

Blue Dragon Hillingdon Limited

BS EN14065 : 2016 RISK ASSESSMENT BIOCONTAMINATION CONTROL SYSTEM



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EN14065 RISK ASSESSMENT-BASED BIOCONTAMINATION CONTROL SYSTEM

Foreword

This system of management of biocontamination risks is based closely on the European Norm EN 14065 as applied across all parts of the European Union and to which due acknowledgement is made. The Company supports the uniform adoption of this common standard as the basic code of practice for the laundering and textile rental sector.

Introduction

Whilst there have been standards for control of biocontamination risks for healthcare textiles for some years, the standard now adopted by the Company (and embodied in the system documented here) represents a significant step improvement in the level of risk.

The Company works to the same biocontamination standards for commercial laundry and healthcare laundering, because there are no alternative controls in place (for example to control the risk of a pandemic or of bio-terrorism in the healthcare sector). The improvement this represents in this sector is even greater than for healthcare and represents future best practice, well ahead of our competition.

This manual is intended to define every aspect of the Company's business relevant to biocontamination management. The actions needed are built into every employee's duties rather than being the responsibility of an additional department. They represent a streamlined system of simple common sense rules, processes and procedures, with sufficient measurements to assure each customer of final biocontamination quality.

The decontamination achieved by these procedures is designed to meet the requirements set out by the UK Department of Health and the UK National Health Service. These currently define **disinfection** as calling for a log 5 reduction in the concentration of microbiological contaminants. This is different to **sterilisation** which calls for a complete kill. Certain healthcare textiles, for use in operating theatres for example, are first disinfected following the procedures set out in this manual, then sent separately for sterilisation. **This manual covers disinfection and its management, not sterilisation.**

In order to achieve its objectives, this manual covers the relevant aspects of purchasing textiles and raw materials, the use of equipment for transport, processing textiles and machine/premises cleaning and procedures which are followed. This in turn leads to task descriptions and staff training, all of which are covered in this system.

1. Scope



This Quality Assurance system is designed to address biocontamination control by disinfection and the maintenance of a textile product in its disinfected form. It includes all essential components needed to ensure this, including relevant checks by the detergent supplier, staff clothing issues, machine cleaning and maintenance and so on. However, its contents are limited to those factors which are essential for control of decontamination.

The Scope of this Quality Assurance system is limited to disinfection and does not include sterilisation or the special requirements of cleanroom textiles for operating theatres, manufacture of ethical pharmaceuticals or of micro-electronic components.

Within this Scope, this manual is intended to be a standalone document, with references to other documents kept to a minimum.

2. Normative references

The following documents have been used in designing this Quality Assurance system and their requirements have been adopted, so that apart from one or two exceptions (which are clearly stated where they occur), this system complies with the following documents/protocols:

2.1. HSG(95)18: Hospital Laundry Arrangements for Used and Infected Linen

This document was published by NHS Health Service Estates in 1995 and provides methods of achieving implied thermal disinfection in the wash process for different types of textiles. It also provides an excellent colour code system for the identification of the contents of bags of healthcare textiles (e.g. red for Infective, white for Used {soiled and foul} and so on). However, it offers only very limited opportunity for non-thermal methods of disinfection or other methods of achieving reductions in carbon emissions. The sections on Continuous Batch Tunnel Washers are comprehensive, as are the engineering requirements for laundry installations.

2.2. HTM 01-04:

This document was first published in 2012, as the successor to HSG(95)18. It is much more extensive and it is designed to apply also to small on-premise laundries in wards and nursing homes. It introduces the concepts of risk analysis, critical control points, monitoring and corrective action, which were omitted from its predecessor.

2.3. BS EN 14065: 2002:

This document was published in 2002 and is the predecessor of the current standard BS EN 14065: 2016

3. Terms and definitions

See BS EN 14065: 2016 Textiles – Laundry processed textiles – Biocontamination control system section 3 for terms and definitions.

4. General Principles and Requirements

The Company's Quality Assurance system for biocontamination control operates in accordance with the seven RABC.



4.1. Principles and framework

The RABC system is integral to the operation of the business and is designed to manage uncertainty as well as institutionalising a systematic iterative and responsive approach to bio-contamination control following the diagram laid out in the standard at 4.1 on page 9.

4.2. General requirements

This document sets out how management have established, documented, implemented and maintain the RABC system in order to manage, reduce or eliminate the risk of textile bio-contamination in a manner that is appropriate to the end use, which in this laundry, is for NON ACUTE linen provision for MINOR SURGICAL and HOSPITALITY use.

5. Alignment with a quality management system

This is not applicable in this facility

6. Application of the risk Analysis and Bio-contamination Control system in this laundry

6.1. General

As can be seen later in this document, through the control and critical control point locations, the RABC system has been implemented throughout the laundry cycle.

6.2. Prerequisites and Preliminary Actions

6.2.1. Management Commitment

This document sets out the detail of the management's commitment to the process through ensuring that this document has been produced to set out the scope and structure of the RABC system and documenting the system through a principle of "reporting by exception" in order to minimise the amount of recording required to a manageable level.

Management take their responsibility for reviewing the system to ensure it is fit for purpose very seriously and manage this through RABC team meetings and by conducting an annual root and branch review of the system placing particular emphasis to ensure **CORRECTIVE ACTIONS** are appropriate.

The RABC team is headed by the Decontamination Executive of the Company, which demonstrates the total commitment of the business to its EN14065 system and the centrality of this to the Company ethos.

This is further reinforced by the fact that all textiles produced by the Company are delivered to the same biocontamination standard, whether for hospitality or healthcare.

6.2.2. Constitution of the RABC team

6.2.2.1. The RABC team comprises the following:

6.2.2.2. **Executive Manager:** William who is ultimately responsible for the operation and effectiveness of the system.

6.2.2.3. **Decontamination Engineer:** Paul Frith who is also the Authorising Engineer in matters relating to decontamination.

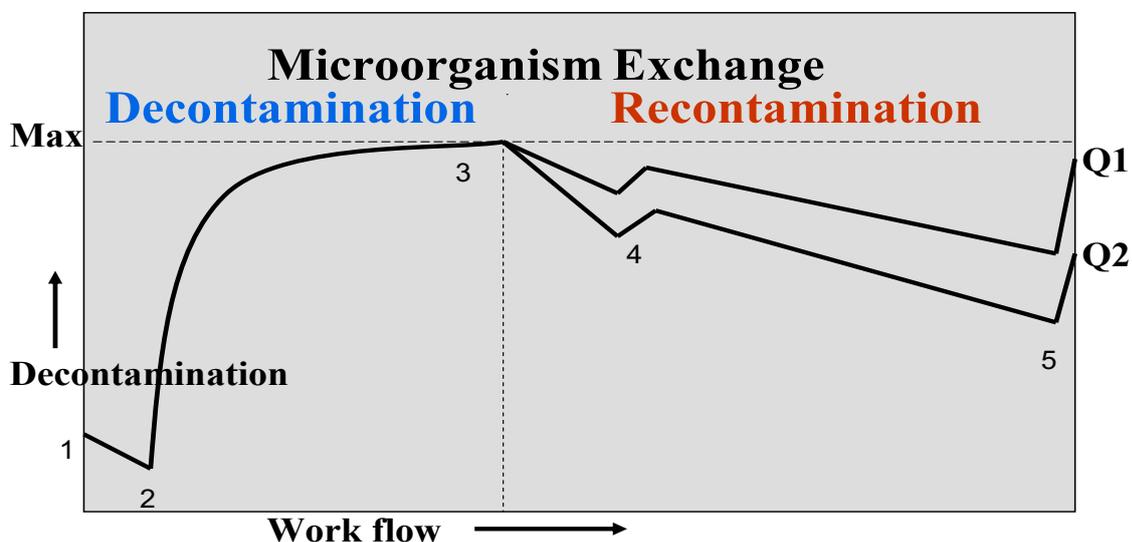
- 6.2.2.4. **Decontamination Team Manager and Control of Infection Officer (Decontamination):** Rakesh Baden
- 6.2.2.5. **Cleaning Team Manager –** Mohamed
- 6.2.2.6. **Decontamination Team Leader – Soiled Area:** Graham Harding
- 6.2.2.7. **Decontamination Team Leader Quality and Clean Area** Mrs Northay
- 6.2.2.8. **Decontamination Manager – Transport:** Dee Morrison.
- 6.2.2.9. **Note:** all of the decontamination team leaders are trained and are regarded as Competent Persons for decontamination duties.
- 6.2.2.10. **External/Internal Microbiologist:** LTC&DTC Limited
- 6.2.2.11. **Decontamination sub-contractor:** the detergent supplier, Christeyns UK Limited, who conducts monthly checks on disinfection conditions, both thermal and chemical as appropriate and also quality checks.
- 6.2.2.12. **External auditor and Certification (EN14065 compliance):** Steve Anderton LTC&DTC Limited and JUKQA Limited
- 6.2.3. Prerequisites Programme (PRP)**
- 6.2.3.1. **General**
- 6.2.3.1.1. Management plans and systems are designed to limit the potential for contamination from the environment and cross contamination
- 6.2.3.2. **General Prerequisites**
- 6.2.3.2.1. **Construction, layout and maintenance of premises**
- 6.2.3.2.1.1. The design and shape of the laundry has evolved over time as is the case with most laundry facilities. The facility has been extensively updated and at such times the suitability of design and materials has been extensively considered.
- 6.2.3.2.2. **Cleaning and hygiene plan.**
- 6.2.3.2.2.1. The cleaning and Hygiene plan can be seen at appendix 10
- 6.2.3.2.3. **Water and steam systems**
- 6.2.3.2.3.1. The water system forms one of the controlled points and is therefore regularly monitored as part of this RABC system
- 6.2.3.2.3.2. There is no impact on the system from the steam system per say. The steam supply system is however closely monitored by the Decontamination Engineer to ensure that target process conditions, in particular temperatures for thermal disinfection, are achieved.
- 6.2.3.2.3.3. Water supply/storage is monitored as Control Point 1
- 6.2.3.2.3.4. Treatment – N/A

