

DOUCMENT PARTICULARS	
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**Gowning & De-gowning in Clean Zone**

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## Gowning & De-gowning in Clean Zone

### A) Objectives:

This document describes the proper gowning & de-gowning 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, and students entry-and-exit to-and-from the clean room while minimising the number of particles and microorganisms in the clean room.

### B) Scope

The SOP applies to gowning and de-gowning performed in the changing room for all personnel entering and exiting a CRMH clean zone.

### 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

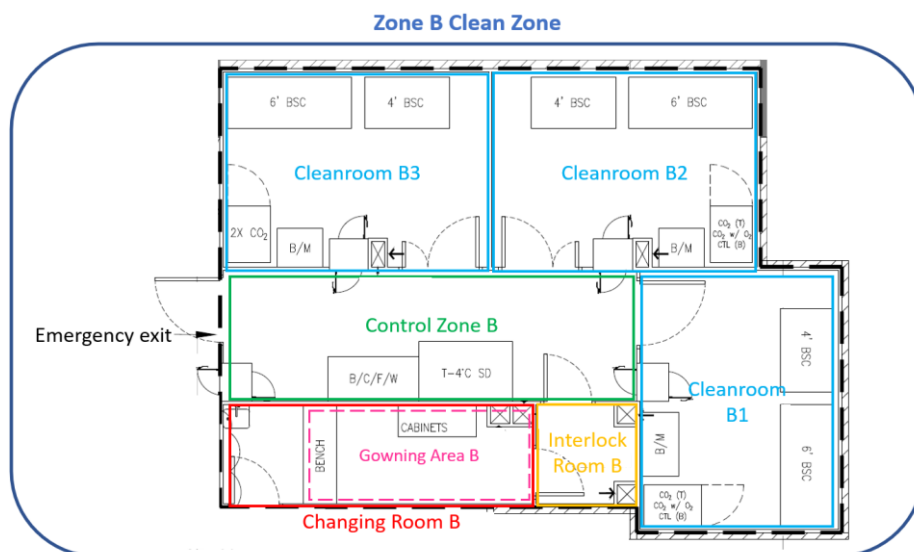
1. Team manager provides the training of this SOP to their member and to oversees if their member properly follows the gowning and de-gowning procedures.
2. The personnel entering the clean zone should adhere to the established clean room SOPs diligently and inform the team manager if deviations occur.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

### 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:



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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. Bouffant cap
4. Spectacles
5. Sterile mask
6. Clean room gown
7. Non-powdered nitrile gloves
8. Foot covers
9. Clean room shoes
10. Clean room trousers
11. Dustless tissue (e.g. Kimwipes)

### I) Procedures

1. *Best practices*
  - 1.1. All personnel must be well-trained about the proper gowning/ de-gowning procedures by team manager or his/her delegates before using the clean room. The training must be documented, and the record must be retained 1 year after that personnel left the Centre. The training log template is attached in Appendix 1 for reference.
  - 1.2. All personnel must follow this SOP before entering the changing room.
  - 1.3. Personal indoor clothing should be clean and should not shed particulates.
  - 1.4. Do NOT start gowning procedures when another personnel is in the process of entering/exiting the changing room.
  - 1.5. Do NOT enter changing room when someone is in the process of gowning.
  - 1.6. Activities like making-up and wearing jewellery are NOT allowed in the clean zone.
  - 1.7. Handling of contact lenses is NOT allowed in the clean zone.
  - 1.8. It is recommended to wear a pair of spectacles for low-risk procedures and goggles for high-risk procedures.

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- 1.9. All personnel must wear long trousers to cover their legs to conduct the experiment in clean zone and open laboratory.

**2. Gowning procedures**

- 2.1. Always inspect every PPE to ensure no defects before putting it on.
- 2.2. Step onto the sticky mat at the entrance of the clean zone for dusts/dirt removal.
- 2.3. Sit on the bench in the gowning area and take off your own shoes. Store your shoes inside your own shoe shelf.
- 2.4. Put on slippers.
- 2.5. Wash your hands and dry them thoroughly according to the "Entry to clean zone" procedures stated in the CRMH-SOP-002: SOP for Clean Zone Entry & Exit". Put on nitrile gloves.
- 2.6. Sit on the bench in the gowning area and take off slippers.
- 2.7. Immediately sanitize gloves using 70% ethanol spray.
- 2.8. Put on foot covers and clean room shoes while still sitting on the bench.
- 2.9. Put on a bouffant cap, which is stored in the drawer of gowning area.
- 2.10. Put on facial hair cover to cover all facial hair if applicable. If facial hair is still exposed, use a hood (not provided) instead.
- 2.11. Wear a facemask and make sure not to touch the outside of the mask.
- 2.12. Wear safety spectacles/ goggles if needed.
- 2.13. Put on a clean room gown. (Wearing long trousers is the dress code in conducting experiment in laboratory. In case, any part of the legs is exposed, please obtain the clean room trousers from F&OC, and put on the clean room gown and clean room trousers in gowning area). Clean room gowns and trousers are not allowed to touch the floor at any time.
- 2.14. Use full-sized mirror to reinsure that no body part is exposed.
- 2.15. Sanitize gloves using 70% ethanol spray before touching the door handle of interlock room.
- 2.16. Step on the sticky mat before entering the interlock room.

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#### 3. *De-gowning procedure*

- 3.1. After leaving from the interlock room back to gowning area, step onto the sticky mat.
- 3.2. Take off clean room gown and put it onto your own hanger if it can be worn again later, or put it into the dedicated laundry box if it is contaminated.
- 3.3. Put a soiled clean room coat in a covered dedicated laundry box which is switched out every Wednesday and Friday, or whenever it is full.
- 3.4. Put off safety spectacles/ goggles and place them back in the drawer.
- 3.5. Remove and dispose of the facemask in the waste bin, wear a new facemask.
- 3.6. Remove and dispose of the bouffant cap in the waste bin.
- 3.7. Sit on the bench in gowning area, and take off clean room shoes. Put them back to the shoe shelf.
- 3.8. Take off shoe covers. Flip them inside-out and then dispose of them to waste bin.
- 3.9. Take off gloves. Flip them inside-out and then dispose of them to waste bin.
- 3.10. Put on your own shoes.
- 3.11. Wash your hands with detergent thoroughly according to the “Exit clean zone” procedures stated in the CRMH-SOP-002: SOP for Clean Zone Entry & Exit”
- 3.12. Exit changing room.

#### 4. *Entry permissions for non-qualified personnel*

- 4.1. Non-qualified personnel (persons e.g., maintenance worker, that have not received relevant cleanroom training) should not enter the changing room without the express permission from the team manager and F&OC.

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- 4.2. Upon permission, non-qualified personnel must follow the clean room SOPs in the presence of a qualified operator.
- 4.3. All occurrences of non-qualified personnel entering the clean zone must be well-documented.

**J) Abbreviations:**

1. F&OC: Facility and Operations Compliance Department
2. PPE: Personal protective equipment
3. SOP: Standard operating procedure

**K) Appendix**

1. Appendix 1: CRMH Training Log Template

**Appendix 1: CRMH Training Log Template****CRMH Training Log****Training:**

Date of Training	Type of Training*	Research Team (Rp1/ Rp2/ Rp3)	Name of Research Personnel	Signature of the Research Personnel	Name and Affiliation of Trainer(s)

\* Type of Training: F – Face-to-Face; V – Video; Z – Zoom; Other (please specify)

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