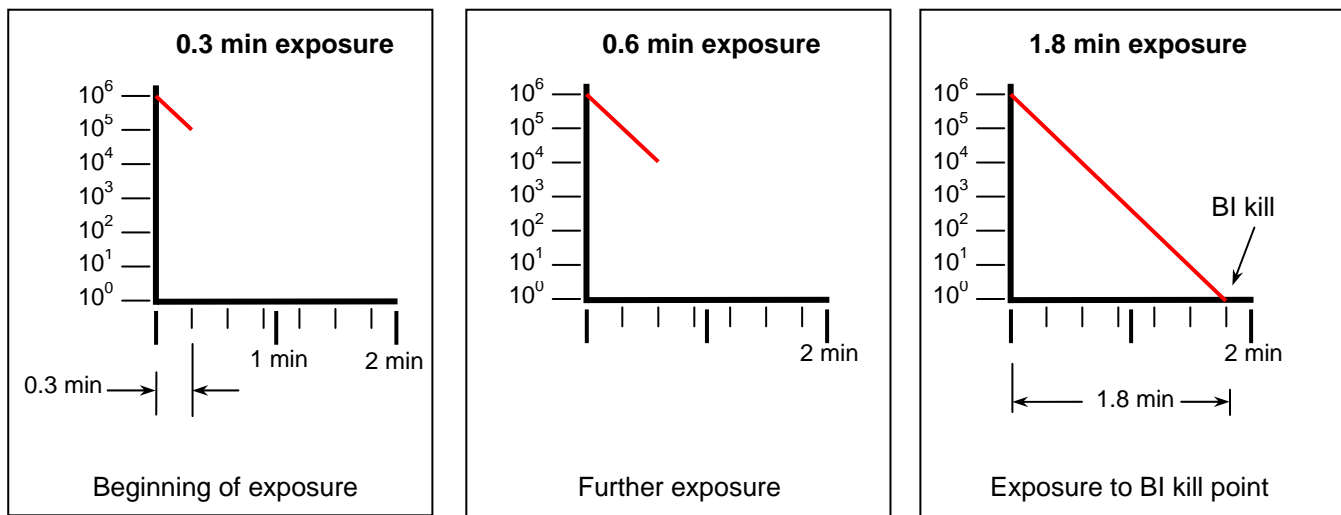


# TECHNICAL BULLETIN

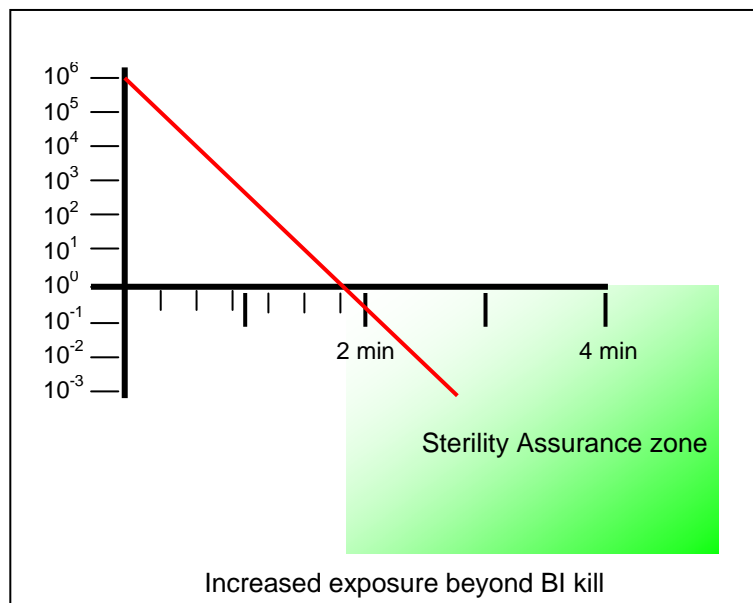
## SAL $10^{-6}$

The starting population of BIs is approximately  $10^6$  spores (one million). As BIs are exposed (to 270°F sterilizing steam in this example) the spores begin to die and the living population becomes lower and lower the longer they are exposed. The rate at which the living population decreases is given by the D value. If the D value is 0.3 minutes, then after 0.3 minutes of exposure, the living population of spores will be reduced by one log. In other words, the living population decreases from  $10^6$  to  $10^5$  in 0.3 minutes (18 seconds). If an additional 0.3 minutes of exposure follows the first, then the living population will be reduced by another log. This will continue as exposure time lengthens. Reduction of living population follows the graph below.

