TSA GUIDANCE

Interim Healthcare Laundry Certification / Response to COVID-19

Inc. Appendix on Isolation Gown Processing

JULY 2020

INTRODUCTION

The TSA has previously issued guidance on re-starting laundries in the context of Covid-19. This document focuses on scenarios whereby customers need new or improved services, particularly for healthcare. Consequently, commercial laundries need to provide these services effectively, providing the assurance the market needs and proving compliance with regulations, national/international standards and best practices as they apply.

The Department of Health's Health Technical Memorandum (HTM 01-04: Decontamination of Linen for Health and Social Care provides a clear path for commercial laundries to prove they consistently decontaminate healthcare linen and manage related risks to patient safety.

Healthcare linen is clearly defined in HTM 01-04 to include a wide range of textile products, including bedding, towels, patient clothing, professional uniforms, mops etc. and can include PPE (e.g. isolation gowns) and medical devices (e.g. OR drapes and gowns). Appendix A to this document details additional laundry specifications for isolation gowns.

Healthcare linen compliance to HTM 01-04 is assured where laundries achieve certification to BS EN 14065. This standard specifies an approach to managing bio-contamination risks and consistently providing fit for purpose textiles with sufficient microbiological quality.

BS EN 14065 does not, however, specify controls or performance measures for laundries. In this context, where laundries are entering the healthcare market now or need to validate or change their operating standards in the context of Covid-19, this "TSA Laundry Operation Guidelines" provides a detailed and practical set of recommendations, enabling laundries to make clear, appropriate, timely and cost effective decisions. Laundries should be able to use this guidance to assure their current services are appropriate and to direct any changes where needed.

These Operation Guidelines also serve to provide a bridge for laundries to qualify to provide Healthcare linen services on a provisional basis through the Covid-19 crisis and on to certification to BS EN 14065 where healthcare linen service is a long-term prospect.

This guidance was drafted in consultation with NHS England and Improvement. All commercial laundries that submit an expression of interest to provide laundry services to the NHS must first confirm that they operate laundry standards which conform to HTM 01-04. This certification scheme will ensure you meet those essential requirements.

This document has also been reviewed by the Cabinet Office and forms part of their healthcare guidance of maintaining a resilient high-quality laundry supply to the healthcare sector during covid-19 outbreak. It also acknowledged as an essential element to the Government's drive to inject reusable products as opposed to single use.

Queries relating specifically to the provision of services to the NHS or on HTM 01-04 can be directed to nhsi.estatesandfacilities@nhs.net.

The following classifications of laundry processing standards should be noted as current market positions and this guide purely focuses on point 3 below:

1. Sterile, surgical supplies, fully certified to BS EN 13485
2. Non-Sterile, fully certified to BS EN 14065
3. Essential compliance to HTM 01-04, as a response to Covid-19

HOW TO USE THIS GUIDANCE

Laundries are not obliged to follow this guidance and can go straight to BS EN 14065 certification if they choose. The TSA have issued guidance (TSA Guidance Document Implementing BS EN 14065) on this, which can be found on the TSA website**.** However, where a laundry does not yet have BS EN 14065 certification, the TSA recommends:

- Inform the TSA of an 'expression of interest' with an anticipated timeline.
- Implement the guidance as detailed in this document.
- Develop a Risk Analysis and Biocontamination Control (RABC) plan as part of your Quality Management System
- Implement and document your RABC plan. If required, the TSA can support this process with their supply partner consultants (list can be found in Appendix F) to guide the laundries through the implementation process.
- When the business is ready to be assessed, inform the TSA who will arrange for a UKAS independent auditor to conduct the assessment.
- The auditor will confirm the qualification to the outlined requirements in this guidance. The first phase will be desktop based followed by an onsite audit.
- The auditor will issue a status report with a gap analysis along with improvement recommendations if needed.
- When the audit is satisfactory, you will be included within the TSA approved directory.
- NHSI will conduct semi-annual review of the overall scheme. Any amendments to the interim certification potentially including withdrawal, will be subject to a minimum 3-month notice period.
- If the scheme runs for more than 18 months, there will be a requirement for a reassessment.
- Where you expect to continue processing healthcare linen/gowns, you should continue to develop your RABC plan and secure certification to BS EN 14065 as soon as possible.

NB. BS EN 14065 certification is the only proven route to compliance for commercial laundries providing Healthcare linen in the UK.

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GUIDANCE FOR PROCESSING HEALTHCARE LINEN
(HTM 01-04 and BS EN 14065)

Both HTM 01-04 and BS EN 14065 focus on patient safety, via clean & safe textiles. HTM 01-04 comprises several volumes. For commercial laundry compliance purposes, a combination of the following elements was used to draft this guide:

- HTM 01-04 Management and Provision
- HTM 01-04 Equipment and validation
- Essential elements of BS EN 14065

GENERAL

As detailed earlier, this guide is dealing with essential compliance to HTM 01-04, as part of the response to Covid-19.

The above requires a competent RABC plan that includes three core elements:

- General Prerequisites: relating to general practices throughout the business and the laundry facility
- 7 RABC principles: applied to ensure more detailed and demanding controls and measures are effective for the most critical process steps, where textiles are decontaminated and disinfected
- Operational Prerequisites: additional measures required to protect textiles after disinfection and before packaging is completed

The guidance below provides practical, detailed recommendations for individual RABC controls and measures, under those 3 headings. This document also provides guidance on laundry staff health and safety measures, as advised by HTM 01-04 referenced in Appendix B

of this guidance. For isolation gowns, Appendix A provides additional recommendations.

