

Standard Operating Procedure for Clean Zone Entry & Exit

DOCUMENT PARTICULARS	
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Clean Zone Entry & Exit

Review History

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

Clean Zone Entry & Exit

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Clean Zone Entry & Exit

A) Objectives:

This document describes the proper procedures used by *Centre for Regenerative Medicine and Health, Hong Kong Institute of Science & Innovation, Chinese Academy of Sciences Limited* (refer to CRMH below), staff, students, and visitors for entering and exiting a clean zone.

B) Scope:

This document applies to all personnel who enter and exit the clean zones.

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

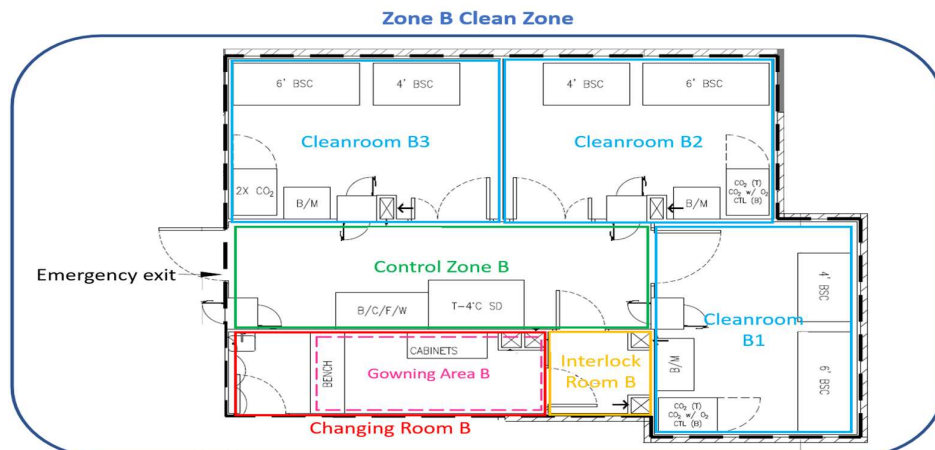
1. Team manager provides the training of this SOP to their member and to oversees if their member properly follows the entry and exit procedures.
2. The personnel entering the clean zone should adhere to the established clean room SOPs diligently and inform the team manager if deviations occur.
3. F&OC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

E) References:

1. International Organisation for Standardisation. *Cleanrooms and associated controlled environments – Part 5: Operations*. ISO 14644-5: 2004, 2004.

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. Disinfecting hand soap
2. 70% ethanol
3. Sticky mat
4. Dustless tissue (e.g. Kimwipes)

I) Procedures:

1. *Pre-entry preparation*
 - 1.1 Personal indoor clothing should be clean and should not shed particulates.
 - 1.2 Remove jewellery before proceeding into a clean zone.
 - 1.2.1 Earrings, rings & watches etc. are not recommended in the clean zone.
2. *Entry to clean zone*
 - 2.1 Check if the changing room is free.
 - 2.2 Enter the changing room, ensuring to step on the sticky mat at the entrance.
 - 2.3 Wash hands
 - 2.3.1 Wet hands with water, then apply sufficient amount of soap.
 - 2.3.2 Scrub hands for at least 15 seconds and cover all surfaces.
 - 2.3.3 Rinse off soap with water.
 - 2.3.4 Dry hands using Kimwipes.
 - 2.4 Put your mobile phone, if any, into a plastic zip bag provided.
 - 2.5 Put on nitrile gloves.
 - 2.6 Follow gowning procedures stated in the "CRMH-SOP-004: SOP for Gowning & De-gowning in Clean Zone".
 - 2.7 Before touching the door of interlock room, sanitize gloves with 70% ethanol spray.
 - 2.8 Both foot step on the sticky mat before entering interlock room from changing room.
 - 2.9 Enter interlock room and close the door behind. DO NOT let both doors open at the same time.
 - 2.10 Open door and enter control zone.

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3. *Exit clean zone*

- 3.1 Before touching the door of interlock room, sanitize gloves with 70% ethanol spray.
- 3.2 Enter interlock room and ensure door is closed behind. DO NOT let both doors open at the same time.
- 3.3 Check if the changing room is free for use.
- 3.4 Open the door connecting to changing room.
- 3.5 Both foot step on sticky mat of changing room near the door.
- 3.6 Follow de-gowning procedures stated in the “CRMH-SOP-004: SOP for Gowning & De-gowning in Clean Zone”.
- 3.7 Put on your own shoes.
- 3.8 Remove and dispose of gloves.
- 3.9 Wash hands:
 - 3.9.1 Wet hands first with water, then apply sufficient amount of soap.
 - 3.9.2 Scrub hands for at least 15 seconds and cover all surfaces.
 - 3.9.3 Rinse off soap with water.
 - 3.9.4 Dry hands using Kimwipes.
- 3.10 Both foot step on sticky mat before exit changing room.

J) **Abbreviations**

- CRMH Centre for Regenerative Medicine and Health, Hong Kong Institute of Science & Innovation, Chinese Academy of Sciences Limited
- SOP Standard Operating Procedure