OBSERVATION 1

The ISO 5 laminar air flow hood was not certified under dynamic conditions.

Specifically, the smoke study performed in (b) (4) of the ISO 5 laminar air flow hood was not conducted with all personnel and containers present. The smoke study was conducted with (b) (4) instead of there was no bulk container present, and (b) (4) did not simulate the filling of product during the (b) (4) video to assess uni-directional air flow under actual conditions.