GENERAL PREREQUISITES - MEASURES REQUIRED THROUGHOUT THE FACILITY AND PROCESSING

To develop a competent and comprehensive set of general prerequisites, you will need to apply the following prerequisites and preliminary actions.

Project uncertainty cannot be eliminated as there may not be absolute standards applicable or there may be uncertainty about the best measures to employ to achieve the appropriate standards. However, this section sets out to guide RABC implementation decisions. Research by the RABC team and reference to individual customers or sectors may also be necessary or advisable to support choices made for individual RABC plans.

Prerequisites and Preliminary Actions

FUNCTION	RECOMMENDATIONS
Management commitment	A director (or equivalent) should take personal and documented responsibility for the RABC plan.
RABC team	Train at least 2 members of the core RABC team in HACCP or RABC or Infection Prevention RABC-trained staff should be on the premises through the plant core hours (e.g. the day shift).
Prerequisites	Significant changes may be required to enable consistent product safety, e.g. to facilities, cleaning, packaging.
Laundry diagram **(or Maps)**	Consider and map separately by product category/ market sector. Completed maps should account for each significant variation in processing. Good, clear maps, specific to product and use and production line can greatly improve and simplify a RABC plan and its documentation.
Specification	The laundry process (wash and dry steps in particular) should be chosen and designed based on the temporary requirements of the healthcare linen and gowns.
Training	Laundry and distribution staff should be trained in Basic Hygiene and/or Good Manufacturing Practice. The level of training should reflect the type of work being done and the goods being handled.
Purchasing	This relates mainly to textiles, washing supplies (detergents etc.) and packaging materials.

PLANT, FACILITIES AND PROCESSING

This guidance does not cover Government guidance on Covid-19 secure operation. Refer to TSA Guidance on Re-opening a Hospitality Laundry During the Covid-19 Pandemic/ Level 1.

Before full operational implementation, make sure your plants are able to deliver the following prerequisites:

- Assess full laundry facility and equipment for state of maintenance, integrity, capability to maintain controls detailed herein. Replace, upgrade or repair as appropriate. Appendix C (HTM 01-04 Design & pre-purchase considerations) provide guidance on equipment capability considerations.
- Employ preventative maintenance plans for all processing and measurement equipment.
- Calibrate all measurement equipment.
- Map the flows of rinse, wash and re-use waters through the plant. Ensure only potable water is used for rinsing textiles. Ensure water from infectious or other high-risk classifications is not re-used.
- Control air and splash borne contamination from the wash process. E.g. vent to outside the plant and shield drains.
- Map the flows of air through the plant. Avoid flow from soiled to clean. Provide adequate ventilation for all work areas.
- Provide functional separation of soiled and clean processing areas. E.g. Barrier washing, sealed work zones, air pressure gradients.

- Controlling transfers is particularly crucial where segregation is limited. E.g. staff, container and wash equipment surfaces where barrier washing is not in place. Implement detailed SOPs and frequent disinfection regimes (at least daily).
- Separate containers and transfer systems (e.g. conveyors) for clean and soiled textiles. Where a container used for soiled is to be re-used with clean goods, disinfect it every time.
- Ensure textiles, materials and equipment cannot leave the soiled area and enter the clean work area unless they first undergo thorough cleaning and sanitising as appropriate.
- Ensure staff entry and exit points are managed, equipped with hand washing and donning and doffing facilities for relevant PPE.
- Segregate soiled and clean goods at all stages.
- Segregate healthcare from non-healthcare soiled linen.
- Clearly classify returns from customer into “soiled” and “infectious” linen.
- Ensure Infectious Linen practices as in Appendix B are in place and effective at all times.
- Store returned products in dry conditions.
- Operate wash equipment disinfection schedules, e.g. 1 per 24 hours on a continuous tunnel washer.
- Avoid overnight holding of soiled goods where practical.
- Avoid overnight holding of used waters in wash equipment.

COLLECTION & DELIVERY

- Segregate soiled and clean goods at all times. Ensure soiled goods are enclosed to the point of sorting in the plant, e.g. in sealed containers or cages, cage hoods, barriers in vehicles
- Train drivers thoroughly in hygiene practices.
- Issue appropriate PPE to all drivers depending on risk assessments.
- To implement best controls, limit contact between staff, vehicles and soiled goods.
- Regularly sanitise the interior of delivery vehicle cargo areas, with particular attention to doors (inside and out) and inner walls.

STAFF-FOCUSED MEASURES

- Provide separate access to soiled and clean work zones for people.
- Ensure all staff wash hands on leaving soiled work areas and before entering clean work areas.
- Ensure all staff use dedicated outerwear when in the soiled area and remove it on leaving that area.
- Ensure all staff use dedicated hygienically clean outerwear when in the clean area.
- Locate toilet facilities outside production zones, beyond hand wash and clothing stations.
- Keep food and drinks away from production areas. Provision of drinking water is possible, subject to risk analysis.

CLEANING

- Document all cleaning plans, detailing priority, frequency, methods, materials, equipment, cleanliness standards and how to measure effectiveness of cleaning.
- Train cleaning staff in hygiene principles and appropriate cleaning techniques.
- Cleaning should always be most critical areas first, High to Low, Back to front of surface.
- Cleaning priorities – surfaces in contact with textiles and immediate environments.
- Cleaning throughout – methods, materials, equipment etc.
- Use separate cleaning equipment and materials for clean and soiled work areas.

PURCHASING

- Control your purchases of materials, particularly those in direct contact with textiles during or after laundering.
- Washing materials should be bought to documented specification, particularly with regard to concentration of active agents. Ensure disinfectants comply with Biocide regulations.
- Ensure washing materials are used before degradation affects ability to disinfect or clean textiles (e.g. Hypochlorite bleach)
- Ensure primary packaging (directly in contact with processed textiles) is disinfected or supplied to “food grade” or equivalent level of cleanliness.
- Store these materials so as to prevent contamination before use with processed textiles.

