

SOP Title: Responding to Power Outages in Buildings [REDACTED]
SOP Number: 21525
Revision: 05

TABLE OF CONTENTS

1. **PURPOSE** 1
2. **SCOPE** 1
3. **RESPONSIBILITIES** 1
4. **DEFINITIONS** 2
5. **PROCEDURE OR USE** 2
6. **ACTIONS AND SEQUENCE OF EVENTS DURING A POWER INTERRUPTION OR POWER OUTAGE** 6
7. **REFERENCES AND RELATED DOCUMENTS** 8

1. PURPOSE

This procedure describes how the GMP environment and support areas (i.e. staging, prep, and controlled temperature storage) of Buildings [REDACTED] and [REDACTED] respond to power loss and emergency power supply during a power outage. Additionally, this SOP will describe the actions that should be taken by personnel during an outage and after full power is restored. This SOP will outline, in conjunction with **SOP 11166 Operation and Maintenance of the [REDACTED] SCADA System**, how to use available monitoring to determine the impact to concurrent and future processing due to a power outage.

2. SCOPE

This procedure applies to power outages experienced in the GMP Production and Support Areas in the [REDACTED].

This SOP applies to all personnel entering or exiting controlled environments in the [REDACTED].

The Emergency Generator and UPS [REDACTED] include four transfer switch panels and one UPS panel. There is also an additional stand-alone UPS system for the [REDACTED] GMP area.

3. RESPONSIBILITIES

- 3.1 Director / Technical Operations, Biopharmaceutical Development Program (BDP)
- Defines procedure.

SOP Title: Responding to Power Outages in Buildings [REDACTED]

SOP Number: 21525

Revision: 05

3.2 Production personnel / Manufacturing

- Protects product.
- Protects environment.
- Documents event(s).
- Addresses product-related issues.
- Prevents or mitigates any adverse quality issues caused by the activation of the emergency generator or the generation of alarms signaling an environmental excursion.

3.3 Biopharmaceutical Quality Assurance Engineering (BQAE)

- Assesses and communicates facility status.

3.4 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight.

4. DEFINITIONS

- [REDACTED]
- **BDP** - Biopharmaceutical Development Program
- **DP** - Differential Pressure

5. PROCEDURE OR USE

5.1 The Emergency Power System (EPS) is comprised of an Emergency Generator and two Uninterruptable Power Supply (UPS) for the BDP Areas. The generator has a fuel tank with a capacity to provide service for approximately 24 hours. The following loads must be powered by the EPS:

- Emergency egress lighting
- Exit Signs
- Fire Pump
- Elevators
- Stand-By Power System

5.2 The Stand-by Power System serves the following loads:

- UPS Systems
- Laboratory Exhaust and Supply Fans
- Exhaust fans for fume hoods and biosafety cabinets
- High value specimen refrigerators, freezers, and cold rooms
- Incubators

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Responding to Power Outages in Buildings [REDACTED]
SOP Number: 21525
Revision: 05

- Exhaust fans for flammable storage rooms
- Card access locking doors
- Non-Domestic Water Pumps
- Lab Waste Lift Stations
- Automatic Flush Valve / Faucets
- Select process and utility equipment

5.3 The standby generation system consists of one diesel engine generator [REDACTED].

5.4 A UPS is provided in each building for supplying power to critical systems and loads as follows:

- Card Access System
- Room Pressurization Monitors
- Scientific Alarm System
- BAS System
- SCADA System
- CCTV/Security System
- Telephone Paging System
- Data Closet Equipment
- Critical scientific equipment (Defined during construction/renovation)

5.5 A dedicated UPS (UPSS002B) for [REDACTED] GMP production areas supplies power to the HVAC (SAHU014B, SAHU015B), all BSCs, and critical processing equipment to eliminate RTS needs from power bumps or other interruptions.

5.6 Generator and UPS Functionality and SCADA Monitoring of Manufacturing Areas

5.6.1 The generator and UPS systems do not provide 100% backup to all [REDACTED] systems. The UPS system maintains power predominantly to control systems until the generator is running. Only select utilities and processing equipment are connected. The power details for each critical system are provided below.

5.6.1.1 Compressed Air is kept operational via the use of a city water bypass valve to allow cooling as chilled water is not on standby power.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Responding to Power Outages in Buildings [REDACTED]
SOP Number: 21525
Revision: 05

5.6.1.2 Compressed Gases (CO₂, N₂, O₂) are not on backup power. The vaporizers for some of the systems are powered. The effectiveness of these systems during a loss of power will be dependent upon the outdoor temperature and the demand. (The systems will perform better during a power loss with higher outdoor temperatures and lower demand.)

5.6.1.3 Door Interlocks are not powered and not active. The Sliding Door between Corridor [REDACTED] and PAL [REDACTED] is on standby power.

5.6.1.4 HVAC

- [REDACTED] (SAHU001A and SAHU002A) - [REDACTED] (non-VPF) is on standby power.
- [REDACTED] (SAHU-003A and SAHU004A) - [REDACTED] VPF Area is on standby power.
- ISO-5 Fill Room LAF Units are on standby power.
- SAHU005A – [REDACTED] Clean Corridor/Staging Areas is on standby power.
- [REDACTED] (SAHU011B and SAHU012B) - [REDACTED] Areas is on standby power.
- SAHU014B and SAHU015B – [REDACTED] GMP area is on UPS and standby power.

