DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

Observation 1) Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically,

The repeater pump used to dispense drug stocks into smaller unit vials is wheeled from the ISO-7 Ante room to the ISO-6 IV Clean Room when needed and wheeled back to the Ante room when not needed.

Observation 2) The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically,

I observed that gaps in the emergency exit double doors from the ISO-6 IV room are sealed with tape, but there were some areas where the tape had been worn or was not fully maintaining the seal, thus possibly compromising the integrity of the ISO-6 room.