

# Standard Operating Procedure *for Maintenance of Clean Zone*

DOCUMENT PARTICULARS	
Document No.	CRMH-SOP-006
Version No.	01
Issue Date:	09 Jan 2023
Effective Date:	01 Feb 2023
Authorized by: Name/ Title/ Signature	<div></div> <hr/> Prof. Pan Guangjin Director of CRMH

**Maintenance of Clean Zone**

<b>Version No.</b>	<b>Issue Date (DD/MMM/YY)</b>	<b>Effective Date (DD/MMM/YY)</b>	<b>Next Review Date (DD/MMM/YY)</b>	<b>Highlights for revision</b>
<b>01</b>	<b>09 Jan 2023</b>	<b>01 Feb 2023</b>	<b>01 Aug 2023</b>	<b>New SOP</b>

**Maintenance of Clean Zone****Table of Contents**

<b><u>Section</u></b>	<b><u>Title</u></b>	<b><u>Page no.</u></b>
A	Objectives	4
B	Scope	4
C	Facilities covered	4
D	Responsibilities	4
E	References	4
F	Nomenclature	4
G	Precautions	5
H	Materials	5
I	Procedures	5
	1. <i>Daily monitoring</i>	5
	2. <i>Cleaning and disinfection</i>	6
	3. <i>Clean room system check</i>	7
	4. <i>Microbial testing</i>	7
J	Abbreviations	7
K	Appendixes	
	<i>Appendix 1 Log Sheet for Cleaning Work at Clean Zone (weekly/ biweekly)</i>	8
	<i>Appendix 2 Log Sheet for Maintenance Work for CO<sub>2</sub> incubator</i>	9

## Maintenance of Clean Zone

### A) Objectives

This document describes the proper procedures to maintain the clean zone of the Centre for Regenerative Medicine and Health, Hong Kong Institute of Science & Innovation, Chinese Academy of Sciences Limited (refer to CRMH below) at a suitable standard.

### B) Scope

This SOP applies to maintenance work to be done in the 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

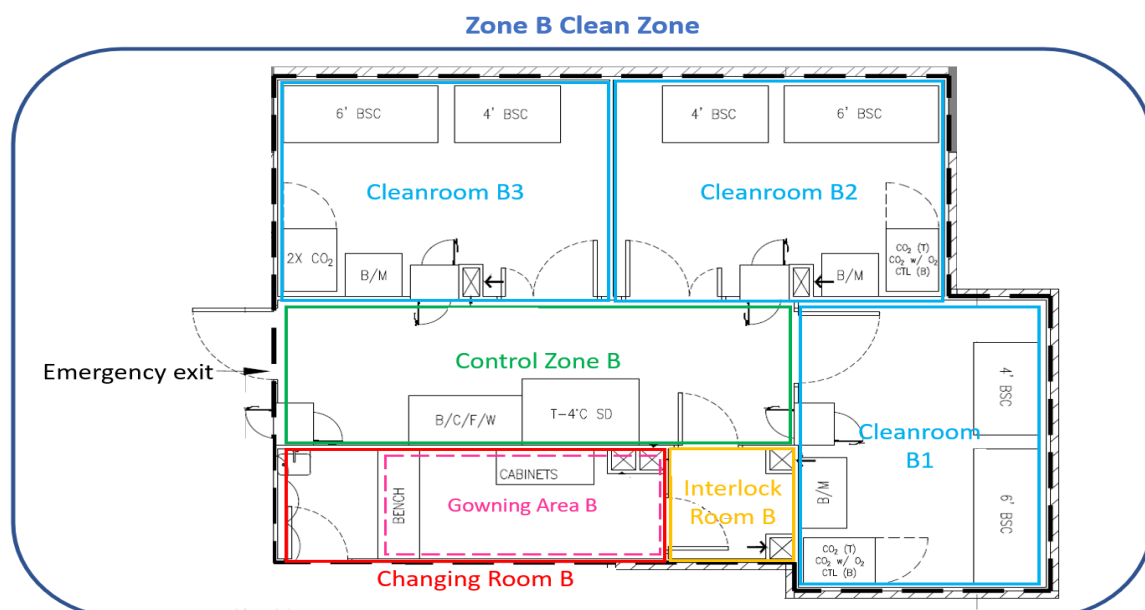
1. Team manager provides the training of this SOP to their members and to oversees if their members properly follow the maintenance procedures.
2. F&OC provides necessary support to the team managers (or their delegates) to implement this SOP.
3. Every member working in the clean zone should share the appointed clean zone maintenance duties to keep the cleanliness of the clean zone to achieve a high standard of cell culture practices.

### 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*, 4<sup>th</sup> Ed. 2020.

### F) Nomenclature

Names of rooms/areas of a typical cleanroom complex in CRMH:



Floor plan of a typical Clean Zone in CRMH.

## Maintenance of Clean Zone

### 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. 1:99 bleach solution
3. Clean room specific mop and fabric
4. Clean room wipers
5. Gas inlet filters
6. Cleaning log sheets

### I) Procedures

#### 1. *Daily monitoring*

The track records of the following parameters of the system/ equipment shall be stored at an electronic system (including built-in sensors and Thermo Scientific Smart-View System). The records can be retrieved if needed.

##### 1.1. Clean Zone

- a. Temperature
- b. Pressure
- c. Humidity

##### 1.2. CO<sub>2</sub> incubator

- a. Temperature
- b. CO<sub>2</sub> level
- c. O<sub>2</sub> level (for the incubator with oxygen control)
- d. Humidity

##### 1.3 Fridges and freezers

- a. Temperature

##### 1.4 Air Handling Unit (AHU)

- a. The airflow and status of the HEPA filter system should be recorded.