OTHER PREREQUISITES

- Operate a fixed schedule of sampling key surfaces/materials for biocontamination, using swabs, contact media and/or active sampling as appropriate. Focus mainly in finishing zones, but also on water - raw to the plant, as stored for washing and rinsing and at point of supply to wash equipment for rinsing at least.
- Operate a pest control service with an independent, qualified provider at “food grade” or “healthcare” specific service levels. Address crawling and flying risks and secure regular pest control assessment reports, at least 8 times per year.
- Remove and disqualify inappropriate materials: all work surfaces should be washable. Wood is not acceptable, particularly for finishing areas. Ensure all glass in production areas is shatter-proof or encapsulated/protected e.g. fluorescent light bulbs/tubes.

SEVEN RABC PRINCIPLES - TIGHT CONTROLS FOR DISINFECTION PROCESSES, i.e. Critical Control Points (CCPs)

Apply the seven principles fully for all CCPs in the laundry, as detailed below and in BS EN 14065. This will address the essential requirements, best practices and decontamination arrangements set out in HTM 01-04 Management and Provision.

PRINCIPLE	RECOMMENDATION
Principle 1: List hazards and controls	Template documents are provided in Appendix E
Principle 2: Determine Control Points (CPs) and Critical Control Points (CCPs)	It is essential to identify, prioritise, and plan in detail to maintain a much higher degree of control at the most important/critical steps in the laundry process.
Principle 3: Establish target levels and limits (CCPs only)	The RABC plan should be very clear on the criteria for accepting that a process has completed successfully and whether product from that load/batch should be released or re-processed. This requires clear pass/fail criteria for the process and for each load processed.
Principle 4: Establish monitoring (CCPs only)	For CCPs only. The RABC plan must be capable of identifying failures in processing, preventing release of the affected product and enabling investigation of the underlying issues. Using a “traffic lights” colour code for results can simplify the process I.e. AOK Alert Action.
Principle 5: Establish corrective actions (CCPs only)	Actions should be timely and should be assessed for effectiveness.
Principle 6: System checking	This section is about process validation. Appendix D (HTM 01-04 Section 6) to this document provides guidance on approaches. It is recommended as part of the validation programme to use bio-indicators at least annually to demonstrate the capability CCPs to reduce the bioburden to an acceptable degree and to the appropriate microbiological quality.
Principle 7: Documentation	Records should be retained from operating the prerequisites and RABC elements of the plan (e.g. microbiological monitoring data) and from regular reviews of the completed RABC plan. Reviews should be annual, at a minimum.

Your RABC plan should address the essential requirements detailed in the HTM 01-04 document and ensure that the following provisions are in place. Some of these are detailed below. Refer to Appendix F for detailed Implementation Checklist.

- Functional separation of soiled and clean work areas.
- Consistent application of the Infectious Linen Practices as in Appendix B .
- Wash process validation methods and frequencies, to include the use of bio-indicators as process capability verification. See Monitoring and Measuring section below.
- Wash load size – weigh every load accurately, never overload.
- Ensure wash and dry programmes designed and managed to achieve disinfection.
- Ensure your wash process is fail-safe.
- Validate each CCP and revalidate annually.
- Review and revise your Risk Analysis and Risk Control Plans at stages during RABC implementation, e.g. every three months, before and after control regimes are in place and when you have several months of monitoring data (e.g. microbiology data).

OPERATIONAL PREREQUISITES - ADDITIONAL MEASURES REQUIRED FROM DISINFECTION THROUGH TO PACKAGING INCLUDING CONTROL POINTS

To develop competent Operational Prerequisites, you will need to apply the seven RABC principles. Further practical recommendations are detailed below.

- Control and minimise all sources of biocontamination into the clean processing area, e.g. borne by air, liquids, people, materials, equipment and the textiles themselves.
- Control points (CPs) - Identify those points in space or the process where further additional measures are required, e.g. hand hygiene at finishing workstations, cleaning of work surfaces that come into contact with disinfected textiles.
- Protect all laundered textiles from re-contamination and cross contamination until they are packaged.
- Ensure all walls, floors, equipment and work surfaces in these work areas are washable or at least moist wipeable
- Regularly sanitise all surfaces that come in to contact with disinfected textiles.
- Once laundering is started, complete the process (washing and drying) without delay.
- Clearly establish specifications and limits for laundering process steps, e.g. accurate weighing and limits for washing and drying.
- Microbiological services – Engage the ongoing services of a qualified microbiologist or laboratory, using recognised testing techniques and with reports from a qualified microbiologist, addressing identification/classification and enumeration of species and total bioburden and interpretation of results.
- Microbiological monitoring – operate a set schedule of testing, with a combination of random and targeted sampling. Focus on CPs, surfaces that come in contact with disinfected textiles, e.g. hands, equipment, tables, conveyors, primary packaging, shelving, transport containers. Also include washed wet + dried + stored textiles in the schedule. NB sampling of water is advised under “general prerequisites” above.

- Microbiological data – Review the data, track the performance, learn and respond to variations and trends. The data is crucial for establishing and demonstrating to others that your RABC plan is effective.
- Cleaning – detailed advice is provided under general prerequisites above. The clean processing area is the highest priority for cleaning, particularly for CPs and surfaces as described above.

MEASUREMENT & MONITORING

Establishing system checking procedures is the fourth RABC principle. As BS EN 14065 does not set product, process or laundry environmental standards, additional guidance is useful to establish to what extent an RABC plan is working effectively. The TSA therefore recommends the following parameters and performance levels be consistently achieved by a laundry implementing RABC for Healthcare linen supply.

