspection or test the efficacy of the disinfection process on each individual item of linen prior to use. In consequence:

- disinfection processes should be validated before use;
- the performance of the process should be monitored during routine use;
- the calibration of controls and instrumentation should be verified; and
- the equipment should be subjected to a suitable maintenance programme.

6.58 The control protocols recommended in this section provide the means for ensuring that the disinfection stage of the washer is fit for its intended purpose and includes tests and checks carried out after delivery, during validation and periodically thereafter. Tests are also recommended before a washer is returned to service:

- after repairs that affect one or more of those components that influence the attainment of critical disinfection-process control variables; or
- after modification.

Location	Production of washer		Responsibility
Factory	Type tests and works tests		Manufacturer
On site	Validation	Installation Operational	Manufacturer
		Performance qualification	User
		Periodic routine tests Annual revalidation tests	

Manufacturers' type tests and works tests

6.59 The manufacturer will carry out type tests on representative samples of washers in serial production to demonstrate compliance of the

design with its specification/ published standards (as appropriate).

6.60 The manufacturer may carry out works tests on each washer before it leaves the manufacturing site to ensure that it meets the specifications for some types of washers.

6.61 For washers in serial production, the programme of tests for the works test should be a reduced set of the tests in the schedule for type testing. For washers of one-off design, the schedule of works tests should be the same as the schedule for type testing.

6.62 Type tests, and more rarely works tests on one-off designs, may be carried out or witnessed by a third party to allow certification of the product to a relevant standard. The product certification scheme run by the British Standards Institution (BSI) leads to the award of the Kitemark for certified products. A similar scheme is operated through the European Committee for Standardization (CEN) for products conforming to European Standards, in which compliant products carry the CEN Keymark.

6.63 The manufacturer will normally make the results of type tests and works tests available to the purchaser on or before delivery of the washer if required.

Installation qualification

Checks on ancillary equipment

6.64 Ancillary equipment should, whenever practicable, be installed and commissioned before validation of the equipment begins.

6.65 The contractor for the equipment is not responsible for the correct functioning of services and ancillary equipment unless this was agreed in the purchase contract.

Engineering services

6.66 Checks should be made for the following services:

- a. Engineering services:
 - (i) should be installed correctly;
 - (ii) should be adequate to meet the demands of the equipment; and
 - (iii) should not leak.

All necessary isolating valves/switches and test points should be installed.

- b. Drains should remove effluent effectively when all plant (including equipment) is connected and operating.
- c. The water treatment plant (if fitted) should operate correctly, and the quality of water supplied for the disinfection stage of the process should be in accordance with the specification.
- d. The ventilation discharge system should be checked to ensure the duct is not blocked and the exhaust air is being discharged safely.

Additional checks for washers using a chemical disinfectant

6.67 Further tests to the ventilation and safety systems of laundry equipment using chemical disinfectants should be carried out where necessary or demonstrated by a suitable risk assessment because of the possible emission of toxic gases or vapours. For laundry equipment using a chemical disinfectant, the ventilation system within the loading (or unloading) area of the equipment, the plant room (if applicable) and the storage area for the chemical should meet the recommendations given. Particular attention should be paid to the following:

- a. The installation should meet the manufacturer’s specifications.
- b. Air flow should be from the operator towards the equipment, and air should not flow from the plant room (if applicable) or chemical storage area into the loading (or unloading) area.

- c. Exhaust systems should be non-recirculating and their discharges should conform to relevant safety regulations.

6.68 When the chemical disinfectant is intended to be discharged to drain, the drainage system should be trapped, sealed and vented to a safe position.

6.69 The drainage system should be checked to ensure that it is not possible for toxic materials to be vented into any other part of the laundry. The maximum permitted concentration and the method of detection and analysis will depend on the chemical being used.

Schedule of installation and operational tests

6.70 It is the responsibility of the User to ensure that the following tests are undertaken (click the links in the table).

