SPECIFICATION SPN146/2

Cleanroom Garment Laundering

This Specification replaces SPN146/1.1	**Copy Number**
	Effective **19/02/20**

Summary of Significant Changes

Update of 'Applicable Documents'

Purpose

To specify the requirements for a cleanroom garment laundry

Definitions

NHSBT – National Health Service Blood and Transplant

ISO – International Standards Organisation

Applicable Documents

ESD1 - Current edition of the Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book).

EU Guidelines to Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use.

EU Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

IEST-RP-CC-003.3 Garment System Considerations for Cleanrooms and other Controlled Environments.

International Standard ISO 14644-5. Cleanrooms and associated controlled environments Part 5: Operations.

Advisory Committee on Dangerous Pathogens - Spongiform Encephalopathy Advisory Committee: Annex B, Transmissible Spongiform Encephalopathy Agents: Safe Working and prevention of infection.

Directions given under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2018. Human Tissue Authority.

SPN145 – Re-usable Cleanroom Garments

SPN147 - Cleanroom Undergarments

SPN148 - Cleanroom Garment Sterilisation

SPN150 - Cleanroom Garment Components

Requirements

These requirements are based on guidance given in:

- EU Guidelines to Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use.
- EU Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- Directions given under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2018. Human Tissue Authority
- Advisory Committee on Dangerous Pathogens - Spongiform Encephalopathy Advisory Committee: Annex B
- Guidelines for the Blood Transfusion Services in the United Kingdom
- ISO 14644-5
- IEST-RP-CC-003.3.

The garments referred to are specified in **SPN145**, **SPN147** and **SPN150**.

Laundry/Decontamination of Cleanroom Undergarments

Undergarments. There are no guidelines for the laundering of cleanroom undergarments. However, as a minimum, undergarments must be collected and laundered weekly although there is no requirement to sterilise undergarments or provide testing or monitoring data.

Replace undergarments with the same frequency as replacement of the over garment to avoid deterioration to a point where particles or fibres may be shed.

Laundry/Decontamination for Outer Garments

1. Identification of Garments. The laundry must use bar coding or an alternative tracking method which will give the following management information for each garment set:

   a) Date of manufacture
   b) Operator name and any personnel number and department or cleanroom
   c) No of wash cycles
   d) No of sterilisation cycles
   e) Length of time in use
   f) Any repairs or adjustments to the garment

   This management information can then be related to test data and to the maximum allowable number of wash/wear sterilisation cycles recommended by the supplier.

   Bar coding must take place at the issue of new garments and it is the responsibility of the laundry to check bar codes as the garment is accepted for a decontamination or sterilising service.

The laundry must be willing to apply bar codes or an alternative tracking method to garment sets that are owned outright by NHSBT.

2. Any garment that has been contaminated with blood or blood products/tissue products must be assessed at the point of use in terms of the extent of the soiling and hence the suitability for laundering or disposal and replacement.

   In the case of garments with minor contamination, and in order to protect NHSBT and laundry staff and reduce the risk of cross-contamination between garments, the use of water-soluble bags or bags with a water-soluble stitched seam or membrane must be considered for the transport of such garments to the laundry.

3. Collection. Garments must, ideally, be collected from NHSBT sites once a week. However, a less frequent collection is acceptable where local requirements define a given number of garment sets to be ready for laundry prior to collection. These garments must be collected in suitable containers from the outer cleanroom changing area or preliminary changing area. Bags or collection containers must be left in areas of restricted access. In some cases, it may be appropriate to use special laundry disposal lockers, which allow for used garments to be posted in the locker for collection later.

   The container must be made of appropriate material that is durable and has a seal which would prevent soiled garments being left open to the atmosphere.

4. On arrival at the laundry, garments must be checked in using their bar code and then progress to a visual inspection. This would be to identify damaged garments for which only repairs to existing seams and closures which can be repaired to the standard of a new garment may be authorised. Any other forms of damage would result in rejection of the garment and replacement.

5. Laundry Process. The water quality used during the laundering of cleanroom garments must be of a quality acceptable to produce decontaminated garments fit for use in the appropriate grade: A, B, C or D. The laundry must be able to provide such assurance either upon request or through supplier audit. The purification methods in use may be deionising, reverse osmosis, UV radiation, filtration or distillation.

6. The barrier method of laundry processing must be used with the inspection, grading and repair decisions carried out in at least a Class 10,000 (ISO Class 7) cleanroom. The removal of garments from the washing machine into the drying and packing area must be within at least a Class 100 (ISO Class 5) cleanroom. The laundry must be able to provide assurance that these requirements are being met either upon request or through supplier audit.

7. Drying of Garments. Drying may be carried out in tumble dryers or a continuous laminar air flow rack system using air quality to ISO Class 5 or Class 100 standard. Drying and decontamination cycles within the dryer must be monitored and documented to prevent high temperatures or long drying periods damaging the garments.

   After the drying and cooling phase the garments must be removed into an ISO Class 5 or better clean room for packing and testing.

8. Garments must be folded and packaged in a cleanroom grade polythene bag and garments must be double packed separately as hood, coveralls, overboots and coats. Where garments are to be irradiated, an irradiation Detex or indicator label must be included to identify garments which have been correctly radiated, giving the date of irradiation and batch number. See "Cleanroom Garment Sterilisation" specification **SPN148**.

   Double bagged garments must then be placed in containers suitable for transport. Each batch of garments delivered must contain the following documentation:

   a) A Batch Record showing numbers of garments processed and bar coding management information for sterile garments.

   b) A Laundry Certificate of Conformity for the batch. Tests must be carried out on samples from each batch to verify the level of surface particulates. This must be carried out using one of the following test methods:

      - The ASTM F/51 (68) Particulate Cleanliness Standard. The garments must be within Class A for particulate cleanliness under this standard.
      - The Helmke Drum Particulate Contamination Method. Garments must be within category 1 classification of particulate cleanliness for this standard.

   c) A Certificate of Irradiation for the batch, where appropriate.

Comment:

Please note that both steam sterilisation and gamma irradiation will cause degradation of the fabric over time and with the number of cycles, ("Cleanroom Garment Sterilisation" specification: **SPN148**). The supplier of garments should advise on the maximum number of sterilisation and wash cycles possible before garments must be replaced. This may be monitored using the bar code system to avoid over use of garments which have deteriorated beyond acceptable use.

There may also be degradation to accessories: zippers, fasteners, elasticated closures etc and this should be monitored by the cleanroom laundry with advice on the maximum recommended number of cycles possible before discarding and replacement of the garment.