These target levels are based on experience and best practice from healthcare laundries throughout Europe and North America. Testing is required to provide evidence for some of these performance aspects. Methods used must be internationally established and appropriate for the intended use. Sources for test methods include the BP & EP (Pharmacopeias from Britain & Europe or USA respectively) and ISO and CEN standards.

- Ensure water for rinsing is potable; suitable for human consumption as set out in local regulations, in particular in terms of biocontamination. Test mains-sourced water at least quarterly. Test well water or surface water to control biocontamination at least monthly until consistent compliance with potable water standards is established. Filter or treat to achieve control if necessary. Testing thereafter should be as for mains water. Samples for testing must be taken from raw (untreated) and process (as supplied at the wash equipment) waters.
- Ensure water used for washing is clean. Where re-cycled water is to be used, document your risk analysis in detail and secure supporting data on biocontamination impact. Water used for initial wetting out or break-washes may be recycled from rinse water.
- Steam used in linen-contact processing (e.g. washing) must be clean and substantially free of pyrogens.
- Air used in linen-contact processing (e.g. drying) and in the clean linen work areas must be filtered before use and must not be subject to contamination from soiled goods areas.

MICROBIOLOGICAL MONITORING

At several points in this document, advice is detailed for microbiological monitoring. In general, plans should be dynamic and should include random sampling. The key question should be: Where and how might contamination affect the linen (and thereby the patient)? This guides your sampling plan. The following tables show recommended targets for frequency of test and for expected performance.

NOTES: Mtly- monthly/ TBA- to be agreed locally/ cfu- colony forming units/ ml- millilitre/ cm^2-10x10cm

ITEM	FREQUENCY	QUANTITY	TARGET (MAXIMUM) VALUE)	UNIT OF MEASUREMENT	EXPLANATION
Water	*	*	100	cfu/ml	* Details as described in the text above
Hands	Mtly	TBA	100	cfu/dm^2	Any people in the clean-linen area. Those who handle clean linen are most critical
Linen containers	Mtly	TBA	100	cfu/dm^2	E.g. cages, linen bags
Material	Mtly	TBA	100	cfu/dm^2	E.g. packaging, tools, cleaning equipment
Equipment surfaces	Mtly	TBA	100	cfu/dm^2	Where surfaces come in contact with clean linen
Work surfaces	Mtly	TBA	100	cfu/dm^2	
Random surfaces	Mtly	TBA	100	cfu/dm^2	All surfaces in the clean-linen areas
Truck holds	Mtly	TBA	100	cfu/dm^2	All internal surfaces. Particularly walls and inside back door/roller.

ITEM	FREQUENCY	MINIMUM QUANTITY	TARGET	UNIT OF MEASUREMENT	EXPLANATION
Wash process Bio-indicators	Annually	→	→	→	Bio-indicators are normally sourced from a lab with a protocol. The protocol must be followed. The minimum value for success is included in the protocol. This must be achieved, or the wash programme cannot be used for releasing linen to the customer. In any event, all washes must demonstrably reduce viable contamination of the named species by log6, or log4 for sporing species.
Moist clean linen	Mtly	10	30	cfu/dm^2	Each sampled area must be above 20 dm^2. A minimum of 10 samples to be taken on each occasion for moist and for dry. Average must be below the stated target. Only 1 sample above 50 cfu/dm2 is allowed. Each sample set must include samples from “worst case” zones of the linen, such as stitched seams or pockets.
Dry clean linen	Mtly	10	20	cfu/dm^2	

USEFUL DOCUMENTS

- HTM 01-04 2016 comprises of four volumes as follows:
    - Management and Provision
    - Engineering, equipment and validation
    - Social Care
    - Guidance for linen processors implementing BS EN 14065

These are available via the following link:
https://www.gov.uk/government/publications/decontamination-of-linen-for-health-and-social-care

- BS EN 14065:2016 – Laundry processed textiles – Biocontamination control system, available for purchase from the BSI or other sources online.
- TSA Guidance Document Implementing BS EN 14065 – Risk Analysis and Biocontamination Control (RABC) in Laundries

APPENDIX A: ISOLATION GOWNS PROCESSING SPECIFICATION

INTRODUCTION

Since the onset of Covid-19, the requirement for gowns has risen enormously. These are barrier garments that minimise transfer of biocontamination in healthcare work areas. At the peak of the crisis over 460,000 gowns were being issued to healthcare workers every day. These products were intended for single use and were disposed of as clinical waste.

Throughout the crisis, the TSA with the support of existing healthcare laundry operators has been lobbying for a change from single use gowns to commercially launderable multi use gowns. The justification being focussed on environmental, cost and reliability.
The focus has been on the requirement for an isolation gown that can be delivered to the healthcare worker in a clean, disinfected, safe to use and well presented, but non-sterile state.

The commercial laundry service sector is well placed to support this need. Laundries processing isolation gowns will implement the full requirements of these guidelines and will also follow the process specification for gowns set out in this appendix.

We expect a gradual switch over from single use to multi use gowns during the summer months and are working with the Cabinet Office to support the production of fully specified fit for purpose isolation gown manufactured and certified to EN 13795. This guide is to ensure we have created adequate processing capacity to process the newly manufactured gowns.