Installation tests – undertaken by the Contractor
1. Automatic control test of disinfection stage
2. Verification of calibration of washer instruments
Operational tests – undertaken by the Contractor
1. Safety checks required by manufacturer
2. Automatic control test of disinfection stage
3. Verification of calibration of washer instruments
4. Chemical vapour emission (where chemical disinfection is used)
5. Chemical additive dosing tests (where chemical disinfection is used): <ul style="list-style-type: none"> a. Disinfectant chemical additive – reproducibility of volume admitted b. Indication of insufficient chemical additives – low level detection
6. Thermometric test for disinfection stage (where thermal disinfection is used)
7. Microbiological test for disinfection stage (where chemical disinfection is used)

Performance qualification tests

6.71 Performance qualification (PQ) is the procedure for obtaining documented evidence that the washer, as commissioned, will produce disinfected linen of the standard required when

operated in accordance with the operational instructions for a particular load type.

6.72 PQ tests are performed as part of the initial validation procedure, as part of any repeat validation procedure and whenever the User judges that new loading or operating conditions require a new PQ test.

6.73 Circumstances that may lead to new PQ tests would include changes to the chemical additives used in the disinfection process, changes to the loading system or the requirement to process a new type of material.

6.74 PQ tests are most likely to be performed on chemical disinfection processes where the effectiveness of the process is sensitive to the interaction of the chemical disinfectant and materials being processed.

6.75 Performance qualification should not be undertaken on any washer until the requirements of the installation and operational tests have been met. The PQ tests for disinfection performance will be the same as that detailed in paragraph 6.119, 'Microbiological test for disinfection stage', but for a particular load type.

Schedule of periodic tests

6.76 Periodic tests are carried out at quarterly and yearly intervals. They are the responsibility of the User. The yearly test schedule is identical to that required for revalidation. It contains the tests recommended for recommissioning and for requalification of the disinfection performance of the equipment.

6.77 Tests should only be undertaken after completion of the planned maintenance tasks recommended by the manufacturer/supplier.

6.78 Maintenance Engineers, Users and Operators (when delegated) should receive the appropriate training before carrying out any of these tests. This training should be documented on personal training records.

6.79 In future editions of this volume, subject to the inclusion of appropriate training within the syllabus, it may be appropriate for quarterly and annual tests to be undertaken only by Competent Persons (Decontamination).

6.80 Unless otherwise specified, the tests should be carried out with the machine at normal working temperature.

6.81 The results of periodic tests should be filed securely (for example in the plant history file).

Periodic test schedule

6.82 Please click on links in the table below.

Monthly tests (User or Operator):
1. Automatic control test of disinfection stage
2. <i>Bacillus cereus</i> test (for CTWs, typically only during June to September inclusive as highlighted by the customer)
Quarterly tests (Maintenance Engineer):
1. Weekly safety checks
2. Automatic control test of disinfection stage
3. Verification of calibration of washer instruments
4. Chemical vapour emission (where chemical disinfection is used)
5. Chemical additive dosing tests (where chemical disinfection is used)
6. <i>Bacillus cereus</i> test (for CTWs, typically only during June to September inclusive as highlighted by the customer)
Yearly and re-validation tests (Maintenance Engineer):
1. Weekly safety checks
2. Automatic control test of disinfection stage
3. Verification of calibration of washer instruments
4. Chemical vapour emission (where chemical disinfection is used)
5. Chemical additive dosing tests (where chemical disinfection is used):
a. Disinfectant chemical additive – reproducibility of volume admitted
b. Indication of insufficient chemical additives – low level detection
6. Thermometric test for disinfection stage (where thermal disinfection is used)
7. Microbiological test for disinfection stage (where chemical disinfection is used)
8. <i>Bacillus cereus</i> test (for CTWs, only during June to September inclusive as highlighted by the customer)

Validation and process monitoring

6.83 A programme of process monitoring of key variables is recommended for those laundries that process infectious healthcare linen. The key variables identified in paragraph 4.13, 'Instrumentation' should form the minimum data set for any process-monitoring batch-recording system. The series of validation and periodic tests identified within this section should be used to form the basis of a monitoring and control point system similar to that advocated in BS EN 14065 for biocontamination control. The adoption of an independently certified BS EN 14065 system would demonstrate compliance with the relevant aspects of this HTM.

General test methods

Automatic control test of disinfection stage

Introduction

6.84 The automatic control test is designed to show that the operating cycle functions correctly as shown by the values of the cycle variables indicated and recorded by the instruments fitted to the washer.

6.85 It should be carried out monthly on most machines and is the main test for ensuring that the equipment continues to function correctly.

