Observation # 1: Personnel were observed increasing the risk of contamination in the ISO 5 area.

Specifically,

On 05/22 - 24/2017, it was observed that the technicians’ head and upper torso entered the ISO 5 area during the processing of TPN bags thereby exposing skin to the ISO 5 environment.

Observation # 2: Materials were observed increasing the risk of contamination in the ISO 5 area.

Specifically,

On 05/22 - 24/2017, the technicians were observed using non-sterile wipes in the ISO 5 area.