SERVICE ARRANGEMENTS

As the isolation gowns start to enter the healthcare market there are a range of service offers the commercial laundering will be able to provide:

- **Add on to existing framework agreements** – Gowns within the NHS estate will typically be added to an existing framework agreement and is likely to be a service by a member with BS EN 14065 depending on existing arrangements, these will be either supplied by the NHS trust or form part of a rental service provided by the laundry.
- **Facility Owned Gowns** – end user will select prequalified laundry to process gowns on a COG (customer own goods) basis with commercial contract/framework put in place.
- **Facility Rents service from commercial laundry** – the preferred long-term route is typically the rental model where the end user commits to a min period and volume and the laundry manages the entire process.

When implementing a reusable gown service, it is essential to ensure the facility is visited and training is given in the process and use of the service. The TSA have produced guidance to support this process which is especially relevant if the facility is new to a gown service or switching from single use to multi use. It will help prevent misuse and losses which can be excessive if not well managed.

GUIDANCE

This section provides the specifications for laundries to follow when processing isolation gowns for healthcare services. This specification is additional to the requirements for general healthcare linen in this TSA document.

PRIOR TO PROCESSING

For services relating to isolation gowns, the foundations need to be secure.

For isolation gowns these are as follows:

- Only buy or process isolation gowns that qualify for the purpose. Qualifying gowns comprise of the following options:
  - Surgical gowns or yellow Isolation gowns, made and tested to EN 13795
  - UK Government or NHS approved Isolation gowns supplied under approved Covid-19 response procedures (will also be manufactured or aligned to BS EN 13795).
  - Substandard or unlabelled gowns should only be processed at a customer's own risk basis and should not form part of a rental full-service solution.
- The isolation gown manufacturer is required to prove that the gowns supplied qualify to the standard and to provide full instructions and information on the laundry process to the laundry processor via the purchaser, as follows:
  - Full technical specification for the gowns, including materials, methods of manufacture and performance to tests required by European Norms and/or UK Government/NHS documented purchasing specifications (including any derogation protocols).
  - Laundry instructions, including wash and dry specifications as necessary to preserve the technical and functional safety of the gowns.
  - Intended maximum number of laundry cycles before removal from use
  - Labelling – the sample labels below identify key product information and washing instructions (they may be combined):

Washing Instructions
<Insert Symbols>

Processed in accordance with
(BS EN 14065 or TSA L2 Guide)
Batch No._____

Washing and manufacturing label

Usage grid: Mark each wash process with permanent marker pen if no other tracking in place. WITHDRAW WHEN GRID IS FULL													

Usage Grid Label (10cm X 5cm): Grid should relate to the number of processes.

The following label should be high profile and readily visible to the use.

Reusable Isolation Gown
(BS EN 13795-1:2019)

DO NOT THROW AWAY
Return to laundry

- Reusable isolation gowns are limited to a number of washes before disposal is required. When purchasing a reusable gown under BS EN 13795, certification of the number of wash cycles should be obtained. Ideally a standard asset management system will be implemented for the garment's use in a healthcare setting, such as bar coding or RFID tagging to accurately track the number of wash cycles and maintain the integrity of the yellow isolation gown.
- All laundries should establish the method they will adopt to record every laundry cycle of the isolation gown.
- Use the above information to drive inspection planning and to remove all gowns from use when damaged or when the maximum number of laundry cycles has been reached, or earlier as necessary.
- Launder all new isolation gowns prior to use.

REGULAR LAUNDRY PROCESSING

Wash and dry completely in accordance with manufacturer instructions.

WASHING RECOMMENDATIONS (to be used in conjunction with Manufacturer's Instructions)

- Load ONLY to the limit recommended by the manufacturer/detergent supplier for polyester, 65-70% of nominal load limit is typical.
- Keep the pH below 10 in the wash stages to preserve fabric and garment performance.
- Non-ionic detergent is preferred where possible.
- Use of oxidative bleaching agents, such as sodium hypochlorite, hydrogen peroxide and per(oxy)acetic acid (PAA) should only be used in consultation with competent detergent suppliers. High concentration of these substances may have a detrimental effect on the longevity of the garment.
- Washing temperatures should be set in line with the manufacturer's guidance however, adequate to meet wash disinfection parameters.
- Implement gradual cool down process to 40°C after washing to minimise creasing.
- Rinse thoroughly, to remove all traces of surfactant, as residual detergent will adversely affect the water repellence properties.
- Neutralise (i.e. souring) to achieve pH of 6. Remove all traces of alkali from the fabric.
- Avoid fabric softeners.
- Low-speed spins will minimise creasing.

Sample programme. Work with detergent supplier to refine and customise to your needs and to optimise product performance.

Step	Operation	Time	Temperature	Level	Conditions
1	Rinse	3 min.	Cold	High	See note **1.2** below
2	Wash	3 min. (minimum)	71°C (160°F) minimum for 3 mins	Low	Detergent & alkali pH 10
					See note **1.6** below
3	Rinse	3 min.	60°C (140°F)	High	
4	Spin	2 min.			Preferably low speed
5	Rinse	2 min.	50°C (120°F)	High	

6	Rinse	2 min.	40°C (100°F)	High	
7	Rinse	2 min.	Cold	High	
8	Acidify	5 min.	Cold	Low	Acidify to pH 6
9	Spin	3-5 min.			Preferably low speed

DRYING RECOMMENDATIONS

Ensure that the washed items are thoroughly dried with heat. Finished garments should feel bone dry. Heat enhances fabric barrier performance.