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- 6.2.3.2.3.5. Disposal – all effluent is disposed of into sealed drains in line with HSG 95/18 (appendix 11)
- 6.2.3.2.4. **Equipment suitability and control** – a full assessment of the suitability of proposed new equipment is undertaken by the Decontamination Executive who calls upon the specialist knowledge of other team members if appropriate when assessing the suitability and control of said machine.
- 6.2.3.2.5. This could result in compliance to HSG95/18 – CFPP 0104 or EN14065 being specified in the order or simply “health service compliant” to indicate the need for infection control measures to be incorporated into the design and control of the equipment being considered.
- 6.2.3.2.6. Cleaning of equipment is conducted in line with the cleaning plan at appendix 10
- 6.2.3.2.6.1. Calibration of the relevant monitoring equipment is controlled by the Decontamination engineer who ensures that items are calibrated annually. The decontamination subcontractor Christeyns UK are also responsible for calibration of temperature monitoring equipment used to check the calibration of thermostats in the washing machine. See appendix 11
- 6.2.3.2.6.2. Maintenance is conducted in line with supplier’s recommendations. See appendix 12
- 6.2.3.2.7. **Control measures before decontamination and after packing**
- 6.2.3.2.7.1. **Pre – wash (decontamination) controls**
- 6.2.3.2.7.2. At the start of each day the main washing equipment – the Tunnel Washers (CBTW) Start-up of Tunnel washers. Every morning after each Tunnel washer (CBTW) undergoes a special start up routine where by the entire machine (and any contents) are decontaminated regardless of any decontamination the previous day. This means that the temperature of the water within the machine (from the main wash zone forward) is raised above thermal disinfection temperature.
- 6.2.3.2.7.3. Temperature checks are conducted by the CBTW operative periodically throughout the day to ensure that thermostat temperature readings are above the level required for thermal disinfection – i.e. 71°C.
- 6.2.3.2.7.4. The decontamination engineer is responsible for checking that thermostats are calibrated at least annually. (further calibration is undertaken independently by the decontamination sub-contractor Christeyns UK and can also be confirmed by the external microbiologist upon request.
- 6.2.3.2.7.5. PPE is available, in line with risk assessments conducted by the external contractor (Mike Clarke Associates) and internal procedures, to ensure that staff are protected from the risk of contamination.
- 6.2.3.2.7.6. Workwear is colour-coded to identify staff who are dedicated to the soiled area and clean area respectively.

- 6.2.3.2.7.7. Soiled potentially infectious linens are sent to the laundry in Water Soluble Red bags. This identifies the contents as potentially infectious and also means that this work is not pre-sorted to protect the work force. The unopened soluble bag enters the washing machine and releases its contents in the washing machine.
- 6.2.3.2.7.8. Cleaning and disinfection of the washing equipment is conducted in line with the cleaning plan and schedule.
- 6.2.3.2.7.9. The most challenging area for cleaning and decontamination is the CBTW press area. This is why this is one of the most frequently tested areas with the highest level of issues.
- 6.2.3.2.8. **Post decontamination controls**

Figure 1. Decontamination during laundering



- 6.2.3.2.9. The diagram above is useful as it shows that recontamination is inevitable. The focus of the laundry is to put in place systems and good practice in order to prolong the time between decontamination and re-contamination.
- 6.2.3.2.10. Decontamination mainly occurs in the thermal disinfection washing phase but will also be enhanced by the drying phase.
- 6.2.3.2.11. Training is important and the company places a high degree of emphasis on this. Initial induction training covers the basic principles and this is reinforced and built upon on an ongoing basis.
- 6.2.3.2.12. Staff uniforms are colour coded to ensure that people can be quickly identified if they are working in the wrong place.

- 6.2.3.2.13. The management promote a positive culture of reporting any failures in the RABC system and regularly test this by purposely generating failures to ensure they are reported.
- 6.2.3.2.14. Microbiology is conducted regularly on-site both internally and externally by the external microbiologist from LTC Worldwide the microbiology sub- contractor.
- 6.2.3.2.15. There is a schedule for testing and tests are conducted at the control and critical control points using both basic and advanced techniques.
- 6.2.3.2.16. Disinfection is validated using specialist microbiologically impregnated swatches in a semi permeable membrane. This can be conducted by the external microbiologist or the decontamination sub -contractor Christeyns UK.
- 6.2.3.2.17. Cleaning and disinfection plans have been drawn up and can be seen at appendix 10. These are reviewed in the RABC team meetings and annually as part of the executive review.
- 6.2.3.2.18. Cage decontamination is a particular area within the plan that is designed to minimise the risk of recontamination.
- 6.2.3.2.19. Packaging has been tested to ensure it does not contribute to recontamination
- 6.2.3.2.20. **Company training plan for management of bio-contamination**
- 6.2.3.2.21. The Company operates a rolling programme of training that achieves the following objectives:
 - 6.2.3.2.21.1. All staff on the Control of Infection Team are trained in the basics of Laundry decontamination, so that they understand the principles of decontamination and industry best practice.
 - 6.2.3.2.21.2. All staff on the Control of Infection Team are also trained in accordance with the Laundry Technology Centre syllabus in Infection Control in Laundering. This covers all of the technical knowledge needed to underpin the mechanisms of BS EN 14065, as set out in this manual.

Outline syllabus for training

- 6.2.3.2.21.3. **Handling principles for healthcare work**, covering colour coding, double wrapping, sharps, infective work, labelling, RTS items, dangerous items and so on.
- 6.2.3.2.21.4. **Infection control**, including Control of Infection Officer, monitoring of disinfection, cleaning routines, special bugs to watch out for, internal monitoring using dip-slides, external monitoring using transport swabs, validation using pre-infected swabs and so on.
- 6.2.3.2.21.5. **Minimising documentation requirements** for compliance, covering what to record, how often to record it, electronic records, amber and red warnings, communication with the rest of the Control of Infection Team, reports for the customer and so on.

- 6.2.3.2.21.6. This training for the RABC team is then cascaded to individual operatives, with separate training for them, based on the Risk Assessments covered in section 5.10 of this manual. This is done at induction and on an ongoing basis. Training is recorded.
- 6.2.3.2.21.7. **Operator training for healthcare**, covering special health and safety provisions (including hand washing, inoculations and vaccinations), handling procedures for healthcare bundles, leaking packages, sorting precautions for healthcare and so on.
- 6.2.3.2.22. **Purchased Materials - Company purchasing specification for materials needed to meet the requirements of this system**
Materials and services required to meet the requirements set out in this manual are purchased against the specifications listed in section A5 of this manual.
- 6.2.3.2.23. Pest Control is managed both internally and via an external sub-contractor.
- 6.2.3.2.24. Internally there are several controls in place. Firstly, ingress of flying insects and birds is controlled by curtain screening to clean areas as well as mesh covering roof vents.
- 6.2.3.2.25. Insects are also controlled by ultraviolet insect attracting devices which kill the insect electrically.
- 6.2.3.2.26. Crawling insects and mammalian vermin are managed with various trapping devices.
- 6.2.3.2.27. The ingress of vermin is also managed through good housekeeping practice which is designed to manage vermin ingress. For example, emptying bins regularly and cleaning floors. (see cleaning plan)

6.3. Applications of the seven principles for implementing the RABC system

6.3.1. General

6.3.2. Principle 1: List of microbiological hazards and list of control measures.

6.3.2.1. Identification of the hazards associated with the environment, process or product

6.3.2.1.1. See appendix 9 for risk assessments

6.3.2.1.2. The following is a list of the hazards identified by the Company and monitored in this RABC Quality Assurance system:

6.3.2 Hazard	6.3.2.2 Assessment of the Textile Biocontamination Risk	6.3.2.3 Identification of Control Measures
Overloading of washing machines	Poor soil removal and failure to disinfect in the washing machine	Weighing scales regularly calibrated

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Contamination of Incoming Water	A dead bird or other vermin in the storage tank or contamination in the water supply	All tanks are covered Regular microbial testing of the water system
Failure to reach disinfection temperature in hot wash zone of the CBTWs	Failure to disinfect in the washing machine	Regular checks on wash temperatures Regular calibration of thermostats
Re-contamination in CBTW rinse/press area	Contamination in the washing machine causing re contamination	Daily start up routine to decontaminate the machine Regular cleaning of the press and recirculation tray. Regular microbial testing
Failure to reach disinfection temperature in Washer extractor	Failure to disinfect in the washing machine	Regular checks on wash temperatures Ozone injected into the wash cycle Regular calibration of thermostats
Work not properly dried	Possible microbe growth	Checked by packers before packing. Regular testing or clean work to demonstrate bioburden removal
Finished goods recontamination before packaging Surfaces Handling Airborne	Contact with the floor, dirty hands, contaminated surfaces or the air causing re-contamination	Surfaces and floor in clean area regularly cleaned Hand washing training and monitoring Barrier and curtain screening between soiled and clean areas
Ingress of Vermin	Re-contamination caused by vermin ingress	Barrier and curtain screening between soiled and clean areas Vermin control equipment (insect and other)
Finished goods re-	Contamination from	Clean items both bagged and

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contamination after packing Cage and vehicle decontamination Microbial load of packaging	packaging or failure of packaging causing cross infection with soiled linen	placed in lined cage or cloth bag (two levels of protection) Testing or packaging as delivered before use All cages and healthcare transportation is decontaminated before use.
Inside walls of vehicle to be used for clean deliveries	Clean linen contact with contaminated interior of vehicle	Clean items both bagged and placed in lined cage or cloth bag (two levels of protection) All cages and healthcare transportation is decontaminated before use.

