Observation 1

Equipment, materials, and/or supplies are not cleaned prior to initiating aseptic production after the performance of smoke studies.

Specifically, the base for the smoke used in the study is [b] (4). There is no documented cleaning after the smoke study to remove residues from [b] (4). There is no verification check to ensure the removal of [b] (4) from the ISO 5 laminar flow hood after the completion of the smoke study.

Observation 2

Personnel engaged in aseptic processing failed to prevent cross-contamination on the working surface of the ISO 5 laminar flow hood work bench.

Specifically, a Technician was observed in the aseptic production room using a sterile wipe to clean her gloved hands between compounding different products; also, she used the same wipe to clean the ISO 5 hood work bench. This practice could lead to possible product contamination.
Observation 3

Non-sterile disinfecting agents are used in the aseptic processing (ISO 5) area.

Specifically, For example, Disinfectants, (b)(4) are diluted with (b)(4) and then used in the ISO 5 processing area.