


STANDARD OPERATING PROCEDURE (SOP)		
Department: Regenerative Medicine Research Center		
SOP No: 05	Ver: 01	
SOP Title: Clean room cleaning & disinfection		

SOP Number: 05-ver 01




SOP Title: Clean room cleaning & disinfection

	NAME	TITLE	SIGNATURE	DATE
Author	Sajjad Babaei	Research Assistant		
Reviewer	Dr.Farjam Goudarzi	Faculty member		
Authoriser	Dr.Amir Kiani	Assistant manager		

Effective Date:	
Review Date:	

READ BY			
NAME	TITLE	SIGNATURE	DATE

STANDARD OPERATING PROCEDURE (SOP)	
Department: Regenerative Medicine Research Center	
SOP No: 05	Ver: 01
SOP Title: Clean room cleaning & disinfection	



1. PURPOSE

The purpose of this SOP is to set out the procedures for clean room cleaning and disinfection.

2. INTRODUCTION

Even if a cleanroom's primary and secondary engineering controls are sufficient and if strict garbing, hand-washing, and particulate control measures are put in place, consistent and effective cleaning procedures are still required to continually minimize the overall bioburden present in the facility. This procedure is a guideline for cleaning and disinfection of ISO Class 5 to 8 cleanrooms. Cleanrooms are classified by how clean the air is. For example, ISO Class 5 rooms would be the cleanest, and ISO Class 8 rooms would be the dirtiest. According to Federal standards, the number of particles equal to and greater than 0.5mm is measured in one cubic foot of air, and this count is used to classify the cleanroom.

3. SCOPE

3-1- All staff involved in the process of clean room cleaning and disinfection in tissue processing center.

3-2- ISO Class 5 to 8 cleanrooms

4. DEFINITIONS

4-1- Cleanroom: A cleanroom or clean room is an engineered space, which maintains a very low concentration of airborne particulates. It is well isolated, well-controlled from contamination, and actively cleansed

4-2- Disinfection: the process of cleaning something, especially with a chemical, in order to destroy microbial pollutions.


4-3- Tissue processing center: cleanroom area in which biological tissues are processed and prepared for medical applications.

5. RESPONSIBILITIES

5-1- Supervisor: Supervise the full implementation of the SOP

5-2- Clean room Staffs: Execute the standard steps listed in the SOP

5-3- Quality control officer: Checking the steps of clean room cleaning and disinfection and their compliance with the SOP and recording the relevant data for validation.

STANDARD OPERATING PROCEDURE (SOP)		
Department: Regenerative Medicine Research Center		
SOP No: 05	Ver: 01	
SOP Title: Clean room cleaning & disinfection		

6. SPECIFIC PROCEDURE

6-1- Appropriate personal protection should be taken for those responsible for the decontamination of a cleanroom:

- Disposable gloves
- Lint free shoe covers
- Bouffant caps
- Surgical masks
- Safety glasses
- Gowns
- Beard covers (if needed)

6-2- Disinfectant chemistries approved for disinfection of cleanrooms include:

- Accelerated Hydrogen Peroxide® (AHP®)
- Sodium Hypochlorite
- Isopropyl Alcohol
- Quaternary Ammonium Compounds (QUATs)
- Phenols
- Iodophors

6-3- The concentration and contact time for each product will differ. For that reason it is important to read the product label prior to commencing any cleaning and disinfection process.

6-4- Some chemistries such as QUATs and Phenols leave behind active residues which can contribute to resistant microflora by allowing bacteria to build up resistance. If using these kinds of chemistries, the development of resistant microflora should be prevented by rotating cleaning agents.




6-5- Procedures for preparing cleaning solutions:

6-5-1- It is imperative that the cleaning-agent manufacturer's instructions be followed with regard to storage, handling, and dilution. Safety Data Sheets (SDS) are readily available from solution manufactures and must be available on site.

6-5-2- Solutions must be diluted and mixed immediately prior to use, and documentation of their preparation is strongly recommended. Make glass or plastic graduated cylinders available at the sink where solutions are mixed and thoroughly rinse them after.

6-5-3- Sterile water for irrigation is used with the appropriate cleaning agent in any ISO Class 5 area, including work bench or hood surfaces, walls or other surfaces of the area, and any compounding equipment.

STANDARD OPERATING PROCEDURE (SOP)	
Department: Regenerative Medicine Research Center	
SOP No: 05	Ver: 01
SOP Title: Clean room cleaning & disinfection	



6-5-4- Sterile water for irrigation should also be used for intermittent hand decontamination.

6-5-5- Ensure that Spray-bottle solutions are changed in accordance with manufacturer's instructions for the shelf life of the product once diluted. Prepared solutions should be labeled with their expiry dates, and kept immediately outside the ISO Class 5 area for use in re-sanitizing hands prior to re-entry.

