


STANDARD OPERATING PROCEDURE (SOP)		
Department: Regenerative Medicine Research Center		
SOP No: 06	Ver: 01	
SOP Title: Cleanroom entrance & gowning and working		


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1. PURPOSE

The purpose of this SOP is to set out the procedures for cleanroom entrance & gowning and working

2. INTRODUCTION

Working in a cleanroom environment presents many hazards and it is imperative that users fully understand the rules and regulations in place to protect them. The procedures and precautions outlined in this SOP are for the purpose of protecting cleanroom users, equipment, and infrastructure. On the other hand, maintaining clean room standards and cleanliness is very important for producing a standard product. A user must be fully trained before he/she is allowed to operate in the cleanroom. It is important that users come to the cleanroom manager or the assistant director with any questions and fully read and understand this SOP before beginning work in the cleanroom.

3. SCOPE

3-1- All cleanroom users.

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

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 cleanroom entrance & gowning and working and their compliance with the SOP and recording the relevant data for validation.

6. SPECIFIC PROCEDURE

6-1- Pre-gowning procedure: The following items and activities are required to begin the process of entering/using the cleanroom:


6-1-1- Personnel with colds, temporary sneezing and coughing, and severe sunburns should not enter the cleanroom until they have recovered. The majority of particles come from the users of the cleanroom.

6-1-2- A daily bath/shower is recommended for all users as well as the wearing of clean, freshly laundered under garments and outer clothing.

6-1-3- Shampoo regularly and take action to control dandruff.

6-1-4- Users must abide by the following dress code:

- No sleeveless shirts

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- Full length pants must be worn
- No slippers, sandals, open-toed shoes, or worn out/dirty shoes
- No jewellery that can puncture garments or gloves
- Avoid clothing that sheds, such as wool, etc.

6-1-5- The use of cosmetics and make-up, hair spray and gel, colognes and perfumes, body lotions, as well as other personal skin care products should be kept to a minimum as these products have the potential to affect the rate at which the human body sloughs particulates or contaminate cleanroom attire and equipment that is re-usable.

6-1-6- Users must not smoke within 45 minutes of use of the cleanroom. This is strictly prohibited because personnel, who smoke, shed sub-micron sized particles for well over a half-hour after smoking a cigarette. This can be a severe source of contamination within the cleanroom.

6-1-7- Users should plan out their work prior to entry into the cleanroom so that traffic going in and out of the facility is minimized. This includes making a list of all materials, solvents, tools, etc. that the user will need to successfully complete their cleanroom session as well as preparing these items for entry into the cleanroom according to the procedure for bringing items into the cleanroom.

6-1-8- The user will need to:

- Ensure all items being carried into the cleanroom are cleanroom-approved (i.e. stationary, tools, equipment, etc.)
- Ensure that approved items are wiped down prior to entry with a solution of 70% IPA and 30% DI H₂O
- Ensure that larger approved items are transferred onto a cleanroom cart

6-1-9- Prior to entering the gown room, remove extraneous street clothing that is not easily covered by the cleanroom jumpsuit and attire, i.e. hats, jackets, or sunglasses, and leave these elsewhere or in the lockers provided in the service corridor.

6-2- Entrance:

6-2-1- The buddy system is recommended in the cleanroom

6-2-2- Only authorized users may enter the cleanroom unescorted

6-2-3- Users must be trained and properly gowned before entering the cleanroom


6-2-4- If special equipment set-up is required, consult the Assistant Director.

6-2-5- Remove cartons and packaging material before taking materials into the cleanroom area

6-2-6- Do not bring in tools or boxes with rust, oil, or peeling paint

6-2-7- Only cleanroom paper or plastic-laminated paper will be allowed in the cleanroom.

6-2-8- If you are not sure if something belongs in the cleanroom, ask before you bring it in.

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6-2-9- Clean equipment and materials before entering the cleanroom

6-2-10- Do not use cosmetics, colognes, and perfumes in the cleanroom and gowning areas

6-2-11- Keep all hair and ears covered with hood or cap

6-2-12- Keep personally clean – particularly hands, face, hair

6-2-13- NO ONE who is physically ill, especially with respiratory or stomach disorders, may enter. (This is a good practice in any cleanroom environment).

6-3- Cleanroom required garments includes:

- Gown (cover all): Used to cover body from neck to ankle
- Shoe covers: Used to prevent excessive dirt contamination coming off of street shoes
- Bouffant: Contains hair and minimizes shedding of particles
- Hood: Used to cover body from head to neck
- Face-mask: Used to minimize particle contamination from breathe and breathing
- Booties: Used to contain particles from shoes within the booties and serves as “clean shoes”
- Cleanroom gloves: Used to prevent oils and skin particles from contaminating the surface of the work benches and equipment
- Safety eyewear: Used to protect against particles from entering inside the eyes (if needed)

6-4- Cleanroom gowning:

6-4-1- Remove unnecessary items and place hat, coat, and any other street garments in a locker. Enter into service corridor. Remove street garments along with valuables; secure in designated locker.

6-4-2- Swipe into the gown room. Before entering the door, be sure to step THREE times on the sticky mat.


6-4-3- Put on shoe covers located just inside the entrance of the gowning room.

6-4-4- Put on face mask and bouffant

6-4-5- Carefully put on a hood. The hood must completely cover your hair and ears.

6-4-6- Inspect the coverall of your gown. Take care to keep the garment completely off of the floor at all times. Inspect your garment each time before donning, look for tears or soiling. If damaged, do not wear and dispose.

6-4-7- Put on your cleanroom gown. First, step into the gown legs, taking care not to let the garment touch the ground at any time. Then pull on the upper half of the gown and zip it all of the way up. While wearing a hood, be sure the “skirt” of the hood is completely inside the collar of the jumpsuit.

