DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The ISO 5 classified aseptic processing area was located within a non-classified room (segregated production area).

Specifically,

A. Your ISO 5 (b) (4), (b) (4) , which is utilized to produce human sterile drug products that are administered with Beyond Use Dates greater than 12 hours, is in a non-classified segregated room. For example, the following prescriptions for human sterile drug products were produced in the ISO 5 (b) (4) between 6/10/2018 - 9/10/2018:

- Vancomycin 225 mg/NS 45 mL for Rx (b) (6) on 8/09/2018. BUD = 14 days refrigerated.
- Gammagard S/D Less IgA 30 g/600 mL for Rx (b) (6) on 8/14/2018. BUD = 3 days refrigerated after reconstitution.

B. The ISO 5 (b) (4), (b) (4) , is (b) (4) in the open position during cleaning and (b) (4) certification operations, exposing both ISO 5 chambers (ante & main) to unclassified air from within the non-classified room. Additionally, technicians do not don sterile gowning garb when performing such operations inside the ISO 5 (b) (4).

This was observed on 9/11/2018 during post-cleaning of the ISO 5 (b) (4) after the production of
Gammagard S/D Less IgA 30 g/600 mL for Rx (b) (6) and on 9/13/2018 during (b) (4) certification of the ISO 5 (b) (4).

C. Your ISO 5 (b) (4) (b) (4), does not always maintain a positive pressure differential ((b) (4)" wc) between the main chamber and the ante chamber during material-transfer processes from the surrounding non-classified room into the ante chamber. On 9/11/2018 and 9/13/2018, the pressure differential between the ante chamber and the main chamber was observed to be compromised (<0.02" wc) at times during material-transfers to produce Gammagard S/D Less IgA 30 g/600 mL for Rx (b) (6) and when performing the ISO 5 (b) (4) (b) (4) certification, respectively. Additionally, the ISO 5 (b) (4) is periodically turned off when not in use, thus not always maintaining a positive pressure differential with the surrounding non-classified room, as reported by management.

OBSERVATION 2
Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

You utilize the following non-sterile cleaning products to clean the ISO 5 (b) (4) (b) (4), which is utilized to produce human sterile drug products:

- (b) (4) spray solution (germicidal)
- (b) (4) cleaning wipes (lint-free)

On 9/11/2018, after production of Gammagard S/D Less IgA 30 g/600 mL for Rx (b) (6), you
used the aforementioned non-sterile cleaning products during post-cleaning of the ISO 5 (b) (4).

These non-sterile cleaning products are also used to clean the ISO 5 (b) (4) at the beginning of each work day, as evidenced in your cleaning logs and referenced in your Policy SOP, PO-10 Hood Cleaning Policy and Log.

**OBSERVATION 3**

Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

Specifically,

The germicidal agent, (b) (4) used when cleaning the ISO 5 (b) (4) (b) (4) (b) (4), before and after aseptic processing of human sterile drug products, is not considered to be a sporicidal agent.

**DATES OF INSPECTION**

9/10/2018(Mon), 9/11/2018(Tue), 9/12/2018(Wed), 9/13/2018(Thu), 9/19/2018(Wed)