

## Unplanned Cleanroom Power Outage Time Limit and Recovery

### **Regulatory Basis:**

FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

### **General Discussion**

How can the time between a cleanroom power outage and loss of environmental control in the critical area be determined? Once the power is restored, how can the time it takes to recover the desired environmental conditions be determined?

An interruption of power supply to the HVAC systems may produce a “loss of control” which can be defined as a breach in the integrity of the controlled areas in sterile manufacturing. Appropriate steps to be taken during and after an interruption of air supply to the aseptic processing area (APA). (These steps should be placed into site procedures before the studies recommended in this document are executed.)

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.

To assist in meeting these requirements, this guidance will provide recommendations:

- To assist in the qualification of an “in control” time period after power loss to a controlled environment.
- To assist in the qualification of a time period for full recovery of the controlled environment following power restoration.

It should be noted that this guidance is intended for Aseptic Processing Areas which are defined as those controlled environments consisting of Grade A or Grade B classifications. The recommendations of this document can be applied to other classifications (e.g., Grade C) depending upon a risk analysis by the site.

In addition, this guidance is primarily concerned with pressure drops in a controlled environment due to a power outage to the central HVAC system. A Power failure occurrence in an individual air handling unit is beyond the scope of this document.

The most effective way to deal with interruptions in power supply to air handling systems is to prevent them from happening in the first place. 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 (UPS).

However, in situations where such equipment is not installed, a contingency plan for handling power outages to air handling systems is needed. It is important to consider three questions when developing a procedure to deal with power interruptions to air handling equipment.

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conservative approach would be to assign lower acceptance criteria in order to provide a margin of safety.

### ○ **Process simulations (Media Fills)**

After the power interruption time limit has been established, it can be qualified by incorporation into process simulations. Like the other tests mentioned above, it would be appropriate to incorporate power outages into process simulations only during qualification or requalification of the cleanroom (i.e. after major changes). As is the case with routine production, processing should be completed for units exposed to the environment during the power interruption with subsequent segregation of these units from the rest of the batch. Positive units from the segregated portion of the batch do not indicate failure of the entire media fill provided that written procedures and batch documentation are adequate to describe the associated clearance during routine production. It does however, indicate a need to revisit the data generated during the power interruption time limit determination and potentially perform this work again with more stringent acceptance criteria. It may also indicate a need for retraining of personnel. It should also be noted that releasing the portion of a product batch segregated during a routine production power outage would be extremely difficult to justify until the time limit has been qualified successfully with process simulations.

### ○ **Revalidation**

A minimum of one validation study should be performed for the initial determination of a power interruption time limit. A revalidation should be conducted if significant changes are made to the HVAC system that may effect the initial validation.

### • **How long will it take to return the APA to a controlled state?**

This is another question that requires data to answer. The Recovery Test is the standard method for determining the time interval for a controlled environment to return to its specified cleanliness class after being exposed to a source of airborne particulates<sup>6</sup>. It is essential that a recovery test be performed after the power outage study unless recovery time data was generated during the initial qualification of the APA. In the recovery test, a particulate source (smoke or aerosol) is generated from the center of a predefined grid area in the room until the particle count is above the controlled environment's at-rest level.

After the particle generator is shut off, the particle concentration should be allowed to decrease to a point (e.g., 1 minute) where the counter will not be saturated with smoke or aerosol. Particle measurements are subsequently taken until the original at-rest air particulate level is reestablished. The recovery time is defined as the time interval between the particulate source shut off and when the particle levels return to the original state. In routine production, product processing should not restart until after the qualified recovery time has been exceeded and the requisite sanitization, sterilization, and HVAC/environmental monitoring steps (e.g., total particulates, temperature, humidity, & pressure differentials) have been completed<sup>1</sup>.

### • **Case Study Example.**

The following is an example for conducting a power outage study for a class 10,000 (100 at rest) APA. This is only *one example* of how to perform this type of study as various approaches can be utilized according to the needs of the