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6-4-8- Put on shoe covers. To put on cleanroom shoe covers, sit on the gowning bench with your feet on the dirty side of the bench. Put on one bootie and swing the “clean” foot to the clean side of the gown room. Then put on second cleanroom shoe cover and swing fully to the clean side and stand up.

6-4-9- Be sure the top of the boot is over the bottom of the jumpsuit leg so that any particles falling down the gown leg will be trapped in the shoe cover.

6-4-10- Put on cleanroom gloves. Carefully put on the first glove, touching the outside of this glove as little as possible. Put on the second glove using the previously gloved hand, taking care not to touch your skin with the gloved hand. Pull the cuff of the gloves over the sleeve of the jumpsuit so that any particles falling from your sleeves are trapped in the glove.

6-4-11- Put on goggles/Safety eyewear (if needed). Before putting on your safety glasses, make sure to wipe them down with an IPA wipe provided in gown room. This will ensure that the glasses are free of any particles and clear.


6-4-12- Step on sticky mat THREE times upon entrance into the cleanroom.

6-5- Notes:


- Use mirror to verify proper closure of garments: ensure all hair and clothing is covered.
- Cleanroom garments shall be worn only within the cleanroom complex, except under emergency conditions.
- Do not wear soiled, dirty or lint-producing street clothes under cleanroom garments.
- Do not hang street clothes or lab coats in the gown room. Use lockers located outside the gowning room in the service corridor.
- Facemasks are to be worn over the top of the nose.
- Never open your gown in the cleanroom.
- If garment is ripped during use, replace immediately
- Gloves are to be disposed of upon leaving the cleanroom. Booties and bouffant are to be disposed upon leaving the work area.

6-6- Proper working behaviour in the cleanroom

- Walk and move slowly to prevent air turbulence.
- Anticipate and gather all materials and tool supplies to perform the task at hand before entering the cleanroom.
- Clean, inspect, and wipe down all materials and tools entering the cleanroom with a 70% IPA solution.
- Understand your cleanrooms airflow patterns and organize accordingly with special attention as:
 - Not to block HEPA filtered air from reaching the product with your body or equipment.

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- Pin or tape note or instruction sheets on a wall or laminar flow tables so as to not block HEPA filter air.
- Keep tools, chemicals, and supplies in proper containers or storage cabinets; ensure that placement is downstream from the product as not to contaminate it.
- During lunch or long interruptions, and at the close of the work shift, ensure that all products, supplies, and materials are stored or covered as to protect them from contamination.
- Wipe up any spills or replace soiled garments immediately.
- Wipe down any object that is potentially contaminated with a 70% IPA or discard depending on the item and associated risk.
- Use special care to keep fume-hoods and wet benches in ultra-clean conditions.
- IMPORTANT – Hot plates (one of the main causes of cleanroom fires):
 - Never leave on when unattended
 - Make sure that the temperature is: 20°C below the flash point of its contents and 20°C below the melting point of beaker materials.
- Minimize the amount of materials stored. Excess storage in the cleanroom is not permitted. Only items relevant to cleanroom work should be in the cleanroom.
- Users will make proper entry each time a piece of equipment is used that has a logbook.
- At no time will paper in any form be torn or mutilated within the cleanroom.
- Be aware of supplies. If quantities of stock appear to be low, report it to the Cleanroom Manager.
- If you are not sure how a piece of equipment works, ask before you use it.
- Use only cleanroom materials present in the cleanroom.
- Minimize traffic through the gown room and service corridor.
- Use knife or scissors to open bags.
- Use cleanroom approved paper, notebooks, ball-point pens, and tape. Pencils, erasers, and retractable pens shall not be used within the cleanroom.
- Obey signs in the cleanroom and on equipment.
- When working with acids or solvents, wear chemical resistant nitrile/neoprene gloves available on the storage rack. Before using the gloves, be sure they are in good shape. Replace them if they are not. When disposing of acid mixtures, dilute with lots of water.
- Do not dump solvents down the drains. Use the solvent waste bins located at the fume-hoods.
- Be considerate by not touching or messing up someone else's work.

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- Personal items such as combs, cigarettes, matches, tissues, and similar particle shedding products SHALL NOT be exposed in the cleanroom.
- In some cases, a cell phone is allowed to enter the clean room. But be sure to put it in a sterile plastic bag. Never put the cell phone beneath your gown.
- Do not wear jewellery, watches, and pierced ear studs.
- Report adverse changes in environmental conditions (particle generation or accumulation, marked changes in humidity or temperature) and/or changes in your physical condition (profuse nasal discharge, skin conditions, etc.) to the cleanroom Assistant Director.
- Wipe down work areas at the end of each shift (see SOP: 05-ver 01)

6-7- Habits to avoid while in the cleanroom:

- Avoid scratching exposed skin areas, touching face or skin with gloves, if you do, replace gloves immediately with clean gloves.
- Never comb or brush hair within the cleanroom or gowning area.
- Walking rapidly, or moving unnecessarily, including running or horseplay, or any other fast motions is prohibited. Try to minimize air disturbance.
- Never chew gum or use tobacco, smoke, eat, or drink in cleanroom or clean areas.
- Never wear torn or soiled cleanroom garments.
- Avoid wearing cleanroom garments outside of the cleanroom.
- Never unfastening cleanroom garments in cleanroom.
- Never remove items from beneath the cleanroom garments.
- Coughing or sneezing persistently should be avoided.
- Never bringing wooden tool boxes, wooden-handled tools into cleanroom.

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7. FORMS/TEMPLATES TO BE USED

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8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

8-1-1- SOP: 05-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: 06-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.