

**APF Pressurization Part II****Introduction**

APF (Aseptic Processing Facilities) room differential pressurization (dP) is critical for controlling the migration of contaminants. The HVAC control system must be designed to attain dP stability during normal operation, recover fully and within the desired pressure range after an upset event (such as a generator testing), and minimize potential for pressure reversal during failure conditions. Pressure sensors must remain calibrated over the period of operation, as sensors drift over time.

**Room Pressure Control**

Space pressure differential is actively controlled through the Building Automation System (BAS). In APFs, passive cascading flow tracking (fixed offset) pressurization with limited pressure reset control is the most commonly used method. On the other hand, direct pressure measurement-based active pressurization control is not allowed in APFs.

Supply and exhaust air terminals are provided with fast-acting actuators and airflow monitors. For positive pressure rooms, the actuator on a supply air terminal controls airflow to its setpoint. The actuator on an exhaust valve then modulates to maintain a volumetric offset between the measured supply and exhaust air volumes, thereby maintaining directional airflow control. If the measured room dP is less than the lower alert pressure limit, the offset airflow setpoint value is increased by a small amount of airflow per minute. If the measured room dP is greater than upper alert pressure limit, the reverse occurs, and if the measured room dP is between the alert limits, the offset airflow setpoint shall remain fixed. The total offset airflow setpoint value shall also be restricted to the selected range. With negative pressure rooms, the reverse of this process occurs.

**Pressure Stability**

To the extent possible, dP between rooms is achieved using gaps around doors and door undercuts to control differential airflow between spaces, thereby controlling the differential pressure. Where inaccuracies in airflow measurement exceed the amount of air that can be passed around door gaps, an adjustable transfer louver may be installed between adjacent

rooms to allow greater transfer of air in order to achieve pressure stability.

**Loss of Pressurization**

The potential for loss of pressure control due to power loss, emergency generator testing, or controller failure is a concern in APFs. According to DRM section 13.9.8, fail positions (fail in last position or total shut-off) of the air terminal "shall be such that classified space pressurization is maintained to the extent possible." Upon main system failures (such as loss of an AHU or exhaust fan), DRM 13.9.9 states that a cross-limiting loop sequence shall be provided in order to "restrict the leading system from exceeding the lagging system [and]... prohibit excessive door-opening forces" or reverse pressurization. Cross-limiting loops shall not apply to biological safety cabinets (BSCs) or other safety equipment.

**Alarm/Data Capture Requirements**

Time delays are provided to minimize nuisance alarms whenever a door is opened. DRM 13.9.5 says that "The duration of the time delay should be sufficient (not less than 120 seconds) to permit the normal passage through an open door and for the system to recover." Differential pressure data is typically collected at 1-minute intervals or every Change of Value (COV), whichever is less.

**Calibration**

Calibration is required initially during start-up of the facility and then periodically (12 months or as indicated in the SOP) as sensors drift over time. Calibration must be traceable to NIST or equivalent standards. The accuracy of the dP electronic pressure transducers will be  $\pm 1.25$  Pa ( $\pm 0.005$  in. w.g.). Field calibration for critical differential pressure sensors shall be performed using a 3-point calibration procedure at minimum, and EMS and BAS sensors should be recalibrated contemporaneously.

**Conclusion**

The combination of design elements (described in Part 1) and HVAC controls help maintain desired pressurization and stability in APFs. These elements are critical for APF facilities to maintain proper functionality and meet design and operation requirements.

