

Loria Pharmaceutical, LLC

PROTOCOL

Protocol No.	600
Subject	Procedure Room Construction / Retro-Fit Guidelines
Effective Date	08-04-2021

INTRODUCTION

The OR / procedure room is one of the most important areas in a medical practice where medical or surgical procedures are performed. During these procedures, whether medical or surgical in nature, the treated area of the patient is exposed to manipulation, pathogens present in the patient's skin, transmitted by the medical personnel, the surgical instruments, or the air in the room. Even though medical procedures such as dermal injections carry a significant inherent lower risk of infection in comparison to more invasive surgical procedures, it is our goal and duty to minimize such risks.

Airborne transmission infections could account for up to 20% or more of all infections associated with medical procedures, not to mention the percentage associated with pathogens found in the surfaces of the rooms. Skin and soft tissue infections is and should always be a preventable must, and there are many measures that we can take to prevent this, and many standards that can be applied to improve the quality of the procedure areas. We could control the humidity, temperature, airflow, exchanges of air per minute, pressure differential, exhausts from the room, etc.

A relatively easy measure that we can take to improve the quality of the air and prevent airborne contaminants or pathogens is trying to adopt the ISO standard for cleanrooms, with a laminar unidirectional flow, directed from "clean" areas towards "less clean" ones. A perfect laminar airflow room is impossible to achieve, but creating good conditions is quite achievable.

CEILING

- **Ceiling tiles**

When considering ceiling tiles, we prefer durable, smooth, pvc, vinyl ceiling tiles that are waterproof, easy to clean and/or wash, rust, corrosion, mold, mildew, and bacteria resistant.

These ceiling tiles must cover the entirety of the ceiling with no available gaps that would allow contact between the procedure room and the actual ceiling of the room.

There are several available options in the market and most of the tiles used in the food, medical or electronic industry comply with federal standards of emission.

Loria Pharmaceutical, LLC

PROTOCOL

- **Ceiling tape**

Another important aspect to keep in mind is that to properly create a differential in air pressure, it is crucial to close the gap between the ceiling tiles and the ceiling rails. In order to do so we recommend a simple solution by taping it with a metalized foil for HVAC equipment. This simple and affordable solution is a suitable alternative to more complex and expensive closure systems.



- **Ceiling lights (Ceiling mounted OR/Procedure lights)**

This is the preferred method to illuminate the procedure area. Ceiling mounted procedure lights come in a wide variety of presentation and options, with the main goal to provide a strong focal illumination point with little to no shadows in the procedural area. We understand that it may not be possible in every room, but whenever possible it will be the preferred solution. If you already have some installed, you can work with those. If you don't have installed any ceiling mounted procedural lights, and you would like to install some, we recommend a LED option which will provide better illumination (more lumens) and less heat.



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PROTOCOL

- **Ceiling lights (Floor stand mounted OR/Procedure lights)**

Floor stand lighting is an acceptable option when not possible or desired to install a ceiling mounted procedure light. There are several floor stands options available that offer similar capabilities to the ceiling mounted ones, although depending on the model, the lumens that these units could provide might be limited, a two unit set up is recommended to cover several possible angles limiting the shadows that could be projected on the treatment area.



VENTILATION

- **HEPA Unit (Main/large HEPA Unit)**

The most important element concerning the ventilation of the procedure rooms are the HEPA units. Our recommendation is to have HEPA units with a 99.99% effectiveness to remove particles 0.5 μm (preferably 0.3 μm), or at the very least a HEPA unit 99.97% effectiveness to remove particles 0.5 μm (preferably 0.3 μm).

Operating/procedure rooms should have total Air Changes per Hour (ACH) between 10-25 times, meaning that the air in the room needs to be filtered and changed completely every 2.4 – 6 minutes. To determine this, number, we need to measure the volume of the room (length x width x height) and then calculate the ACH using the Cubic Feet per Minute that the HEPA unit can deliver.



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PROTOCOL

The formula to apply would be as follows...

$$\text{ACH} = \frac{\text{CFM} \times 60 \text{ Minutes}}{\text{L} \times \text{W} \times \text{H}}$$

So, to put some examples, if you have a 12 x 14 x 9 feet room, and you have a HEPA unit able to deliver 600 CFM, the formula will look like this...

$$\text{ACH} = \frac{600 \times 60}{12 \times 14 \times 9}$$

$$\text{ACH} = \frac{36,000}{1,512}$$

$$\text{ACH} = 23$$

This results in 23 air changes per hour, which is excellent, and between the range that we are looking for. Each procedure room should be equipped with two independent HEPA units, one focused on the air exchange in the room (with a higher capacity) and the other one (with less capacity) focused solely on the procedure area.

