Title: Responding to Power Outages in Buildings [redacted] and [redacted] of the ATRF

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1.0 Purpose

This procedure describes how the GMP environment and support areas 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 ATRF SCADA System,*** how to use available monitoring to determine the impact to concurrent and future processing as a result of a power outage.

2.0 Scope

This procedure applies to power outages experienced in the GMP Production and Support Areas in the ATRF.

This SOP applies to all personnel entering or exiting controlled environments in the ATRF.

The Emergency Generator and UPS for [redacted] and [redacted] include four transfer switch panels and one UPS panel.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

3.0 Authority and Responsibility

3.1 The Director, Technical Operations, Biopharmaceutical Development Program (BDP), has the responsibility and authority to define this procedure.

3.2 Production personnel have the authority and responsibility to:

3.2.1 Protect the product (as much as possible) in the event of a power outage.

3.2.2 Protect the environment (as much as possible) in the event of a power outage.

3.2.3 Document the event according to ***SOP 21526, Engineering Events Management and Status Placarding***.

3.2.4 Participate in any activities deemed appropriate by Biopharmaceutical Quality Assurance (BQA) or the Project Scientist to address product-related issues caused by a power interruption or outage.

3.2.5 The Project Scientist and manufacturing have the authority and responsibility to make appropriate decisions to prevent or mitigate any adverse quality issues caused by the activation of the emergency generator or the generation of alarms signaling an environmental excursion.

3.3 BQA is responsible for quality oversight of this procedure.

4.0 Procedure

4.1 The Emergency Power System (EPS) is comprised of an Emergency Generator and an 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:

4.1.1 Emergency egress lighting

4.1.2 Exit Signs

4.1.3 Fire Pump

4.1.4 Elevators

4.1.5 Stand-By Power System

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

4.2.1 UPS Systems

4.2.2 Laboratory Exhaust and Supply Fans

4.2.3 Exhaust fans for fume hoods and biosafety cabinets

4.2.4 High value specimen refrigerators, freezers, and cold rooms

4.2.5 Incubators

4.2.6 Exhaust fans for flammable storage rooms

4.2.7 Card access locking doors

4.2.8 Non-Domestic Water Pumps

4.2.9 Lab Waste Lift Stations

4.2.10 Automatic Flush Valve / Faucets

4.2.11 Select process and utility equipment

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4.3 The emergency/standby generation system consists of one diesel engine generator each for Building [redacted] and [redacted].

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

4.4.1 Card Access System

4.4.2 Room Pressurization Monitors

4.4.3 Scientific Alarm System

4.4.4 BAS System

4.4.5 SCADA System

4.4.6 CCTV/Security System

4.4.7 Telephone Paging System

4.4.8 Data Closet Equipment

4.4.9 Critical scientific equipment identified in Section 4.5.1.5**.**

4.5 Generator and UPS Functionality and SCADA Monitoring of Manufacturing Areas

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

4.5.1.1 Compressed Air is kept operational via the use of a city water bypass valve to allow cooling.

4.5.1.2 Compressed Gases (CO_2, N_2, O_2) 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.)

4.5.1.3 Door Interlocks are not powered and not active. The Sliding Door between Corridor [redacted] and [redacted] is on standby power.

4.5.1.4 HVAC

4.5.1.4.1 [redacted] - [redacted] Areas (non-VPF) is on standby power.

4.5.1.4.2 [redacted] - [redacted] VPF Area is on standby power.

4.5.1.4.3 ISO-5 Fill Room LAF Units are on standby power.

4.5.1.4.4 [redacted] – [redacted] Clean Corridor/Staging Areas is on standby power.

4.5.1.4.5 [redacted] - [redacted] and [redacted] Areas is on standby power.

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4.5.1.4.6 Process Equipment

4.5.1.4.7 Bioreactors [redacted] and [redacted] in Room [redacted] are on UPS. Bioreactors are powered although utility operation will be affected. Refer to specific utility section.

4.5.1.4.8 Fermentors are not powered.

4.5.1.4.9 Autoclave [redacted] is on standby power.

4.5.1.4.10 RPM (Room-to-Room Differential Pressure Panels) are on UPS.

4.5.1.4.11 +5°C Walk-In Cold Rooms are on standby power.

4.5.1.5 Receptacles

4.5.1.5.1 Receptacles marked SRA through SRD and colored red are on generator power.

4.5.1.5.2 Receptacles marked UPS through UPG are on UPS and generator power.

4.5.1.6 DPRO and WFI

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

4.5.1.7 Process Chiller

4.5.1.7.1 The Process Chiller is on generator power.

4.5.1.8 Domestic Water and Lab Waste

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

4.6 Detection and Management of Out-of-Specification Conditions

4.6.1 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 following system design. Excursions in data beyond the alarm setpoints are recorded and all data may be trended for review at any time.

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

5.0 Actions and Sequence of Events during a Power Interruption or Power Outage

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

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

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5.1.2 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.

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

5.2 If a power outage exceeds 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.

5.2.1 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.

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

5.2.3 Continuation of work in areas without HVAC is not permitted.

5.3 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.

5.4 When normal power resumes the reverse process will also create temporary airflow fluctuations.

5.4.1 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.

5.4.2 A physical inspection of the main corridors after this transition period (~20-30 minutes) should find all DPs returned or returning to normal.

5.4.3 The SCADA system should be monitored to verify operability of all systems.

5.4.4 Failure to return to normal conditions may indicate open doors or an HVAC unit that failed to restart automatically.

5.4.5 Contact BDP Engineering or FME to assess this condition.

5.5 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.

5.6 Power interruptions must be documented according to ***SOP 21526, Engineering Events Management and Status Placarding***. Excursions involving product will follow ***SOP 21301, Deviations from Written Documents***.

6.0 Definitions

6.1 ATRF - Advanced Technology Research Facility

6.2 BDP - Biopharmaceutical Development Program

6.3 DP - Differential Pressure

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7.0 References and Related Documents

7.1 **SOP 11166** Operation and Maintenance of the ATRF SCADA System

7.2 **SOP 21301** Deviations from Written Documents

7.3 **SOP 21526** Engineering Events Management and Status Placarding

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