Observation 1:

Your ISO 5 classified workstation where sterile product are prepared is located within a non-classified room.

Specifically,

A. Your \( (b) (4) \) "compounding aseptic \( (b) (4) \) " is not located in a controlled environment/room in order to prevent the risk of contamination. On 7/31/2017, during the production of saline water bags, the \( (b) (4) \) was observed to be equipped with \( (b) (4) \) and is therefore not completely enclosed to the environment. Additionally, \( (b) (4) \) is not used every day and it is turned off when it is not in use.

B. The ISO 5 classified area is in close proximity to the sink and no barriers exists between the sink and the "compounding aseptic \( (b) (4) \) " to prevent risk of contamination.