

Standard Operating Procedure

Title: Entry Procedure to Sterile Filling Areas

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.

The "Participant" and the "Observer" will be selected by the Production Manager and the records will be assessed and acted upon by the Production Manager.

NOTE: