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PROCESS VALIDATION

Process validation is now an essential requirement contained in two very important documents for those washing for the healthcare sector – BS EN 14065 (Decontamination in laundering) and CFPP01– 04 (Decontamination of healthcare textiles, which replaced HSG(95)18.) The implementation of the Choice Framework for Local Policy and Procedures, (CFPP 01-04) outlines two key requirements for users and processors of healthcare linen. They must meet the guidelines' Essential Quality Requirement (EQR) but in doing so they must aim to move to the Best Practice (BP) level of service over the life of the document. It is divided into four manuals setting out the requirements for the safe decontamination of linen for health and social care. Guidelines detailed over a total of 161 pages effectively replace the previous standard, HSG95 (18), which consisted of only 12 pages. Guidance manuals available only provided an overview and linen users and linen processors must review the full guidance to identify the action needed to comply with the updated requirements and expectations. Published by the DoH (department of health), in July 2012, CFPP 01-04 amalgamates earlier versions of laundry guidance and replaced HSG(95)18 with immediate effect.

In the Full Guidance the four manuals cover:-

- * Management and provision (which includes DoH policy on safe linen decontamination and processing).
- * Social care (which provides guidance on how to implement linen decontamination in social care settings).
- * Specific guidance for linen processors that plan to implement the European standard BS EN 14065, or have already done so.
- * Engineering, equipment and validation.

This last covers standards and regulatory frame work, the roles of key personnel and design and pre-purchase considerations (of equipment and linen). It also looked at validating and verifying the disinfection performance of washers, washer-extractors and continuous tunnel washers. All laundries including small scale operations and local linen processors have been expected to meet the quality requirement since July 2012 after the formal release of the CFPP 01-04 guidelines. Which in essence means Laundry and Healthcare organisations must have written policies and procedures for the safe operation of all processes and equipment. All relevant laundry processors must meet the quality requirement for the decontamination arrangements for linen used in health and adult social care sectors. This includes all parts of the guidelines for:-

- A) service delivery,
- B) process control,
- C) risk analysis,
- D) bio-contamination control,
- E) overall process validation.

In addition, linen processors that launder infectious linen must adopt post-wash sorting of linen.

Two compliance routes are the NHS route to EQR (**Essential Quality Requirements**); and the BS EN 14065 route to EQR and Best Practice (BP). The textile hygiene standard BS EN 14065, which is commonly referred to as "Risk Analysis and Bio-contamination Control" (RABC) requires laundries to segregate clean and dirty linen to deal with the risk of bio-contamination and to ensure there is no chance of recontamination. Providers who attain BS EN 14065 certification immediately meet the quality and best practice requirements of CFPP 01-04. Process validation forms an essential requirement of both routes to best practice and must be carried out for each wash load. A laundry's first step towards achieving BS EN 14065 certification is to hold a copy of the standard and to implement its quality management system and specific requirements. This is not a task to be undertaken lightly as it requires a thorough commitment, and a great deal of effort and also has a financial cost, however, those that have achieved it comply with CFPP 01-04 and could benefit from a significantly improved business operation as a result. In the later stages of implementation, or on its completion, the company may wish to be evaluated for certification.

Low temperature validation—The practice of washing healthcare linen at 65°C for 10 minutes or 71°C for three minutes to achieve thermal disinfection remains unchanged, which was the guidance contained in **HSG(95)18**. NHS trusts require temperature validation inspections and certification; Government guidelines recommend that temperature checks on each laundry machine's disinfection cycle are carried out every six weeks.

Validation for CFPP01-04/BS EN14065 should provide Key Process Indicators (KPIs) that have a significant effect on quality and determine what can be monitored in real time to provide immediate (parametric) release of product. A parametric release system requires validation of the sterilisation process. This requires evidence (data) that all equipment to be used in the overall sterilisation process has been:- installed properly (installation qualification), that the equipment operates as intended (operational qualification), and, in the most important and complicated step, that the overall process consistently produces a sterile product (performance qualification). The majority of this test data to support the validation process is likely to be generated in the laundry.

CFPP 01-04 and OPL design, and how CFPP 01-04 will impact on OPL and single machine installations in the healthcare and social care sectors - Best practice for the disinfection stage requires annual valida-

ucted by the validator contractor, or machine manufacturer. There is no simple method to verify by inspection, or to test the efficacy of the disinfection process on each piece of linen before it is used. Testing a laundry's washers has several requirements.

