Rationale for Autoclave Performance Analysis & Validation

Abstract Fluctuations in SPD, due to changes in surgery schedules, impacts the use of steam autoclaves. Steam autoclaves are complex and depend on multiple support systems. Changes in use patterns have a negative impact on process quality. Even under normal use, performance varies and degrades over time. Performance analysis testing can flag underperforming machines and identify developing problems before they become failures. Such testing can also ensure compliance with current ANSI/AAMI standards[1].

Rationale Because surgery schedules vary, sterile processing departments routinely move from low activity to peak demand levels.

The majority of instrument sets and equipment processed by SPD will undergo steam sterilization. Many autoclaves have seen limited use for the last month or two, and some have been in "hibernation". This change from low (no) use to high demand will result in challenges to these autoclaves.

Autoclaves are complex machines, using multiple systems to operate; steam, water, vacuum, electrical and mechanical systems all interact to generate a sterilization cycle. These systems depend on outside utilities and support (e.g. steam and water from facilities) to function properly. These utility supplies can and do vary in quality and reliability. In addition, some components of autoclaves wear over time, and are routinely replaced (e.g. door gaskets).

As autoclaves "hibernate", or have limited use, they can cool. This results in changes in tolerances of various components, which can lead to component failure. Although consistently used autoclaves fare better, routine maintenance and testing is still required, as parts wear and settings can drift.

Routine monitoring (biological indicators, chemical indicators, air removal tests) may not be precise enough to expose poor performance though-out the chamber. Among these are pressures and vacuums, temperatures, steam saturation and steam concentration.

In a review of 1,500+ Autoclave Performance Analysis studies[2], conducted on autoclaves with no routine monitoring flags, a 7.8% failure rate (defined as not meeting AAMI standards[3]) was noted. Another 48.7% demonstrated performance variances considered to be precursors to cycle failures (exposure overtemp, wet steam, poor vacuum).

Electronic autoclave performance analysis conducted by an independent 3rd party is more precise than traditional daily testing or autoclave self-monitoring, measures multiple locations frequently throughout the entire cycle, and results in an unbiased result and certification.

This testing and certification can be used to demonstrate compliance with recent AAMI recommendations[4], and provides independent documentation that autoclaves are performing properly.

Conclusion Routine autoclave performance analysis can provide an additional measure of safety to ensure proper sterility assurance to AAMI guidelines, and should be considered as a standard part of SPD quality assurance.

[1]ANSI ST79's 2.85 and ST90's 3.19 standards for Performance Qualification (PQ) testing (AAMI/ISO TIR11139:2006, 2.32).

[2]Studies were conducted over a 3 year period of 90+ autoclaves, each autoclave being tested at least twice a year. All studies conducted by Sterile Services in the Houston, Texas area, using NIST traceable calibrated equipment.

[3]AAMI recommended parameters of 270° f for 4 continuous minutes, with steam saturation of 97-100%, and no more than 3.7% noncondensable gases present.

[4]ANSI/AAMI ST79:2017 Steam Quality and Autoclave Validation References 3.3.3.2 Steam Quality.