



TECHNICAL TIP

OVERVIEW OF AN ETHYLENE OXIDE VALIDATION

Prior to beginning routine ethylene oxide sterilization, a product with a sterile claim needs to complete a validation process to ensure the Sterility Assurance Level claimed is met. The globally harmonized standard that provides guidance for completing such a validation is ANSI/AAMI/ISO 11135:2014, *Sterilization of health care products – Ethylene oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices*.

This TechTip will provide a step-by-step overview of an ethylene oxide validation process that complies with the guidelines established in 11135 using a Half Cycle Overkill Approach.

What is a Validation?

Broadly speaking, an ethylene oxide process validation consists of three steps: Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). The IQ and OQ portions are often performed ahead of time by the contract facility and provided in the form of a commissioning package to the Customer.

Installation Qualification

The installation qualification demonstrates that the sterilization equipment and any ancillary items have been supplied and installed in accordance with their specification.

Operational Qualification

The operational qualification demonstrates that the installed equipment is capable of delivering the specified process within defined tolerances.

Performance Qualification

The performance qualification demonstrates that the ethylene oxide sterilization equipment consistently operates in accordance with predetermined criteria and that the process produces product that is sterile. The performance qualification consists of two parts: microbiological PQ and physical PQ.

- The Microbiological PQ demonstrates that, on application of the sterilization process, the specified requirements for sterility are met.

- The Physical PQ demonstrates 1) reproducibility of the process (a minimum of three consecutive runs in which all the specified acceptance criteria are met) and 2) that the specified acceptance criteria are met throughout the load for the duration of the proposed routine process specification.

Steps to an EO Validation

1. Process Challenge Device Selection

The process challenge device (PCD) is selected, providing a microbiological challenge system used to evaluate the delivered lethality of the selected process parameters. This is done by placing a biological indicator (BI) within the product at a location where sterilizing conditions are the most difficult to achieve.

- Internal PCDs are usually medical products or devices selected by the manufacturer as one of the more difficult to sterilize products based upon product design and material composition and are used for validations.
- External PCDs are placed external to the product during routine processing to facilitate retrieval from the load after processing.

2. Reference Load Selection

A reference load selection is performed to identify the worst case load anticipated for routine sterilization. Items considered are product load density and volume, and product/packaging/load venting.

3. Protocol Generation

A protocol is generated documenting all validation activities, including:

- Objective
- Scope
- Normative references
- Definitions

FOR MORE INFORMATION

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- Responsibilities
- Equipment
- Procedures
- Acceptance criteria

4. Ancillary Laboratory Testing

Ancillary laboratory testing is performed, including:

- Bioburden testing
- BI population verification testing

5. Physical and Microbiological PQ

The Physical and Microbiological PQ are typically performed in parallel with the Half Cycle Approach, structured as follows:

- A **Winter Conditions/Preconditioning Study** may be done to simulate conditions in a trailer during colder weather months.
- **1 Fractional Cycle** is performed with a minimal EO exposure time to validate the recovery of the biological indicator (BI) and establish the relationship between the BI and the natural product bioburden. The qualification consists of:
 - Cycle performance analysis
 - Product sterility testing
 - Bacteriostasis/Fungistasis testing
 - BI sterility testing (process challenge devices)
- **3 Half Cycles** (4th half cycle needed if establishing a minimum load size) are performed to demonstrate the repeatability of a 6 spore log reduction of the BI utilizing minimum parameters, including one half of the intended routine exposure time. The qualification consists of:
 - Cycle performance analysis
 - BI sterility testing (PCDs)

- Load temperature/humidity monitoring
- EO concentration monitoring (parametric release only)

- **3 Full Cycles** are performed for determination (and confirmation) of residues and for product/packaging functionality evaluations. The qualification consists of:

- Cycle performance analysis
- BI sterility testing (PCDs)
- EO/ECH residual testing (for 1X and 2X processing)
- Load temperature/humidity monitoring
- EO concentration monitoring (parametric release only)

6. Final Report

A final report is generated to:

- Document a review of the validation data
- Confirm the acceptability against the approved protocol for the sterilization process
- Approve the process specification

7. Revalidation

Revalidation of the established ethylene oxide process is performed on an annual basis. The revalidation consists of a review of the original validation data to confirm no changes have taken place. A reduced PQ (consisting of one Half Cycle and one Full Cycle) may be performed if product or packaging changes have been made or if significant equipment or process changes have occurred. The reduced PQ is required every year for a parametric release process, but is commonly performed every other year for a BI release process.

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REFERENCES

1. ANSI/AAMI/ISO 11135:2017 – Sterilization of health care products – Ethylene oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices

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