The cleaning, disinfecting and upkeep of the equipment used to produce and prepare sterile drug products are inadequate. Specifically,

(A) Non sterile wipes are used to clean and wipe down the surfaces of the Class II (b) (4) at the (b) (4) regardless the number of usage throughout the day.

(B) (b) (4) at unknown concentration is used to clean the Class II (b) (4) (b) (4).

(C) Apparent brownish soiled material was observed on the inside bottom edges of the Class II (b) (4)

(D) The (b) (4) certification of the Class II (b) (4) was not performed (b) (4) and the certification raw data from (b) (4) were not available for review.

Inadequate aseptic techniques demonstrated by the operators who prepare and handle sterile drug products. Specifically, during the simulation performed by the operators (b) (4) it was observed that

(A) Non sterile gloves were used in the preparation of sterile drug products inside the Class II (b) (4)

(B) The operators have never received any training nor have been qualified to prepare sterile drug products.

Inadequate facility design to prevent microbiological contamination of sterile drug products. Specifically,

(A) The Class II (b) (4) is located next to the main refrigerator and in close proximity of the (b) (4) area without any air quality control in the surrounding area.

(B) A sink is located approximately five feet away from the Class II (b) (4).
OBSERVATION # 4
Drug products purporting to be sterile are not tested to determine conformance to such requirements. Specifically,
(A) The IV flush bag containing (b) (4) does not bear an expiration date determined by appropriate stability data to assure it meets applicable standards of identity, strength quality and purity at the time of use, which could be used on patients for over a period of (b) (4) on average until the inventory has been depleted.
(B) There is no sterility testing performed on the IV flush bag containing (b) (4) to assure sterility after multiple withdrawals from the IV bag ports.
(C) Expired sterile injectables were stored in the cabinet, including but not limited to Heparin (b) (4)
Lot# (b) (4) expiry MAY 2015; Lidocaine (b) (4) Lot# (b) (4) expiry JAN 2016;
Lidocaine (b) (4) Lot# (b) (4) expiry DEC 2015 and (b) (4) Lot# (b) (4) expiry 10/15.