

Loria Pharmaceutical, LLC
POLICY

Policy No.	116
Subject	Retro-Fit Room Maintenance
Effective Date	3/1/2021

SUMMARY, DESCRIPTION:

Retro-Fit Room routine maintenance includes but is not limited to:

1. Daily cleaning

- a. Understanding daily cleaning (also known as light cleaning) as the proper cleaning, set up, and sanitation of each procedure room (retrofit room) after each use and prior to the introduction of any other patient into the procedure room, as well as after the patient has leave the room in preparation to the next day.
- b. Daily cleaning shall be performed using an appropriate approved cleaning disinfectant solution, cleaning disinfectant method, or a combination of both, with emphasis in the procedure area and any other areas intended to be sterile or in direct contact with the patient.
- c. A proper cleaning log must be kept and reviewed periodically.

2. Weekly cleaning:

- a. Understanding weekly cleaning (also known as deep cleaning) as the proper thorough cleaning, set up, and sanitation of each procedure room (retrofit room).
- b. Weekly cleaning shall be performed using an appropriate approved cleaning disinfectant solution, cleaning disinfectant method, or a combination of both, with emphasis in the procedure area and any other areas intended to be sterile or in direct contact with the patient, in addition to all other areas of the procedure room.
- c. Weekly cleaning involves the cleaning of the procedure room ceiling, walls, and floor.
- d. Weekly cleaning involves the thorough cleaning of any storage intended surface or container, with the removal and cleaning of each individual storage bin or container with an adequate disinfectant solution, disinfectant method, or a combination of both.
- e. A proper cleaning log must be kept and reviewed periodically.

3. Monthly cleaning:

- a. Understanding monthly cleaning (also known as deep cleaning) as the proper thorough cleaning, set up, and sanitation of each procedure room (retrofit room).
- b. Monthly cleaning shall be performed using an appropriate approved cleaning disinfectant solution, cleaning disinfectant method, or a combination of both, with emphasis in the procedure area and any other areas intended to be sterile in direct

or indirect contact with the patient, in addition to all other areas of the procedure room.

- c. Monthly cleaning involves the thorough cleaning of the room ceiling, room walls, and room floors following clean room standards.
- d. Monthly cleaning involves the thorough cleaning of any storage intended surface or container, with the removal and cleaning of each individual storage bin or container with an adequate disinfectant solution, disinfectant method, or a combination of both.
- e. Monthly cleaning involves the thorough cleaning of any other fixture not previously mentioned in the room.
- f. A proper cleaning log must be kept and reviewed periodically.

4. Inventory check and rotation:

- a. Licensee agrees to review the BUD of all medications and disposable materials that apply and discontinue the use of any expired BUD medications or materials.
- b. Licensee agrees to maintain a proper stock rotation of all medications and disposable materials used in relation to the procedure.
- c. Licensee agrees to maintain a proper stock rotation of the permanent dermal filler formula provided by Loria Medical Pharmaceutical, understanding, and respecting the BUD of 45 days in cold/frozen storage.
- d. A cold/frozen storage is a place in which the temperature is controlled between -25° and -10° (-13° and 14° F) according to the USP 659.
- e. Licensee agrees to maintain a proper stock rotation of the topical anesthetic formula provided by Loria Medical Pharmaceutical, understanding, and respecting the BUD of 6 months in cold/refrigeration storage.
- f. A cold/refrigeration storage is a place in which the temperature is controlled between 2° and 8° (36° and 46° F) according to the USP 659.

5. HEPA Filter Changes:

- a. The most important element concerning the ventilation of the room are the HEPA units. Our recommendation is to have HEPA units with a 99.99% effectiveness to remove particles $0.5\ \mu\text{m}$ (preferably $0.3\ \mu\text{m}$), or at the very least a HEPA unit 99.97% effectiveness to remove particles $0.5\ \mu\text{m}$ (preferably $0.3\ \mu\text{m}$).
- b. A pre-filter is a synthetic material mesh placed in the inlet or intake of each HEPA units, and it is intended to reduce the total amount of particles that the HEPA unit itself will filter.
- c. Licensee agrees to verify the proper functioning of the main and secondary HEPA filter units.
- d. Licensee agrees to replace the main HEPA filter unit (the main filtration component of the main and secondary HEPA unit) if the units does not prove to properly function.

- e. Licensee agrees to replace the pre-filter of the main and secondary HEPA unit regularly throughout the year, in a period no greater than 6 months for each pre-filter or sooner than that if the air quality of the procedure room deteriorates in said period.
 - f. Licensee agrees to replace the pre-filter of the main and secondary HEPA unit upon Licensor request if the Licensor considers doing so after inspection.
 - g. Licensee agrees to purchase all filters and pre-filters from Loria Medical enterprises.
 - h. Licensee agrees to maintain a proper maintenance, filter and pre-filter replacement log that must be reviewed periodically.
6. Patient overhead Diffuser cleaning:
- a. Licensee agrees to maintain and provide proper cleaning of the patient overhead diffuser (also known as overhead eggcrate diffuser) on a regular basis.
 - b. Weekly cleaning and monthly cleaning of such diffuser is mandatory.
 - c. A proper cleaning log must be kept and reviewed periodically.
7. Particle Counts:
- a. Particle count are the default method to quantify and monitor the air quality inside the procedure/retrofit room.
 - b. As the default method of monitoring, daily particle counts must be taken in order to guarantee the proper air quality.
 - c. Three distinctive areas are to be tested for air quality, which will give you a fairly clear representation of the overall conditions in the rooms.
 - d. The anteroom. Which is the area of transition when entering the room and advancing into the treatment area, located in the immediate adjacence of the entryway to the procedure room. A transitional area between the outside of the room and the area in which the exchange with the filtered air takes place.
 - e. The buffer-room (the buffer area). This is the area where the permanent dermal filler procedure injections are administered. It is considered to be directly on top of the patient and under the Patient overhead Diffuser that is connected to the secondary HEPA unit.
 - f. The hood area (also known as the laminar flow cabinet area). This area to be tested is located inside the laminar flow cabinet (or hood) located inside the room, where the medication is reconstituted and mixed.
 - g. Anteroom particle count goal is ISO 6, less than 35,200 0.5 μm particles/m³ according to the ISO 14644-1 cleanroom standards.
 - h. Buffer-room, ideal goal is ISO 5, less than 3,520 0.5 μm particles/m³ according to the ISO 14644-1 cleanroom standards.
 - i. Hood-area, ideal goal is ISO 4, less than 352 0.5 μm particles/m³ according to the ISO 14644-1 cleanroom standards.

- j. Licensee agrees to maintain a proper record and datalogging of the air quality in each tested area on a regular basis.
8. Refill Hypochlorous Acid and Sterile Alcohol Bottles; and
- a. Licensee agrees to review the BUD of all Hypochlorous Acid and Sterile Alcohol Bottles and discontinue the use of any expired BUD medications or materials, as well as to refill and thoroughly clean each bottle regularly.
 - b. Cleaning of these bottles is to be included in the Weekly and Monthly cleaning of the procedure rooms.
9. All taped areas remain intact.
- a. Licensee agrees to visually inspect on a regular basis the cleanliness of each procedure room and provide access or audiovisual material of the conditions of the rooms including the ceiling tape upon request.
 - b. Licensee understands that the ceiling tape or any other taped areas must provide a flushed finish, to prevent any crevice's that could either after the air flow inside the procedure room creating turbulence or that could potentially act as a possible fomenting site of bacterial growth.
10. Licensee shall maintain a written log of all Retro-Fit Room maintenance.