Section Name: Sterile Compounding Facility Management	**SOP Name:** Actions in the Event of Unexpected or Planned Power Loss in a Sterile Compounding Facility
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1.0 Purpose Statement

The purpose of this SOP is to provide guidance and action procedures in the event of an unexpected or planned power loss and subsequent shutdown.

2.0 Policy Statements

2.1 Prior to facility startup or before any unforeseen power loss or shutdown events, it is best practice (a CGMP requirement) to do a facility shutdown to perform a qualification study to establish baseline and excursion levels for temperature, humidity, and total particle counts. These excursion levels may be used to establish the maximum time that the air handlers can be in shutdown mode before certain cleaning, disinfection, and other procedures are initiated. This can most easily be accomplished during the commissioning process or during a planned shutdown.

2.2 During normal operations, perform a facility walkthrough noting all the equipment, devices, and control systems that will be affected by a shutdown (planned or unplanned) and rank them in order of operation criticality. In addition to the cleanroom air handler and primary engineering controls, consider automated compounding devices, autoclaves, dry heat ovens, filling lines, security cameras, alarms, etc.

2.3 If feasible, provide a backup generator for cleanroom air handlers and primary engineering controls and uninterrupted power supplies for smaller equipment (e.g., automated compounding devices, incubators, etc.).

2.4 Generators require monthly testing and regular preventative maintenance, which is memorialized in written SOPs.

2.5 For facilities that do not operate on a 24/7 basis, the installation of continuous monitoring systems in all critical areas may be considered, since unplanned shutdowns may occur when there are no personnel in the facility. Monitoring systems should include temperature, humidity, total particle counts, and differential pressures for the cleanroom, and temperature for climate-controlled equipment, such as drug storage refrigerators/freezers and incubators.

3.0 Reference Documents

3.1 Internal documents

3.1.1 F-308.a: Facility Power-Up Log

3.1.2 SOP-200: Viable Air Sampling and related forms

3.1.3 SOP-202: Surface Sampling

3.1.4 SOP-208: Airflow Considerations and Pressure Differential Monitoring and related forms

3.1.5 SOP-210: Temperature and Humidity Monitoring in Compounding and Controlled Storage Areas and related forms

3.1.6 SOP-304: Sanitization of the Controlled Sterile Compounding Environments and related forms

3.1.7 F-803.a: Corrective and Preventative Action Form

3.2 External resources

3.2.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding—Sterile Preparations. 2024.

3.2.2 United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. 2021.

3.2.3 United States Pharmacopeial Convention, Inc. <1072> Disinfectants and Antiseptics. 2013.

4.0 Equipment and Materials

4.1 Facility excursion level (limit) qualification study defining a time after which the controlled environments exceed acceptable limits for particles, temperature, humidity, and pressure differential

4.2 Battery-powered, NIST-calibrated particle counter

4.3 Battery-powered, NIST-calibrated temperature recorders

5.0 Specific Work Practices and Procedure Descriptions

5.1 Determining excursion levels by performing a facility-specific, excursion-level qualification study during a planned shutdown

5.1.1 In the absence of continuous particle monitoring equipment, perform particle sampling at predetermined locations and predetermined intervals at the beginning of the planned shutdown. The greater the number of locations and intervals monitored, the finer the ability to identify the “excursion” time.

5.1.2 Personnel placing and programming the particle counter in the controlled environment must be properly garbed and with no visible skin showing. Even properly garbed (per USP 797) personnel will be an additional source of contamination that cannot be completely controlled; so, it is recommended that hoods, masks, and goggles be worn during this testing period.

5.1.3 Monitor temperature and humidity initially and at predetermined intervals.

5.1.4 When particle counts exceed the ISO limits or facility criteria, note the amount of time it took to reach this excursion limit.

5.2 Power loss (shutdown) in the absence of qualified excursion levels

5.2.1 Note the time of the power loss.

5.2.2 Personnel inside the ISO-controlled environments must exit immediately, stopping any work in progress and leaving it in place.

