

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

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

Approved 30 January 1998

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

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-5762

© 1998 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this draft should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact Kurt C. Larrick, Director, Technical Publishing, at AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201. Phone: (703) 525-4890, Ext. 239; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1-57020-101-3

AAMI TECHNICAL INFORMATION REPORT

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, there is value in releasing the information because of the immediate need for it by the industry and the professions.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted upon—either reaffirmed, revised, or withdrawn—and the action formally approved usually every 5 years but at least every 10 years. For a TIR, AAMI consults with a technical committee about 5 years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI Technical Information Report may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

CONTENTS

	Page
Committee representation	vi
Foreword	viii
Introduction	1
Guidance	2
Annex A—Simulated-use extraction procedure	6
Figure 1—Flow chart	8