Summary - Sterilization/Depyrogenation Validation for Non-Product

Preventive Maintenance (PM) Measures should include, and not be limited to, the following:

For Steam

- Calibrate instruments and elements (I/Es);
- Check operation of vacuum pumps;
- Clean chamber, steam traps and drains;
- Perform leak test of the chamber;
- Replace and integrity test vent filter;
- Verify the operation of safety devices; and

Sterilizer Monitoring and Control I/Es should be calibrated before the operational qualification (OQ) study and routinely according to a defined calibration schedule

For continuous belt depyrogenation tunnels, thermocouples should be fed into the tunnel (i.e., trailing thermocouples) in containers distributed across the belt, at least in the first and last rows of each load.

Custom Prepared BIs for moist heat sterilization or dry heat sterilization should be tested prior to use for survival time and kill time under the conditions in which they will be used. *D*-values and kill time required for complete inactivation of prepared BIs should be determined experimentally. BIs having high *D*-values and/or large spore populations can result in some survivors when using the overkill sterilization cycle.

Steam Sterilization OQ/PQ Studies should be performed and include, and not be limited to, the following:

- A minimum of three (3) temperature distribution runs on an empty chamber to confirm heating uniformity and identify the slowest-to-heat zone;
- Heat penetration runs on each different load configuration to identify cold spots, the effect of loading on thermal input, and the worst case load configuration;

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