5.2.3 Take completed compounded sterile preparations (CSPs)/batches and any completed and in-process compounding worksheets/batch records out of the room.

5.2.4 Outside of the room, document the time the work was halted on these worksheets/batch records.

5.2.5 Employees working in a nonhazardous sterile compounding environment exit the buffer room and anteroom and doff garb in the *non-ISO-classified* area.

5.2.6 Employees working in the hazardous drug sterile compounding environment doff outer gloves, outer shoe covers, and outer back-closing gowns before leaving the C-SEC, perform hand hygiene in the anteroom, then doff the remainder of garb in the *non-ISO-classified* area.

5.2.7 Once personnel are outside of the room(s) affected, place a "NO ADMITTANCE" sign on the entrance to the affected area.

5.2.8 Document the temperature, humidity, and particle counts (if particle counter is in place) at the time of the shutdown. Continue to monitor these values regularly (e.g., every 10 minutes or per other facility-specific parameter).

5.2.9 Systematically evaluate the equipment that is affected by this shutdown beginning with the controlled environments, working through the facility (autoclaves, refrigerators, freezers, office/warehouse HVAC, etc.).

5.2.10 Document the cause of the shutdown (if known) and whether this is a facility-wide issue, compounding area issue, or a larger geographical area issue.

5.3 Power loss in absence of qualified excursion levels and when power is restored in *less than* 1 hour

5.3.1 Follow 5.2.1 through 5.2.10.

5.3.2 Note time power was restored.

5.3.3 Verify that the HVAC is fully restored to the buffer rooms and anterooms.

5.3.4 One person must enter each buffer room after performing hand hygiene and garbing according to SOPs.

5.3.5 If primary engineering controls (PECs) were not on a backup power source, verify that every PEC has successfully turned itself back on. In some cases, it may be necessary to manually turn on the PECs. Check all gauges and verify proper function.

5.3.6 Leave the controlled environment immediately after performing these activities.

5.3.7 Depending on the size of the air handlers and number of PECs in each room, the room's particulate count should return to acceptable levels within 10 minutes but determine your own facility wait time by working with your cleanroom builder, designer, or certifier.

Remember USP 797 requires the buffer room to have at least 30 ACPH, which means the air is completely changed in the room every 2 minutes. If all personnel immediately exited the room and no further activity took place during the power outage, particulate counts should return to acceptable levels quickly.

5.3.8 Monitor room air pressure differentials, which also should return to normal within 10 minutes; but monitor their levels every 5 minutes.

5.3.9 Monitor temperature and humidity. Both temperature and humidity usually increase during power outages and are influenced heavily by the temperature and humidity of adjacent areas.

5.3.10 When temperature, humidity, and pressure differentials return to normal for the facility, properly garbed personnel may reenter the controlled compounding environments. If possible, the workers who exited the room and were working on a specific batch or CSP should be the ones returning to that area with the batch record or compounding worksheet.

5.3.11 Discard any hanging bags or vials that are accessed with transfer or other tubing (any in process items).

5.3.12 Remove all items from the PEC.

5.3.13 Perform daily cleaning activities for that PEC by cleaning with the facility's sterile EPA-registered one-step sporicidal disinfectant cleaner (achieving proper dwell time), followed by an application of sterile 70% IPA. If a C-PEC, then perform decontamination followed by cleaning with a sterile EPA-registered one-step sporicidal disinfectant cleaner, and wipe with sterile 70% IPA.

5.3.14 Perform room-related, daily cleaning activities (easily cleanable horizontal surfaces, high-touch surfaces, then floors).

5.3.15 Exit and allow all surfaces to dry.

5.3.16 Enter, garb, and resume compounding as long as temperature, humidity, and pressure differentials have returned to normal.

