

# SPECIFICATION SPN148/1.1

## Cleanroom Garment Sterilisation

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*This Specification replaces*  
SPN/DDR/TM/004/04 (SPN148/1)

**Copy Number**

**Effective**

**10/05/11**

### ***Summary of Significant Changes***

Update of document control numbers.

### ***Purpose***

To provide a specification for cleanroom garment sterilisation

### ***Definitions***

#### **Gamma Irradiation**

Sterilisation using a beam of electromagnetic gamma particles

#### **ISO**

International Standards Organisation

#### **Autoclaving**

Sterilisation employing the use of saturated steam (moist heat) under pressure to generate temperatures in excess of 100°C within a pressure vessel.

### ***Applicable Documents***

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

**ESD3** - Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide).

Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

**SPN146** - Cleanroom Garment Laundering

**MPD363** - Cleanroom Gowning

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

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

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

Directions given under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Human Tissue Authority.

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### Requirements

These requirements are based on guidance given in:

- Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide)
- Commission Directive 2006/86/EC
- Directions given under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Human Tissue Authority
- Advisory Committee on Dangerous Pathogens - Spongiform Encephalopathy Advisory Committee: Annex B
- Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book)
- ISO 14644-5
- IEST-RP-CC-003.3.

(See Applicable Documents).

Preparation of garments for sterilisation is specified in [SPN146](#). When garments need sterilising is specified in [MPD363](#).

### Specification for Sterilising Clean room Outergarments

There are two accepted methods for cleanroom garment sterilisation. These are autoclaving and gamma irradiation.

1. **Autoclaving.** Garments must be autoclaved at 121°C for 20 minutes at 15 lbs. of steam pressure per square inch. Garments must not be autoclaved at 134°C (the temperature recommended to inactivate the prion protein) as this seriously damages the polyester fabric.

Autoclaving must be carried out to standard methods using autoclavable packaging with autoclave tape or an identification method to prove sterilisation has been carried out. The batch number and date of sterilisation must be attached to the garment and the following information must also be provided.

- a) A report from a recent validation procedure carried out on the autoclave to verify correct function, temperature, pressure, time.
  - b) Number of garments sterilised, type of garment and pack size (this should be signed by the process operator).
  - c) An indication of shelf life of the garments for the sterilising process.
  - d) Certificate of Sterility showing the above data.
2. **Gamma Irradiation.** Garments to be irradiated must be correctly packed, double bagged and boxed in a suitable container for the irradiation process. Each garment packaging set

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must include a Detex or other irradiation indicator sticker with the batch number and date of sterilisation.

A Certificate of Irradiation must be issued with each batch which describes the type of garment, the number of garments sterilised, the date of sterilisation, the dosage level of irradiation (which must be at a minimum of 25 KiloGrays) and an indication of shelf life for the sterilisation process carried out.

A validation of the gamma irradiation process must be available from the supplier either upon request or through supplier audit. This would normally be in the form of a dosimetric test which measures the dosage levels throughout the container used in the process. This must show a minimum absorbed dose of 25 KiloGrays throughout the container and at all points tested. The dosimetric validation must be carried out at least annually, and if any changes are made to the process or container.

#### **Comment:**

Please note that both steam sterilisation and gamma irradiation will cause degradation of the fabric over time and with the number of cycles. The garment supplier must advise on the maximum number of sterilisation and wash cycles possible before garments should 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 such as zippers, fasteners and elasticated closures. This should be monitored by the cleanroom laundry with advice on the maximum recommended number of cycles possible before discarding and replacing the garment.