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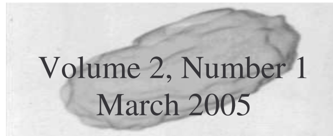
Spore News



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How Much Variation Should You Allow When You Specify a D-value?

Today we had a customer who requested a D_{121} of 2.0 minutes. The customer stated that a product with a D_{121} of 2.1 minutes would not meet his purchase specification, which stated a D-value of 2.0 minutes.

There is a lot of misunderstanding regarding D-values. Here are some facts that may help to clarify this issue.

- AAMI and ISO have or will be establishing standards for BIER vessel performance (BIER – Biological Indicator Evaluator Resistometer). These are very specialized test instruments used to perform D-value testing.
- The temperature control tolerance required is $\pm$ 0.5°C.
- Spores die at very predictable rates. The higher the temperature, the faster they will die.
- The D-value is defined as the time that it takes at a **specified set of conditions** to reduce the spore population by 90% or one log.
- The Z-value is the temperature change necessary to alter the D-value by one log.
- A common Z-value for steam processes is 10°C.

All that said, let's look at the capabilities of a BIER vessel's performance. A BIER vessel that controls $\pm$ 0.5°C from its set-point and come-up to sterilizing conditions within 10 seconds meets all current regulatory standards. What does a temperature control condition of $\pm$ 0.5°C mean to the potential D-value variance? Keep in mind that this is the most sophisticated test equipment available. If spore performance is as predictable as the D-value and Z-value mathematical equations imply, then we can use those biological values to demonstrate the different lethality rates based on equipment variances of temperature delivered to BIER vessels.

Let's use the example of:

> The D-value calculated at 121°C in a BIER vessel operating at a theoretical temperature variance of ± 0.0°C was 2.0 minutes. When the temperature was at -0.5°C (lower acceptable limit), the calculated D-value increases to 2.2 minutes using a Z-value of 10°C. Conversely, when the BIER vessel operates at the + 0.5°C (higher acceptable limit), using the same calculation with the Z-value, the D-value is decreased to 1.8 minutes. Bear in mind that the spores have not changed, only the operating conditions within the BIER vessel and these parameter variances are those required and allowed in the regulations.

Therefore, if all test conditions are met for those spores, the expected and predictable D-value variance is 2.0 ± .2 minutes. That means any D-value expressed between 1.8 minutes and 2.2 minutes is exactly the same predictor of spore performance based on a 121.0 ± 0.5°C cycle. These spores are responding only to the acceptable variances allowed for control of BIER vessel test equipment.

SGM performed a study using our BIER vessel, which has a much narrower temperature variance than allowed by the standard. We normally expect a temperature variance of 0.15°C. The product in this study had a D_{121} of 2.0 minutes as reported on the certificate. The BIER vessel was programmed with a set point of 121.0°C. A series of tests were performed with the programmed set points ± 0.5°C. D-values were calculated using the Limited Holcomb Spearman Karber method. Sample replicates were 10 units and exposure intervals were less than 75% of a D-value. At 120.5°C the empirical D-value calculated was 2.3 minutes, at 121.5°C the empirical D-value calculated was 1.9 minutes. The theoretical calculated values are 2.2 and 1.8 minutes. However, the original product D-value calculated at 121.0°C was actually 2.038 and rounded down to 2.0 minutes, thus a slight shift upward in the empirically calculated D-values could be expected.

This demonstrates that the spores remained a reliable evaluator of the mechanical test equipment conditions. In the past we were only too quick to blame the spores for disparate data. As indicated above, the spores remained consistent and predictable. The spores demonstrated that it was the calibrated instruments and the mechanical device that varied.

Therefore, one should conclude that if the standards allow a ± 0.5°C tolerance on the mechanical test equipment than it goes without saying that we have to expect a corresponding variance of approximately ± 10% of the D-values on the certificate.

When it comes right down to it what does ± 0.2 minutes really mean? That is a variance of ± 12 seconds. The application of BI's is to monitor loaded process vessels. Process vessels may take 10 to 20 minutes to come up to sterilizing conditions depending on the load. The most rigid process standard requires the empty sterilizer variance of 3°K in the sterilizing chamber; no individual location can vary by more than 1°K and at any time during exposure all locations must be within 2°K. There will be significant deviations from these parameters when a fully loaded chamber is monitored and the above conditions will vary with each different load.

A report published by FDA (Oxborrow et. al. 1990) indicated that D-values performed in the same laboratory have a normal expected variance of $\pm$ 20% from the stated certificate value. Testing performed by second party laboratory verification of the certificate value could be expected to have variances of 43%.

Don't paint yourself into a corner by establishing an unobtainable limit in your purchase specification. A D_{121} tolerance window of 0.4 minutes can only be achieved if all requirements are met by the standards. Any tighter tolerances exceed predictable results required by the current regulations. They may be achieved for any one lot of BI's, but to expect it time and time again is unrealistically restrictive.

Please email us with topics you would like to see addressed in "Spore News".