

Standard Operating Procedure for *Material Entry & Exit* of Clean Zone

DOUCMENT PARTICULARS	
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Material Entry & Exit of Clean Zone

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01	09 Jan 2023	01 Feb 2023	01 Aug 2023	New SOP

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Material Entry & Exit of Clean Zone

A) Objectives

This document describes the procedures to move samples & items in and out of the clean zone and clean room through the passbox. The clean zones locate at the Centre for Regenerative Medicine and Health, Hong Kong Institute of Science & Innovation, Chinese Academy of Sciences Limited (refer to CRMH below).

B) Scope

This SOP applies to any material that be brought in-and-out of the clean zone and clean room through the passbox.

C) Facility Covered

Clean zones in CRMH, 5/F, 15 Science Park West Avenue, Hong Kong Science Park, Pak Shek Kok, Hong Kong

D) Responsibilities

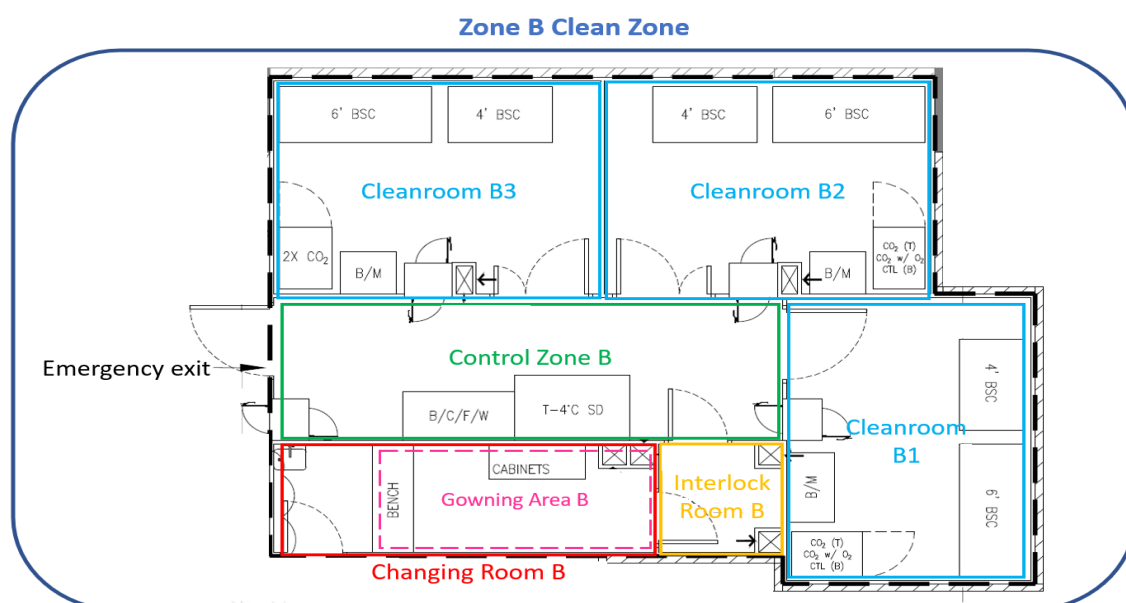
1. Team manager provides the training of this SOP to their member and to oversees if their member properly follows the entry and exit procedures of the materials.
2. F&OC provides necessary support to the team managers (or their delegates) to implement this SOP.
3. Trained personnel moving items in & out of the clean room should adhere to the established SOP diligently and inform the team manager if deviations occur.

E) References:

1. International Organisation for Standardisation. *Cleanrooms and associated controlled environments – Part 5: Operations*. ISO 14644-5: 2004, 2004.
2. World Health Organisation. *Laboratory Biosafety Manual*, 4th Ed. 2020.

F) Nomenclature:

Names of rooms/areas of a typical clean zone in CRMH:



Floor plan of a typical Clean Zone in CRMH.

