TECHNICAL TIP

ANATOMY OF AN ETHYLENE OXIDE STERILIZER

Introduction

Understanding the sterilization equipment which is used to deliver the ethylene oxide (EO or EtO) sterilization process is advantageous in considering sterilization options. This is especially true if the articles to be sterilized are of a new design and have never been previously subjected to the EO sterilization process. The following information, although generic in nature, is designed to provide basic information on ethylene oxide sterilizers.

The Ethylene Oxide Sterilization Process

The EO sterilization process is delivered in equipment which has been designed to consistently deliver the different processing parameters in a safe and reliable fashion. Ethylene oxide is an extremely dangerous gas when allowed to mix with air1. It is very flammable and is a suspected carcinogen in humans2. The equipment engineers must take this into consideration when designing or modifying sterilizer equipment.

The EO process utilizes humidification in the form of steam, sterilant in the form of liquid ethylene oxide, heat, and time. All equipment is designed for the specific task of delivering the sterilization process. The control equipment must control the process; the sterilizer vessel and ancillary equipment must be capable of safely delivering the different phases of the process time after time.

Due to the extreme importance of sterilization, inconsistency cannot be tolerated.

Sterilizer Systems

Ethylene Oxide sterilizers consist of a collection of different systems, which work together to deliver the EO sterilization process. Those systems are the:

- Vessel
- Controls
- Recirculation
- Vacuum
- Nitrogen injection
- Humidification
- Gassing
- Sterilant removal/abatement
- Nitrogen washing
- Air inbleed

The following is a brief description of the required systems, which are listed in the order utilized during a 100 percent EO sterilization process.

1. Sterilizer Vessel

This vessel is sometimes referred to as the chamber, rEOrt, or clave. The sterilizer vessel is constructed of steel or stainless steel. It is designed to withstand pressures ranging from an almost complete vacuum (1″ HgA – pronounced “one inch of mercury absolute”), to pressure almost twice that of atmospheric pressure (15 psig). The vessel is sized to optimize the manufacturing lot size, or in the case of contract sterilization, it is sized to optimize transportation. It is not uncommon to have a vessel which will accommodate a single pallet for a manufacturing facility or a vessel which will accommodate 13 pallets stacked 106″ high (which equates to half of a tractor trailer load). State-of-the-art vessels have doors located at each end of the vessel to facilitate conveying of the unsterilized product into one end of the vessel (unsterile door) and out of the process end (sterilized door). This protects the potential mixing of sterile and nonsterile products.

The vessel is heated to provide consistent heat in the process. The most common method of heating the vessel is by recirculating hot water, or by heated air, through a shell or jacket around the exterior walls. As identified previously, heat is

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2. Control Systems

The control systems utilized today are dedicated computerized systems which have been designed and validated to control the EO sterilization process. They are usually industrial grade computers, which contain the recipes (process parameters) of the sterilization processes performed in a particular sterilizer. In contract sterilization, the computers hold many recipes to provide the flexibility required to comply with the many different Customer requirements. The systems are password protected to assure that recipes are not inadvertently changed, which assures process repeatability and system security.

3. Recirculation Systems

A recirculation system is designed into the sterilizer vessel to assure that the sterilizing atmosphere, which is established during the course of the process, is homogenous. A header system is utilized which removes the gasses from the vessel floor level and injects them back into the vessel next to the vessel ceiling. This type of circulation is required due to ethylene oxidebeing heavier than air (very similar to carbon dioxide, or dry ice). The recirculation system is active during the entire process.

4. Vacuum Systems

Vacuum systems are selected based on the size of the sterilizer vessel and the time selected to remove air to a preset value. Most 100 percent EO processes will remove air to a pressure of 1"- 2" HgA to assure a safe working environment is established. Each system is designed with a method of rate control or the rate in which air is removed from the vessel. This type of evacuation control is utilized when the articles to be sterilized have pressure sensitive components or packaging.

