



Standard Operating Procedure

Title: Clothing Requirements Inside The Factory Areas

Department	Manufacturing		Document no	MAN-005	
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Document Owner

Operations Manager

Affected Parties

All Site Colleagues

Purpose

This SOP covers the clothing requirements needed in all Factory areas in Site. The different levels of cleanliness must be maintained to minimise microbial and particle contamination.

Scope

It is the responsibility of each and every employee, contractor and visitor to follow this SOP. Clothing restrictions apply at **all** times unless approval is given in writing by QA management to deviate for a specified period.

Definition

Beard	A facial growth of more than 24hr prior to the start of your shift or first entry to the factory.
Environmental Graded Areas	Areas of the manufacturing plant which have specific environmental requirements .

Related Documents

N/A	
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EHS Statement

- Personal factory clothing must be changed on a daily basis for cleanliness and hygiene.
- **Safety Glasses and gloves** must be worn when using IPA or solvent.

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Procedure

1. General

Due to the nature of the work carried out in the factory as well as cleanliness requirements, a minimum standard of protective clothing is required. More stringent protective clothing requirements

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16. **Fingernails** are not to be above the top of fingers, ("netball rule"), and no nail polish or false fingernails to be worn. Nail polish remover is supplied near all female change room if necessary.
Exception: Nail hardener is permitted if required to protect flaking nails. If this is the case, this must be reported to your area Manager to inform the Quality Manager.
17. **Disposable aprons and sleeve covers** must be worn when handling printing inks, when there is any risk of staining or damaging factory clothing, these are stored in the Solvent room.

3. Environmental areas

3.1. Environmental D grade area

3.1.1. Environmental Grade D areas include

- Product Packing lines
- Inspection areas
- Clean side of change rooms
- Corridors throughout factory
- WIP area.

3.1.2. Environmental Grade D "Quick Change" uniform consists of:

- All above restrictions
- Undergarments, if entering to gain access to B-Grade area:
 - Navy Blue pants.
 - White collared, full length sleeved throwover.
 - Designated factory safety shoes
- For Visitors, Navy Blue "Visitors" overalls placed on over street clothes:

3.1.3. For Visitors and occasional entry staff:

- If entering a Grade D area only, you may put the "visitors" overall on over street clothes. That is if the visitor is only walking through the factory or not working on a commissioned line.
- All guests **MUST** remove any jewellery, and if it is not possible to remove a ring then a glove must be worn to enter the factory.
- Shoe covers must be worn over street shoes before entering the factory and a beard cover (if applicable) and hair net.
- If visitors are to be working on the line, (inside a commissioned Production Bay) or with machinery that is in direct contact with the making of a saleable product, they must have removed their street clothes and have on safety shoes.

3.2. Environmental Grade C and (Restricted access)

3.2.1. Environmental Grade C areas include:

- Sterile Air Lock
- Component or Equipment Preparation rooms
- Sampling and Dispensing booths

3.2.2. In addition to all above, [Environmental Grade C](#) clothing includes:

- All above restrictions and Grade D uniform
- Blue smocks/coveralls
- Shoe covers over Factory safety shoes, or designated Grade C shoes.
- **No street clothes**, which includes T-shirts, unless this is a clean one, worn as a singlet.

3.2.3. For Visitors and occasional entry staff:

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- 4.1.2. Remove all outer personal clothing, jewellery and shoes, leaving on your underwear and socks, and place all belongings in full-length personal locker allocated. Lock the locker and take the key. If only entering the Grade D.
- 4.1.3. While crossing to the other side of the room – Wash your hands. Then cross to the other side of the change room. This is known as the “Clean side” of the change room.
- 4.1.4. Open the half-length locker with the corresponding number to your personal locker, and take out the uniform.
- 4.1.5. If you have been sterile trained and validated, and are about to enter the Grade B area from grade D, place on the Navy pants and White top, this is your “Quick change” Grade D Factory uniform.
- 4.1.6. Place on your designated Grade D safety shoes, or Blue shoe covers over personal shoes if not issued with designated shoes.
- 4.1.7. Put on White hairnet, (and beard net, if you have 24 hrs or more growth on face) and enter factory via the door on the “Clean side”.
- 4.1.8. Wait here for your host to collect you, (if you are new or a casual), otherwise go to workstation.
- 4.2. **To enter an Environmental Grade C area (Restricted access)**
 - 4.2.1. Enter Grade C Airlock, wash hands, if hand basin is available in the area.
 - 4.2.2. Place on area specific Blue coat/coverall, (over the top of your Grade D uniform).
 - 4.2.3. Place on area-specific shoe covers provided.
 - 4.2.4. Put on gloves if required. (See signs in change area.)
 - 4.2.5. Enter the Grade C area.
- 4.3. **Environmental Grade B (Authorised and Validated Staff only)**
 - 4.3.1. “Sterile Entry Training” and validation of full surgical scrubbing procedure is required.

Summary table

Graded Area	Activity Type	Clothing Requirement
A/B Sterile preparation and Filling	CRITICAL. Sterile filling, exposed product or containers.	Sterile garments No makeup or jewellery.
C – Preparation of components for sterile	Less CRITICAL Exposed components, non-sterile filling, Solution & Filter Preparation., Equipment Prep.	Factory clothing + Blue coats &/or Blue coveralls & shoe covers No makeup or jewellery.
D – Packaging	CONTROLLED Packaging – no exposed product and components Tablet Packaging	Factory clothing and shoes, hair nets, beard covers No makeup or jewellery, sleepers only.
E – Controlled Access	Controlled access Office, Warehouse and Laboratories	Warehouse uniform, laboratory uniforms and Lab. coats

5. Procedures After Evacuation

- 5.1. After an evacuation of the factory all staff wearing Grade D factory clothing are to report to the Shoe Cleaning Station. If staff did not use disposable Blue shoe covers when evacuating, their shoes will need to be cleaned. First with a mild cleanser, to remove all traces of dirt and grass and then sprayed with 70% IPA. Cleaned shoes must be carried (not worn) to the clean side of the factory change rooms. Uniforms worn outside the building during the evacuation must be put in the dirty clothes bins and fresh set worn to re-enter the factory.
- 5.2. After an evacuation, all staff wearing Grade B Sterile clothing must remove their undergarments, sterile overshoes, hood and coverall and place in the factory change room