5.6.1.5 Process Equipment

- Bioreactors BIOR002A and BIOR003A [REDACTED] are on UPS. Bioreactors are powered although utility operation will be affected as plant steam and pure steam are not powered resulting in loss of proper agitator seal control and heating control. Refer to specific utility section. Select outlets for disposable bioreactors may also be on UPS or use external UPS systems for continuity.
- Fermentors are not powered.
- Autoclave 3001AUTO008A is on standby power to maintain containment aspects of operation.
- RPM (Room-to-Room Differential Pressure Panels) are on UPS.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Responding to Power Outages in Buildings [REDACTED]
SOP Number: 21525
Revision: 05

- +5°C Walk-In Cold Rooms are on standby power. However, [REDACTED] cold rooms, with the exception of COLD-007-A with air cooled backup, are liquid cooled and the connected chilled water source is not on generator power. For this reason, storage of critical items is not recommended for other [REDACTED] cold rooms.

5.6.1.5 Receptacles

- Receptacles marked SRA through SRP are colored red and are on generator power.
- Receptacles marked UPS through UPG, UDB, and URB are colored orange and are on UPS and generator power.
- In some cases, higher voltage (i.e. $\geq 208\text{v}$) receptacles may not follow this color scheme.

5.6.1.6 DPRO and WFI

- The DPRO and WFI (Ambient and Hot) Distribution/Circulation Pumps are on generator power. However, the pumps will not reactivate without manual intervention.

5.6.1.7 Process Chiller

- The Process Chiller is on generator power.

5.6.1.8 Domestic Water and Lab Waste

- The Domestic Water Booster Pumps, Lab Waste System Lift Station and Reclaim Water Lift Station are on generator power.

5.7 Detection and Management of Out-of-Specification Conditions

- 5.7.1 A SCADA system monitors the Manufacturing Areas for specific operational parameters. Operational data for utility systems including HVAC differential pressures is continuously evaluated and values are recorded by the historian server following system design. Excursions in data beyond the alarm setpoints are recorded and all data may be trended for review. Be aware that data drops occur at select intervals when attempting to gather latest data.

SOP Title: Responding to Power Outages in Buildings [REDACTED]
SOP Number: 21525
Revision: 05

5.7.2 The SCADA system is on UPS and generator power and will therefore record all configured parameters for the duration of the outage.

6. ACTIONS AND SEQUENCE OF EVENTS DURING A POWER INTERRUPTION OR POWER OUTAGE

6.1 In the event of a power interruption or outage, the following actions must be taken:

6.1.1 Personnel must take appropriate actions (if any are required) to protect their own safety.

6.1.2 Personnel must immediately protect the product from a potential impending out of specification environmental condition (preventing exposure of the product to the environment by covering, capping, et cetera.) until the power interruption ends and preferably until normal environmental conditions are reestablished.

6.1.3 Protect the manufacturing and support areas by restricting unnecessary access and movement of personnel into and out of the areas.

6.2 If a power outage exceeds approximately 30 seconds the generators will start. Once the generator is running the load will begin being transferred in 10 seconds. This means that not all systems will transfer to standby power at the same time. The sequential initiation of HVAC units will create temporary airflow fluctuations. These fluctuations may be perceived in the form of whistling noises or difficulty in opening or closing doors.

6.2.1 Not all HVAC units are on generator power. Therefore, the volume of airflow will be reduced approximately by half in the [REDACTED] areas with the exception of the VPF which is 100% powered. The directionality of the air is designed to remain unchanged. However, due to the fact that fans will stop during the switch to standby power and again when switching back, the potential for airflow reversals exist.

6.2.2 For this reason, continuation of open processing [REDACTED] is not recommended until power is restored and impact assessed.

6.2.3 Continuation of work in areas without HVAC or during active reversals is not permitted.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Responding to Power Outages in Buildings [REDACTED]
SOP Number: 21525
Revision: 05

- 6.3 Be aware that areas with a high density of CTUs on standby power will generate significant heat.
 - 6.3.1 For Accessioning, the doors to corridor [REDACTED] and office [REDACTED] need to be opened and fans placed at the doors in a push/pull fashion to bring in cooler air and expel warm air.
 - 6.3.2 For MMIC Freezer Farm [REDACTED], the area has auxiliary cooling but may require doors to be propped.
 - 6.3.3 Keeping ambient air cooler is better for compressor health of the CTUs.
- 6.4 Take special care during ingress or egress to make sure that you close doors behind you to reduce the risk of a cascade effect. Also take special care to only open one door at a time as the door interlock system will not be active.
- 6.5 When normal power resumes the reverse process will also create temporary airflow fluctuations.
 - 6.5.1 Generator shut off is not instantaneous and power will be systematically transferred back to normal power and the generator will power down when the programmed sequence is completed.
 - 6.5.2 A physical inspection of the main corridors or a review of SCADA after this transition period (~20-30 minutes) should find all DPs returned or returning to normal.
 - 6.5.3 The SCADA system should be monitored to verify operability of all systems.
 - 6.5.4 Failure to return to normal conditions may indicate open doors or an HVAC unit that failed to restart automatically.
 - 6.5.5 Contact BDP Engineering or FME to assess this condition.
- 6.6 Transient power interruptions usually less than 3 seconds, resulting in no operational excursion, do not require formal documentation. Normal area activities may resume without the need for corrective action.
- 6.7 Power interruptions must be documented according to **SOP 21526 Engineering Events Management**. **SOP 21553 Guidance for Return-to-Service Activities for Utility Systems and GMP Areas** is used to determine any RTS activities. Return to service actions or any changes to facility status are communicated via **SOP 21554 GMP Area Status Management**. Excursions involving product will follow **SOP 21301 Deviations**.



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Responding to Power Outages in Buildings [REDACTED]
SOP Number: 21525
Revision: 05

7. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
11166	Operation and Maintenance of the [REDACTED] SCADA System
21301	Deviations
21526	Engineering Events Management
21553	Guidance for Return-to-Service Activities for Utility Systems and GMP Areas
21554	GMP Area Status Management