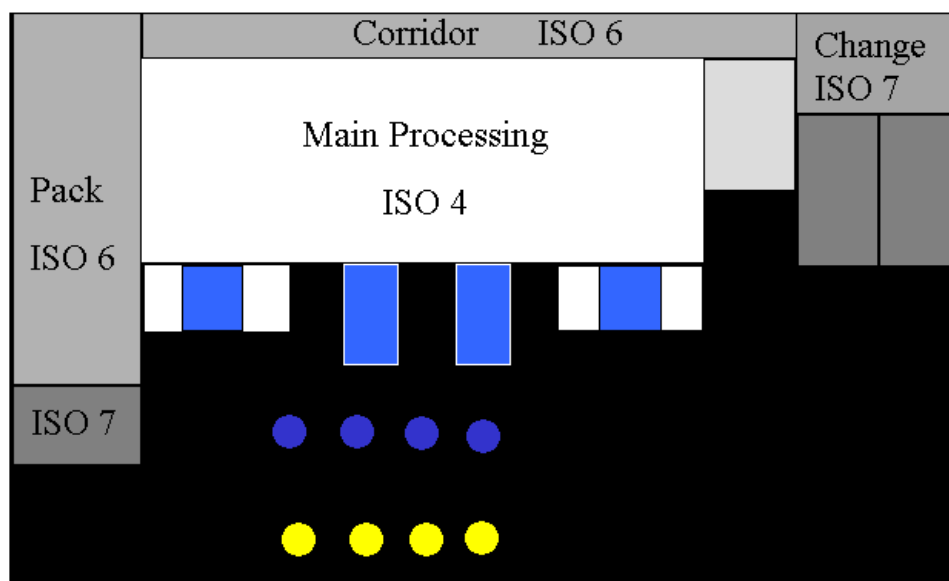


An ISO Class 4 (EU GMP Grade B) Cleanroom garment processing facility with decontamination to Class A of the ASTM 51/00 standard for garment particulate control. A semi-automated facility, the Skegness site provides complete garment traceability providing detailed management information. All production processes are fully validated and data logged providing total batch control history.

Cleanroom Laundry Layout and Classifications



Quality Systems

- QA Checks and repair options
- Each garment is inspected individually prior to and after the decontamination process
- If damaged, garments may be repaired or replaced in accordance with an electronic customer datasheet (mutually pre-agreed)
- Information on garment damage is retained for analysis



Critical process stages

- Thermal disinfection - Dept. of Health recommend 71 deg.C for 3 mins or 65 deg. C for 10 mins
- Soil removal
- RO water used for rinse stages
- Tumble drying and particle removal
- Garment conformance checks - surface resistivity, particle count to ASTM 51/00
- Primary and secondary packaging
- Sterilisation
- Batch documentation and records
- Delivery, distribution and collection



Sterilisation

- Gamma irradiation at min. 25 kGy using Swann Morton (Services) Ltd, Sheffield
- Annual dosimeter load validation, Micronclean audits
- Each pack has detex label, batch certification
- Fully auditable records

Garment tracking and traceability

- Each garment has an individual barcode to enable traceability throughout the facility
- Scanning the transponder also gives the ability to flag garments by size, date and number of cycles
- Production of management information reports detailing:
 - number of wash cycles
 - repair history
 - exception (identifying garments not frequently used)

Microbiology and Quality Assurance

- Providing environmental monitoring to EU GMP recommendations
- Routine in-house Microbiology utilising settle plates, contact plates, finger dabs
- The high purity Reverse Osmosis water system is continuously monitored and routinely sampled to ensure compliance with microbiological standards
- Additional garment testing and fabric qualifications
 - * Routine auditing by centralised QA