6.86 During the commissioning, quarterly and yearly test programmes, the temperature sensors for subsequent thermometric tests will be connected to the machine during this test. If a sensor is placed adjacent to each of the sensors connected to the installed temperature measuring instruments, the calibration of these instruments can be checked during periods of stable temperature in the automatic control test.

Method

6.87 Load the washer with a standard production load. In the case of a CTW, ensure that the measurements are taken as and when

a typical load is progressing through the disinfection stage.

6.88 Start the cycle.

6.89 Ensure that a process record is made by any recording instrument fitted to the machine. If the machine does not have a recorder, observe and note the elapsed time, indicated washer disinfection temperatures and pressures at all significant points of the disinfection stage (for example the beginning and ending of the stage, and the maximum values during the holding time).

6.90 At the approximate mid-point of the disinfection stage, record the elapsed time and the indicated temperature.

Results

6.91 The test should be considered satisfactory if the following recommendations are followed:

- a. A visual display indicates "cycle complete" in the case of a washer-extractor.
- b. During the whole of the disinfection stage, the values of the cycle variables (as indicated by the instruments on the washer and any independent monitor or as shown on the process record) are within the limits established as giving satisfactory results either by the manufacturer or during operational qualification.
- c. For machines using thermal disinfection, during the disinfection hold period determined from the indicated and/or recorded chamber temperature:
 - (i) the indicated, recorded and any independent monitor chamber temperatures are above the disinfection temperature detailed in 'Disinfection by heat' under 'Disinfection of linen' in the 'Management and provision' volume of this HTM;

- (ii) the time for which the disinfection temperature is maintained is not less than that detailed in 'Chemical disinfection including chemo-thermal processes' under 'Disinfection of linen' in the 'Management and provision' volume of this HTM for the appropriate band used above.
- d. The person conducting the test does not observe any mechanical or other anomaly.

Verification of calibration of washer instruments

6.92 Calibration of the washer instruments used to measure the physical parameters of the disinfection stage (indicated value) should be verified by comparison with calibrated test instruments (recorded value) (compliant with the guidance given in Chapter 4, 'Design and pre-purchase considerations') during steady-state conditions (for example the temperature during the disinfection hold period).

6.93 For thermal disinfection methods, this should include the instruments used to control and measure the temperature of the water within the machine during any disinfection stages, areas or chambers.

6.94 For chemical disinfection methods, the washer manufacturer or disinfection system supplier should state the parameters used to control the effectiveness of the chemical disinfectant. The test should include comparisons of the instruments used to control those parameters (for example temperature, humidity and/or pressure).

Results

6.95 For thermal disinfection, the indicated and recorded temperatures are within 2°C of the calibrated test instrument.

6.96 For chemical disinfection, the results should be within the tolerances stated as acceptable by either the washer manufacturer or the disinfection system supplier (as appropriate).

6.97 This may be carried out concurrently with other testing, for example during the automatic control test.

Chemical additive dosing tests (where chemical disinfection is used)

Disinfectant chemical additive – reproducibility of volume admitted

Introduction

6.98 This test is intended to verify the setting for any dispensed disinfectant additive(s) and to ensure that it is reproducible within defined limits. The test should be carried out for each disinfectant dosing system on the washer.

Apparatus and method

6.99 The washer manufacturer or disinfection system supplier should specify the method of determining the reproducibility of the dosing system.

6.100 If this is not possible (such as in the case of some ozone disinfectant systems), they should supply a method of validating any disinfectant activity monitoring system so that the User can be assured that the system has achieved a successful outcome via its parametric monitoring and control system.

6.101 Furthermore, such systems should incorporate a monitoring system that will abort the cycle and indicate a failure should there be insufficient disinfectant delivered to satisfy the parameters for chemical disinfection (see paragraph 4.20, 'Chemical disinfection'). A method should also be provided for testing the reproducibility of such systems.

Indication of insufficient chemical additives – low level detection

Introduction

6.102 The correct volume of chemical disinfectant additive(s) for the correct functioning of the washer disinfection stage should be used. The washer should be equipped with means to either:

- ensure that a cycle is not initiated when there is insufficient chemical additive remaining in the reservoir to complete a cycle; or
- incorporate a monitoring system that will abort the cycle and indicate a failure should there be insufficient disinfectant delivered to satisfy the parameters for chemical disinfection required in the 'Management and provision' volume of this HTM.