- * The disinfection processes must be validated before use;
- * The process must be monitored during routine use to judge its performance.
- * The calibration of controls and instrumentation must be verified
- * In addition equipment must undergo a suitable programme of maintenance.

Performance qualification 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 instructions for a particular load type. Performance qualification tests are performed as part of an initial validation procedure and also as part of any repeat validation procedure and whenever the operator judges that new loading or operating conditions require a further test. Fresh performance qualification tests may be needed if there are changes to the chemical additives used in disinfection, if the loading system changes, or if the laundry has to process a new type of material. Independent Monitoring System needs to be installed, as a result of this development, in hospital and social care environments in the UK to prove the efficacy of the process.

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

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

The guidance provided in this CFPP promotes a principle of continuous improvement in linen processing performance at all levels. It provides options that allow laundries, launderette operators and local linen processors to choose how to meet EQR and how to progress to BP. This CFPP amalgamates earlier versions of laundry guidance. Earlier documentation incorporated in and superseded by this guidance includes HSG(95)18 and parts of Health Building Note 25 – 'Laundry'.

If any laundry installation or premises includes facilities for the sterilization of medical devices, then the Essential Quality Requirements of CFPP 01-01 Part A will also apply to the sterilizer installation. Other existing regulations and industry standards are discussed in the 'Engineering, equipment and validation' volume of this CFPP.

BS EN 14065 describes a management system for assuring the microbiological quality of processed textiles used in specifically defined sectors in which it is necessary to control microbiological contamination. The Department of Health encourages the adoption of this standard for those operating laundries both in a commercial setting and within the NHS.

BS EN 14065 the Risk Analysis and Bio-contamination Control (RABC) cross match against the roles identified in 'Management and provision'. It is a European Standard and describes a management system for assuring the microbiological quality of processed linen used in specifically defined sectors to control microbiological contamination. It describes a Risk Analysis and Biocontamination Control (RABC) system designed to enable linen processors to continuously assure the microbiological quality of the processed linen.

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

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

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

The principles of an RABC system are:

- Principle 1. List of microbiological hazards and list of control measures:
 - (i) identification of the microbiological hazard(s) associated with each step of the process, with the product or with staff;
 - (ii) assessment and classification of levels of risk(s) of the microbiological contamination of textiles at each step of the process as a consequence of the hazard;
 - (iii) identification of control measures to eliminate or reduce the risk(s) of the microbiological contamination of textiles to reach the agreed microbiological quality for the end-use of the textiles.
- Principle 2. Determination of the control points: Determination of the points/steps/environmental conditions that can be controlled (control points) to eliminate or reduce the risk(s).
- Principle 3. Target levels and limits – tolerances: Establishment of limits at each control point, which should not be exceeded in order to assure microbiological quality of textiles.
- Principle 4. Monitoring system: Establishment of scheduled testing or observation to monitor the control points.
- Principle 5. Corrective actions: Establishment of corrective actions to be taken when monitoring indicates that a particular point/procedure/operational step/ environmental condition is not under control.
- Principle 6. RABC system checking procedures: Establishment of procedures to verify that the system is working effectively.
- Principle 7. Documentation: Establishment and maintenance of appropriate documentation.

If correctly implemented, the BS EN 14065 standard builds on this foundation, providing users with an RABC approach to assure consistently effective disinfection of linen and reliable protection thereafter from recontamination. The standard fully describes the RABC approach, but it cannot provide for every laundry/market variable and leaves specification of process and product performance to local jurisdictions and/or industries.

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

BS EN 1465, Essential Quality Requirements (EQR) and Best Practice (BP)

There is no requirement in this CFPP for linen processors to adopt BS EN 14065. However, those linen processors that do obtain independent certification of their BS EN 14065 system may consider this status to contribute to Best Practice (BP) and to satisfy all Essential Quality Requirements of this CFPP.

References; BS EN 14065; BS EN ISO 9001; 'Implementation of Risk Analysis and Bio-contamination Control (RABC) in laundries'. Textile Services Association; BS EN ISO 9000; Guild News Issue 68 2012 GCL.