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Introduction to Stability in Aseptic Processing Facilities – Part 2

Introduction

Part 1 of this article series discussed the importance of achieving and maintaining stability for NIH's Aseptic Processing Facilities (APFs) and briefly introduced the acceptance criteria for stability. This article will cover the stability trend review process and how it is utilized to ensure that the critical environmental parameters (i.e., differential pressure [dP], air changes per hour, temperature, and relative humidity) meet their stability acceptance criteria.

Stability Trend Review

Precursors to Stability Trending: Complete all construction that impacts room leakage prior to stability trend review. This includes HVAC system Testing, Adjusting, and Balancing (TAB); Building Automation System (BAS) sensor calibration; and BAS loop tuning.

Stability Trending: The commissioning, qualification, and validation (CQV) team executes BAS pre-functional commissioning, a process which includes collecting 72-hour (minimum) initial and final trends, though shorter trend periods may be utilized to assess corrective actions and adjustments. Trends are typically taken based on one-minute intervals for both static (at rest) and dynamic modes. During trend collection, access to APFs is controlled and activities are logged. Trending the following is also recommended concurrent with static and dynamic trending: outdoor air conditions; control valve and air damper positions; and air handler unit (AHU) supply air temperature, relative humidity, and supply and exhaust system duct static pressure and fan speed.

Trends must show the cleanroom is operating within the acceptance limits for both static and dynamic modes. Trends shall also show the ability to recover quickly from an upset condition such as power loss, power blip/voltage sag, emergency generator test. For major disruptions such as those requiring restart of the AHUs, the proportional integral derivative (PID) loops shall be set to allow for all room critical parameters (temperature, relative humidity, differential pressure, and air changes per hour) to recover and achieve stability within 30 minutes.

Stability Trend Review: Room stability is evaluated by reviewing the collected trend graphs for each of the critical parameters. For static mode trends, the cleanroom must have all services functioning and production equipment installed and capable of being operated or operating, but without operating personnel within the facility. For dynamic mode trends, the cleanroom must be configured as in a static mode, but with normal production activities or simulated production activities during testing.

During the critical parameter trend stability review, the review team identifies and evaluates areas that do not meet stability acceptance criteria, then identifies the root cause of these failures. This evaluation generally includes, but is not limited to, door sweeps; door operations; BAS controls (such as valve hunting or drastic change in damper position, sensor/device issues, control loop tuning, infrastructure/utility support, different modes of operation, schedule of lead/lag equipment switchover, setpoint change); personnel log; and activity log. Corrective actions are then identified and executed prior to the next trend review. Any activities performed between the static and dynamic trend reviews should be documented so that the action can be reverted if it improves one trend but worsens the other. This process is repeated until all parameters have met the stability acceptance criteria defined in Part 1 of this article series. Once stability is achieved, it is expected that this stability will be maintained until the facility turned over to the Division of Facilities, Operation, and Maintenance (DFOM) for Operations and Maintenance phase activities.

It should be noted that large and complex APFs typically require more time for the balancing, tuning, and adjustments required to achieve stability than smaller, less complex facilities, specifically for room dP. The project team should consider these influences when establishing the acceptance criteria.

Conclusion

Stability trend review is an iterative process that is utilized to ensure that all critical parameters successfully meet the stability acceptance criteria. At NIH, stability is monitored throughout the life of the cleanroom facility, and any changes made to the facility during Operations and Maintenance phase are subject to an Engineering Change Management Standard Operating Procedure to minimize any unintended consequences of changes.