

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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| DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661 | DATE(S) OF INSPECTION 7/8/2019-7/29/2019* |
| | FBI NUMBER 3015468054 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patricia Caruso-Prendergast, MS, PharmD, BCPS, Director of Pharmacy, AVP
Pharmaceutical Services, Department of Pharmacy, Maimonides Medical Center

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| FIRM NAME Maimonides Medical Center - Pharmacy | STREET ADDRESS 4802 10th Avenue, Sub-Basement |
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| CITY, STATE, ZIP CODE, COUNTRY Brooklyn, NY 11219 | TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products |
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This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:
OBSERVATION #1**

Actionable microbial contamination was present in the ISO 5 area or in adjacent areas during aseptic production without adequate product evaluation and remedial action. Specifically, environmental monitoring failures were identified in the following ISO classified areas:

- a) ISO Class 5, IV (b) (4) (b) (4) (in ISO 7 nonhazardous cleanroom), (b) (4) media, surface sampling: 1 CFU of Penicillium on 6/12/19;
- b) ISO Class 5, Hood (b) (4) (b) (4) (in ISO 7 nonhazardous cleanroom), (b) (4) plate, viable air sampling: 1 CFU of Gram-positive rods, performed by (b) (4) on 4/10/19;
- c) ISO Class 5, Hood (b) (4) (b) (4) (in ISO 7 nonhazardous cleanroom), (b) (4) plate, viable air sampling: 1 CFU of Micrococcus, performed by (b) (4) on 4/10/19;
- d) ISO Class 5, Hood (b) (4) (b) (4) (in ISO 7 nonhazardous cleanroom), (b) (4) plate, viable air sampling: 3 CFU of Bacillus (2 CFU) and Micrococcus (1 CFU), performed by (b) (4) on 4/22/19;
- e) ISO Class 5, ED Hood (b) (4) (in ED Satellite Pharmacy), (b) (4) plate, viable air sampling: 1 CFU of Micrococcus, performed by (b) (4) on 4/15/19; and,
- f) ISO Class 7, Work cart adjacent to ISO 5 hood (in ISO 7 hazardous cleanroom), (b) (4) with (b) (4) media, surface sampling: 1 CFU of Yeasts on 6/12/19.

No investigation was performed, and no corrective and/or preventative actions were documented.

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OBSERVATION #2

Non-microbial contamination was observed in your production area. Specifically,

- a) There are visible indications of the use of damaged, dirty, discolored HEPA filters as observed in nonhazardous ISO 5 (b) (4) Hood (b) (4), Hood (b) (4), and Hood (b) (4) as well as, in the ISO 5 (b) (4) hood located in the Medical ICU pharmacy satellite. On 7/8/19, I observed multiple orange/brown-tinged rust stains on all four of these hoods.
- b) Multiple cracks in the top right corner were observed on 7/8/19 in the front glass shield of the ISO 5 (b) (4) hood, located in the ISO 7 hazardous cleanroom.
- c) Cracks in the top of the hood where the light is located in both ISO 5 (b) (4) hoods in the Medical ICU satellite pharmacy and the PACU satellite pharmacy were observed on 7/9/19.
- d) Cracks in the floors, walls, ceilings, and doors in the ISO 7 hazardous cleanroom, ISO 7 nonhazardous cleanroom, and ISO 7 anteroom were observed on 7/8/19.
- e) On 7/8/19, I observed the sticky mat, located in the unclassified pharmacy area prior to entrance into the ISO 7 anteroom, to be dirty. The entire mat appeared to be filled with dirt and dust.

OBSERVATION #3

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination. Specifically, on 7/9/19, I observed a chemo pharmacist making drug products while multiple different drug products for eight different patients were staged in the same ISO 5 (b) (4) hood, located in the ISO 7 hazardous cleanroom, including:

- Paclitaxel Albumin 175mg/(b) (4) NS for Patient (b) (6);
- Cisplatin 40mg (b) (4) NS IVPB for Patient (b) (6)

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- Irinotecan 590mg (b) (4) D5W IVPB for Patient (b) (6);
- Etoposide 152mg (b) (4) NS IVPB for Patient (b) (6);
- Daratumumab So1430mg (b) (4) NS IVPB for Patient (b) (6);
- Bevacizumab 480mg (b) (4) NS IVPB for Patient (b) (6);
- Oxaliplatin 130mg (b) (4) D5W, Leucovorin 420mg (b) (4) D5W IVPB, and Fluorouracil 840mg (b) (4) IVP for Patient (b) (6); and,
- Gemcitabine 860mg (b) (4) NS IV, Leucovorin 300mg (b) (4) NS IVPB, Irinotecan 155mg (b) (4) NS IVPB, Fluorouracil 940mg (b) (4) NS, and Fluorouracil 2830mg QS (b) (4) 0.9% NaCl for Patient (b) (6).