### Maintenance of Clean Zone

#### 2. *Cleaning and disinfection*

2.1. A cleaning schedule and cleaning log sheet for the clean zone and equipment shall be established. The cleaning log sheet should be filled out after cleaning, disinfection, and routine maintenance (Appendix 1, 2).

2.2. Avoid the introduction of non-cleanroom specified cleaning agents, and materials

##### 2.3. Clean zone

2.2.1 Disinfect the clean zone using the UV light for 30 minutes at the end of every shift.

2.2.2 The surface of the bench and clean room trolley shall be cleaned by DI water, 70% ethanol and clean room wipers once per week.

2.2.3 The wheels of the trolley shall be cleaned by DI water, 70% ethanol and clean room wipers biweekly.

2.2.4 The clean room floors should be vacuum dried and cleaned once per week. Vacuum cleaner equipped with HEPA filter should be used.

2.2.5 A stainless steel mop and clean room-specific fabric should be used to mop the clean room floors. Alternating disinfectants (e.g., use 1:99 bleach solution in 1st week and use the DETTOL in another week, or vice versa) should be used to disinfect the clean room floors more effectively. It is important to change the water between rooms to reduce the risk of cross-contaminating separate rooms.

2.2.6 The cleaning should start from the room furthest away from the exit, then gradually working through the gowning room to the exit. Once the floor is dry, vacuum the floor again to remove every debris distributed during the mopping process.

2.2.7 When there is clear soiling on benches, trolley, or walls, follow "SOP for Spills and Exposure".

2.2.8 It is recommended to wipe the ceiling and walls with DI water and damp cleanroom sponge 3-6 months or whenever necessary. If disinfection is needed, 1:99 bleach solution or DETTOL should be used alternatively. The scrubbing shall be conducted in single direction.

2.2.9 Change cleanroom sticky mats as needed.

##### 2.3 Passbox

2.3.1 Wipe the passbox down with 70% ethanol and clean room wipers **before AND after** each use.

2.3.2 Turn on UV light for at least 30 mins at the end of the shift.

##### 2.3.3 Biosafety Cabinet (BSC) and Pipettes

2.3.4 Wipe a BSC and pipettes down with 70% ethanol and clean room wipers **before AND after** each use.

2.3.5 Turn on UV light for at least 30 mins at the end of the shift.

2.3.6 F&OC shall arrange fumigation for the BSC by a third party once a year.

### **Maintenance of Clean Zone**

#### **2.4 CO<sub>2</sub> incubator**

- 2.4.1 Clean the trays of the incubator, water reservoir, and the platform of the shaker once a month by wiping it down with 70% ethanol and clean room wipers.
- 2.4.2 After routine cleaning, the incubator may be followed by the incubator's disinfection program (i.e., Steri-run) if necessary. The shaker must be taken out from the incubator when performing disinfection program.
- 2.4.3 Replenish the water to the water reservoir before/ when the "low water level" message is noticed.
- 2.4.4 Change the water from water reservoir with autoclaved distilled water at least monthly.
- 2.4.5 Replace gas inlet filters once a year.

#### **2.5 Fridge and freezer**

- 2.5.1 The inside surfaces of the fridge/freezer is needed to be wiped down using 70% ethanol and clean room wipers once per year.

#### **2.6 Centrifuge**

- 2.6.1 The interior of centrifuges and all surfaces of buckets should be wiped with 70% ethanol and clean room wipers once every two weeks.

#### **3. Clean room systems check (arranged by F&OC)**

- 3.1. In-house tests of air flow, HEPA filter, humidity, particle count at rest testing should be conducted quarterly.
- 3.2. Airflow and air filter checks are recommended to be conducted by a third party once per year.

#### **4. Microbial testing (arranged by F&OC)**

- 4.1 In-house microbial testing should be conducted quarterly.

### **J) Abbreviations**

- 1. AHU: Air Handling Unit
- 2. BSC: Biological safety cabinet
- 3. CRMH: Centre for Regenerative Medicine and Health, Hong Kong Institute of Science & Innovation, Chinese Academy of Sciences Limited
- 4. F&OC: Facility and Operations Compliance Department
- 5. SOP: Standard operating procedure

### **K) Appendix**

- 1. Log Sheet for Cleaning Work at Clean Zone
- 2. Log Sheet for Maintenance Work for CO<sub>2</sub> Incubator

## Maintenance of Clean Zone

### Appendix 1

#### CRMH Clean Zone

#### Log Sheet for Cleaning Work at Clean Zone (weekly/ biweekly)

	Weekly			Biweekly		
Date	Floor	Bench	Surface of Trolley	Wheels of Trolley	Centrifuge	Signature

✓ when cleaning at that column is completed

- Alternating disinfectants (e.g., use 1:99 bleach solution in 1st week and use the ethanol in another week, or vice versa) should be used to disinfect the clean room floors.
- Area other than floor shall be cleaned by 70% ethanol.

Page \_\_ of \_\_



**Maintenance of Clean Zone****Appendix 2****CRMH Clean Zone  
Log Sheet for Maintenance Work for CO<sub>2</sub> incubator**

Date	Replace water from water reservoir (Monthly)	Clean the water reservoir (Monthly)	Clean the trays (Monthly)	Clean the platform of the shaker (Monthly)	Perform Steri- Run (if necessary)	Other Maintenance	Signature

✓ when maintenance work at that column is completed

Page \_\_ of \_\_