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G) Precautions:

1. Ethanol is a flammable liquid and a dangerous fire hazard.
2. Inhaling ethanol can irritate the nose, throat, and lungs. Exposure to ethanol can cause headaches, drowsiness, nausea and vomiting, and unconsciousness. Therefore, an adequate amount of ethanol shall be applied to perform disinfection. Over-use of ethanol may harm the member working in the clean zone.

H) Materials:

1. 70% Ethanol
2. Personal protective equipment (PPE) e.g., powder-free gloves

I) Procedures:

1. *Maintenance of Inventory*

- 1.1. Inventory sheet must be updated on server by team members before entering and after leaving the clean zone.
- 1.2. Stock taking and Checking of the expiry date of the reagents and consumable are recommended to conduct periodically.

2. *Preparation of passbox*


- 2.1. Wipe the passbox down with 70% ethanol with clean room wipers **before AND after** each use.
- 2.2. Close the door. Let the fan automatically run for 15 seconds if the transfer is an entry. Turn on UV light for at least 20 minutes **at the end of the shift**.



Figure 1 Passbox located in the clean room

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3. *Packaging of biological specimens/agents*

- 3.1. Obtain a sealable, leak-proof container with biohazard label .
- 3.2. Put and seal the biological specimens/agents in the container, and then put this package in a secondary container.

4. *General procedures for material transfer through passbox (from Area A to Area B)*

- 4.1. To ensure that the passbox is clean and clear, wipe the surface inside the passbox with 70% ethanol.
- 4.2. Close the passbox door. The fan will automatically run for 15 seconds if the transfer is an entry.
- 4.3. Put the material to transfer into a suitable container. Wipe down the surface of the container with 70% ethanol.
- 4.4. Open the passbox door facing Area A and put the container in.
- 4.5. Close the passbox door. The fan will automatically run for 15 seconds if the transfer is an entry. (Caution: must NOT open the two doors of a passbox at the same time.)
- 4.6. (Optional) Turn on the UV light in passbox manually when appropriate. Make sure the container has enough protection for the materials inside against UV light. Switch off the UV light after use.
- 4.7. Open the passbox door in Area B, remove the materials from the passbox to Area B immediately. After use, wipe the surface inside the passbox with 70% ethanol again.

5. *Entry and exit procedures for **biological specimens/agents***

- 5.1. Equip appropriate powder-free gloves to handle the biological specimens/agents.
- 5.2. Package the biological specimen/agents according to the Section 3 (above) *Packaging of biological specimens/agents*.
- 5.3. Follow Procedures in Section 4 (above) *General procedures for material transfer through passbox (from Area A to Area B)*

6. *Entry and exit procedures for **chemicals/ reagents/ items/ equipment***

- 6.1. Equip appropriate powder-free gloves to handle the chemicals/agents/items/equipment.
- 6.2. Wipe a basket with 70% ethanol for the materials entry.
- 6.3. Place the chemical/reagents/items/equipment into the basket.
- 6.4. Reagents containing halogenated chemicals or UV sensitive chemicals/reagents/items/equipment should be placed into a secondary

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container to protect it from UV. This procedure is applicable only when UV light sterilization is needed during the transfer in passbox.

- 6.5. Follow Procedures in Section 4 (above) *General procedures for material transfer through passbox (from Area A to Area B)*

7. Exit procedures of *daily waste*

- 7.1. Collection of daily waste including biological waste, chemical waste, and sharps waste can refer to the CRMH-SOP-008: SOP for Collection and Disposal of waste.
- 7.2. Wipe the outside of the waste bag and discarded reagent bottles with 70% ethanol.
- 7.3. Put waste bags and discarded reagent bottles into another waste bag.
- 7.4. Waste containing halogenated chemicals or UV sensitive waste should be placed into a secondary container to protect it from UV. This procedure is applicable only when UV light sterilization is needed during the transfer in passbox.
- 7.5. Follow Procedures in Section 4 (above) *General procedures for material transfer through passbox (from Area A to Area B)*.