Technical Information Report

AAMI TIR67: 2018/(R)2026

Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities

AAMI
Advancing Safety in Health Technology

Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities

Approved 23 February 2018 and reaffirmed 1 March 2022 and 1 July 2026 by
AAMI

Abstract: This technical information report (TIR) provides additional guidance to sterile processing managers and others regarding compliance with occupational safety and environmental regulations.

Keywords: disinfectant, EPA, OSHA, preventing exposure, regulation, risk, safety, standard, statute, sterilant

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, releasing the information is valuable because the industry and the professions have an immediate need for it.

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, by 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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five 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 TIR 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.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203

© 2018 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. 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 Copyright Clearance Center.

Printed in the United States of America

ISBN 978-1-57020-697-9

Contents

Page

Committee representation iv

Foreword vii

Introduction 1

1 Scope 2

2 Definitions 2

3 U.S. legal and regulatory structure 9

4 Consensus and other standards 12

5 Occupational safety laws applicable to safe use of sterilant and disinfectant chemicals and other chemicals in health care 16

6 Environmental laws pertaining to chemical use in health care 33

7 Hazard and risk analysis 35

8 Promoting safe practices 39

9 Response to exposure 49

Annex A (informative) Contact information for occupational safety offices in states and territories 54

Bibliography 59

Committee representation

Association for the Advancement of Medical Instrumentation

Chemical Sterilants Hospital Practices Working Group

This technical information report was developed by the AAMI Chemical Sterilants Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the TIR does not necessarily mean that all working group members voted for its approval. At the time this TIR was published, the **AAMI Chemical Sterilants Hospital Practices Working Group** had the following members:

Chair: Janet Prust

Members:
Anas Aljabo, SteriPro Canada Inc
Nola Bayes, Sanford Health
Marcia Benedict, STERIS Corporation
Jon Burdach, PhD, Nanosonics Limited
Jennifer Burrell, St. Luke's Hospital and Health Network
Xiaolan Chen, Johnson & Johnson
Nancy Chobin, RN, CSPDM, Sterile Processing University LLC
Ramona Conner, RN, MSN, CNOR, FAAN, Association of periOperative Registered Nurses
Jacqueline Daley
Mary Ann Drosnock, Healthmark Industries Company Inc
Gordon Ely, MiMedx Group
Gloria Frost, Cardinal Health
Zory Glaser, PhD, Johns Hopkins University School of Public Health
Rachel Hill, Becton Dickinson & Company
Nupur Jain, Intuitive Surgical Inc
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management
Doug Kruger
Jean-Luc Lemyre, TSO_3 Inc
Stacey MacArthur
Jo Ann Maltais, Maltais Consulting
Jason Marosi
Elaine Mayhall, PhD, FDA/CDRH
Candace McManus, PhD
Astrid Merrifield, Boston Scientific Corporation
Rusty Mills, GE Healthcare
Frank Myers, UC San Diego Healthcare System
Richard Ormsbee, Cantel Inc
Alpa Patel, Nelson Laboratories LLC
Janet Prust, 3M Healthcare
Cheron Rojo, Valley Children's Hospital
Mandy Ryan, Stryker Instruments Division
Mike Schoene, Bausch & Lomb Inc
Rose Seavey, Seavey Healthcare Consulting, LLC
Frank Sizemore, Wake Forest University Baptist Medical Center
Joan Spear, B Braun of America Inc
Karen Swanson, Connecticut Children's Medical Center
Radhakrishna Tirumalai, US Pharmacopeia Convention Inc
Dawn Tomac, Association for Professionals in Infection Control and Epidemiology
Donald Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc
Richard Warburton, ChemDAQ Inc
Jill Warren, WuXi AppTec Inc
Roberto Zumbado, Philips

Alternates:
Dave Dion, Cardinal Health
Christopher Dugard, FDA/CDRH
Susan Flynn, 3M Healthcare

Elyse Gaudreau, TSO_3 Inc
Brent Geiger, Cantel Inc
Sharon Hadley, STERIS IMS
David Hilliker, ChemDAQ Inc
Nancy Kaiser, STERIS Corporation
Kaumudi Kulkarni, Healthmark Industries Company Inc
Elan Lopezcuba, Becton Dickinson & Company
Patrick McCormick, Bausch & Lomb Inc
Kathleen McMullen, Association for Professionals in Infection Control and Epidemiology
Emily Mitzel, Nelson Laboratories LLC
Navid Omidbakhsh, Johnson & Johnson
Leslie Tavares, WuXi AppTec Inc
Brian Wallace, Intuitive Surgical Inc
Jon Wood, International Association of Healthcare Central Service Materiel Management
Bryan Worwa, Boston Scientific Corporation

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.