Tumble Dryer

- Keep the tumble dryer exhaust temperature and the fabric surface temperature below 75°C
- A cool down period will minimise creasing
- Inspect and fold immediately after tumbling
- Where possible, use tumblers well positioned for clean air intake

Tunnel Finish Dryer

- Maintaining the fabric surface temperature is crucial. Keep the dryer exhaust temperature and the fabric surface temperature below 75°C.
- Turn entry steam off (at the first stage of drying) to optimise the fluorocarbon finish.
- Trials on tunnel processing is recommended, following advice from the garment/fabric manufacturer.
- Secure gown well to hanger to avoid falling off
- Exit to segregated inspection area

INSPECTING

- Environment specification - Lighting levels in immediate inspection area, at & around gown surface to be consistent, white and above 500 Lux levels.
- Visually inspect 100% of gowns in-process, after washing & drying are complete.
- Performance focus – damage (e.g. no visual holes), integrity, dryness (bone dry on cuffs).
- Lighting options
    - light tables or alternative, providing backlighting (from below/behind the gown)
    - white inspection table underneath the gown with strong background light from ceiling or above, behind the inspector

FOLDING (HANGING MAY BE CONSIDERED)

- Garments should be neatly folded
- Standard fold would typically be – 2 lateral (French) 2 cross
- Machine folding (test for concerns around static)

PACKAGING

- Mostly customer driven. Ability to pack singular or multi pack using Food grade LDPE or equivalent.

TRACKING

- Performance focus – monitoring performance and age of product and removing product at end of intended life.
- Standard – Track every gown through every laundry cycle. Remove from use at the appropriate point. This may be done at any point through the process but is normally done at inspection.
- Options – IT enabled solutions such as RFID chips or barcodes are possible. Alternatively, a grid on the gown can be updated (with ink) to countdown each laundry cycle.

REPAIRING

- Garments should NOT be repaired without detailed validated processes

LABELLING

- The manufacturer will include permanent labels on the gown.
- No further labelling is specified at the laundry at the single product level.

TESTING (LIFE CYCLE TESTING)

- In addition to the Initial Type Testing by the manufacturer, each laundry will carry out random hydrostatic pressure testing to BS EN ISO 811. Minimum acceptable performance is ≥ 20cm H^2O. Minimum test schedule is every six months on five gowns at “one cycle before intended end”, supplemented by a further five randomly selected gowns from stock in the laundry. The purpose is to ensure integrity of fluid repellence. and to provide early warnings on stock performance.
- Regular in-house droplet tests will also provide a useful performance indicator

APPENDIX B: INFECTIOUS LINEN PRACTICES (**HTM 01-04)**

MANAGEMENT AND PROVISION – Section 5.15 to Section 5.45

5.15 This definition applies to:

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

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

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

Heat-labile items

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

Items contaminated with radiation

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

CLASSIFICATION AND SORTING OPTIONS

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

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

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

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

5.23 **Infectious linen** in this category should not be sorted but should be sealed in a water soluble[1] bag, which should then be placed in an impermeable bag immediately on removal from the bed or before leaving a clinical department.

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

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

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

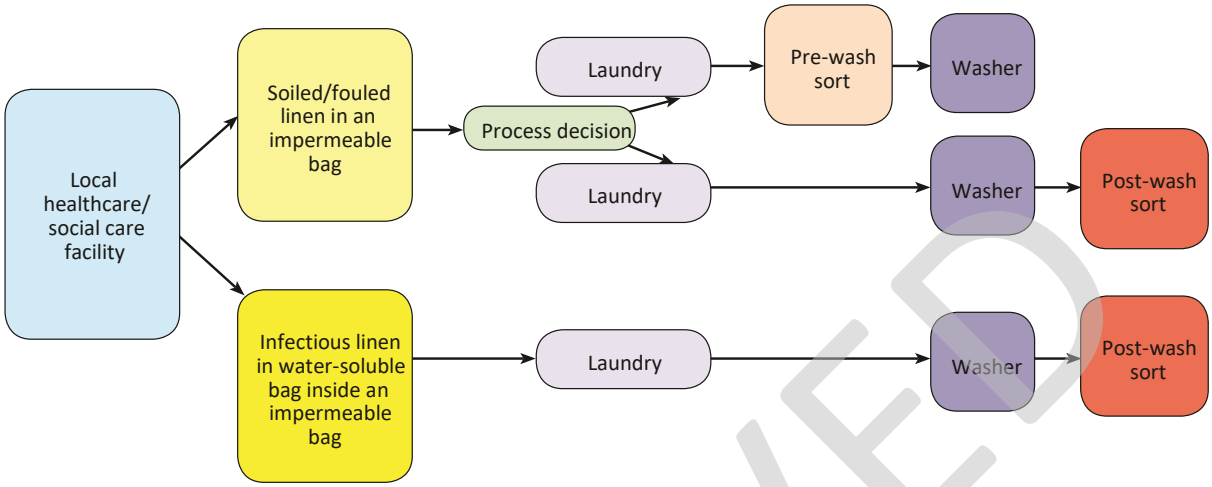
Option 2: Standard precautions by the user with no segregation of linen

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

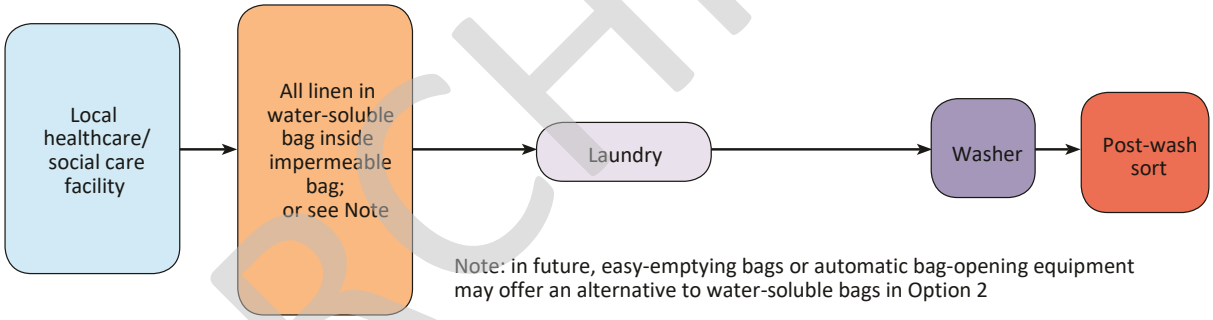
[1] Bags with water-soluble seams are also included within this term but should only be used with the linen processor's agreement in order to prevent damage to tumbler-drying equipment.