6.3.3. Principle 2: Determination of the Critical Control Points (CCPs) and Control Points (CP)

6.3.3.1. The following is a list of the CP's and CCP's identified by the Company and monitored in this RABC Quality Assurance system:

CP or CCP	Parameters monitored	Person responsible
CP1 Weigh scales in sorting	Weight of each load of soiled textiles.	Decontamination Engineer
CP2 Incoming Water	Bug count in water	Control of Infection Officer
CCP1 Hot wash zone of the CBTWs	Wash temperatures.	Control of Infection Officer
CP3 Cheese of freshly laundered and pressed textiles or press water	Surface bug count measured.	Control of Infection officer
CCP2 Washer extractor	Temperature in the hot wash; time for which this temperature maintained.	Control of Infection Officer
CP4 Washer extractor washed items	Bug count on freshly washed and hydro-extracted textiles immediately on opening the cage door.	Control of Infection officer
CP5 Air bourn contamination near barrier	Settlement onto dip slide – CFU/10cm ²	Control of Infection officer
CP6 Finished goods	Assessment of total	Control of Infection officer

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CP or CCP	Parameters monitored	Person responsible
	Biocontamination on finished items.	
CP7 Finished goods conveyor belts and Surfaces	Assessment of surface microbial contamination	Control of Infection officer
CP8 Surfaces of clean cages	Assessment of surface microbial contamination	Control of Infection officer
CP9 Inside walls of vehicle to be used for clean deliveries	Assessment of surface microbial contamination	Control of Infection officer
CP10 Operator Hands	Assessment of surface microbial contamination	Control of Infection officer

6.3.4. Principle 3: Establishment of target levels and tolerances limits for each CP and CCP.

The following are the target levels, limits and tolerances for the control parameters at the CP's and CCP's:

Control point	Parameters monitored	Target levels, limits and tolerances	Rationale
CP1 Weigh scales in sorting	Weight of each load of soiled textiles	Weigh scales on CBTW bags to be Alert level weight ± 1 kg. Target weights for CBTW to be 47kg depending on classification.	This is a sensible level given the units of measurement on the scales.
CP2 Incoming Water	Microbe levels	<100 cfu/10cm ² – no pathogens.	In line with TSA guidance.
CCP1 Hot wash zone of the CBTWs	Target wash temperature. Wash time at or above target temperature.	Target temperature in the hot wash compartments for implied thermal disinfection to be 71°C minus 0°C plus 9°C.	In line with HSG 95/18
CP3 Cheese of freshly laundered and pressed textiles or	Surface bug count measured for Total Viable Count (TVC),	Target level to be 0 colonies for all three categories. Up to 10 ³	In line with environmental levels

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Control point	Parameters monitored	Target levels, limits and tolerances	Rationale
press water	Moulds & Fungi and Coliforms.	triggers an alert level warning for a re-check and emphasis on next clean-down. More than 10^3 colonies trigger an action level - immediate stoppage and clean-down.	
CCP2 Washer extractor	Temperature in the Main-wash; time for which this temperature maintained.	Target temperature is 71°C minus 0°C plus 4°C . Target time is 3 minutes plus 4 minutes mixing time, i.e. 7 minutes total, minus 0 plus 3 minutes.	In line with HSG 95/18
CP4 Washer extractor washed items	Micro-organism count for Total Viable Count (TVC), Moulds & Fungi and Coliforms on freshly washed and hydro-extracted textiles immediately on opening the cage door.	Target to be 0 colonies for all three categories. Up to 10^3 triggers an alert level warning for a re-check and emphasis on wash parameters. More than 10^3 colonies triggers an action level immediate investigation.	In line with environmental levels
CP5 Air bourn contamination near barrier	Assessment of airborne re-contamination of goods and surfaces in the finished goods area using petri dish and agar left exposed for 30 minutes.	Target to be 0 colonies for all three categories. Up to 10^3 triggers an alert level warning for a re-check and emphasis on barrier screening. More than 10^3 colonies triggers an action level immediate investigation.	In line with environmental levels

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Control point	Parameters monitored	Target levels, limits and tolerances	Rationale
CP6 Finished goods Assessment of total bio-contamination on finished items (towels, pillowcases and sheets).	Assessment of total bio-contamination on finished items (towels and Scrub suit trousers).	Target to be 0 colonies for all three categories. More than 0 triggers an action level immediate investigation followed by re-testing	In line with environmental levels
CP7 Finished goods conveyor belts and Surfaces	Assessment of surface microbial contamination of the clean cage for Total Viable Count (TVC), Moulds & Fungi and Coliforms.	Target to be 0 colonies for all three categories. More than 0 triggers an action level immediate investigation followed by re-testing	In line with environmental levels
CP8 Surfaces of clean cages	Surfaced microbial contamination for Total Viable Count (TVC), Moulds & Fungi and Coliforms.	Target to be 0 colonies for all three categories. Up to 10^3 triggers an alert level warning for a re-check and emphasis on next clean-down. More than 10^3 colonies triggers an action level immediate stoppage and clean-down.	In line with environmental levels
CP9 Inside walls of vehicle to be used for clean deliveries	Surfaced microbial contamination for Total Viable Count (TVC), Moulds & Fungi and Coliforms.	Target to be 0 colonies for all three categories. Up to 10^3 triggers an alert level warning for a re-check and emphasis on next clean-down. More than 10^3 colonies triggers an action level immediate stoppage and clean-down.	In line with environmental levels
CP10 Operator Hands	Total Viable Count (TVC), Moulds & Fungi and Coliforms.	Target to be 0 colonies for all three categories. Above 0	

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Control point	Parameters monitored	Target levels, limits and tolerances	Rationale
		triggers re-training in hand washing techniques followed by re-testing.	

6.3.5. Principle 4: Establish a monitoring programme for each CP and CCP.

The frequency of each type of monitoring at the CP's and CCP's is set out in the following chart:

Control point	Frequency
CP1 Weigh scales in sorting	Spot checks every four hours by team leader to ensure sorters are not overloading Quarterly re-calibration
CP2 Incoming Water	Dip-slide checks bi-weekly by the Control of Infection officer
CCP1 Hot wash zone of the CBTWs	Spot checks every four hours by washhouse team leader. Weekly checks by the Control of Infection officer Monthly external checks by the detergent supplier
CP3 CBTW press area	Dip-slide checks bi-weekly by the Control of Infection officer
CP4 Washer extractor	Dip-slide checks bi-weekly, by Control of Infection officer, on the freshly washed, rinsed and spun load
CCP2 Washer extractor	Time-temperature check weekly, by Control of Infection officer (and/or external microbiologist), to verify that disinfection conditions are being achieved consistently
CP5 Air bourn contamination near barrier	Control of Infection officer (and/or external microbiologist) collects airborne contamination on a dip-slide over 30 minutes, once per month.
CP6 Finished goods area	Control of Infection officer (and/or

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Control point	Frequency
	external microbiologist) checks one scrub suit trouser and one towel each week using dip-slides to detect any failure of the disinfection regime.
CP7 Finished goods area conveyor belts and Surfaces	Control of Infection officer (and/or external microbiologist) samples surfaces randomly on a weekly basis.
CP8 Cages for finished goods	Control of Infection officer (and/or external microbiologist) samples one clean goods cage each month using dip-slides, to verify that cage cleaning is consistently effective.
CP9 Inside walls of vehicle to be used for clean deliveries	Control of Infection officer (and/or external microbiologist) inspects one vehicle interior each day and logs the visual cleanliness. An internal wall is tested with a dip-slide bi-weekly
CP10 Operator Hands	All new staff in first week of employment. Other staff randomly tested with samples taken on a weekly basis

6.3.6. Principle 5: Establish corrective actions

The following table indicates the corrective action to be taken in the event that a parameter at a control point deviates from the requirement.