6-6- Procedures for cleaning equipment and supplies:

6-6-1- Appropriate cleaning equipment and supplies should be used for the cleaning and decontamination of a cleanroom.

6-6-2- Buckets and other cleaning equipment, such as mop handles, heads, and covers, must be dedicated to the area where they are used.

6-6-3- To prevent cross-contamination, equipment used to clean walls and ceilings should not be used to clean floors, nor should they be taken outside of the clean room area.

6-6-4- Equipment to clean an ISO Class 6 or 7 area should not be used to clean an ISO Class 8 area.

6-6-5- Buckets must be metal free and made of heavy-duty plastic.

6-6-6- Conventional mops with cellulose heads should be changed every 48 hours to prevent shedding, and conventional mop handles should be replaced every month.

6-6-7- Low-lint (low particle generation) cleaning tools made from synthetic microfibers should be used in ISO class 5 to 8 areas. Larger wipes are generally preferred as they cover more surface area.

6-6-8- Low-lint wipes dipped in the diluted cleaning agent can be used to clean work benches and hoods and to wipe molding, doors, handles, furniture, product storage bins, as well as to wipe products before they enter the cleanroom and to dry hands.

6-7- Procedures for cleaning and disinfection:

6-7-1- Cleaning and disinfection should generally occur from the cleanest area to the dirtiest – from an ISO Class 6 or 7 cleanroom to the ISO Class 8 anteroom.

6-7-2- Generally cleaning and disinfection should be done from top to bottom.


6-7-3- Daily cleanings should be performed at the end of the work shifts.

6-7-4- For ISO Class 5 cleanrooms, workstation surfaces should be wiped with the designated agent at the beginning of each work shifts.

6-7-5- It is important to make certain that all surfaces are thoroughly coated and wetted with the cleaning and disinfectant agent.

6-7-6- Daily cleaning:

- Empty waste receptacles and replace liners (daily or as often as needed)
- Remove hazardous-waste receptacles
- Remove biohazardous materials (see SOP: 02-ver 01)
- Clean ISO Class 5 workstations

STANDARD OPERATING PROCEDURE (SOP)		
Department: Regenerative Medicine Research Center		
SOP No: 05	Ver: 01	
SOP Title: Clean room cleaning & disinfection		

- Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers
- Mop floors

6-7-7-Weekly cleaning:




- Empty waste receptacles and replace liners (daily or as often as needed)
- Remove hazardous-waste receptacles
- Remove biohazardous materials (see SOP: 02-ver 01)
- Clean ISO Class 5 workstations
- Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers
- Mop floors
- Clean windows, walls, and all other horizontal surfaces, including doors and side, front, and back of hoods, from top to bottom
- Empty, clean and sanitize storage shelving and bins
- Clean and sanitize any other non-compounding furniture such as carts, stools, and waste containers

6-7-8- Monthly cleanings:

- Empty waste receptacles and replace liners (daily or as often as needed)
- Remove hazardous-waste receptacles
- Remove biohazardous materials (see SOP: 02-ver 01)
- Clean ISO Class 5 workstations
- Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers
- Mop floors
- Clean windows, walls, and all other horizontal surfaces, including doors and side, front, and back of hoods, from top to bottom
- Empty, clean and sanitize storage shelving and bins
- Clean and sanitize any other non-compounding furniture such as carts, stools, and waste containers
- Clean and sanitize interior and exterior of refrigerators and incubators (not kept in controlled environments)
- Clean ceilings of all controlled environments
- Change cleanroom sticky mats as needed, and without hesitation

6-8- At the end of each weekly and monthly cleaning & disinfection process, complete the cleanroom disinfection check list.

STANDARD OPERATING PROCEDURE (SOP)	
Department: Regenerative Medicine Research Center	
SOP No: 05	Ver: 01
SOP Title: Clean room cleaning & disinfection	


RMRC

7. FORMS/TEMPLATES TO BE USED

7-1- Cleanroom disinfection check list

8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

8-1-1- SOP: 02-ver 01

8.2 External References

8-2-1-<https://blog.gotopac.com/2018/01/26/cleanroom-cleaning-procedure-contamination-control-iso-14644-1-protocol/>

9. CHANGE HISTORY

9-1- Initial version:

- SOP No: 05-ver 01
- Effective Date: "see page 1"
- Significant Changes: --/
- Previous SOP no.: --/

9-2- Replacing a previous SOP:

- SOP No: --/
- Effective Date: --/
- Significant Changes: --/
- Previous SOP No: --/

SOP No.	Effective Date	Significant Changes	Previous SOP No.