5. Nitrogen Injection System

To assure a safe working environment, nitrogen is introduced into the vessel after the initial vacuum is performed. This establishes an inert gas atmosphere which contains a minimum amount of oxygen, thus preventing a flammable mixture in the vessel.

Nitrogen is stored in a bulk tank in a liquid form. Prior to injection into the vessel, it is vaporized into a gas by the nitrogen system heat exchanger. The nitrogen is then heated with the sterilization system vaporizer prior to being injected into the vessel. This is accomplished to assure that the articles to be sterilized are not cooled by the nitrogen just prior to injecting of the sterilant.

6. Humidification System

During the initial evacuation and subsequent nitrogen injection, some heat and moisture are removed from the vessel. This occurs when evacuating air from the vessel and injecting the inert gas. The nitrogen will tend to desiccate or dry the articles to be sterilized.

To replace the moisture (usually referred to as relative humidity), steam is introduced into the vessel. The steam is supplied by the facility boiler and is piped to the vessel through a system which has been designed to keep the steam hot and dry. When the control system calls for steam, a valve opens and slowly allows steam to enter into the vessel. This occurs over a predetermined period of time (humidity dwell) to replace the missing moisture in the articles to be sterilized.

7. Gassing System

Ethylene oxide is received into the facility in specially designed drums which contain approximately 55 gal (208 L) or 400 lbs (181 kg) of liquid ethylene oxide. Prior to injecting the EO into the vessel, the liquid must be vaporized into a gaseous state. This is accomplished by the sterilizer vaporizer (sometimes referred to as the volatilizer).

After the humidification dwell phase of the process is complete, the control system calls for the gassing phase to begin. A series of valves is opened, allowing the liquid EO to enter the vaporizer. The rate of gassing is controlled either via the control system rate control or a manual flow rate control needle valve.

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Controlling the rate is important to assure completevaporization of the gas prior to allowing it to enter to the vessel.

The vaporized gas is injected into the air stream which iscreated by the vessel recirculation system. This type of injection will assure a complete dispersion of the gas and prevents any local hot spots from occurring, which may be caused by the heated gas.

After the predetermined gas concentration is attained, injection stops and the control system dwells (exposure dwell) the process for the amount of time required to sterilize the articles in the vessel. During this dwell period, the control system monitors the concentration (pressure) and automatically adds ethylene oxide to maintain the optimum sterilizationenvironment.

8. Sterilant Removal and Abatement Equipment

After the exposure dwell phase of the process is complete, the vacuum system once again activates and the gasses are removed from the vessel. The gasses are routed via a series of valving to the gas scrubbers or abatement equipment, resulting in a high destruction recovery efficiency based on federal and local regulatory standards.

9. Nitrogen Washes

After sterilant removal, a series of nitrogen washes is performed utilizing the previously described nitrogen inject system and vacuum system. A nitrogen wash consists of a vacuum followed by a subsequent nitrogen repressurization. A complete vacuum and pressurization constitutes a nitrogen wash. The number of washes is predetermined to allow removal of the ethylene oxide until a level is attained in which the product may be safely removed from the vessel.

10. Air Inbleed System

At the end of the final vacuum, room air is injected into the vessel through the air inbleed system. The air inbleed system consists of a microscopic sized filter, piping, and a control valve. Clean air is introduced through the air inbleed system until atmospheric pressure is attained and the vessel doors can be opened.

Helpful Hints

Knowledge of the equipment is of great benefit in addressing any process related problem. It is imperative to understand the limitations of the equipment and how they affect the articles to be sterilized. A good example is packaging. If the article is to be packaged in a pouch and the pouch is improperly designed (no vents, for example), the evacuation process will likely destroy the pouch seals, thus rendering the article unsuitable for EO sterilization. STERIS can assist Customers in addressing a range of issues related to EO sterilization to ensure the production of a safe and effective product.

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