Control point	Corrective Actions
CP1 Weigh scales in sorting	Retraining of sorting operative on the spot, explaining the importance of correct load weights on effective disinfection
CP2 Incoming Water	Call in Decontamination Engineer and RABC sub-contractor to decontaminate tanks and retest
CCP1 Hot wash zone of the CBTWs	Call in Decontamination Engineer

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Control point	Corrective Actions
	to verify that readings reflect actual conditions, then verify thermostat settings, then verify that steam injection available. Re-calibrate thermostats if required
CP3 CBTW press area	Clean and re-check area by resampling Depending on findings a deep clean may be necessary. Call in decontamination sub-contractor and/or external microbiologist if issue persists after re-testing
CP4 Washer extractor	Call in Decontamination Engineer to verify that readings reflect actual conditions, then verify thermostat settings, then verify that steam injection available. Re-calibrate thermostats if required If micro-organisms are surviving the hot wash then either the time temperature conditions are not being achieved or the machine is being over-loaded. Follow the next load through its cycle right through to ironing/drying, then weigh the dry goods and compare the weight with the washer extractor capacity.
CCP2 Washer extractor	Call in Decontamination Engineer to verify that readings reflect actual conditions, then verify thermostat settings, then verify that steam injection available. Re-calibrate thermostats if required

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Control point	Corrective Actions
CP5 Air bourn contamination near barrier	If high levels of airborne contamination are found to be resulting in high microbial counts in the finished goods area, these are first investigated with the sorting team leader nearest to the goods inward doorway; the condition of the screens/doors in this area is also checked.
CP6 Finished goods area	If high levels of microbial contamination are found on finished goods all surfaces are decontaminated and immediate additional dip-slide tests are performed on the critical control points at the end of washing. Ensure the curtain screen is not compromised Ensure hands are not causing re-contamination
CP7 Finished goods area conveyor belts and Surfaces	If high levels of microbial contamination are found on finished goods all surfaces are decontaminated and immediate additional dip-slide tests are performed on the critical control points at the end of washing. Ensure the curtain screen is not compromised Ensure hands are not causing re-contamination
CP8 Cages for finished goods	Ensure cage has been through decontamination unit. If this is confirmed check correct operation of unit and that decontamination chemical is being dosed correctly.

Control point	Corrective Actions
CP9 Inside walls of vehicle to be used for clean deliveries	Ensure vehicle has been through decontamination using the unit provided. If this is confirmed check correct operation of unit and that decontamination chemical is being dosed correctly.
CP10 Operator Hands	If operator hands fail, then re-training is conducted followed by re-testing.

6.3.7. Principle 6: RABC system checking procedure.

The most senior member of the RABC team (Executive Manager) is the person ultimately responsible for the effectiveness of the RABC Quality Assurance system checks the working of the Company RABC system on a weekly basis.

This check is to establish, by going through the week's records and management meeting minutes, that all of the checks have actually been done, that where results are inadequate then the correct corrective action has been taken and a re-check carried out to verify that the corrective action has been effective.

The check covers new staff who have joined in the week, to ensure that arrangements have been made for them to be trained in the RABC system.

The check covers minutes of the monthly meeting of the RABC team (which should be extremely brief bullet points).

The check covers any information published to customers regarding warnings issued and advice given (for example to ensure customers comply with the colour coded bag system).

The Decontamination Executive then signs off that the system appears from the documentation to be working correctly.

6.3.7.1. Validation and re-validation of CCP's

6.3.7.1.1. Introduction

6.3.7.1.2. General

The medical processes are the ones to be validated.

A 5 log reduction is required

6.3.7.1.3. Microbial reduction

Process parameters, targets and tolerances

Acceptance Criteria

Confirmation that the process is within identified parameters

Verification of control measures and direct verification during validation –

Validation is conducted annually by use of DES-CONTROLLER® KT4-6 supplied from Meducomp GmbH

The DES controller makes it possible to measure the actually achieved degree of bacterial reduction. By applying this method, the influence of temperature and disinfectants (chemicals) are demonstrated and optimal adjustment of the disinfection process is made possible for achieving the objectives established regarding bacterial reduction and therefore validation of the process.

The used indicator-organism is encased in a mechanically, chemically and thermally stable membrane. Micro-organisms cannot pass through the membrane, but water and disinfectants can. The membrane makes it impossible to rinse test bacteria during the process of the medium and ensures that all the germs undergo the entire disinfection procedure.

The DES-CONTROLLER® was developed with the Institute for Hygiene of the University of Lübeck in accordance with scientific standards. It is subject to continuous quality and production control based on the international norms DIN EN ISO 9001 and DIN EN ISO 14001 and meets international standards for disinfection control.

The results are checked to ensure a log reduction above log 5 in line with DHSS guidance and the certificates retained for inspection

Additional verification is conducted by visual checks of wash time and temperatures which are recorded by the operative. This is supported by thermostat calibration quarterly by the decontamination engineer as well as independently by the decontamination sub-contractor.

5.1.1. Principle 7: Documentation.

The Company operates a system of reporting by exception.

Routine checks and maintenance and clean-downs are recorded on the weekly sheets and initialled by the manager responsible.

The RABC log book is then reserved for logging non-conformities, action taken, re-check results and so on.

In this way the Company keeps the minimum of paper records whilst maintaining an audit trail in the event of a customer inspection or external audit by the appropriate body.

5. How the EN14065 system is applied by the Company

5.1 Management commitment and ethos

5.2 Constitution of the RABC team

The RABC team comprises the following:



Executive Manager: William who is ultimately responsible for the operation and effectiveness of the system.

Decontamination Engineer: Paul Frith who is also the Authorising Engineer in matters relating to decontamination.

Decontamination Team Manager and Control of Infection Officer (Decontamination):
Rakesh Baden

Decontamination Team Leader – Soiled Area: Graham Harding

Decontamination Team Leader Clean Mohamed and Mrs Northay

Decontamination Manager – Transport: Dee Morrison.

Note: all of the decontamination team leaders are trained and are regarded as Competent Persons for decontamination duties.

External/Internal Microbiologist: LTC&DTC Limited

Decontamination sub-contractor: the detergent supplier, Christeyns UK Limited, who conducts monthly checks on disinfection conditions, both thermal and chemical as appropriate.

External auditor and Certification (EN14065 compliance):

Steve Anderton LTC&DTC Limited

5.3 Responsibility for facilities and for achieving control of biocontamination

The responsibilities of each member of the Control of Infection Team are set out in Annex A to this manual, section A2.

5.4 Customer requirements for biocontamination, based on end-use

The customer bio-contamination requirement for healthcare and for hospitality textiles is the same:

Target level: of micro-contamination on any washed or finished textile item to be 0 colonies when plated using a dip-slide, equivalent to no more than 10^2 when measured numerically.

Alert level (amber warning for staff): 10^2 colonies on the TVC or Fungal dip-slide or Coliform dip-slide.

Action level (red condition for staff): 10^3 or more colonies on the TVC or Fungal dip-slide or Coliform dip-slide.

Staining: no more than 10 visible stains per 100 items (to control the nutrients for microbial growth to an effective minimum).

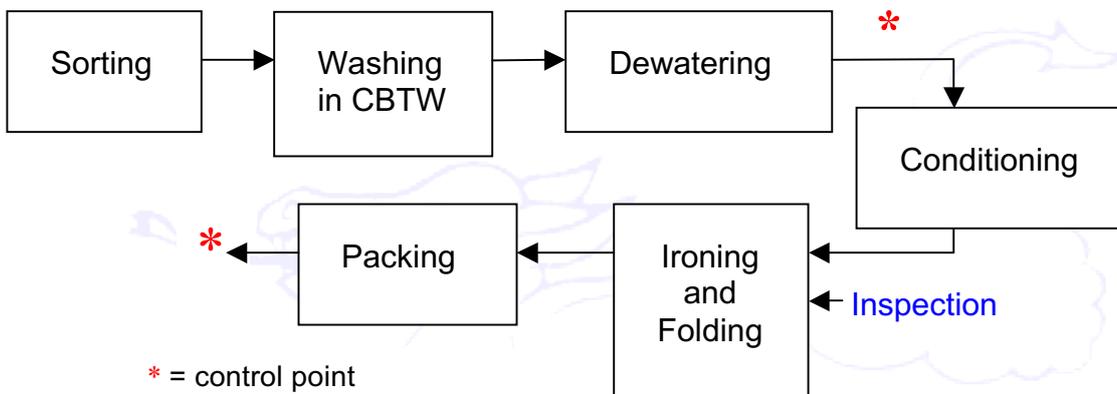
Whiteness reflectance: to be 86% minimum for white woven items, to ensure there is insufficient redeposition of soiling from the wash liquor to provide nutrient for any significant microbial growth. The allowance will be 84% for white towelling items, to reflect the broken surface of terry towelling.

Delivery cage: to be visibly clean and checked to meet the biocontamination standard for textiles.

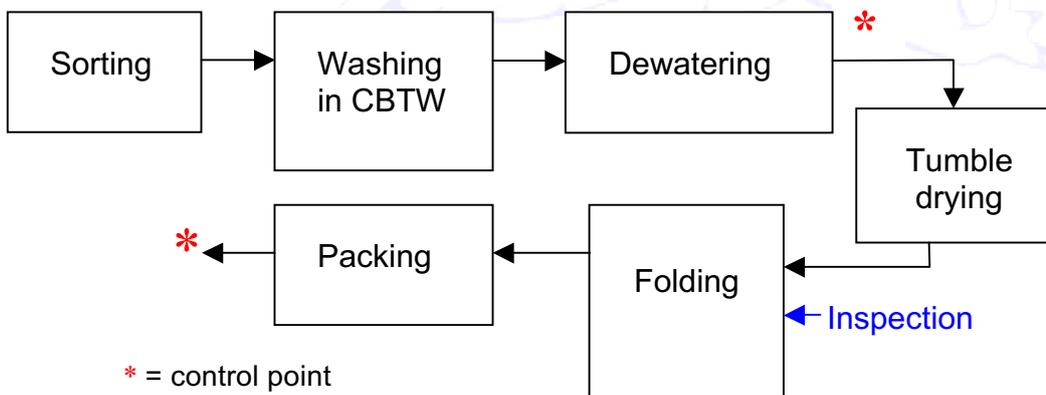
Delivery vehicle: to be visibly clean and the surfaces meet the alert level for the biocontamination standard for textiles.

