Validation Guide

Ethylene Oxide Biological Validation Process Guideline For Process Challenge Devices (PCDs) (per ISO 11135 and EN 550)

EO Half-Cycle Processing

1. Three 1/2 cycles are required for validation.
2. Product biological indicators should be placed inside the load at the most difficult place to sterilize.
3. Place temperature and humidity sensors as required.
4. PCD's should be placed outside the load on the same cartons as containing the product biological indicators.
5. Process the 1/2 cycle validation run using minimum pre-conditioning time, the 1/2 cycle EO process parameters and the minimum specified Aeration time.
6. Remove all temperature and humidity sensors, biological indicators and the PCD's from the load.
7. Send the biological indicators and the PCD's to the Microbiology Laboratory for testing per the Instructions For Use as soon as possible.
8. Repeat until three successful(no growth) 1/2 cycles have been processed.

EO Survival-Cycle Processing

9. A cycle of short duration from which biological indicator survivors can be recovered should also be run to document the adequacy of the recovery technique.
10. Product biological indicators should be placed inside the load at the most difficult place to sterilize.
11. Place temperature and humidity sensors as required.

12. PCD's should be placed outside the load on the same cartons as containing the product biological indicators.
13. Process the 1/2 cycle validation run using minimum pre-conditioning time and a minimum EO exposure time.
14. **Remove all biological indicators and the PCD's from the load prior to aeration.**
15. Send the biological indicators and the PCD's to the Microbiology Laboratory for testing per the Instructions For Use as soon as possible.
16. There should be at least one product biological and one PCD survivor from the Survivor cycle. If not, repeat the cycle using a shorter EO exposure time.
17. Remove all temperature and humidity sensors from the load after aeration.