6.103 For those systems incorporating low level detection: the test should be carried out for each chemical disinfectant dosing system on the washer.

Method

6.104 Place a low level of additives in the dispenser reservoir and run repeated cycles.

6.105 Fill an otherwise empty container with sufficient chemical for more than two, but less than four, operational cycles. Run the washer on three consecutive cycles. Estimate the volume remaining at the end of each cycle (pre-marked container, dipstick, or weight).

Results

6.106 The washer should indicate at the beginning of the third or fourth cycle that there is insufficient chemical remaining to complete a cycle.

6.107 For those systems incorporating in-process monitoring: the washer manufacturer or disinfection system supplier should specify the method of validating the disinfectant activity monitoring system so that the User can be assured that the system has achieved a successful outcome via its parametric monitoring and control system. This should include as a minimum a method of demonstrating a failure arising from insufficient disinfectant being delivered.

Chemical vapour emission (where chemical disinfection is used)

Introduction

6.108 When a washer employs chemical additives for which there are workplace exposure limits (usually disinfectants) under the COSHH Regulations, it should be determined that the emissions from the machine do not cause personal exposure to exceed the legal limits.

6.109 The method of sampling for airborne emissions and the method of analysis or detection will be specific to the chemical additive(s) being used. Advice should be sought from the washer manufacturer, the supplier of the chemical additive(s) and/ or the HSE in order to determine an appropriate test method.

Results

6.110 Emissions from the washer during normal operation and maintenance, including when opening an extractor type at the end of the cycle or when changing or refilling chemical additive reservoirs, should not expose personnel to concentrations in excess of the legal maxima.

Thermometric test for disinfection stage (where thermal disinfection is used)

Introduction

6.111 Thermometric tests should be used for thermal disinfection and chemical disinfection processes where temperature is a critical parameter.

6.112 Temperature monitoring of the load should be used to determine the attainment of the required time–temperature conditions.

6.113 The load under test will consist of a standard production load of discrete items of the type that the washer under test is intended to process.

Apparatus

6.114 The following equipment should be used:

- a. temperature recorder (see paragraph 6.23, 'Temperature measurement'); and
- b. self-contained data-loggers (see paragraph 6.23, 'Temperature measurement').

6.115 For washer-extractors, it may be easier to use a temperature recorder and two data-loggers, but CTWs may require the use of four self-contained data-loggers. A combination of four temperature channels or data-loggers is required.

6.116 Place temperature sensors in the following positions in compartments or chambers where disinfection occurs:

- two placed within the load (data-loggers);
- one adjacent to the automatic control temperature sensor;
- one adjacent to the process recorder sensor (if fitted) in each chamber or compartment.

6.117 The sensors should be in good thermal contact with the item or installed sensor that they are monitoring.

Results

6.118 The test should be considered satisfactory if the following recommendations are followed:

- a. the recommendations of the automatic control test are followed;
- b. during the holding time, the measured temperatures are within the disinfection temperature band recommended for the operating cycle as detailed in 'Disinfection of linen' (in the 'Management and provision' volume of this HTM);

c. the indicated and recorded chamber temperatures are within 2°C of the temperature measured at the automatic control sensor;

d. at the end of the cycle, the temperature sensors have remained in position.

Microbiological test for disinfection stage (where chemical disinfection is used)

Introduction

6.119 This test is intended to demonstrate that the disinfection performance required in paragraph 4.21, 'Chemical disinfection' is achieved.

Test method

6.120 A suitable test using sterile swatches and the recovery method described in BS EN ISO 14698-1 Annex E should be conducted with a full load made up of a normal production load received in the laundry and the test pieces.

6.121 The pieces made from a desized textile should be representative of the textiles that undergo the laundering process to be validated. They should be used only once. The pieces should have an overall size of 10 cm by 5 cm and free end(s) used to attach them to a textile load. Before use, the pieces should be sterilized using a validated sterilization process.

6.122 The sterile swatches should be recovered immediately after the completion of the CTW or WE process (which may include pressing in the case of CTWs and spinning in the case of WEs) and before commencement of the drying process. Recovery and transport procedures should be used that do not introduce contamination. The recovery method is detailed in BS EN ISO 14698-1 Annex E.

Test result

6.123 No bacteria are recovered from the swatches.

Additional test to demonstrate Best Practice

6.124 Semi-permeable dose strips containing a heat-resistant vegetative bacterium such as *Enterococcus hirae*, *Enterococcus faecium* or *Enterococcus faecalis* at levels of at least 5 log₁₀ viable organisms per strip should be processed in the washer with a full load made up of a normal production load received in the laundry. A control strip that has not been processed in the washer should also be evaluated for comparison.

6.125 The process should result in at least a 5 log₁₀ reduction in the number of viable organisms per strip and thereby demonstrate a disinfection efficacy of at least that of thermal disinfection when the dose strips are recovered using a general purpose non-selective recovery medium.

Note

There is currently no definitive published test method for measuring the performance of chemical disinfectants on healthcare linen during laundering. The test methods described here are adapted from BS EN ISO 14698-1 Annex E. This international standard relates to a standard linen process. In the absence of any other published tests, the modified test described above should be used. The Department of Health is considering the continuing suitability of this test or alternative tests.

Bacillus cereus testing

Introduction

6.126 The following test can be applied to linen that will be provided to high-risk units in acute healthcare and which is processed by CTWs in accordance with agreed local policy.

6.127 Links have been shown between clean linen that has high levels of contamination with *Bacillus* species spores (particularly *Bacillus cereus*) and surgical wound infection and colonisation of special care babies.

6.128 This contamination is thought to result from replicating *Bacillus* species to high numbers on soiled linen and the incomplete removal of these heat-resistant bacterial spores by water-economic processes such as CTWs. The higher the ambient temperature of soiled linen storage, the greater the bacterial numbers. Problems result during prolonged periods of hot weather over a number of wash cycles. It is not associated with contamination of the washers themselves. Because of the mixing of process water between compartments during CTW processing, all linen processed is likely to be equally contaminated.

Test methods

6.129 This HTM does not prescribe a particular method for sampling of all *Bacillus* species on processed linens, but allows each healthcare linen processor to document its own method for doing so with a validated efficiency and sensitivity, such that the total numbers of *Bacillus* spores on processed items can be determined.

6.130 The linen processor should identify an action point (in conjunction with a risk assessment) that will trigger a notice to all its customers and will thereby alert them to increase vigilance and introduce any necessary protective measures.

6.131 Actions to reduce the contamination on processed linens should be initiated at a trigger level below this customer-notice alert level. It is recommended that an increase in the dilution during the wash process should be considered as a control measure. Sporicidal biocides should only be considered if they have been shown to be effective at the concentrations achieved in the wash process, and at the temperatures and contact times that would occur.

6.132 The sampling should be undertaken regularly during the months June to September, with an increased frequency during higher ambient temperatures.

References

- Health Technical Memorandum 00 – ‘Policies and principles of healthcare engineering’.
- Health Technical Memorandum 06-01 – ‘Electrical services and distribution’.
- Health Technical Memorandum 07-01 – ‘Safe management of healthcare waste’.
- BS EN 14065.
- IHEEM Technology Platforms.
- Pressure Systems Safety Regulations.
- Workplace exposure limits. Health and Safety Executive.
- COSHH Regulations.
- The management, design and operation of microbiological containment laboratories. Health and Safety Executive.
- Biological agents: managing the risks in the laboratory and healthcare premises. Health and Safety Executive.
- The approved list of biological agents. Health and Safety Executive.
- Safe working and the prevention of infection in clinical laboratories and similar facilities. Health and Safety Executive.
- Personal Protective Equipment at Work Regulations.
- EMC Regulations.
- [DH/2015/001 ‘Mandatory reporting of defects and failures and disseminating DH Estates and Facilities alerts’.](#)
- ‘The Laundry Handbook’. Textile Services Association.
- IEC 60751.
- IEC 60584-1.
- “Target specification for recycled water to meet final rinse quality”. Textile Services Association, 2008.
- United Kingdom Accreditation Service (UKAS).
- BS EN ISO/IEC 17020.
- BS 3693.
- BS 5164.
- BS EN ISO 9001.
- BS 6447.
- BS EN 837-1.
- BS EN ISO 4064.
- ISO 384.
- BS EN ISO 14698-1.