5.5 Description of laundry flow-diagram for each product

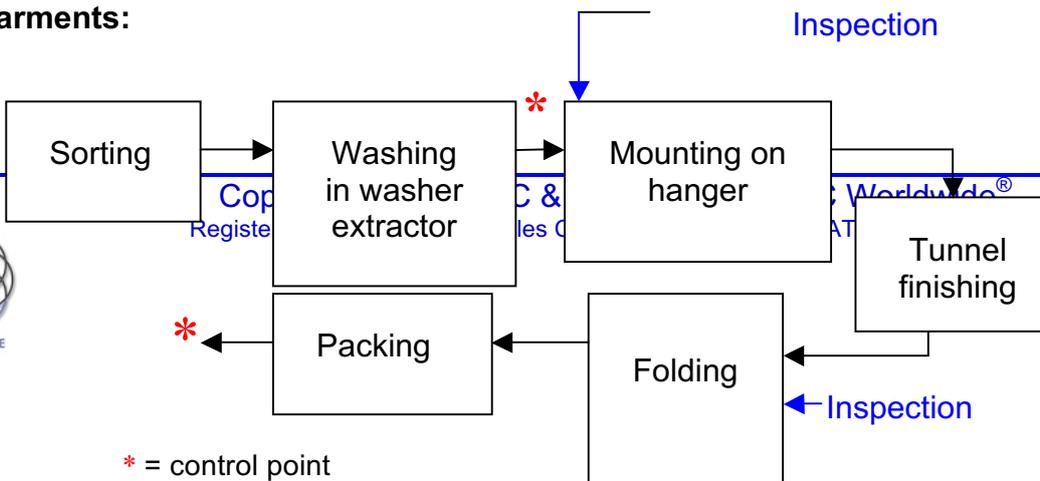
Sheets and pillowcases:



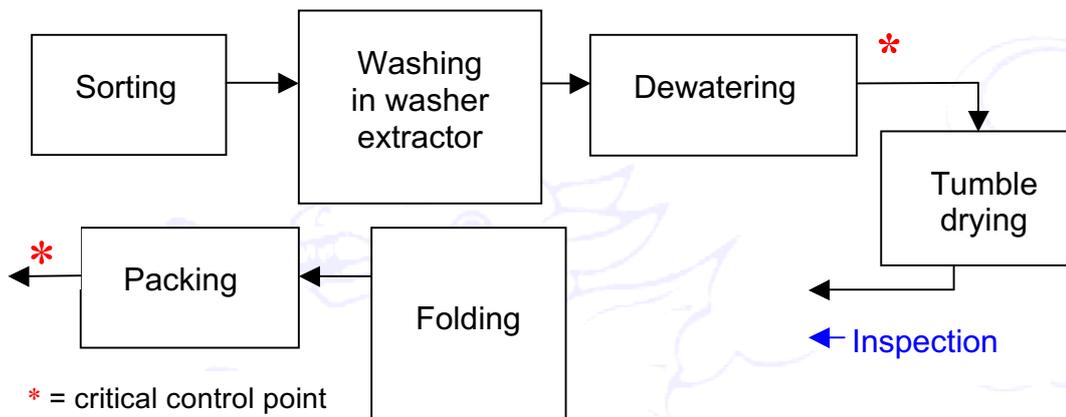
Towelling products:



Garments:



Infective textiles:



5.6 Specification of processes used by the Company to achieve and maintain the required degree of biocontamination

Each of the wash processes used by the Company for healthcare textiles currently involves implied thermal disinfection. This means a wash stage for 100% cotton goods and for all infective red-bag work that maintains 71°C for 7 minutes in the main wash. For polyester cotton goods the process maintains 14 minutes at 65°C in the hot wash.

5.7 Microbiological hazards identified by the Company

The list of microbiological hazards identified by the Company is given in column 1 of the Risk Assessment of microbiological hazards presented in Annex B of this manual.

5.8 Risk assessment of the hazards identified

The full Risk Assessment of the microbiological hazards is given in columns 2 to 5 of the Risk Assessment presented in Annex B of this manual.

This Risk Assessment follows the preferred five-column layout recommended by the Health and Safety Executive. Column 4 of the Risk Assessment details the control measures adopted by the Company for the control of each risk and it is this column which forms the backbone of the Operator Training regime for the Control of Infection Team and for the individual operatives themselves.

5.9 Control measures implemented in this system to control risks adequately

The control measures themselves are listed in column 4 of the Risk Assessment in Annex B of this manual.

The control measures implemented form part of the responsibilities of each operative and the responsibility for ensuring that these are adopted consistently forms part of each supervisor's duties.

5.10 Identification of Control Points

The Company has identified the Control Points listed in Section 4 of this manual, under compliance with Principle 2. These are the points at which the entire control of infection scheme is effectively managed.

5.11 Target levels and tolerances at each Control Point

The target levels and tolerances at each Control Point are as listed in Section 4 of this manual under Principle 3. These are the limits within which the Control of Infection team and the staff in the Company have been trained to operate.

5.12 Monitoring system at each Control Point

The monitoring system at each Control Point is set out in section 4 of this manual under Principle 4. This system has no loopholes and is designed to ensure that the Control of Infection Team is kept continuously informed of the state of Infection Control at any given time.

5.13 Corrective actions taken in the event of deviation

The corrective actions to be taken by staff in the event of any deviation from the target levels are set out in section 4 of this manual under Principle 5. These actions are designed to ensure that the production system is brought back within tolerance levels in the shortest possible time.

5.14 Validation of the laundry process

The Company organises validation of the infection decontamination system at the intervals set out in the latest draft of CFPP01-04. This is done by the one of the following RABC Team members, Control of Infection Officer, External Microbiologist or Decontamination Sub-contractor through use of a calibrated data logging device processed via the CBTW's and washer extractors to validate that target time and temperature is achieved

Alternatively this can be done by ordering pre-infected swatches from the External Microbiologist or disinfection contractor

These swatches are infected with harmless (non-pathogenic) micro-organisms which are selected to act as “markers” for target pathogens, such as E.coli, C.Diff, Bacillus Cereus, MRSA and any other micro-organism which is appropriate

One set of pre-infected swatches is passed through each washing machine with a healthcare classification. This classification is selected as follows:

- a. **Washer extractors:** infective (red-bag) or mops.
- b. **CBTWs:** Sheets, pillowcases or towels.

After processing, the swatches are recovered in the correct manner (to avoid re-contamination) and returned to the Microbiologist for analysis. This analysis indicates the precise concentration of the marker species remaining on each swatch and enables the calculation of the log reduction in concentration of the species targeted.

In the event that any result gives a log reduction of less than $5\log^{10}$ then the Control of Infection Officer immediately informs the Control of Infection team, so that the appropriate corrective action can be instigated.

5.15 Periodic review of the RABC System

The RABC is reviewed annually in its entirety. This review is conducted by the Decontamination Executive (the ultimate management responsibility) and the Decontamination Team Manager, with the Control of Infection Officer in attendance.

In the event that the system is found to be not giving the degree of decontamination assurance required, then a meeting of the entire Control of Infection Team is called in order that the review may be conducted in depth.

5.16 Documentation of the RABC System

The principles via which the Company documents the Decontamination Control system are as follows:

- a. All relevant data are recorded.
- b. Data which generate either an amber or red warning are highlighted on report forms, so that they cannot be lost or overlooked.
- c. All unusual activities are highlighted on the report forms.

The following documents form part of the Documentation System:

- a. Daily and weekly dip-slide readings (TVC, mould/fungus and coliforms)
- b. Quarterly recontamination results (from petri-dish in the finished goods area)
- c. Quarterly process decontamination validation results using pre-infected EMPA swatches.
- d. Quarterly results of contamination checks on finished goods using transport swabs analysed by the External Microbiologist.
- e. Calibration records completed by the Decontamination Engineer

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- f. Results of random dip-slide checks (e.g. on the hands of operatives in the clean goods packing area and on clean cages to be used for clean goods deliveries).

**End of main manual.
Annexes A and B follow.**



ANNEX A DETAILED ARRANGEMENTS AND SPECIFICATIONS IN THE COMPANY RABC SYSTEM

A1 Legal requirements

The Company has identified the following legal requirements and has prepared this manual accordingly:

- a. This manual, the training associated with it and the procedures to be followed are designed to comply with the *Management of Health, Safety and Environmental Guidelines* published by the Textile Services Association. This document is the interpretation of the thirty or so UK Acts and Regulations which govern safety in laundering, agreed with the UK Health and Safety Executive.
- b. The Company is aware of its duties under Common Law with respect to the safety of its customers and has designed the procedures in this manual to reduce to the minimum level the risks to its customers and their patients of any form of cross-infection or other adverse outcome arising from its activities as a responsible provider of healthcare linen.
- c. The Company is aware of its duties to transport infective linen safely and correctly packaged and has built this into its arrangements for transport of this, both on customers' premises and on public streets. It acts proactively to minimise risks to members of the public, not least by providing its customers with the correct means of bagging (and therefore identifying) infective goods.
- d. The Company is aware that it depends on its trained staff to deliver the detailed implementation of this Decontamination and Infection Control System. It has accordingly taken every reasonable step via training and via proper job descriptions in every contract of employment, so that every employee knows what is expected and had been properly trained to deliver this.
- e. By these means the Company believes that it has identified and implemented best practice across all of its infection control activities. Insofar as there are residual risks at a low level the Company maintains sufficient insurance to guard against the financial consequences of an unforeseen incident and injury.

