



# SAFE HANDLING Q&A

## VENTILATION PRESSURES AND FACILITY ISSUES

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To appropriately monitor temperature, pressure, and humidity in the compounding area, a properly designed cleanroom should be constructed to maintain low levels of airborne particles and contaminants that can be harmful to the products and personnel. One method to mitigate particulates and bioburden is to supply filtered air from an HVAC system to create pressure differentials between areas with temperature, humidity, and ventilation control. The change in pressure establishes unidirectional airflow to supply the workspaces with a continued source of filtered air and sweep contaminants away from the product being prepared. Temperatures at or below 68°F allow compounding personnel to be comfortable while fully garbed, minimizing sweating, which can be a contamination risk. Humidity in the compounding spaces is suggested to be at or below 60%. Higher humidity allows for a proliferation of bacteria and mold growth, a buildup of condensation within the cleanroom, and an uncomfortable environment for compounding personnel. The proper air balance, temperature, and humidity must be maintained and monitored frequently to ensure product integrity and staff safety.

There are a variety of monitoring systems that can be employed to alert the user to the current functionality of the room. Monitors should be installed in the compounding suite so that the user can verify that the proper temperature, humidity, and pressure differentials are maintained among the various rooms. Ideally, a digital monitor equipped with audible and visual alarms that can immediately alert the occupants of the space to any changes in pressures, temperature, or humidity outside of the recommended parameters should be used. The monitor should also be able to continuously record readings to allow the user to trend fluctuations during dynamic and static conditions. These data should be reviewed on a regular basis to ensure proper functionality of the cleanroom suite. The monitors should be calibrated at least annually or more often per manufacturer guidance.

Given the critical balance in cleanroom air dynamics that must be maintained for sterile compounding activities,

communication and cooperation between engineering and pharmacy services is vital. The users of the compounding space should be able to view and record room temperature, humidity, and pressurization at any given time. To maintain healthcare worker safety, workers should be able to be alerted if there is an excursion of these parameters outside of acceptable ranges. Open communication between the compounding personnel and the engineering team should be established so that repairs to the HVAC system and other equipment can be addressed quickly to bring parameters back into acceptable range. Written policies and procedures should be developed jointly between the two services and include specific call cascades to inform either service to issues with room control. There should be specific language in these documents addressing method of contact, expectations of response, and coordination of repairs if needed (accounting for off hours and emergencies). If the HVAC system is equipped with alarm capability on the facility engineering control side, it is important to configure the settings so that the alarms are sending alerts appropriately. This will require collaboration with pharmacy services to ensure proper levels are established for temperature, humidity, and pressure differentials. This process should be reviewed regularly and updated with changes as necessary. Every effort should be made to have issues addressed quickly and efficiently to maintain the integrity of the compounding space.

In addition, if the negative pressure is less than the required  $-0.01$  inches of water pressure or other scenarios arise that would render the compounding space out of compliance, the proposed practice would be to terminate compounding of anti-neoplastic medications until the appropriate negative pressure range is restored. If timeliness to patient care is at stake, the institution should consider partnering with a local compounding pharmacy to compound these products in a safe and compliant manner.

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