1. Personnel were observed conducting aseptic manipulations that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.

Specifically, on 07/09/2018 I observed a sterile technician filling vials of Testosterone Cypionate/Anastrozole®GS®Oil 200MG/0.5MG/ML RM Injectable lot number 486380, in a (b) (4) laminar ISO 5 classified bio-safety cabinet, break first pass unidirectional air flow at least four times by placing hands over an open top of the (b) (4) while (b) (4) drug product in a syringe during the fill operation. Since the January 2017 there have been (b) (4) sterility failures which may be an indication of insanitary conditions.

2. The ISO-classified area has difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically, caulking around joints of the ISO 5 area between the laminar flow hood and (b) (4) and on ceilings in the non-hazardous and hazardous areas were not smooth.

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, since December 2017 lots of hazardous Human Chorionic Gonadotropin (HCG) were filled and (b) (4) in the non-hazardous ISO 5 classified area of the facility.