TECHNICAL TIP

REFERENCE LOAD SELECTION FOR ETHYLENE OXIDE VALIDATION

In an ideal world, product loads presented for ethylene oxide sterilization would be homogenous, fill the usable volume of the sterilizer, and enter into the process at the same environmental conditions. During processing the load temperature rise would be predictable and the gas consumption would be repeatable. Each pallet within the load would receive the process gasses at a predictable rate and total penetration would be achieved delivering the same concentration of the process gasses to each area required to be sterile.

While the ideal conditions described above are desirable, they very seldom occur. Manufacturers of medical devices seldom produce a single device or product family that would result in totally uniform loads. Most manufacturers produce a gamut of devices ranging from very simple single material components to very complex devices containing many different materials and packaged in a variety of pouches, boxes or trays. Loads sterilized with ethylene oxide routinely contain a mixture of products which represent different densities, volumes and materials. To assure that the process is effective each and every time it is executed, careful consideration must be practiced in selecting the load mix to be utilized for process validation.

ANSI/AAMI/ISO 11135-1:2014 addresses varying load configurations in section C.9.4 as follows:

“When the load is composed of products, such as surgical kits, lumens of varying size and length, various packaging, and varying physical mass that contain a number of different materials (e.g. plastics, metals, cotton, etc.), it is important to verify the load configuration because these materials might not behave similarly when heated during preconditioning and conditioning.” In addition, when varying load is to be validated, a worst case reference load should be defined. Accordingly, evaluation of all relevant factors should be considered. These include, but are not limited to:

- Ethylene oxide absorbency;
- Tortuous pathways;
- Thermodynamic profiles.”

One of the most difficult determinations for the sterilization specialist is the impact of ethylene oxide absorbency and its potential depletion of the process gases during the exposure phase of the sterilization process. Tortuous pathways and thermodynamic profiles can be ascertained through physical examination of the device or physical measurement during the validation process. Unfortunately, there is very little guidance which addresses material absorbency rates, and instrumentation for analytical measurement of that rate is not available to the industry today.

Historically absorbency has been addressed through association with load density. It is assumed that a denser load will absorb a greater amount of ethylene oxide than a load of less dense materials. In addition a denser load will, in most cases, be more difficult to heat than a lighter or less dense load, thus defining the denser load as worst case. This is the type of decision that sterilization specialists must address when designing a process validation program.

When mixing densities within the same sterilizer load, caution must be exercised to assure that the higher density products contained in the load do not consume the available process gasses at a rate that will deprive the lower density products of the necessary time/concentration required to achieve the targeted process lethality.

Fortunately, the control systems for modern sterilizers are designed to minimize the impact of non-uniform and varying product loads. In most sterilizers, the control systems automatically add sterilant as necessary to maintain the target concentration throughout the exposure phase of the process. As gas is absorbed into the material, the headspace concentration of ethylene oxide and the pressure within the vessel is reduced proportionally. Sensing this declining pressure, additional ethylene oxide is added to replenish the absorbed gas and maintain the target process concentration and pressure, thus assuring a reliable and repeatable process.

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TECHNICAL TIP

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There are systems within the industry that do not use gas make ups during the exposure phase of the process. This may be due to concerns of flammability or compliance with regulatory commitments to local, state, or federal agencies. This type of process injects ethylene oxide during the gas injection phase of the process and make ups, if any, are performed with nitrogen or another inert gas. The headspace concentration of ethylene oxide is at its maximum at the end of gas injection and lessens as the gas is absorbed into the product load during the exposure phase.

During reference load selection for this type of process, one must be careful to select the load mix which will challenge the process at worst case. If the headspace concentration is not held constant, the rate at which ethylene oxide is absorbed into each pallet within the load must be understood and caution exercised to assure that the target concentration is achieved in all parts of the load to achieve the target lethality.

One method to assure that a worst case challenge is presented to the process is to select a reference load which represents the maximum density that will be presented for routine sterilization and also a reference load which represents a minimum density that will be presented for routine sterilization. This, in effect, will bracket all densities which may be sterilized during routine production.

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REFERENCES

1. ANSI/AAMI/ISO 10993-7:2008/(R) 2012, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

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