5.3.17 Perform dynamic air and surface sampling near the conclusion of the compounding day.

5.4 Power loss in the absence of qualified excursion data and when power is restored *in greater than* 1 hour

5.4.1 Follow 5.3.1 through 5.3.12.

5.4.2 Perform a triple clean, which is all the activities in the monthly clean performed three separate and distinct times using an EPA-registered one-step bactericidal disinfectant cleaner for the first application followed by an EPA-registered one-step sporicidal disinfectant cleaner for the last two applications. PECs are triple cleaned with sterile agents and then wiped with sterile 70% IPA.

5.4.3 Exit and allow all surfaces to dry.

5.4.4 Enter, garb, and resume compounding as long as temperature, humidity, and pressure differentials have returned to normal.

5.4.5 Perform dynamic air and surface sampling near the conclusion of the compounding day.

5.5 Power loss/shutdown during unstaffed hours

5.5.1 If a shutdown occurs during unstaffed hours, a facility-specific procedure should be established to determine steps to be taken based upon an installed and operational continuous monitoring system.

5.5.2 In absence of an operational monitoring system, a conservative approach should be taken and the assumption made that excursion levels have been exceeded.

5.5.3 It is recommended that actions be taken per section 5.4.

5.6 Emergency compounding

5.6.1 If emergency compounding must be performed, then it must be performed in a PEC that has been cleaned and disinfected (either once or three times depending upon the criteria of 5.3 or 5.4).

5.6.2 All room cleaning must stop while compounding occurs for the emergency.

5.6.3 BUDs assigned to the CSPs compounded under these conditions are limited to 12 hours.

5.7 Climate-controlled devices and equipment (refrigerators, freezers, incubators)

5.7.1 Critical drug storage areas and laboratory equipment such as refrigerators, freezers, and incubators are monitored over time during a planned or unplanned shutdown.

5.7.2 Monitoring devices should be glycol-based and maintained according to the manufacturer's specifications, NIST-tested/calibrated annually and battery powered with regular battery replacement.

5.7.3 As stated previously:

5.7.3.1 Record the time of shutdown.

5.7.3.2 Record the temperature of the device when the shutdown occurred.

5.7.3.3 Monitor the device on a regular basis (e.g., every 10 minutes), and document temperature changes over time.

5.7.3.4 Established minimum and maximum temperatures should be documented.

5.7.3.5 Establish procedures to maintain product at required temperature (e.g., move to a temporary storage location) should the established minimum/maximum temperatures be breached.

5.7.3.6 Establish measures to be taken if drug components or CSPs were kept at unacceptable temperature ranges. These procedures must be specific in terms of product rejection, acceptance, or testing based upon time and temperature conditions.

5.7.3.7 If incubators are affected and are being used to incubate media-fill tests, surface, air, or gloved fingertip and thumb samples, notify the

designated person responsible for these tests. These personnel must decide (with the help of knowledgeable microbiological experts) whether these samples must be rejected or resampled.

5.8 Other considerations

5.8.1 Accept-and-reject criteria must be established for other critical equipment as appropriate to Sample Pharmacy operation (e.g., autoclaves, dry heat oven, or filling lines).

5.8.2 If any hazardous drug operations were in process, determine if containment was affected or breached. Consider wipe testing.

5.8.3 Determine if electronic storage devices or documents were affected; and, if so, ensure backup measures work properly.

6.0 Documentation Elements

6.1 Documentation of any power outage and subsequent actions taken is required.

6.2 F-308.a: Facility Power-Up Log provides the framework and documentation of these issues.

6.3 Any cleaning; environmental sampling; and temperature, humidity, and pressure monitoring must be documented on forms established for those purposes.

6.4 The completed Facility Power-Up Log must be reviewed by the designated person (DP) to ensure that all required actions have been taken and any necessary follow-up occurs.

6.5 If the power loss was unexpected, the pharmacy may also choose to complete a F-803.a Corrective and Preventative Action Form to ensure the cause of the power outage and subsequent issues resulting from the power outage are properly vetted through the pharmacy's Quality Management System.