

Standard Operating Procedure

Title: Entry Procedure to Sterile Filling Areas

| Department | Micro Laboratory | Document no | MICLAB 005 |
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| Prepared by: | | Date: | Supersedes: |
| Checked by: | | Date: | Date Issued: |
| Approved by: | | Date: | Review Date: |

Document Owner

Micro Laboratory Manager

Affected Parties

All sterile manufacturing and Microbiology Laboratory colleagues who enters a sterile area

Purpose

This SOP outlines the gowning procedure that must be followed by each and every person who enters a Sterile Area. The procedure is designed to reduce the risk of contaminating product with bacteria and/or particles.

Scope

Each person who enters Sterile is responsible for following the procedure as set out below.

Only personnel who are currently validated according to **SOP MICLAB 010** are permitted to enter the Sterile areas.

Definition

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| N/A | |
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Related Documents

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| Form 650 | Checklist for Procedure for Entry into Sterile |
| Form 655 | Validation Record For Sterile Gowning Procedure |
| MICLAB 010 | Validation of Aseptic Gowning Procedures |
| MICLAB 095 | Sterile Sampling Procedure for Microbiology Laboratory. |



EHS Statement

- SAFETY GLASSES and gloves are to be worn in the Glass Sterile and when IPA is used.
- **NOTE**
Should you be suffering any infection or illness you must report this to your Process or Production Manager who will consult with the Microbiology and / or QA Manager to determine whether you may work in the Sterile areas. Similarly, if you have been ill, you may not enter the Sterile area unless cleared to do so by the Microbiology Laboratory Quality Manager or QA Manager.
- Safety shoes are to be worn at ALL TIMES in Sterile.

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1.2. Clothing Restrictions for Sterile Areas

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| <p>Sterile Filling (high grade) Environmental (Authorised and Validated Staff only). Entry into this area should be managed by the Microlab team.</p> <p>Higher Environmental Grade uniforms consists of:</p> <ul style="list-style-type: none">Company approved and provided undergarmentsSterile hoodSterile surgical maskSterile coverallSterile designated safety shoesSterile overshoesSterile glovesSafety glasses. |  |
| <p>Sterile Preparation (medium grade) Environmental (Authorised and Validated Staff only). Entry into this area should be managed by the Microlab team.</p> <p>This environmental grade area include:</p> <ul style="list-style-type: none">Sterile Area Scrub Prep. RoomsSterile Air LockComponent or Equipment Prep. roomsDispensing boothsSterile Solution Preparation rooms. <p>Medium Environmental Grade uniforms consists of:</p> <ul style="list-style-type: none">Blue smocks/coverallsShoe covers over Factory safety shoes, or designated shoes. <p>No street clothes, which includes T-shirts, unless this is a clean one, worn as a singlet.</p> |  |

1.3. Surplus dirt and grease etc. to be removed from hands before entering the Sterile scrub room.

1.4. Covered by a current validation Form 655.

2. Upon entry into the Sterile scrub change room

2.1. All outer clothing is to be removed including shoes and socks down to approved undergarments, which must be worn; all this is to be placed onto racks on the "dirty" side of the dividing seat. Remove any band-aids from small, uninfected cuts and discard into rubbish bin.

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B. Procedure For Leaving Sterile Areas

1. Overshoes are to be changed on a daily basis and not on a per entry basis as are gowns and hoods.
2. If you are to re-enter the Sterile area again on that day the procedure for preparing the overshoes for exit and re-entry is as follows:
3. Carefully roll down the leg part of the overshoe exposing the inside while you are still wearing gloves. Slip out the foot and shoe and place the overshoes on the shelf or bench provided. The overshoes and the safety shoes may be removed together if this is preferred provided the foot can be slipped into both after the next gowning. This procedure cannot be carried out in Glass Sterile due to glass fragments being carried into the change room on the soles of overshoes.
4. Remove jumpsuit, hood, mask, gloves and socks and place into used clothing and rubbish bins respectively.

5. GENERAL

Should you suffer any minor cuts while working in the Sterile areas immediately leave the Sterile areas to receive First Aid. If the cut is small and bleeding stops, you may re-enter the Sterile areas provided a clean bandaid is applied to the cut on each entry and surgical rubber gloves are worn over the bandaid.

You may continue working in the Sterile areas on this basis, provided the cut does not become infected. If this occurs you must not enter the Sterile areas until you have been cleared to do so by your Area Manager.

C. Procedure For Changing Clothing After Clothing Has Touched The Floor Both During Maintenance or Normal Operation of The Machines In All Sterile Areas

NOTE

If any part of the sterile jumpsuit touches the floor during manufacturing in a Sterile area it will pick up particles and microbiological contamination.

1. The following procedure must be followed after any part of the jumpsuit comes into contact with the floor during manufacturing:

If any part of the jumpsuit touches the floor and providing all necessary work has been completed then the jumpsuit and gloves must be changed in the sterile scrub room and the uniform placed in the dirty clothing bin.

2. The following procedure must be followed after any part of the jumpsuit comes in contact with the floor during maintenance.

If any part of the jumpsuit touches the floor and providing all necessary work has been completed, then the jumpsuit and gloves must be changed in the sterile scrub room immediately without entry to any other sterile filling areas and the uniform placed in the dirty clothing bin.

THIS MUST BE DONE BEFORE THE DIRTY UNIFORM IS WORN NEAR ANY STERILE EQUIPMENT - FURNITURE, Laminar Flow curtain, WALLS and MACHINERY.

3. **“Checklist For Procedure For Entry Into Sterile”.**

This Checklist (**Form 650**) is to be used as a guide when assessing the Entry Procedure of employees who have had training in Sterile Entry Procedures.

The checklist will be used as one of the training tools for new employees plus it will also be used to monitor Operator performance and attention to detail, on a periodic basis, for every person who works in Sterile.

Validation Record For Sterile Gowning Procedure

(Ref. MICLAB 010)

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| 15. Pulling up Overshoes – leg straps and clips. | |
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| Validated Microbiology Technician | Print | Sign |
| | | |

Complete the following section upon recording validation results

| Actions in the Event of Failure | | Validation Successful (Y/N) | |
|---------------------------------|--|-----------------------------|--|
| | | | |

| Follow up checklist | Tick appropriate |
|--|---|
| Email/Notification of validation result sent to participant: | YES <input type="checkbox"/> NO <input type="checkbox"/> |
| Sterile Entry Master List updated with successful validation date: | YES <input type="checkbox"/> NO <input type="checkbox"/> N/A <input type="checkbox"/> |
| Validation record photocopy sent to Manufacturing Learning: | YES <input type="checkbox"/> NO <input type="checkbox"/> N/A <input type="checkbox"/> |

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| Recorded by: | Print | Sign |
| | | |
| Approved by: | | |