

STANDARD OPERATING PROCEDURES		S.O.P Number : C.12.1.1 PAGE NUMBER: 1 of 4 ATTACHMENTS: 1
TITLE: Material and Personnel Flow Through the Container Preparation Department.		
PREPARED BY: _____ D/M/Y: _____ (Documentation)	REPLACES: C.10.5.3	ISSUE DATE:
APPROVED BY: _____ D/M/Y: _____ (Aseptic Processing)		EFFECTIVE DATE:
APPROVED BY: _____ D/M/Y: _____ (Quality Assurance)		
DISTRIBUTION: 1-4, 6, 8-12, 28, 38, 43		

Revision Highlights:
<ul style="list-style-type: none"> • “New SOP number and format changes

- 1.0 Purpose** To describe the movement of personnel and materials into and out of the Container Preparation Department.
- 2.0 ASSOCIATED DOCUMENTS** S.O.P S.2.1 “Cleaning Solution Preparation”
- 3.0 RESPONSIBILITY** All personnel associated with the Container Preparation area are responsible for following these procedures.
- 4.0 FREQUENCY** As required
- 5.0 Procedure**
- Responsibility: *Aseptic Processing Operator*
- 5.1 Personnel Airlock(Class 1 and Class 2) Room 1/26**
- 5.1.1. Only personnel may pass through the personnel airlock (room 1.26).
- 5.1.2. Check that the inner airlock door is closed. Enter the airlock using your swipe card.
- 5.1.3. Wash hands thoroughly with Hibitane and water. Dry hands with disposable towels.

- 5.1.4. Container Preparation workers must put on gowns reserved for their individual use. Visitors must put on one of the specially labeled “visitor” gowns.
- 5.1.5. Put on appropriate Hygiene Class 2 footwear. Container preparation Workers must wear safety shoes specially designated for the Hygiene Class 2 area. Visitors must put on shoe covers.
- 5.1.6. Enter the Hygiene Class 2 area, making sure that the outer airlock door is closed.
- 5.1.7. When leaving the Hygiene Class 2 area, enter the personnel airlock from the Hygiene Class 2 side, making sure that the outer door is closed.
- 5.1.8. Remove the gown and return it to the gown rack in the correct size location. Container Preparation workers must put on Hygiene Class 1 footwear.
- 5.1.9. Enter the Hygiene Class 1 area, making sure that the inner door is closed.

5.2. Material Airlock(Class 1 and Class 2) (Room 1/25)

- 5.2.1. Only raw material(s) and item(s)/equipment may pass through the material airlock (room 1/25)
- 5.2.2. Check that the inner airlock door is closed. Open the outer door using your swipe card and move the material(s) and/or item(s)/equipment into the airlock.

Equipment/Items

- 5.2.3. Spray the equipment/item with **Solution 1** (check to ensure the solution has not expired prior to use) using the specially designated Hygiene Class 1 sprayer. Ensure that all exposed surfaces come into contact with the **Solution 1** (e.g. trolley wheels, under trolleys, etc.).

Note: Certain items such as some Rommelag filters may be exempt from the procedure. Consult your Supervisor or Group Leader if you are uncertain about which items are exempt.

- 5.2.4. Notify the Hygiene Class 2 operator, either by phone or through the personnel airlock, that the item(s) may be moved into Hygiene Class 2. **At no time shall a person from Hygiene Class 1 open the Material Airlock door to room 1/22**

Raw Materials

- 5.2.5. Raw materials may be temporarily stored on pallets in the airlock
- 5.2.6. Raw materials being moved from the airlock to Hygiene Class 2 must be transferred from the pallets onto stainless steel trolleys especially designated for Hygiene Class 2 use by a Hygiene Class 2 operator.
- 5.2.7. Once transferred, move the trolley from the airlock to Hygiene Class 2, making sure that the outer doors are closed.
- 5.2.8. When moving items from the airlock to Hygiene Class 1, ensure that all part cases/trays are secure and identified.

5.3. Material Airlock (Class 2 to Class 3) (Room 1/2)

Class 2 side

- 5.3.1. Only materials (e.g. tools, trolleys, laminated paper etc.) and equipment (e.g. motors, pumps etc.) may pass through this material airlock (room 1/21).
- 5.3.2. Spray the item(s) with **Solution 1** using the specially designated Hygiene Class 2 sprayer. Ensure that all exposed surfaces come into contact with the **Solution 1** (i.e.: trolley wheels, under trolleys, etc.).

- 5.3.3. Check that the inner airlock door is closed. Open the outer door and move the sprayed item into the airlock.
- 5.3.4. Light items (eg, tools, laminated paper etc.) should be placed onto the small table located in the airlock. Heavy objects must be placed on a trolley which has been appropriately sanitized. **Do not allow the item to be transferred to come in contact with the floor.**
- 5.3.5. Record appropriate information on Attachment 1.
- 5.3.6. Leave the item in the airlock for a minimum of 10 minutes, then notify the Hygiene Class 3 operator that the item is ready.

Class 3 side.

- 5.3.7. Enter the airlock making sure that the outer airlock door is closed.
- 5.3.8. Spray the item(s)/equipment with **Solution 1** using the specially designated Hygiene Class 3 sprayer. Ensure that all exposed surfaces come into contact with **Solution 1** (ie. Trolley wheels, under trolley etc) After spraying, go to the gowning area and change gloves.
- 5.3.9. The item(s)/equipment should be left in the airlock for a minimum of 10 minutes before bringing them into Hygiene Class 3.

Note: Certain items such as some Rommelag filters may be exempt from steps 5.3.8 and 5.3.9. Consult your Supervisor or Group Leader if you are uncertain about which items to exempt.

- 5.3.10. When moving items from the airlock to Hygiene Class 2 make sure that the inner doors are closed.