A2 Responsibilities of Management and of each member of the RABC Team

Each person in the RABC team has the following responsibilities:

Decontamination Executive: William Orford: is ultimate responsibility for the proven effectiveness of the RABC system in meeting customers' decontamination requirements.

Decontamination Engineer: Paul Frith: has responsibility for:

- a. Correct tuning of processing equipment
- b. Functional effectiveness of all automatic controls relevant to RABC
- c. Calibration of all automatic controls and indicators relevant to RABC



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- d. Conducting monitoring of new or existing wash processes using the calibrated data logger and submitting these to the Control of Infection Officer.

Decontamination Team Manager and Control of Infection Officer: Rakesh Baden has responsibility for:

Execution by staff of all day to day RABC activities.

Monitoring the degree of bio-contamination at the critical control points using dip-slides.

Liaison with the Microbiologist for ordering the following:

- a. Dip-Slides swabbing of freshly washed and rinsed textiles.
- b. EMPA pre-infected swatches for periodic validation of the wash processes being used.

Entering all results from dip-slide measurement and from the Microbiologist into the appropriate record sheet.

Immediately informing relevant members of the RABC team (including the Decontamination Executive) of any result which falls short of the Company RABC requirement.

Keeping the floors and other critical surfaces free from spillages, solid soiling and debris.

Verifying that the correct load weights go forward for washing.

Ensuring that work is sorted in accordance with the Company system, into the correct classifications.

Ensuring that the weight of each batch is correct within the limits allowed by the Company system.

Ensuring that cross infection controls in Sorting are enforced.

Maintaining maximum productivity in Sorting so that dirty work is stored quickly ready for washing.

Ensuring that the correct load is placed in the right machine.

Checking that the correct programme has been selected for the classification.

Verifying at least once per day that the conditions for implied thermal disinfection are being achieved in the washing machine.

Ensuring that washed work is unloaded promptly and forwarded correctly.

Maintaining vigilance over the washing line and reacting promptly to error conditions and error warnings.

Checking temperatures in the pre-wash are sufficiently cool to avoid residual protein staining and nutrient for bug growth, at least once per shift.

Checking main wash time/temperature combinations to ensure implied thermal disinfection, at least once per shift.



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Visually checking the cleanliness of the transfer conveyors and reacting appropriately if any soiling found.

Ensuring that dryer loads are not over laden and that barrows sent to the correct destination.

Ensuring no goods for sale are allowed to come into contact with the floor and placing any that do back into re-wash.

Processing goods in sequence, to ensure no long delays and opportunities for bug growth.

Verifying by touch that finished goods from the ironer, towel folders and tunnel finisher are sufficiently dry as to inhibit bacteria or fungal growth.

Investigating and rectifying immediately any instance of poor drying.

Supervising the handling of finished foods in the area to ensure that hand contact is kept to a minimum, in line with Company procedures.

Ensuring that goods are all packed and stacked in accordance with Company procedures, so as to avoid recontamination.

Ensuring that goods rotation avoids idle batches that might attract re-contamination.

Ensuring that all delivery cages have been cleaned prior to loading, to control recontamination from dirty cages.

Matching customer deliveries to customer orders, to ensure sufficient textiles for requirements, with no excess to attract recontamination and no shortages to necessitate double use or late changes.

Decontamination Manager – Transport Dee Morrison is responsible for:

Ensuring that all delivery vehicles are clean prior to loading.

Ensuring that all delivery staff meet Company requirements for visual smartness and cleanliness.

Checking that deliveries fit the vehicle with no external ingress for dirt, birds, insects or animals.

Taking appropriate precautions to ensure that there is minimum opportunity for dirt, birds, insects or animals to enter the premises via the transport area.

External/Internal Microbiologist: Steve Anderton is responsible for:

Issuing correctly labelled pre-infected textile swatches for the marker bugs requested by the Company.

Growing appropriate cultures from the samples submitted by the Company so as to provide an accurate indication of the level of microbial contamination at the critical control points.

Performing analysis and reporting promptly, so as to provide answers whilst they are still relevant.

Reacting intelligently (by telephone or site visit) to poor results, so that corrective action can be accelerated.

Conducting validation testing of new or existing wash processes using the pre-infected EMPA swatches and submitting these to the External Microbiologist for analysis for 'marker species'.

A3 Company standards for technical hygiene requirements of:

a. Buildings

The Company operates to the following standards:

- Spillages of human body fluids in the sorting area are cleaned up immediately, following the procedure described in
- Debris in the Sorting area is cleared and bins emptied every four hours into the external skip.
- Debris in all other areas is cleared and bins emptied at the end of every shift.
- Floors are swept in all areas at the end of every shift, including under equipment to the limit of the broom's reach.
- Overhead lint and other contamination is cleared every three months.
- Liquid leakages are sealed within 24 hours wherever possible.
- Cracked and flaking floors and walls are repaired so as not to allow the creation of dirty areas for micro-organic growth.
- Walls and floors are suitably painted or sealed every two years so as to preserve surfaces which are readily cleanable.
- Cracked glazing is repaired promptly and in any event within 7 days.

b. Washrooms

- All washroom equipment is maintained in good condition with any cracked items replaced promptly.
- Cracks and other damage to washroom surfaces (both walls and floors) are repaired promptly.
- Washrooms are painted bi-annually so as to maintain cleanable surfaces.
- Washroom leaks and damaged glazing are repaired within 48 hours.
- Washrooms are inspected every two hours and cleaned and disinfected daily.
- Washroom abuse is not tolerated and is dealt with promptly and firmly.
- Washrooms are fitted with hot air dryers and disinfecting gel as standard.

c. Water supply

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- The Company reserves the right to use either towns mains or borehole water for the processing of healthcare work.
- The responsibility for the contamination quality of towns mains water is delegated to the supply Company.
- The responsibility for the quality of borehole water is taken by the Company. This responsibility is discharged in the following ways:
 - Micro-organisms: these are monitored with dip-slides on a daily basis.
 - More than two colonies on the TVC or the mould/fungus dipslides or a single colony on the coliform dip-slide triggers a red alert and the Company switches back to towns mains whilst this is investigated and rectified.
 - The water is softened to below 4 degrees Clark, checked daily.
 - Iron contamination in the water is monitored at each technical visit by Christeyns and corrected to maintain this below 0.1 parts per million.
- Hardness: the Company softens all water to below 4 degrees Clark, checked daily, in order to ensure that the cleansing activity of the detergent is not compromised.

d. Effluent disposal

- All effluent from Company washing machines is discharged to the public sewer via drains sealed from the outlet of each washing machine, to prevent atmospheric contamination, especially with infective aerosols and odours.
- Company effluent is subject to charge by the water Company depending on the level of contamination (which is monitored by the receiving Company).

e. Ventilation system and air-flow

- It is Company policy to encourage the flow of fresh air through the factory in order to diminish any risk of airborne contamination of air breathed by the staff. A positive airflow from the clean area towards the soiled area is promoted to diminish any risk of airborne contamination.
- The Company relies on simple means to discourage avian ingress, such as netting beneath roof vents and plastic strips on vehicle entrances.
- The Company regularly monitors the re-contamination of finished goods via the use of dipslides in the finished goods area and keeps the need for controlled airflow under review.

f. Processing machinery

- It is Company policy to purchase only equipment which complies with the EU Machinery Directive, so that reliance can be placed in its control systems and calibration to deliver the requirements of this Decontamination System.

- All CBTWs are purchased with in-built disinfection systems for the rinse zones to enable simple, automatic disinfection before start-up to preclude re-contamination in the rinse.
- All membrane press de-watering equipment is selected so as to be readily accessible for cleaning, to avoid recontamination in the press area.
- All washer extractors are specified with computer controls for dips and temperatures, augmented by automatic weighing of loads added, to enable early warning of overloading and consequent risk of failure of implied thermal disinfection.
- All equipment is specified with sufficient temperature and pressure indicators as to enable staff to have sufficient information to control disinfection. This is extended to the membrane pressing equipment, which indicate time at pressure to enable staff to minimise any risk of inadequately de-watered loads going forward, with the attendant possibility of fungal and microbial growth associated with the production of damp work.

A4 Staff hygiene and health and safety

a. Hand hygiene

Correct hand-washing procedures form part of every operatives training and this is monitored by unannounced checks on the microbial contamination found on operatives' hands. Alcohol hand gel is in common use and widely available to staff members.

b. Care of the body

- Particular attention is paid during staff training to the protection of the body from microbial contamination from incoming infective work.
- This includes the importance of protective clothing, correctly fastened, masks when these are called for (especially during an infection outbreak or pandemic), gloves in good condition and taping over of any sores or wounds.
- Supervisory staff are trained in sensitive techniques for enforcing these requirements as part of their supervisory training.
- All staff receive training in sharps awareness and the procedures to be followed for safe sorting and for action to be taken in the event of a sharps injury.
- This extends to action to be taken with the offending customer who has failed to keep the sharp out of the incoming soiled linen.

c. Staff clothing

- Staff are required to wear the work-wear provided and to cover every item of their own clothing with this.

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- Staff work-wear is laundered by the Company on a weekly basis, more frequently if required.
- Staff who load washer-extractors with healthcare work (usually infective) are required to change their work-wear daily. They are also required to don a disposable apron for loading the extractor and to remove this when unloading the clean work.
- Staff working in the sorting and loading areas wear Raspberry work-wear. Staff in clean areas wear blue work-wear. Staff wearing Raspberry work-wear are not allowed into clean areas and vice versa unless there is a change of workwear (a white coat is worn by clean area staff entering the soiled area and those exiting the soiled area were blue. The Engineering staff must wear GREEN workwear in the soiled area.
- Watches and jewellery are not permitted to be worn whilst operating machinery or handling linen or other equipment.
- Visitors and contractors must follow these requirements.

d. Staff canteen

- Staff are not allowed into the canteen wearing pink work-wear.
- Staff are required to wash their hands and to disinfect them with alcohol gel before entering the staff canteen.
- The canteen is cleared after each break and spillages wiped up.
- Cracks in the walls and floor are repaired promptly, usually within 48 hours.
- The canteen is decorated bi-annually to provide cleanable surfaces.

e. Medical care and precautionary measures

- The Company provides facilities for free inoculations for hepatitis B and tetanus, in line with the policy and recommendations for NHS staff.
- Staff who do not acquire immunity once tested will not be permitted to work in the soiled area.
- In their training in infection control, all staff are taught the principles of staying free of infection and especially what to do in the event of an outbreak of diarrhoea or Norovirus. This training extends to differentiating between the symptoms of the common cold and influenza or meningitis.
- This is backed up by trained first-aiders in all areas.

A5 Specifications for suppliers and external support services

a. Supplier assessment and selection

Equipment suppliers are assessed on the basis of their demonstrable experience of providing equipment that has been shown to be capable of meeting the requirements of



healthcare laundering. This is backed up by site visits to other companies in this market who have invested in the same equipment.

Chemical suppliers are assessed on their ability to demonstrate that they can meet infection control requirements and have at least two reference healthcare sites where this can be verified. In addition, the chemical service team must demonstrate knowledge of decontamination in laundering and the different techniques for achieving this, together with ability to support this knowledge with independent verification of disinfection conditions in each machine on each monthly service visit.

Preference is given to a supplier who can demonstrate a quality system for manufacturing of their products that is ISO 9000 compliant.

b. Purchasing control

All orders for consumables, textiles or equipment have to be countersigned by the Decontamination Executive, Decontamination Team Manager, Decontamination Engineer or Control of Infection Officer who are responsible for verifying that the purchase will enable the Company's decontamination responsibilities to be met.

c. Textile specifications

The Company purchases its own rental textiles for healthcare to be compliant with the British and European draft standard DD ENV 14237, which is designed to enable a rental healthcare textile to deliver up to 200 wash and use cycles without failure from normal wash damage, finishing or fair wear and tear. (It does not cover theft, mislaying and abuse.)

The Company offers a service to its customers for the testing and approval of customers' own goods (return to sender items) in order to offer the same degree of confidence regarding these items to withstand normal healthcare laundry processing for disinfection.

d. Laundry chemical specifications

The Company does not specify the chemical composition of the wash products purchased for de-contamination. Instead it requires its suppliers to guarantee a certain level of performance in respect of de-contaminating standard EMPA pre-soiled test swatches for Blood, Protein, Vegetable Oil, Mineral Oil and Vegetable dye. The performance required is specified in numerical terms, being the whiteness reflectance of the calibrated test swatches after one wash in the healthcare process.

In addition the Company requires that the chemistry of the wash not only removes the soiling and staining, but also suspends this in the wash liquor and prevents it re-depositing onto the clean fabric and providing nutrient for microbial growth. This is monitored by measuring the reflectance of 100 towels and 100 pillowcases at least 6-monthly intervals and plotting S-curves, which clearly indicate any detrimental trend.

e. Monitoring by the laundry chemical supplier



The Company requires the chemical supplier to provide independent monitoring of the conditions for implied thermal disinfection on each visit, or the equivalent for thermo-chemical disinfection if this is being used. This is backed up with a written report on each visit, summarising the results obtained.

f. Specifications for wrapping materials and surface cleaning chemicals

The Company includes in its specification for wrapping materials the requirement that the material be free of microbial contamination on both surfaces and checks this every three months or so using dip-slides.

g. Waste disposal specification

The Company disposes of all commercial waste in line with current legislation. Polythene wrappers and all paper and cardboard are recycled, where possible, in the appropriate manner so that they do not contribute to landfill. Other waste is disposed of via commercial skips.

h. Sub-contracted transport services

The Company has its own fleet of vans for collection and delivery of linen, manned by drivers trained in the handling of contaminated health care textiles and control of cross infection.

In the event that external services are required, in exceptional circumstances, then the Company would opt to hire vans driven by its own trained staff to maintain the quality of service and the required level of infection control.

i. External calibration of RABC control devices

The Company uses calibration devices for monitoring disinfection temperatures and disinfection times. The calibration of temperature indicating and controlling equipment is checked by reference to the temperature of melting ice and of boiling water. The calibration of equipment for measuring disinfection times is checked by reference to the 'speaking clock' service provide by the telephone service Company.

The Company uses check weights to verify the weight of individual batches of textiles to be washed, to ensure that machines are not over-loaded (with consequent incomplete disinfection). These weights are purchased from a reputable supplier and are accurate to within 2% which is more than adequate for this purpose.

The Company commissions the chemical supplier to check the accuracy of all dosages on a monthly basis and report by exception on any errors found and corrected.

A6 Cleaning and disinfecting plan

f) Cleaning and disinfecting products

The Company uses standard materials for floor cleaning and disinfecting, following the guidance of its healthcare customers in this respect. The same applies to wall cleaning.

The Company uses special cleaning chemicals from its chemical suppliers for cleaning equipment surfaces in contact with the finished textile products, such as the underside

of the de-watering press membrane, the surfaces of the conveyor between the de-watering press and the tumble dryers and the sides of the press tank beneath the de-watering press. If required (and especially if there is any visible build-up of residues) the same chemicals are used for cleaning the other re-cycling tanks on the CBTWs.

g) Maintenance of cleaning machines and equipment

All laundering equipment is maintained in accordance with the suppliers' recommendations. The only exceptions are the extensions to these recommendations given in this manual (such as those described in the previous paragraph).

All laundry machine maintenance is carried out under the auspices of the Decontamination Engineer who is also discharges the Chief Engineer/Engineering Manager role for the organisation. This ensures that any machine overhaul or repair leaves the machine in a de-contaminated state as far as infection control is concerned.

h) Cleaning and disinfection procedures for:

- **Rooms and areas**

Floors are cleaned mechanically to pick up debris and are then cleansed with a disinfecting wash. The techniques used are those described in the relevant machine manuals. The disinfecting chemicals are those recommended by the supplier.

Walls are cleaned by wipe-down, where appropriate, usually on an annual basis unless visibly soiled or stained. The same disinfecting cleaning agent is used for the walls as for the floors.

- **Devices and equipment**

The cages in which the soiled work is received are cleaned and disinfected before being refilled with clean, de-contaminated work. It is the Company's intention to achieve this ultimately using steam cleaning or chemical disinfection and cleaning in a purpose built cage cleaning machine. In the meantime, the Company uses a pressure washer to strip off visible surface soiling, followed by a disinfecting spray using chemicals recommended by our chemical supplier.

The only other key area for equipment cleaning is at the de-watering press, which requires cleaning and disinfection of all surfaces in contact with the cleansed textiles. These surface comprise the underside of the press membrane, the entire surface of the press floor against which the cheese of pressed textiles is squeezed and the surfaces of the discharge conveyor and the shuttle conveyor (both belt and sides).

If microbial growth is observed on the sides of the water recycling tanks on the CBTWs, then these will be added to the schedule, even though the textiles are subjected to high temperature implied thermal disinfection after contacting any water from these. This is in order to maintain the highest log kill on individual species and to minimise the proliferation of any spore forming species such as *Clostridium difficile* and *Bacillus cereus*.

i) Cleaning and disinfecting programme

The cleaning and disinfecting programme is as follows:

Location	Criterion for cleaning	Frequency
Floors - sweep clean of debris	Regardless	Daily
Floors – sorting – disinfecting/power wash	Regardless	Weekly
Walls – disinfecting wash	Regardless	Annually
Cage	Before being loaded with clean textiles	Every time
Membrane press – face of membrane and press floor power wash	Regardless	Weekly
Membrane press – face of membrane and press floor chemical disinfect	Regardless	Daily
Discharge conveyor and shuttle conveyor	Regardless	Weekly
Press tank power wash and chemical or thermal disinfect	Regardless	Weekly
Recycle tanks	If visibly contaminated on metal surface	As required

j) Monitoring system and procedures for cleaning and disinfection

The standard method of monitoring of the level of microbial contamination on key surfaces in house is by the use of dip slides.

Two types of dip slide are used, one to give Total Viable Count (TVC) and Moulds/fungi and one to give TVC and Coliforms. The coliform dip slide is particularly useful for healthcare work, because of the high level of human body fluids on incoming work (which leads to a similarly high level of E.coli and similar gut-based micro-organisms).

All results are recorded. The basic monitoring frequency for all measurements is weekly, unless experience reveals a very high incidence of non-zero results, in which case the Decontamination Executive can reduce the frequency to fortnightly.

A7 Pest Control

The Company employs standard procedures for the control of vermin such as rats and cockroaches, involving appropriate traps and bait.