A consequence of this high ACH will be the reduction of the amount of air particles floating freely in the room. The objective will be to adhere to the ISO Class classification for clean rooms as much as possible. Having two main areas/goal in mind. The buffer-room area (that will directly depend on the main HEPA unit), and the hood area (that will have an independent system). When for some reason no calculation is possible, the units should run at the highest speed possible.

- **Areas to be tested**

There are three distinct areas to be tested for air quality, which will give you a fairly clear representation of the overall conditions in the rooms.

1. The anteroom. Which is the area of transition when entering the room and advancing into the treatment area.
2. The buffer-room (the buffer area). This is the area where the procedure (the injections to the patient) take place. It is considered to be directly on top of the patient.
3. The hood area. This is inside the laminar flow hood located inside the room, where the medication is reconstituted and mixed.

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PROTOCOL

- **Airflow inside the room**

When placing the HEPA units inside the room the objective is to sweep the air from one area that is considered to be “clean” towards another area considered to be “dirty” in a seamless manner with as less turbulence as possible, this objective however is impossible to achieve in a room full of people and mobiliary, however, as a rule of thumb, the airflow inside the rooms should be directed from the patient’s area (the buffer-room) towards the door, where this airflow could either be recirculated passing through the HEPA unit or exhaust from the room through a vent located at no more than 8” from the ground close to the door.

You can achieve this design several ways considering the inlet from the office/room AC unit as well, which should pour or direct the air flow coming from the main AC into the intake of the main HEPA unit. If you happen to have an independent AC unit, the exhaust of this independent AC unit should be directed out of the procedure room. To redirect the airflow inside the procedure room we recommend the installation of t a plenum.

- **PLENUM Placement**

The plenum is a part of the ventilation or airflow system inside the procedural room, that is destined to redirect the airflow from the already filtered air coming out of the main HEPA unit. A plenum is nothing more than a metal box connected through a flexible or rigid tube attached to the outflow of the HEPA unit. When placing the plenum, the general idea is to sweep the air in the largest/longest axis of the procedure room, or the axis that will procure the best airflow possible.



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PROTOCOL

- **Small HEPA unit (secondary HEPA unit)**

As previously mentioned, a smaller capacity HEPA unit will also be placed inside the room procedure room. The purpose of this HEPA unit is to direct airflow solely for the treatment area. This small capacity HEPA unit should be placed high on top of a sturdy shelf close to the ceiling, and from the outflow of this unit, a duct will redirect the air into an overhead eggcrate diffuser vent located directly on top of the surgical/treatment area. Keep in mind that the speed of the airflow in this location should be comfortable enough to allow you to perform the procedure without any interruptions caused by the airflow. This small HEPA unit is not subject to the ACH calculation.



- **Overhead Patient Eggcrate Diffuser Vent**

This is the logical continuation of the small HEPA unit placement. Same as it happens with the main HEPA unit connected to the plenum, the small HEPA unit will redirect the filtered air on top of the procedural area. The airflow should be comfortable enough not to cause disturbances on the procedure area.