FIGURE 1 - CLASSIFICATION AND SORTING FLOWCHART

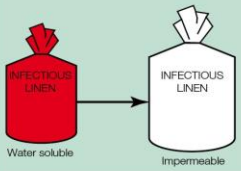
Option 1 Local policy requires that infectious linen be segregated by the service users

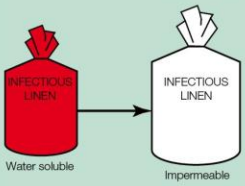
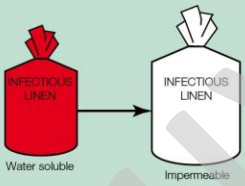
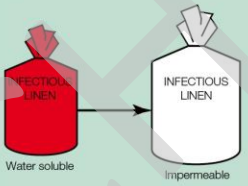


Option 2 Local policy requires standard precautions by the user with no segregation of linen



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

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

Option and processing plant available	Category	Bag/container (see paragraph 5.41, 'Colour coding of linen')	Production sort system
Option 1 with CTW for all categories	Infectious	Water-soluble bag inside impermeable outer: 	Post
	Soiled or fouled	Impermeable: 	Pre or post depending on delivery mechanism to CTW
Option 2 with W/E for all categories		Water-soluble bag inside impermeable outer: 	Post
Option 2 with CTW for all categories		Water-soluble bag inside impermeable outer: 	Post
		or reusable impermeable (not plastic disposable) using easy-emptying and step conveyor (see note below) 	
Notes: Green shading refers to options for meeting EQR Blue shading relates to BP progression			
Note: In future, easy-emptying bags or automatic bag opening equipment may offer an alternative to water-soluble bags in Option 2.			

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

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

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

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

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

5.31 In future, easy-emptying bags or automatic bag opening equipment may offer an alternative to water-soluble bags in Option 2. If easy-emptying bags or an automated procedure is adopted, a bag handling procedure should be used that:

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

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

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

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

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

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

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

5.37 Whichever option is chosen, post-wash sorting of linen for production purposes (production batch sorting) is encouraged and would count as BP. If any form of pre-wash sorting for operational or performance reasons is required within the laundry, option 1 above

should be adopted. It is not appropriate for laundry staff to undertake sorting of infectious linen.

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

5.39 When a machine is used for the processing of infectious linen, the following safety measures need to be adopted. The ability to undertake these measures needs consideration when choosing either option mentioned above:

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

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

COLOUR CODING OF LINEN BAGS

Soiled and fouled linen

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

Infectious linen

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

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

HEAT-LABILE LINEN

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

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

APPENDIX C: DESIGN & PRE-PURCHASE CONSIDERATIONS
(HTM 01-04)

ENGINEERING, EQUIPMENT AND VALIDATION – SECTION 4

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 re-contaminated 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.
- he graduated in degrees Celsius.
- have a scale which includes the range 5ºC to 99ºC.
- have an accuracy of at least ±2ºCover the scale range 10ºC to 99ºC.
- for analogue instruments, be graduated in divisions not greater than 1ºC.
- for digital instruments, have a resolution of at least 1ºC.
- 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 ±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 65ºC for not less than ten minutes or 71ºC 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 65º or 71ºC 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.

APPENDIX D: VALIDATION & VERIFICATION **(HTM 01-04)**

(For those not adopting independently certified BS EN 14065 systems)

ENGINEERING, EQUIPMENT AND VALIDATION – SECTION 6

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 1.0ºC when tested in an ambient temperature of 20 ± 3ºC.

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 ±0.1ºC and within the disinfection temperature band should not differ by more than 0.5ºC 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 10ºC to 110ºC.

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 75ºC.

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 ±0.8ºC when tested over the range 0ºC to 100ºC at an ambient temperature of 20ºC ± 3ºC. 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 90ºC 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 semipositive 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 70ºC 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 ±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 20ºC 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 ±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.

<table>
<tr><th>LOCATION</th><th colspan="2">PRODUCTION OF WASHER</th><th>RESPONSIBILITY</th></tr>
<tr><td>Factory</td><td colspan="2">Type tests and works tests</td><td>Manufacturer</td></tr>
<tr><td rowspan="4">On site</td><td rowspan="4">Validation</td><td>Installation
Operational</td><td>Manufacturer</td></tr>
<tr><td>Performance qualification</td><td rowspan="3">User</td></tr>
<tr><td>Periodic routine tests</td></tr>
<tr><td>Annual revalidation tests</td></tr>
</table>

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 Standardisation (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 nonrecirculating 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): 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 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 (eg. 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. *Bacillus cereus* test (for CTWs, typically only during June to September inclusive as highlighted by 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. *Bacillus cereus* test (for CTWs, typically only during June to September inclusive as highlighted by 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. *Bacillus cereus* test (for CTWs, only during June to September inclusive as highlighted by 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 2ºC 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 dataloggers, 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 (dataloggers).

- 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 2ºC 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 sterilised using a validated sterilisation 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.

APPENDIX E: HAZARDS AND CONTROLS LIST TEMPLATE

Risk Analysis

Note: P = Probability. S = Severity. R = P x S. Use a simple scale. 0 to 3 perhaps. Declare a value or range for each point on the scale. Analyse and document before and after controls are put in place, and review annually.

