

WRITTEN AGREEMENT BETWEEN PRODUCT MANUFACTURER AND CONTRACT STERILIZER

TECHNICAL TIP #15

The Association for the Advancement for Medical Instrumentation (AAMI) provides several guidance documents to augment ANSI/AAMI/ISO 11135¹, Validation and routine control of ethylene oxide sterilization. One such document is AAMI TIR No. 14 - 2009², Contract Sterilization Using Ethylene Oxide. Within this document, much attention is given to the written agreement established between a product manufacturer and a contract sterilization supplier. The following is a summary of the information presented in the TIR.

Before starting contract sterilization processing, a written agreement that outlines the services to be provided by both parties should be developed and approved. Requirements for the agreement between two parties are found in 21 Code of Federal Regulation 801.150(e)³. This section of the regulations requires a written contract when interstate shipping is involved. For intrastate services, a contract is recommended to ensure compliance with the GMP requirements for device master records (21 CFR 820.181)⁴. The regulation specifies the contents of the agreement, including a requirement for a detailed delineation of the sterilization process. It is necessary to examine the contract sterilizer's compliance with this regulation. In addition to the requirements of 21 CFR 801.150, good business practices may require other inclusions in the written agreement to clarify the division of responsibilities.

The written agreement may be in the form of a formal business contract or in the form of internal Standard Operating Procedures (SOPs) that are signed by both parties. The written agreement shall, directly or by reference to existing documents, indicate the responsibilities of each party for assuring the completion of all GMP requirements related to the sterilization process. For ethylene oxide sterilization, the written agreement should contain or reference the following:

Information Transfer

The agreement should specify the individuals at each facility responsible for coordinating the flow of information between establishments and for approving procedural changes.

Documentation

The agreement should specify all required documentation (for example: procedures, processing records) to be used and maintained. Both parties should agree on the manner in which documentation changes are to be made.

Process Validation

The written agreement should specify all parameters to be qualified by the contractor and the criteria for re-qualification.

Loading Configuration

The agreement should specify the pallet patterns, vessel loading configuration, packaging, and whether the load is pre-wrapped or shrink-wrapped for each product or product family.

Biological Indicators and Product Test Samples

The agreement should specify responsibility for placement, retrieval, handling, processing, and maximum time intervals before shipment of BIs and product test samples. It should include instructions for packaging and shipment of BIs and product test samples to test laboratories for analysis.

Cycle Parameters and Process Control

The agreement should specify the process parameters and the allowable limits that should be achieved for sterilization once the sterilization process has been validated.

Post-sterilization Handling

The agreement should specify procedures for post-sterilization quarantine of the product before release for distribution.

Batch Records and Review

The agreement should specify procedures and responsibility for approving sterilization batch records prior to release.

Finished Product Release

The agreement should specify product release procedures and identify the individuals who are responsible for approving release for distribution.

Audits

The agreement should specify the scope of audits, corrective actions, documentation or audit, and confidentiality.

Control of Changes, Process Deviations, and Product Damage

The agreement should specify the individuals to be notified of any changes or deviations in the manufacturing or sterilization process. It should also specify the individual at the manufacturer or manufacturing facility that should be contacted when product is damaged to determine how the product should be handled at the contract sterilizer.

Reprocessing of Loads

The agreement shall specify how reprocessing procedures are established, implemented, and controlled to assure that the reprocessing steps and product meet the validation and routine processing specification criteria.

Material Handling and Documentation

Adherence to Title 21, CFR, Part 801.150 is required for label control. The agreement should specify how adherence is to be controlled/conducted.

Contract Agreement Criteria

The written agreement shall specify all shipping arrangements including labeling for shipping and should identify laboratories to be used for sample testing.

The contract is a valuable tool to assure sterilization consistency and regulatory compliance, and to help prevent misunderstandings between the parties. It binds both parties to the procedures and agreements which control all aspects of the sterilization process.

References

1. ANSI/AAMI/ISO 11135, 2007 Medical devices – Validation and routine control of ethylene oxide sterilization
2. AAMI TIR No. 14 - 2009², Contract Sterilization Using Ethylene Oxide
3. 21 CFR Part 801.150(e): Medical devices, processing, labeling, or re-packing – 1996
4. 21 CFR Part 820 Medical Devices; Current Good Manufacturing Practice (CGMP) – 1996

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