Technical Information Report

AAMI TIR16:2000

Process development and performance qualification for ethylene oxide sterilization—Microbiological aspects

AAMI
Association for the Advancement of Medical Instrumentation

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Approved 13 March 2000 by
Association for the Advancement of Medical Instrumentation

Abstract: This AAMI technical information report presents the various microbiological aspects of the development of an ethylene oxide sterilization process and the validation of this process. This document does not discuss the effect of the microbiological bioburden or the effect of the environment that the product is exposed to during the manufacturing process. TIR16:2000 is a companion document to ANSI/AAMI/ISO 11135:1994.

Keywords: sterilization, microbiological aspects, validation, ethylene oxide, EO, bioburden

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Association for the Advancement of Medical Instrumentation

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This technical information report was developed and balloted by the AAMI Industrial Ethylene Oxide Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Committee approval of the TIR does not necessarily imply that all committee members and working group members voted for its approval.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

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Foreword

This technical information report (TIR) was developed by the AAMI Industrial Ethylene Oxide Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Ethylene oxide (EO) sterilization is an essential process that is used to render many products safe for use in health care facilities and applicable manufacturing processes. This TIR was written to provide guidance originally included in ANSI/AAMI ST27:1988 (AAMI 1988), which was subsequently superseded by ANSI/AAMI/ISO 11135:1994 (AAMI 1994). In addition, it covers recommended practices currently used by industry to terminally sterilize medical products with EO.

NOTE—Further guidance can be found in ANSI/AAMI/ISO 11737-1:1995 (AAMI 1995b) and ANSI/AAMI/ISO 11737-2:1998 (AAMI 1998).

Proper design of an EO sterilization process is based on sound scientific principles, as outlined in ANSI/AAMI/ISO standards. The cycle parameters must be validated (taking into consideration the complexity of the equipment, process, and product variables) to ensure that they are effective and reproducible. The elements of EO cycle development and validation, as defined in ANSI/AAMI/ISO 11135:1994 (AAMI 1994), should be carried out according to a written protocol or procedure with input obtained from engineering, quality/sterility assurance, and research and development (R&D) personnel.

NOTE—This technical information report is considered "informative," and use of the terms "shall," "should," etc. should be considered within the context of this TIR only. That is, if the decision is made to use a particular method presented in this TIR, then the method should be followed in adherence with the requirements ("shall") and recommendations ("should") as set forth in this TIR. The term "must" refers to regulatory requirements.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

Process development and performance qualification for ethylene oxide sterilization—Microbiological aspects

1 Scope

This technical information report (TIR) addresses various microbiological aspects of the development and validation of an ethylene oxide (EO) sterilization process. It does not cover the various factors that can have an effect on the bioburden of the product and on the sterilization process, nor does it specifically address parametric release. This TIR provides additional guidance to augment ANSI/AAMI/ISO 11135:1994, *Medical devices—Validation and routine control of ethylene oxide sterilization* (AAMI 1994) for medical device manufacturers, including those that use contract sterilization facilities or contract sterilization operations.

NOTE—If parametric release is being considered for the release of the product, the requirements in ANSI/AAMI/ISO 11135:1994 (AAMI 1994) for temperature parameters and monitoring should be followed. An AAMI TIR addressing parametric release is in preparation.

Although the information presented was developed for application to medical devices, the content of this guideline may also be applied to other relevant products or materials.

2 Terms and definitions

For the purposes of this TIR, the following terms, definitions, and abbreviations apply:

2.1 bioburden: Populations of viable microorganisms on a product unit.

2.2 biological indicator (BI): Inoculated carrier that is contained within its primary package and that provides a known resistance to the relevant sterilization process.

2.3 compromised tissue: Skin or mucous membrane that has been intentionally or accidentally opened, exposed, or breached.

2.4 dunnage: Material that exhibits density, temperature, humidity, and EO absorption characteristics similar to those of the actual product load.

2.5 fractional cycle: Sterilization cycle in which exposure to the sterilizing agent is abbreviated.

2.6 inoculated carrier: Carrier on which a defined number of test organisms have been deposited.

2.7 installation qualification (IQ): Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

2.8 operational qualification (OQ): Obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

2.9 performance qualification (PQ): Obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product which meets specifications.

2.10 process challenge device (PCD): Object that simulates the worst case of conditions as they are given for the sterilizing agent(s) in the items of the goods to be sterilized.

NOTE 1—The design of the process challenge device depends on the kind of goods to be sterilized and the sterilization procedure. The device should be so constituted that a biological indicator can be arranged in the place most difficult for the sterilant to reach. The biological indicator should not interfere with the function of the process challenge device.

NOTE 2—In some process challenge devices, an inoculated carrier may be used in place of a biological indicator.