OBSERVATION #4

Beta-lactam drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination. Specifically, beta-lactam drug products are made from sterile commercially-available drug products in ISO 5 (b) (4) Hood (b) (4) in the ISO 7 nonhazardous cleanroom and not made in the ISO 5 (b) (4) hood located in the ISO 7 hazardous cleanroom. Cleaning is performed in between all products using (b) (4) and a nonsterile wipe to wipe down the base of the hood only.

OBSERVATION #5

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves. Specifically, on 7/8/19, a pharmacist, who was making nonhazardous IV sulfamethoxazole-trimethoprim injectable in D5W IV Piggy Back (for MRN: (b) (6)) in ISO 5 (b) (4) Hood (b) (4) located in the ISO 7 nonhazardous cleanroom, was observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves. The pharmacist was also observed throwing out trash in the bin and getting supplies from the cart, outside the ISO 5 hood, without re-sanitizing or changing her gloves before reentering the ISO 5 hood.

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OBSERVATION #6

Personnel engaged in aseptic processing were observed with exposed hands, wrists, legs, hair, or mouth. Specifically,

- a) On 7/8/19, a chemo pharmacist was observed making chemotherapeutic drugs for the Chemo Center with exposed legs.
- b) Personnel engaged in aseptic processing did not wear protective eyewear. Specifically, on 7/8/19, I observed a chemo pharmacist making chemotherapeutic drug products in the ISO 5 hazardous (b) (4) hood without any protective eyewear.

OBSERVATION #7

Personnel engaged in aseptic processing were observed wearing non-sterile gloves. Specifically, on 7/8/19, a chemo pharmacist was observed wearing non-sterile gloves in the ISO 7 hazardous cleanroom while handing another chemo pharmacist supplies in the ISO 5 hazardous (b) (4) hood, so that he did not have to remove his gloved hands out of the ISO 5 hood.

OBSERVATION #8

The ISO 5 classified area is located within a non-classified room (segregated production area). Specifically,

- a) The area surrounding the ISO 5 (b) (4) hoods in all the satellite pharmacies (Medical ICU, PACU, and ED satellite pharmacies) are unclassified.

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b) The ISO 5 (b) (4) hood in the ED pharmacy satellite is turned off in the evening (b) (4) and is turned on in the morning (b) (4). In the morning when the ISO 5 hood is turned on, it is let to run for (b) (4) and then subsequently cleaned prior to the start of any compounding operations. Morning cleaning includes spraying nonsterile (b) (4) followed by wiping the hood with nonsterile wipes; then, laying out nonsterile wipes at the base of the hood and pouring sterile water on the wipes, followed by wiping down the hood with the soaked wipes, allowing the hood to dry; and lastly, laying out nonsterile wipes at the base of the hood and pouring sterile (b) (4) on the wipes, followed by wiping down the hood with the soaked wipes. Cleaning is performed again at the (b) (4) in the same manner, excluding the step with (b) (4).

c) The ISO 7 anteroom and the ISO 7 cleanrooms are not adequately cleaned. Specifically, the ceilings and walls in the ISO 7 classified rooms, as well as the (b) (4) between the (b) (4) and the (b) (4) are not cleaned. The only cleaning that is performed in the sterile compounding area is conducted by an Environmental Worker in the morning and in the evening, who clean the floors, glass windows, and then worksurfaces of the ISO 7 anteroom, ISO 7 nonhazardous cleanroom, ISO 7 hazardous cleanroom, and unclassified refrigerator, respectively.

OBSERVATION #9

The facility is designed and/or operated in a way that permits poor flow of personnel or materials. Specifically,

- a) The door separating the (b) (4) and (b) (4) does not close completely when shut.
- b) Supplies and finished chemotherapeutic drug products are temporarily stored on a stainless-steel tabletop in the ISO 7 hazardous cleanroom without adequate space or separation.
- c) The air return located in the ISO 7 nonhazardous cleanroom is dirty and in disrepair and is blocked by a stainless-steel cart.

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OBSERVATION #10

Sinks or drains are present in the cleanroom where the ISO 5 area is located. Specifically, in the ED satellite pharmacy, the sink is located right across from the ISO 5 (b) (4) hood in the unclassified ED satellite pharmacy.

