

Technical Information Report

AAMI TIR19:1998

Guidance for ANSI/AAMI/ISO 10993-7:1995, Biological evaluation of medical deices—Part 7: Ethylene oxide sterilization residuals



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Guidance for

ANSI/AAMI/ISO 10993-7:1995,
Biological evaluation of medical devices—Part 7:
Ethylene oxide sterilization residuals

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Abstract: This AAMI Technical Information Report (TIR) provides guidance to augment ANSI/AAMI/ISO 10993-7, *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals*. This TIR is intended to assist those individuals using ANSI/AAMI/ISO 10993-7 in understanding the steps necessary to evaluate an ethylene oxide-sterilized device according to the standard and to help those individuals choose appropriate actions where alternatives are given. This TIR also provides limited guidance for the application of other parts of the ANSI/AAMI/ISO 10993 series of standards to the biological evaluation of ethylene oxide-sterilized medical devices.

Keywords: EO, EtO, allowable limits, ethylene chlorohydrin, ECH, ethylene glycol, EG, simulated-use extraction procedure



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This technical information report was developed by the AAMI Sterilization Residuals Working Group under the auspices of the AAMI Sterilization Standards Committee.

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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.

FOREWORD

This technical information report (TIR) was developed by the Task Group on Ethylene Oxide Sterilization Residuals of the AAMI Sterilization Residuals Working Group, under the auspices of the AAMI Sterilization Standards Committee. The Task Group has the following members:

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In Memoriam

The Sterilization Standards Committee and the Sterilization Residuals Working Group would like to gratefully acknowledge the contributions of the late Barbara Whittaker, PhD, Becton Dickinson, whose input and assistance contributed to the writing of this document.

Comments on this technical information report are invited and should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598

GUIDANCE FOR ANSI/AAMI/ISO 10993-7: 1995, BIOLOGICAL EVALUATION OF MEDICAL DEVICES—PART 7: ETHYLENE OXIDE STERILIZATION RESIDUALS

Introduction

This AAMI TIR provides guidance on the application of parts of the ANSI/AAMI/ISO 10993 series of standards to the biological evaluation of medical devices that have been sterilized with ethylene oxide (EO). This TIR primarily addresses evaluation of devices according to ANSI/AAMI/ISO 10993-7:1995, *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals*, but limited guidance is also given for other parts of the ANSI/AAMI/ISO 10993 series.

ANSI/AAMI/ISO 10993-7 specifies the requirements for establishing allowable limits for EO residues and analytical methods to show that an EO-sterilized device is in compliance with the allowable limits. Maximum allowable residues for ethylene chlorohydrin (ECH) when ECH has been found to be present in medical devices sterilized with EO are also specified. No exposure limits are set for ethylene glycol (EG) because risk assessment indicates that when EO residues are controlled, it is unlikely that biologically significant residues of EG would be present. For a complete copy of this AAMI document, contact AAMI at (800) 332-2264 ext. 217 or visit www.aami.org.

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In addition to meeting the requirements of ANSI/AAMI/ISO 10993-7, an EO-sterilized device must meet the biological testing requirements of the other parts of the ANSI/AAMI/ISO 10993 series of standards. While this TIR does provide limited guidance relating to other parts of this series (particularly to ANSI/AAMI/ISO 10993-10, *Biological evaluation of medical devices—Part 10: Tests for irritation and sensitization*), it is not a complete guide for the biological evaluation of EO-sterilized devices. The requirements of the other parts of the ANSI/AAMI/ISO 10993 series should also be considered.

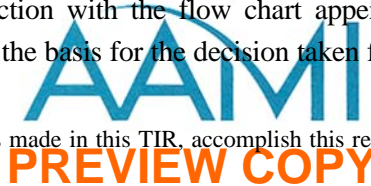
There are certain circumstances (e.g., major surgery) where the lifesaving nature of the therapy significantly alters the risk-benefit analysis of the use of an EO-sterilized medical device. The exposure limits given in ANSI/AAMI/ISO 10993-7 are based on risks and benefits associated with less critical circumstances. In consequence, there is scope for relaxation of the proposed limits in life-threatening situations where it is not possible to meet the specified limits.

The TIR includes a flow chart that is intended to assist a user in understanding the steps necessary to apply the standard. The TIR shows the decision points and provides guidance for choosing the appropriate actions where alternatives are given in the standard. Some of the guidance represents a practical means to apply the standard to different products based on factors such as: nature of exposure, duration of exposure, frequency of use, special situations of use (e.g., as cited in clause 4.3.4 of the standard), and product size. The flow chart is supplemented by more detailed text.

Clause 4.4 of the standard (ANSI/AAMI/ISO 10993-7:1995) gives the requirements for determining EO and ECH residues, and analytical procedures are described in normative annex B. Extraction conditions for the determination of residual EO are given in informative annex D. Guidance on developing an appropriate simulated-use extraction procedure is given in annex A to this TIR. This enables users to develop and document the rationale for an appropriate simulated-use extraction procedure for their EO-sterilized products.

This text should be used in conjunction with the flow chart appended as figure 1. The flow chart is annotated and the text here describes the basis for the decision taken from the standard.

NOTE—Where the statement *Reduce EO* is made in this TIR, accomplish this reduction by additional aeration of the medical device.



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