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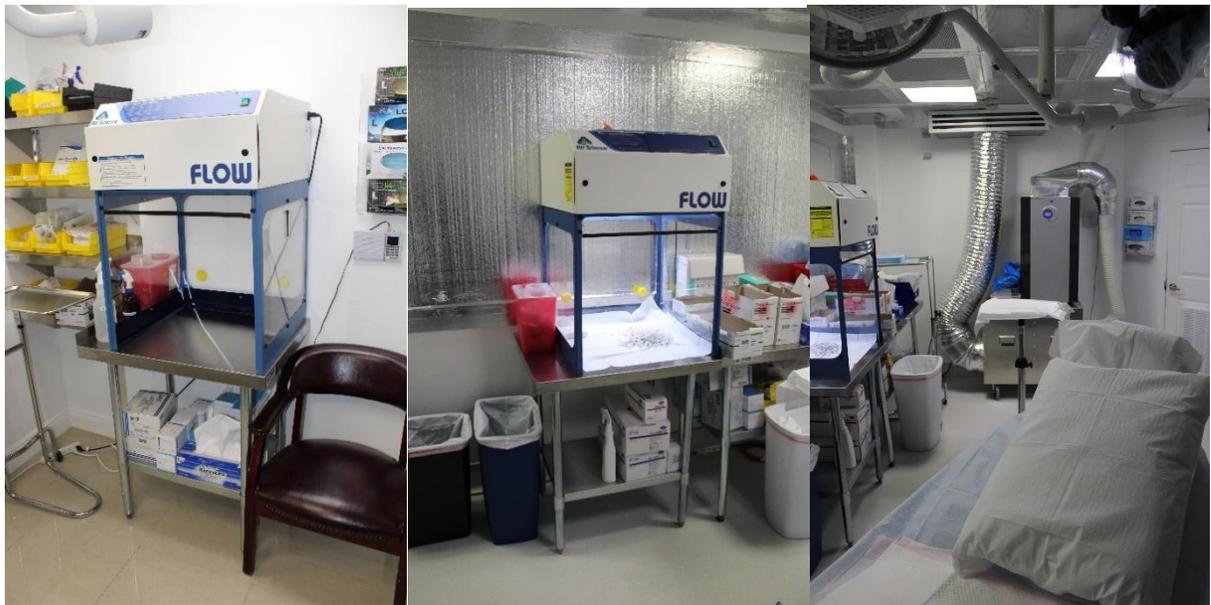
PROTOCOL

- **Laminar flow cabinet**

This is a key element of the procedure room and will be considered in the ventilation sub-section. Technically the laminar flow cabinet is an equipment that comprises two main sections or elements, the housing cabinet section, a three-panel enclosure with the main aperture located towards the front or work access area, and the fan filter unit (FFU) which is basically another HEPA unit blowing the air in a laminar fashion as the name suggest inside the enclosure.

The importance of this enclosure is that it will provide the best air class conditions possible inside the procedure room, to perform the mixing or reconstitution of the dermal filler formula. The most common model is a single person unit, usually placed on top of a workstation.

The work access location of the laminar flow cabinet should not be in any way located facing the airflow from the plenum, to prevent any possible incoming turbulence.



- **Log maintenance.**

You must keep a daily log of the measurements to make sure that the HEPA unit, air flow, room cleanliness is maintained. Such logs are to be reviewed at least once a week to monitor changes in the parameters mentioned above.

Any changes in the particle count numbers should lead to a thorough assessment of the airflow and quality in the room.

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PROTOCOL

- **Particle counter goals.**

1. Anteroom, ideal goal is ISO 6, less than 35,200 total particles 0.5 μm . ISO 7 is acceptable.
2. Buffer-room, ideal goal is ISO 5, less than 3,520 total particles 0.5 μm . ISO 6 is acceptable.
3. Hood-area, ideal goal is ISO 4, less than 352 total particles 0.5 μm . No other class is acceptable.

- **Independent AC unit**

It is permissible if you wish, or if you need, to place an independent AC unit to maintain the thermal comfort inside the procedure room. These units could and should be located in an area where the outflow of these units falls directly on the intake of the main HEPA unit that services the whole room. To achieve this goal, you could use a flexible tubing that will send the cold air into this HEPA with little to no waste into the whole room.



WALLS

Now that the ceiling has been taken care of, we can focus on the walls. The walls should be treated and painted with a special coating or epoxy paint that is clean room grade. This kind of treatment will provide smoothness to the walls, the less crevices available the easier it is to clean and to prevent places for the accumulation and/or growth of bacteria.

Ideally the wall should be treated first with a primer and then the coating with the pre-catalyzed epoxy paint.

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PROTOCOL

- **Wall shelving**

Preferably we recommend full metal wall shelving, several sizes available that will depend on the dimensions of the room. The recommendation for full metal shelving is for cleanliness purposes. These smooth surfaces are easier to clean.



FLOORS

Operating/procedure rooms should be made of a material that also prevents the transmission of infections. For such reason, the materials chosen for the floor should be...

1. Easily cleanable and disinfected.
2. Abrasion resistant.
3. Chemical resistant.
4. Low emission.
5. Non-slip.
6. High traffic resistant.

Any material that meets these recommendations is a suitable material. Ideally the floor should be a flat seamless surface with no sharp angles.