OBSERVATION #11

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area aseptic processing areas are not sterile. Specifically,

- a) The wipes used to disinfect the ISO 5 hoods with (b) (4)
- b) (b) (4) is used to clean/disinfect the ISO 5 hoods (b) (4) and the ISO 5 IV (b) (4) (b) (4).
- c) (b) (4) are used in cleaning of the ISO 5 (b) (4) hood in the ISO 7 hazardous cleanroom to deactivate any chemotherapeutic drug residues.

OBSERVATION #12

Sporicidal agents are not used in your facility's cleanrooms and/or ISO 5 area.

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OBSERVATION #13

Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas. Specifically,

- a) On 7/8/19, I observed a pharmacist in Hood ^{(b)(4)} (ISO 5 (b) (4) hood) in the ISO 7 nonhazardous cleanroom bringing supplies into the hood without disinfecting them.
- b) On 7/9/19, I observed a pharmacist bringing a saline bag from the counter in the ISO 7 hazardous cleanroom to the ISO 5 (b) (4) hood without disinfecting it.

OBSERVATION #14

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions. Specifically,

- a) The TPN Compounder equipment, located and stored in ISO 5 (b) (4) hood, Hood ^{(b)(4)} located in the ISO 7 nonhazardous cleanroom, is not removed during routine cleaning. It is only removed when your firm indiscriminately believes the hood needs to be cleaned without it.
- b) The IV (b) (4), located in the ISO 7 nonhazardous cleanroom, are cleaned (b) (4) No cleaning and/or disinfecting is performed throughout the day even when an IV (b) (4) is opened to replace labels.
- c) (b) (4) cleaning of the following ISO 5 areas and ISO 7 rooms were not adequately performed and/or recorded:
 - (b) (4) cleaning of the ISO 5 IV Station ^{(b)(4)}, located in the ISO 7 nonhazardous cleanroom, was not documented in your firm's cleaning log in (b) (4) on 6/28/19, 7/1/19, 7/3/19, and 7/5/19;
 - (b) (4) cleaning of the ISO 5 IV Station ^{(b)(4)}, located in the ISO 7 nonhazardous cleanroom, was

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- not documented in your firm's cleaning log in (b) (4) on 6/28/19 and 7/5/19; and,
- (b) (4) cleaning of the PACU satellite, Medical ICU satellite, and the sterile suite were not documented as being successfully performed by Environmental Workers and recorded by a pharmacist (marked as "Pass") or were documented as "Fail" in your firm's electronic cleaning log in (b) (4) on 1/8/19, 1/14/19, 1/17/19, 2/18/19, 3/28/19, 7/4/19, and 7/5/19.

OBSERVATION #15

ISO-5 classified areas were not certified under dynamic conditions. Specifically, unidirectional airflow was not verified under operational conditions. Your firm's HEPA certification and smoke studies, performed by (b) (4) in April 2019, state that all smoke studies were performed under dynamic conditions; however, it does not state what that means. Upon confirmation with your firm's contractor, (b) (4) your firm's management stated that (b) (4) remembered that the smoke studies were performed while operators were in the room; yet, there is no documentation of the specific conditions that the smoke studies were performed under.

OBSERVATION #16

Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed. Specifically,

- a) In August 2015, during installation and implementation of your firm's (b) (4), which is used to continuously monitor pressure differentials, temperature, and humidity, three out of the (b) (4) of the V2-Differential Pressure (V2-DP) Sensors were installed incorrectly, including the following: Input (b) (4) (Pharmacy Chemo RM DP (b) (4)), which measures the pressure differential between the (b) (4) and (b) (4); Input (b) (4) ((b) (4) IV ROOM DP), which measures the pressure differential between the (b) (4) and (b) (4) and, Input (b) (4) ((b) (4) ANTE

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ROOM DP1), which measures the pressure differential between the (b) (4) and the (b) (4).

Since implementation of the (b) (4) for continuous monitoring of pressure differentials, multiple out-of-specification (OOS) results were observed for the V2-DP Sensors.

Additionally, the pressure differential results were OOS during your firm's most recent calibration of the V2-DP Sensors, in December 2018, except for Input (b) (4) ANTE ROOM DP2), which measures the pressure differential between the (b) (4) and the (b) (4). There is no documented calibration for Input (b) (4) during your firm's most recent calibration of the (b) (4) in December 2018.

No investigation was performed, and no corrective and/or preventative actions were documented.

- b) There are no alarms or alerts activated in the (b) (4) when pressure differentials are OOS for any duration of time.
- c) Pressure differentials are not monitored between the (b) (4) and the (b) (4).

***DATES OF INSPECTION**

7/08/2019(Mon), 7/09/2019(Tue), 7/10/2019(Wed), 7/11/2019(Thu), 7/17/2019(Wed), 7/22/2019(Mon), 7/29/2019(Mon)

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