Validation Guide

Ethylene Oxide (EO) Biological Validation Process Guideline for Process Challenge Devices (PCDs)

General

This guide is based on the methodology described in ISO 11135[1] and provides information on the Overkill – half-cycle approach. For additional details on this method as well as information on the other validation approaches, please refer to that standard. The biological indicators (BI) used in the Mesa PCDs comply with ISO 11138-2[2].

EO Overkill - half cycle approach

1. Identify appropriate PCD from the options provided in the Mesa PCD Selection Guide. Additional guidance on identifying the appropriate PCD can be found in Choosing a PCD Configuration for your Cycle.

   Note: the appropriate PCD "shall present a challenge to the sterilization process that is equivalent or greater than the challenge presented by the natural bioburden at the most difficult to sterilize location within the product. (8.6.c)"[1]

2. Place BIs (with a population of ≥ 1.0×10^6) in appropriate locations inside the load.

3. Place temperature and humidity sensors as required.

4. PCDs should be placed outside the load on the same cartons as those containing the product's biological indicators.

5. Process the half-cycle validation run using minimum pre-conditioning time, the half-cycle EO process parameters and the minimum specified aeration time.

6. Remove all temperature and humidity sensors, biological indicators and the PCDs from the load.

7. Send the biological indicators and the PCDs to the Microbiology Laboratory for testing per the Instructions For Use as soon as possible.

8. Repeat until three consecutive half-cycles have been performed that result in total inactivation of the BIs. This will confirm the minimum exposure time.

9. The full cycle time shall be at least double this minimum time.

10. 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.

References

1. International Standard, ISO 11135:2014, Medical devices – Sterilization of health care products—Ethylene Oxide—Requirements for development, validation and routine control of a sterilization process for medical devices.

2. International Standard, ISO 11138-2:2017, Sterilization of health care products—Sterilization of health care products—Biological indicators for ethylene oxide sterilization processes.