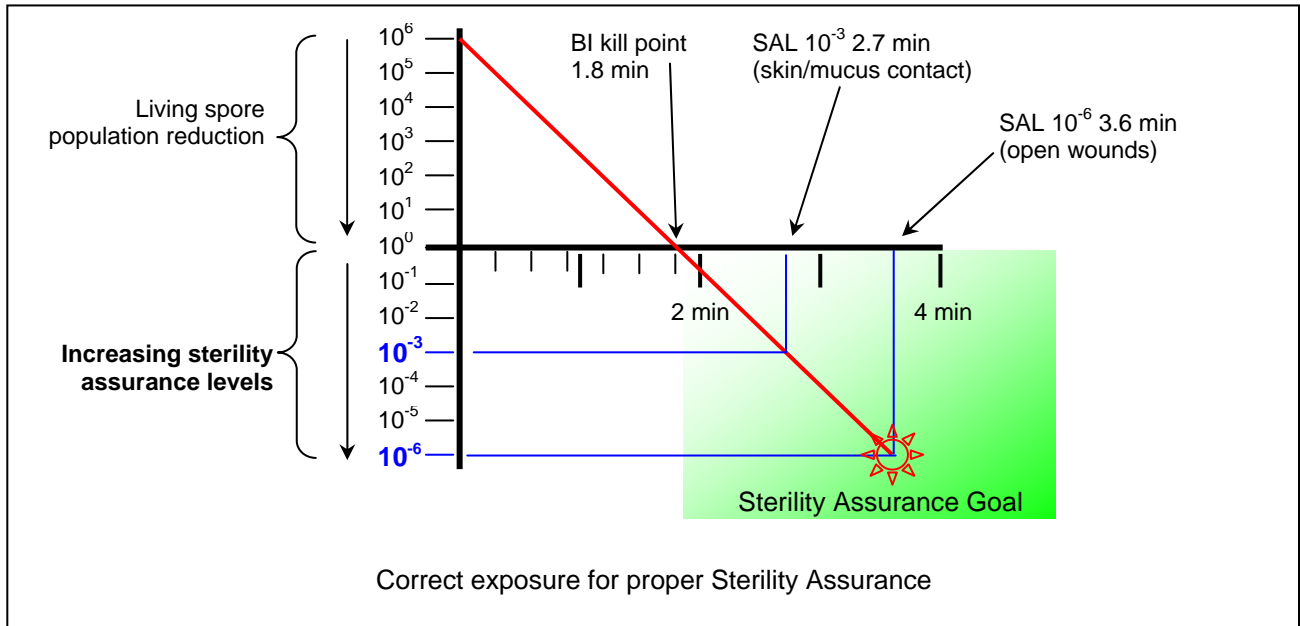


By the time 1.8 minutes has passed, all the living spores on the BIs have been killed. At this point, BIs have been sterilized and they no longer challenge the sterilizer cycle if further exposure is necessary.

The sterilization cycle can continue and should continue. Further exposure to steam is a good thing. Further exposure increases the assurance that a condition of sterility will be achieved. For each 0.3 minutes of further exposure, one additional level of sterility assurance is obtained.



# TECHNICAL BULLETIN



It has been established by FDA, AAMI, PDA, CDC and others that SAL  $10^{-6}$  is the proper level of sterility assurance for surgical instruments and anything that comes in contact with open wounds. For items that come in contact with skin or mucus membranes, SAL  $10^{-3}$  is appropriate. If BIs are no longer functioning beyond SAL  $10^0$ , how can the user verify that he/she has reached an exposure time that generates an SAL of  $10^{-6}$ ? What tools are available? One could run a half cycle in the sterilizer with at least 3 BIs. If the BIs are dead, then it can be assumed that the full cycle will generate a condition of at least twice BI kill resulting in SAL  $10^{-6}$ .

Another approach is to use chemical indicators that take longer to change color than it does to kill BIs in the sterilizer. Indicator timing of twice BI kill or more is the most helpful.

# **SteriTec**

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