



TECHNICAL TIP

SELECTION OF AN ETHYLENE OXIDE STERILIZATION FACILITY

The Association for the Advancement for Medical Instrumentation (AAMI) provides several guidance documents to augment ANSI/AAMI/ISO 11135:1 report titled Validation and Routine Control of Ethylene Oxide Sterilization. One such document is AAMI TIR No. 14 – 20092 titled Contract Sterilization Using Ethylene Oxide. Within this document, much attention is given to selection of a contractor to provide the sterilization services. The following information is summarized from the section titled Selection of an Ethylene Oxide Sterilization Facility.

There are several decisions to be made when entering into the ethylene oxide sterilization arena. A key decision is whether sterilization should be performed by a contract facility or if the capabilities exist in-house. There are distinct advantages of each. In-house sterilization allows total control of product movement and prevents the additional handling and charges associated with shipping the loads to and from the sterilization facility. However, in-house sterilization is only feasible if there is sufficient volume to keep the sterilization facility operating at or near capacity. If in-house sterilization is not available or not feasible, then the use of a professional contract sterilization facility is the least expensive and most desirable option available.

One advantage of using a contract sterilizer is the savings of the capital associated with the purchase of a sterilizer and its ancillary equipment. After the initial capital outlay, maintenance of the equipment and routine operational costs continue throughout the life of the equipment. One great advantage of using a sterilization contractor is the trained and knowledgeable personnel associated with each premier contract sterilization facility. In most cases, literally hundreds of experience years can be associated with the organization of choice.

Once the decision is made to use a contract sterilization facility, the following factors should be assessed and balanced in the selection process.

Location

What is the proximity of the contract sterilization facility to the manufacturer? One of the primary costs associated with contract sterilization is associated with the movement of the product to and from the facility. Usually the facility closest to the manufacturer is the most desirable.

Size

What is the size of the sterilization vessels and how much sterilizer capacity is available? An analysis should be made to assure that products to be sterilized are produced in lot sizes which maximize the use of the sterilizer vessel. In most cases, the costs associated with sterilization are calculated on a vessel time basis. By assuring that each vessel is maximized for loading, the unit cost for each device within the sterilizer load will be less. Of utmost concern is the amount of available capacity at the contract sterilization facility. Is there available capacity to assure that the turnaround time at the sterilizer is within an acceptable time window allowed for sterilization?

Processing Capability

Does the contract sterilization facility have the capability to deliver the process with respect to the preconditioning room(s), sterilization vessels, and aeration room(s)? A review should be made to assure that all products to be processed at the facility are compatible with respect to the temperatures, moisture levels, and pressures associated with the sterilization process provided at the contract sterilization facility.

Safety

Does the contract sterilization facility have documented records of compliance with OSHA, EPA, and other applicable safety regulators? This is important to assure that the contractor can be relied upon to provide ongoing sterilization services.

FOR MORE INFORMATION

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Regulatory Compliance

The contract sterilization facility should be considered as an extension of the manufacturing facility. It must be in full compliance with all applicable regulating bodies and be up to date with all the latest Good Manufacturing Practices (GMPs)³.

To adequately determine the contract sterilization facility's acceptability, the manufacturer or a knowledgeable designee should perform an audit of the contract sterilization facility under consideration. Due to the importance of the audit, the personnel performing the audit should be knowledgeable of the sterilization process. At a minimum, the audit should cover issues such as:

- Maintenance and calibration programs
- Installation/commissioning qualifications
- Operational qualifications
- Personnel training
- Management education and/or experience
- Change control and documentation procedures
- Use of the quality systems
- Software validations

To facilitate the audit procedure, it is often helpful to have a predetermined audit document that reflects the regulatory requirements. This will enable the auditor to make an appropriately informed decision with regards to the contractor's compliance. Once the audit has been successfully completed, the auditor should provide a written report stating the acceptability of the contractor.

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REFERENCES

1. ANSI/AAMI/ISO 11135, 2007 – Sterilization of health care products – Ethylene oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices
2. AAMI Technical Information Report (TIR) No. 14 – Contract Sterilization Using Ethylene Oxide, 2009
3. 21 CFR Part 820 Medical Devices; Current Good Manufacturing Practice (CGMP) – 1996

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