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Lessons Learned – Pneumatic Tubing Installation for Pressure Monitoring of Critical Rooms

Introduction

In an Aseptic Processing Facility (APF), differential pressure (dP) is a critical parameter to monitor in order to maintain the facility in a qualified state. The design, installation, and maintenance of dP sensors is necessary for accurate and consistent measurement during operation. At NIH, APF projects typically have two dP systems: The Building Automation System (BAS), which monitors and indirectly controls the room dP; and the validated Environmental Monitoring System (EMS), which only monitors dP and is utilized by the User for regulatory compliance.

Background

In 2021, the Division of Design and Construction Management (DDCM) opened an investigation to inspect and evaluate problematic dP tubing that was installed in dP monitor displays and pressure pick-ups in two buildings, East Terrace Modular (T10B) and NCI TIL Modular (T-30). In several locations within both buildings, the investigation found dP tubing that was kinked and damaged; connections that were not properly secured; and several instances where incorrect tubing material and connections were used. Additionally, the investigation found that the BAS and EMS dP transmitters shared reference ports and a majority of the dP tubing, which impacted dP readings in affected areas and subsequently caused dP values to shift post-calibration.

In Building T10B, the enclosures that house both the BAS and the EMS were congested, lacking sufficient space for the dP transmitters and associated wiring and tubing. The depth of the enclosure was too shallow to contain all tubing without kinking and bending the tubes. These issues were only discovered post-installation due to inefficiently detailed design documents and lack of review and inspection both prior to and during installation.

Design and Installation Requirements

Pneumatic tubing conveys air from both a room of interest and a reference room to a sensor for the purpose of monitoring the dP in critical rooms, particularly across doorways, which often delineate the boundary between zones of different air quality (e.g., ISO-8 on one side of the door and controlled not classified (CNC) on the other, etc.). To reduce the risk of contamination of the product being produced, the design and operation of the APF must ensure that air only moves from cleaner areas to dirtier ones, never vice versa.

Since there are countless pneumatic tubing types on the market, engineers should always specify Type FR (fire retardant) polyethylene in accordance with DRM Section 7.6.7. This pneumatic tubing is relatively low cost and is rated for its resistance to kinking and a wide range of chemicals and solvents. To ensure a good seal with polyethylene tubing, project installation specifications should require the use of barb fittings for connections. Enclosures should be generously sized to reduce risks of bends and kinks in pneumatic tubing.

It is good engineering practice to have the BAS and EMS systems fully segregated and operating independently from one another (inclusive of all transmitters, probes, wiring, tubing, etc.) to minimize dP reading errors, reduce the impact between systems, and improve overall system reliability. However, unless pressure monitors have built-in pressure transmitters, pressure transmitters for both the BAS and EMS should be located remotely in a common panel where they can be easily accessed and serviced. There are multiple advantages to segregating BAS and EMS systems: ease of maintainability; the ability to calibrate one system without impacting the other; and the ability to eliminate a single point of failure, where one failed sensor or transmitter would cause data from both systems to be compromised and result in the affected facility operating at risk. There are, however, disadvantages to fully segregating the BAS and EMS: SOPs are necessary to provide constant comparison between system dP readings, and each system's sensors require concurrent calibration to ensure that the readings vary within the same tolerance.

Remediation

Post investigation, all non-conforming tubing inside the BAS and EMS enclosures for Buildings T-30 and T10B was replaced with polyethene tubing, and elbow-type fittings were installed to minimize bends and kinks.

In Building T-30, isolation valves were added to the tubing from pressure pick-up enclosures to segregate the BAS from the EMS while calibrations are being performed. This solution allows for one sensor to be operational during calibration. For future installations, full segregation between the BAS and EMS tubing and remote transmitters is necessary.

In Building T10B, the BAS and EMS enclosures were too small to accommodate additional isolation valves to facilitate calibration. The tightness of the back box housing remains an issue that could cause further problems in the future. The back box where the EMS Setra Transmitter is located is narrow; ideally, a larger (and deeper) back box should have been provided to allow adequate room for parts, tubing, and wiring.

Conclusion

For optimal dP measurement installation, designers should follow both NIH's DRM requirements and manufacturer's installation procedures and inspect all materials before and after installation. It is also good practice to provide detailed engineering design drawings with in-situ mockups of pneumatic tubing, wiring, and differential pressure device locations for BAS and EMS to NIH for review and approval prior to installation.