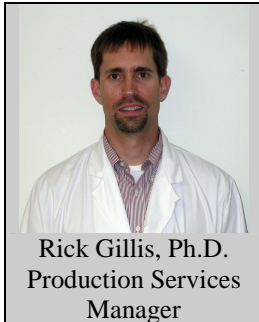


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Why Use Biological Indicators in Routine Sterilization?

The statement “we don’t use BIs routinely to monitor our sterilization cycles; we only use BIs to validate our process” is made frequently in the industry.

The general misconception is that satisfactory validation and requalification of the autoclave and loads, plus the temperature and pressure data generated and monitored during each run should preclude the need to add biological indicators (BIs) to the routine loads as well. We have experienced situations where the accumulated F_0 is in excess of 30 minutes but the biological indicators were not killed. Under saturated steam conditions one would not predict any of those BIs to survive beyond an F_0 of 18 or 19 minutes. It seems counterintuitive, but the facts speak for themselves. As a biological system, the BIs have the ability to integrate lethality and respond to physical conditions that are not measured where the BI is placed or may not be currently possible to measure at all (i.e. small amounts of residual air) during a sterilization cycle.

At the moment, there are sterilization cycles that are performed that do not require the use of biological indicators for routine monitoring. The FDA has permitted parametric release of some products sterilized by steam and ethylene oxide. Parametric release can occur when one has collected extensive physical data on a specific load configuration. This is valid for this specific load configuration only. This is not data collected from a routine validation study. This involves collecting data from many cycles, not just three (3) as is commonly done in validation, to assure that the physical data is accurate and reproducible based upon a consistent and identical load configuration. The problem here lies with the collection of physical data. This is typically temperature and pressure, but are these all of the critical process parameters that need to be measured? Agalloco et al., 1998, addresses this question in Myth #14 (Physical Data on Sterilization Cycles Is Inherently More Reliable Than the Results of Any Microbiological Testing¹). This article states "Physical measurements can easily serve to mislead as they make no allowances for the presence of air, inadequate air or condensate removal, poor thermocouple placement or any of the other possible factors that could result in such

¹ Agalloco, JP; Akers, JE; Madsen, RE; Moist Heat Sterilization – Myths and Realities, PDA Journal, Vol 52, No 6, Nov/Dec 1998, p. 346-350.

seemingly anomalous results." In ethylene oxide sterilization, moisture is a critical process parameter. Current state-of-the-art instruments can't be placed in the "worst-case" position in the product, but BIs can.

Monitoring and releasing product based solely upon physical data collected from routine sterilization cycles has an inherent risk. The physical data is collected from probes, which are mechanical/electronic devices. Once you calibrate, do you ever recalibrate temperature and pressure probes again? Obviously, recalibration is done at routine, defined intervals. Why would you recalibrate if you've already done it once? We all agree that probes can fail and are frequently found to have drifted out of tolerance, thus necessitating routine recalibration. Having acknowledged the potential for probes to drift from accuracy, why would you be comfortable relying on the physical data to release each load?

Compare the use of BIs to the "check engine" light in your car. You think the car seems to be running fine therefore I'm going to turn the light off and "assume" everything is fine. Obviously you don't do this because engines are mechanical and they can fail, no matter how well they're engineered. One should think of sterilizers and sterilization monitoring in the same manner. Just because it didn't fail yesterday doesn't mean it can't fail today.

It is not an either/or situation. A prudent sterilization program needs both physical and biological measurements. We need the best instruments and controls available to provide the confidence in the physical aspects of the process. The use of BIs provides biological confidence in the process. The bacterial spores integrate **all** critical process parameters, known or unknown. If a spore survives a process when all "critical" parametric values are within specification, the process has failed. Without the biological parameter being monitored you won't know until non-sterile "issues" occur downstream. Positive BIs in validated processes are like your "check engine" light; they are not just an annoyance; they are telling you something you'd rather not hear.

Biological indicators are very inexpensive compared to a product recall. They are your insurance policy for sterility assurance. Using the best instruments and controls in tandem with BIs gives the most comprehensive data to assure sterility.

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