

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

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

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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Contents

	Page
Committee representation.....	5
Acknowledgement.....	8
Foreword.....	9
1 Scope.....	10
2 Terms and definitions.....	10
3 Sterilization process development.....	10
3.1 Sterilization equipment.....	11
3.2 Cycle development—Physical parameters.....	11
3.2.1 Introduction.....	11
3.2.2 EO concentration.....	11
3.2.3 Relative humidity.....	12
3.2.4 Temperature.....	12
3.2.5 EO exposure time.....	12
3.3 Cycle development—Microbiological considerations.....	12
3.3.1 Microbiological challenge systems.....	12
3.3.1.1 Types of PCDs.....	12
3.3.1.1.1 Examples of systems listed below that qualify as PCDs.....	12
3.3.1.1.2 Examples of PCDs.....	13
3.3.1.2 PCDs for product families.....	13
3.3.1.3 Placement of PCDs.....	13
3.3.1.4 Appropriateness of the PCD.....	16
3.3.2 Microbiological challenge procedures.....	17
3.3.3 Development studies using microbiological challenges.....	17
3.3.3.1 Overkill method of cycle development.....	17
3.3.3.2 Combined biological indicator/bioburden method of cycle development.....	17
3.3.3.3 Absolute bioburden method of cycle development.....	18
3.4 Cycle selection criteria.....	19
3.4.1 Cycle development considerations.....	19
3.4.1.1 SAL requirements.....	19
3.4.1.2 Products with more than one SAL.....	19
3.4.2 Methods of estimating cycle lethality.....	19
3.4.2.1 Method A—Survivor curve construction.....	19
3.4.2.2 Method B—Fraction-negative method.....	20
3.4.3 Product safety.....	20
4 Performance qualification.....	20
4.1 General considerations.....	20
4.2 Validating cycle selection criteria.....	20
4.3 Placement and handling of PCDs, test samples, and sensors.....	20
4.3.1 General.....	20
4.3.2 Cycle monitoring equipment.....	21
4.3.3 Product handling, shipping, and testing.....	21
4.4 Sterilization load.....	21
4.4.1 General considerations.....	21
4.4.2 Full and partial loads.....	21
4.4.3 Mixed loads.....	22
4.4.4 Reuse of loads.....	22
4.4.5 Failure investigation.....	22
4.5 Shipping products to be sterilized.....	24
4.6 Release of validation loads.....	24
4.7 Release of small batches or lots.....	24
4.8 Revalidation.....	25

Annexes	
A Bibliography	26
A.1 Cited References	26
A.2 Other references	27
Table	
1—Variations of BI-bioburden combinations for cycle development	18
Figures	
1—Example of overkill cycle	14
2—Examples of equivalent biological-indicator challenges for the overkill method	15
3—Example of relationship between the biological indicator and the product bioburden using the combined method	16

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Sterilization Standards Committee

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.

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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.