

STANDARD OPERATING PROCEDURES	SOP Number	C.12.1.1
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Title: Material and Personnel Flow Through the Container Preparation Department.		
Prepared By: _____ D/M/Y : _____ (Documentation)	Replaces	C.10.5.2
Approved By: _____ D/M/Y : _____ (Aseptic Processing)	Issue	D/M/Y _____
Approved By: _____ D/M/Y : _____ (Quality Assurance)	Effective D/M/Y	_____
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Revision Highlights

New SOP number and format changes

DRAFT

This version is a work in progress and is a draft.

Procedures for Container Preparation Department

Covers This S.O.P. describes the movement of personnel and materials into and out of the Container Preparation Department.

Associated S.O.P.s The following S.O.P.s are required to complete the described operating procedure.

S.O.P.	Description
S.2.1	Cleaning Solution Preparation

Responsibility All personnel associated with the Container Preparation

**Materials/
Equipment** N/A

Frequency As required

**Safety
Precaution** N/A

Contains This S.O.P. contains the following procedures for moving personnel and materials through the Container Preparation Department.

Procedure	See Page
Personnel Airlock (Class 1& 2 – room 1/26)	

Material Airlock (Class 1 & 2 – room 1/25	
Material Airlock (Class 2 & 3 – room 1/21	

Procedure for Personnel Airlock (Class 1& 2 – Room 1/26)

When to use When personnel are entering or exiting the Container Preparation Department between Hygiene Class 1 and Class 2 areas.

Personnel only Only personnel may pass through the personnel airlock (room 1/26)

Entering Follow the steps in the table below when entering the Container Preparation department.

Step	Action	
1	Check inner airlock door is closed	
2	Use swipe card to enter airlock	
3	Clean hands by: <ul style="list-style-type: none"> • Washing thoroughly with Hibatane and water • Drying with disposable towels 	
4	If ...	Then put on ...
	Container preparation worker	<ul style="list-style-type: none"> • Gown reserved for individual use, <u>and</u> • Safety shoes specially designed for Hygiene Class 2 area
	Visitor	<ul style="list-style-type: none"> • Specially labeled “visitor” gown, <u>and</u> • Shoe covers
5	Close outer airlock door	
6	Enter Hygiene Class 2 are.	

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Procedure for Personnel Airlock (Class 1 & 2 – Room 1/26), Continued

Exiting

Follow the steps in the table below when exiting the Container Preparation department.

Step	Action				
1	Check outer airlock door is closed				
2	Enter airlock				
3	Remove gowns				
4	Return gown to the gown rack in the correct size location				
5	<table border="1"><thead><tr><th>If ...</th><th>Then put on ...</th></tr></thead><tbody><tr><td>Container preparation worker</td><td>Hygiene Class 1 footwear</td></tr></tbody></table>	If ...	Then put on ...	Container preparation worker	Hygiene Class 1 footwear
If ...	Then put on ...				
Container preparation worker	Hygiene Class 1 footwear				
6	Close inner airlock door.				
7	Enter Hygiene Class 1 area				

Procedure for Material Airlock (Class 1 & 2 – Room 1/25)

When to use When materials are entering or exiting the Container Preparation Department between Hygiene Class 1 and Class 2 areas.

Materials only Only raw materials and items/equipment may pass through the material airlock (room 1/25)

Exceptions Certain items may be exempt from the spraying procedure.
e.g. some Rommelag filters

Consult Supervisor Consult Supervisor or Group Leader if uncertain about which items are exempt

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Procedure for Material Airlock (Class 1 & 2 – Room 1/25), Continued

Entering

Follow the steps in the table below to pass materials into the Container Preparation department.

Step	Action				
1	Check inner airlock door is closed				
2	Use swipe card to open outer airlock door.				
3	Move the materials/item/equipment into the airlock				
Equipment and Items					
1	<table border="1"> <thead> <tr> <th>If the solution ...</th> <th>Then ...</th> </tr> </thead> <tbody> <tr> <td>Has expired</td> <td>Prepare fresh Solution using S.O.P.S.2.1</td> </tr> </tbody> </table>	If the solution ...	Then ...	Has expired	Prepare fresh Solution using S.O.P.S.2.1
If the solution ...	Then ...				
Has expired	Prepare fresh Solution using S.O.P.S.2.1				
2	Use the specially designated Hygiene Class 1 sprayer to spray equipment/items with Solution 1.				
3	All exposed surfaces must come into contact with solution. For example: <ul style="list-style-type: none"> • Trolley wheels, • Under trolleys, • Etc. 				
4	Notify Hygiene Class 2 operator that the items(s) may be moved into Hygiene Class 2.				
5	At no time shall a person from Hygiene Class 1 open the Material Airlock door to room 1/22.				
Raw Materials:					
1	Raw materials may be temporarily stored on pallets in the airlock				
2	Hygiene Class 2 operator must transfer materials from pallets to steel trolleys specially designated for Hygiene Class 2 use.				
3	Close outer airlock door				
4	Move trolley into Hygiene Class 2.				

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Procedure for Material Airlock (Class 1 & 2 – Room 1/25), *Continued*

Moving to
Hygiene Class
1

When moving items to Hygiene Class 1:

- Secure all part cases/trays, and
 - identify
-

Procedure for Material Airlock (Class 2 & 3 – Room 1/21)

When to use When materials are entering or existing the Container Preparation Department between Hygiene Class 2 and Class 3 areas.

Materials and equipment only Only materials and equipment may pass through the material airlock (room 1/21).

only ...	Such as ...	
Materials	<ul style="list-style-type: none"> • tools, • trolleys, 	<ul style="list-style-type: none"> • laminated paper, • etc.
Equipment	<ul style="list-style-type: none"> • motors, • pumps, 	<ul style="list-style-type: none"> • etc.

Entering Class 3 Follow the steps in the table below to pass materials into the Hygiene Class 3 area.

Step	Action
1	If solution 1 has expired: <ul style="list-style-type: none"> • prepare fresh Solution using S.O.P.S.2.1
2	Use the specially designated Hygiene Class 2 sprayer to spray items with Solution 1.
3	All expected surfaces must come into contact with solution. For example: <ul style="list-style-type: none"> • trolley wheels, • under trolleys, • etc.
4	Close inner airlock door
5	Open Outer airlock door
6	Move sprayed item into airlock.

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Procedure for Material Airlock (Class 2 & 3 – Room 1/21), Continued

Entering Cass (continued) 3

Step	Action	
7	If item is ...	Then place ...
	Light	On small table located in the airlock
	Heavy	On appropriately sanitized trolley
8	Do not allow the item to be transferred to come in contact with the floor	
9	Record appropriate information on Attachment 1.	
10	Leave item in airlock for minimum of 10 minutes	
11	Notify Hygiene Class 3 operator that the item is ready.	

Leaving class 3 Follow the steps in the table below to pass materials from the Hygiene Class 3 area.

Step	Action
1	Close outer airlock door
2	Enter airlock
3	Use the specially designated Hygiene Class 3 sprayer to spray items with Solution 1.
4	All exposed surfaces must come into contact with solution. For example: <ul style="list-style-type: none"> • trolley wheels, • under trolleys, • etc.
5	Go to gowning area and change gloves
6	Leave item in airlock for minimum 10 minutes
7	Close inner airlock doors
8	Move items into Hygiene Class 2.