By process step

STEP	RISK	CONTROL MEASURE	Rating			CCP
			P	S	R	(Y/N)
Sort/Classify						
Wash						
Press						
Drying						
Inspection						
Folding						
Packing.						
Despatch						
Delivery/collection						

By process input						
Water						
Energy						
Detergent						

Risk Controls

Note: Document a set of Risk Controls for each named CCP

Risk	Control Measure	Limits	Monitoring Ref	By	Frequency	Corrective Action	Doc. Ref.	Verification
Biological Survival								
Biological Growth								
Biological Contamination								

APPENDIX F: INTERIM HEALTHCARE LAUNDRY CERTIFICATION IMPLEMENTATION CHECKLIST

The checklist below is not intended to be exhaustive. However, the list should serve as a good guide for laundries, auditors and consultants.

Key Stages	What to Do	Task Owner	Done (Yes/No)	Audit Comment
Collect the garments from the customer	Risk assessment (onsite or shared by the customer)			
	Instruct the customer on exact requirements			
	Contract - detailed understanding and agreement			
	Risk assessment - vehicle			
	Prepare the vehicle (with measures to manage the risks identified)			
	Driver training (including covid-19 risks and measures)			
	Provide PPE against risks that may not be managed any other way			
	Use the TSA Guide, Safe Delivery of Goods to Customer premises			
	Special reference to handling infective work			
	Develop a policy on handling infective work			
	Training on handling infective work (enabling effective decision making)			

Deliver to the laundry	Carefully plan and prepare route			
	Develop policy and procedures for segregation of clean/soiled work			
	Effective training on agreed procedures			
	Prepare the laundry to receive work			
	Define soiled storage area			
Design and construct the necessary soiled work reception, storage, signage and connection/route to wash area	Provide segregation of classifications, soiled, infective, etc			
	Specify and select laundry skips/roll pallets, liners, covers, etc			
	Implement cleaning regime for floor, racking, skips, etc			
Modify washer extractors to comply with HTM01-04 requirements Study the machine operation and programme controls along with the detergent supplier Process monitoring(data logging) may be available in the machine functionality	Select and allocate machines for infective work processing			
	Implement modifications:			
	Drain and vent modification			
	Cleaning regime			
	Wash process programmes defined, implemented and written			
	Liaise closely with detergent supplier for service support and training of staff			

	Consider the use of data logger or alternative process validation methods			
	Implement machine logs to specify, record and comment on each load processed			
	General comment on data logging, reference HTM01-04; 6.1 - 6.22			
	Temperature recording reference HTM01-04; 6.23 - 6.36			
	Pressure and water flow measurement are not so critical (6.37 - 6.44)			
	The perpetual monitoring and testing of the m/c performance			
	Proof of its functionality should be undertaken within a written procedure agreed between the laundry and the detergent supplier. See HTM01-04; 6.45 - 6.83			
	Apply the check list logic of HTM01-04; 6.82			
	Apply the General Test Method logic in HTM01-04; 6.84 - 6.132			
Modify CTWs to comply with HTM01-04 requirements Study the machine operation and programme controls along	Implement modifications:			
	Drain and vent modification			
	Cleaning regime			

with the detergent supplier (from tunnel input to dryer discharge) Process monitoring(data logging) may be available in the machine functionality	Wash process programmes defined, implemented and written			
	Liaise closely with detergent supplier for service support and training of staff			
	Consider the use of data logger or alternative process validation methods			
	Implement machine logs to specify, record and comment on each load processed			
	Include press/extractor and dryers in the logs and record comments			
	General comment on data logging, reference HTM01-04; 6.1 - 6.22			
	Temperature recording reference HTM01-04; 6.23 - 6.36			
	Pressure and water flow measurement are not so critical (6.37 - 6.44)			
Design and implement quality control procedures	Ideally this should include data for the work from receipt at laundry, to despatch			
	Liaise closely with detergent supplier			
	Inspect the work at point of unloading washing m/c			

	Re-wash as required			
	Load barrow/container and cover with plastic film			
	Transfer work to finishing/drying area			
Design and implement route for work to be transferred to drying/finishing area.	Mark out and sign the route			
	Implement skip/rollpallet/ wash barrow cleaning, management for next use			
Design and implement modifications required for dryers, tunnel finishers, callenders, etc	Design and specify finishing programme for all classifications			
Design and implement quality control procedures	Reference HTM01-04 Appendix F; Risk Assessment			
	Undertake risk assessment and implement requirements			
	The QA procedure			
	Liaise with customer to specify packaging requirements and implement procedure			

Design and implement packaging equipment and procedures	Ensure the full packaging solution (primary layers, outer bags, boxes, transport containers etc.)			
	protect the linen from contamination until the point of handover to the end user and is capable of preserving the linen until the point of use.			
	Be clear and consistent; assign in advance responsibilities and authority to take effective corrective actions, consistently.			
	Provide evidence that corrective actions as described are in use			
	Provide evidence that these systems work as intended.			
	Records of decisions and tracking of linen are each useful contributors to this capability			
Design and implement clean work storage in despatch area	Mark out and sign the area and storage/ racking facilities			
Prepare vehicles for clean work delivery to customer	Follow the required segregation, cleaning and route load order procedures			

Deliver work to customer	Risk assess the on-site procedure for delivery/off-loading at site			
	Design and implement delivery/receipt of goods confirmation and record			
	Use the TSA Guide, Safe Delivery of Goods to Customer premises			
Collect soiled goods from the customer	Return to top of this column			

APPENDIX G: TSA SUPPLY PARTNER CONSULTANTS

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