The Company is currently addressing the issue of avian access to the factory, which needs to be controlled without limiting the amount of fresh air being introduced into the workroom.

A8 Staff training

Personnel to be trained



The following members of the Control of Infection Team receive exactly the same training, so that everyone understands clearly who is responsible for what and how this responsibility is discharged.

Decontamination Executive responsible for the entire RABC System

Decontamination Team Manager

Control of Infection Officer

Decontamination Engineer

Decontamination Manager - Transport

Syllabus

The syllabus for the training is as follows:

1. **Handling principles for healthcare work**, covering colour coding, double wrapping, sharps, infective work, labelling, RTS items, dangerous items and so on.
2. **Infection control**, including Infection Control Officer, monitoring of disinfection, cleaning routines, special bugs to watch out for, internal monitoring using dip-slides, external monitoring using pre-infected swabs and so on.
3. **Processing principles** for healthcare, including the roles of the Decontamination Executive and the Decontamination Team Manager, removal of soiling and staining, special staining (chlorhexadine, iron, aluminium, plaster, mercurochrome), reasons for monitoring re-deposition and how to do this, thermal disinfection in the wash zone, chemical disinfection in the rinse, towel softness, yellow patches and so on.
4. **Engineering requirements** for healthcare, including the role of the Authorising Engineer (Decontamination), weigh-scale calibration and calibration generally, wash zone temperature management and monitoring, special installation requirements for washer-extractors, infective work risks, single and double washing, hazards with chemical disinfection, ironer set-up for different fabrics, tumble dryer set-up for different fabrics, odours and odour control and so on.
5. **Minimising documentation requirements** for compliance, covering what to record, how often to record it, electronic records, amber and red warnings, communication with the rest of the internal healthcare team, reports for the customer and so on.
6. **Decontamination Team Leader (Competent Persons) training for healthcare**, covering special health and safety provisions (including inoculations and vaccinations), handling procedures for healthcare bundles, leaking packages, implied thermal disinfection, sorting precautions for healthcare, identifying orphan work and so on.

A9 Internal monitoring of the effectiveness of hygiene control

Points monitored, with number of samples in each

Internal monitoring is based on three main critical control points:

**BS EN14065: 2016 Risk Assessment-based
Biocontamination Control System General issue 11 20170823**

1. Immediately after washing by dip-slide assessment of residual microbial contamination on cheese from the membrane press or clean work still in the washer extractor at the end of the final spin. This verifies that the main decontamination stage of the process is functioning correctly.
2. On finished goods, particularly towels and pillowslips, to determine the net effect of decontamination and re-contamination in drying, folding and packing, again using dip-slides.
3. In the finished goods area on surfaces and using an exposed dip-slides and appropriate agar to determine the level of pick-up of airborne microbial contamination with known pathogens (assessed by the Microbiologist).

Records of results obtained

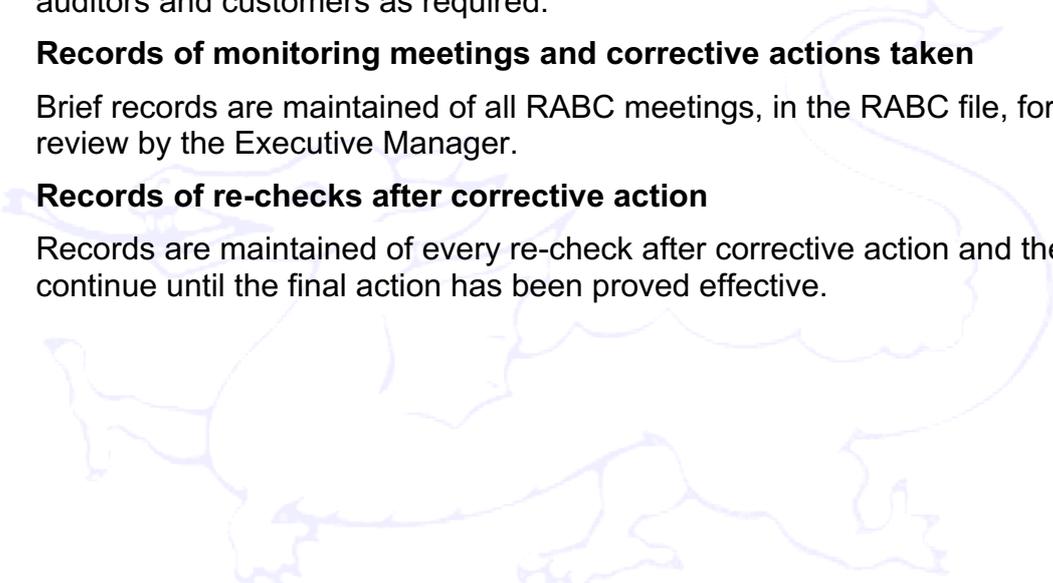
All results are recorded in the Micro Hygiene Test Result file for inspection by auditors and customers as required.

Records of monitoring meetings and corrective actions taken

Brief records are maintained of all RABC meetings, in the RABC file, for regular review by the Executive Manager.

Records of re-checks after corrective action

Records are maintained of every re-check after corrective action and these continue until the final action has been proved effective.



Annex B

B.1 General

This annex provides examples, for considerations when developing a prerequisites programme (PRP). The relevance of individual items, and the standards to which they will require development, follow from the intended use of the textiles, external requirements and from the strategy of the laundry. Requirements and controls are often less strict for General and stricter for Operational prerequisites. Annex D provides an illustration of how and where to apply these considerations in a laundry.

B.2 Premises and structures

The suitability & sufficiency of design, layouts and materials, particularly those in contact with processed textiles have been assessed and tested conducted where appropriate.

Segregation
Zoning
Access facilities
Staff and plant hygiene facilities
Water supply, treatment, storage and disposal
Ventilation system and air flow
Storage

B.3 Cleaning

Clearing, cleaning and if necessary disinfecting for key surfaces, using recognised disinfectants
Order of cleaning (e.g. critical areas 1st, high to low and back to front of surface, back of area to exit);
Standardizing methods (equipment, materials, techniques, schedule, criteria);
Verifying effectiveness.

B.4 Personnel

Hand hygiene, personal hygiene and adornment such as jewellery;
Protective clothing, staff access rules;
Food and drink practices;
Product handling rules;
Staff training and competence;
Medical care and screening.

B.5 Equipment

Processing, transport and cleaning equipment;
Utility equipment;
Measuring and monitoring equipment;
Preventative maintenance, servicing, repair, calibration and cleaning of equipment;
Suitability of equipment and work surfaces for contact with processed textiles (impermeable, washable);
Capability to work within tolerances;
Capability to prevent release or alarm when tolerances are exceeded;
Process all stages of the process, including re-work and transport;

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Prevention, limit, reduction, elimination of biocontamination, including re-contamination and crosscontamination;
Parametric controls, failsafes, monitoring, verification, inspection, testing, checklists.

B.6 Foreign bodies and inappropriate materials

Pest control;
Inappropriate materials in contact with processed textiles (eg. rust, uncovered wood);
Unprotected glass and hard plastics.

B.7 Supplies

Suitability of bought in materials and equipment for direct contact with in-process or processed textiles;
Specifications;
Handling and storage measures.

B.8 Monitoring of PRP effectiveness

Possible measures include inspections, regular checklists, good practice audits, system audits, microbiological monitoring, work records, trending and analysis of data etc.

Appendix 9

Risk Assessments

Risk Analysis and Evaluation							
Description			Analysis P x S=R			Evaluation	
Step	Hazard	Consequence	Probability P	Severity S	Risk R	Control Point Identity	Priority
Wash	Temperature Failure	Failure to decontaminate	1	8	8	CCP	Very High
	Overloading		2				
Dry							
Pack							

Appendix 10



Appendix 11



Health Service
Guidelines

Hospital Laundry Arrangements for Used And Infected Linen

Executive summary

The provision of adequate laundry services is a fundamental requirement of direct patient care and a major feature among a hospital's many activities which contribute to its commitment to care. Primary Charter standards of quality services "Hospital Laundry Arrangements for Used And Infected Linen" sets out the recommended procedures to help meet this commitment. In particular it covers the handling and laundering of linen, the importance of securing the distribution of used and infected linen, and the basic principles of infection control.

Background

The NHS has an obligation under the Health and Safety at Work Act to take steps to prevent the risk of infection to staff handling and laundering linen. There is also a need to deal with the potential for harm to staff and damage to linen by a failure to separate "sharps" from dirty linen before it is placed in laundry bags.

Action

NHS managers are asked to draw the accompanying guidance to the attention of all staff including contract staff, who may need to apply it.

Managers should ensure that relevant legislation, including the requirements of the Registered Homes Act in respect of laundry from social units, is complied with.

Management should adopt procedures to ensure that patients and staff are not put at risk of infection from used and infected linen.

Management should ensure that all staff and laundry contractors, responsible for handling or laundering linen, are appropriately trained.

The advice contained in the HSG should be incorporated into contracts where laundry services are not provided in house.

The help of the Society of Hospital Linen Services and Laundry Managers, in conjunction with the industry technical association, FHLA in drawing up this guidance is acknowledged.



HSG(95)18

Hospital Laundry
Arrangements for Used
And Infected Linen

This replaces HC(BD)30
which expired on 1
December 1992

11 April 1995

Addressees

For whom:
NHS Trusts
County Managed Units

For information:
Regional Health Authorities
District Health Authorities
Special Health Authorities

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