

Summary - Unplanned Cleanroom Power Outage Time Limit and Recovery

Appropriate steps to be taken during and after an interruption of air supply to the aseptic processing area. Qualification studies should be carried out to define a time limit after which the controlled environment reaches or exceeds action levels for particulates, temperature, humidity, and pressure differential.

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Production losses from power outages can be minimized or eliminated by supplying critical equipment with power from generators, automatic transfer switches and uninterruptible power supplies.

Handling power outages to air handling systems is needed. Setting a time limit without supporting data will risk product contamination or the unnecessary destruction of sterile product.

Determination of a time limit consists of extensive environmental monitoring after the aseptic processing area power has been interrupted and the critical air handling systems viable particulates, viable quantitative (active) air and/or viable passive air (settling plates), and pressure differentials.

The Non-viable monitors and pressure differential monitors are the most sensitive monitors.

Non-viable particulate and viable microbiological air tests used to determine a power interruption time limit are quite similar to the qualification studies used to classify the area. The monitors are placed in the controlled area while the air handling system is operational. At time zero, power to the air handling system is shut down and the air is continuously monitored for a defined length of time.

Acceptance criteria for air quality tests should be no higher than the action levels employed during routine production.

Another key parameter in defining a power interruption time limit is the flow of air through the classified area. As in air quality tests discussed above, pressure differentials are monitored after the air handling system is shut down and the time measured until the differential reaches a predetermined acceptance criterion.

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