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

Cochairs:
Michael Scholla, PhD
Patrick Weixel

Members:
Anas Aljabo, SteriPro Canada Inc.
Brett Anderson, Cochlear Ltd
Hank Balch, University Health System
Richard Bancroft, Steris Corporation
Marie Brewer
Trabue Bryans, BryKor LLC
Jon Burdach, Nanosonics Limited
Tim Carlson, Becton Dickinson & Company
Phil Cogdill, Medtronic Inc Campus
Sean Colwell, WuXi AppTec Inc
Ramona Conner, Association of Perioperative Registered Nurses
Lena Cordie, Qualitas Professional Services LLC
Jackie Daley
Gordon Ely, MiMedx Group
Lisa Foster, Adiuvo QS & SA Consulting
Joel Gorski, NAMSA
Joyce Hansen, Johnson & Johnson
Stephanie Homuth, Homuth, Stephanie
Clark Houghtling, Cosmed Group Inc
Sue Klacik, International Association of Healthcare Central Service Materiel Management
Byron Lambert, Abbott Laboratories
Michelle Luebke, Baxter Healthcare Corporation
Patrick McCormick, Bausch & Lomb Inc
Gerry O'Dell, Gerry O'Dell Consulting
Adrian Ponce, Verrix LLC
Janet Prust, 3M Healthcare
Nancy Rakiewicz, IUVO BioScience
Michael Scholla, PhD, DuPont Tyvek Medical and Pharmaceutical Protection
Linda Schultz, Northside Hospital Surgical Services Atlanta
Joan Spear, B Braun of America Inc
Patrick Weixel, FDA/CDRH
Sid Wiggs
Martell Winters, Nelson Laboratories LLC
Stephen Yeadon, Boston Scientific Corporation
Bill Young, Sterigenics International
Roberto Zumbado, Philips

Alternates: Stacy Bohl, Boston Scientific Corporation
Greg Crego, IUVO BioScience
Niki Fidopiastis, Sterigenics International
Dan Floyd, DuPont Tyvek Medical and Pharmaceutical Protection
Gerry McDonnell, Johnson & Johnson
Kim Patton, Becton Dickinson & Company
Christine Render, Cosmed Group Inc
Mike Sadowski, Baxter Healthcare Corporation
Craig Wallace, 3M Healthcare
Lisa Ward, Steris Corporation
Jon Wood, International Association of Healthcare Central Service Materiel Management

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.

© 2018 Association for the Advancement of Medical Instrumentation ■ AAMI TIR67:2018

Foreword

This technical information report (TIR) was developed by the AAMI Chemical Sterilants Hospital Practices Working group under the auspices of the AAMI Sterilization Standards Committee. The objective of this TIR is to provide comprehensive background information on the U.S. federal regulations and industrial hygiene recommendations related to occupational exposure to chemical sterilants used in the health care setting for reprocessing medical devices.

Federal occupational safety laws are broadly written for all industries. This TIR focuses specifically on chemical sterilants used in the health care setting and the aspects of the regulations that apply. This document is not intended to interpret federal law and health care facilities should use this information only as background education to become familiar with the requirements. Health care facilities should not make legal decisions based the information in this TIR but refer to facility employee health and legal counsel. The content and recommendations in this TIR will be reviewed and updated periodically as requirements for occupational safety related to the use of chemical sterilants change.

The objective of this TIR is to assist health care management and personnel who use sterilant and disinfectant chemicals to improve occupational safety by providing relevant regulatory and general advice about safe use of these chemicals.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Road, Suite 300, Arlington VA 22203.

NOTE—This foreword does not contain provisions of AAMI TIR67, *Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities*, but it does provide important information about the development and intended use of the document.

Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities

NOTE—This technical information report (TIR) is not a standard, and the material contained herein is informative in nature. In some instances, the committee has used the terms "shall" and "must" based on its knowledge of requirements contained in relevant standards, regulatory requirements, or both.

Introduction

Sterilant and disinfectant chemicals are usually broad-based biocidal chemicals that effectively destroy a broad range of pathogens including bacteria, fungi, protozoa, and viruses; some chemical sterilants also destroy the more resistant sporicidal forms of bacteria. These chemicals play an essential role in modern health care, and their use has a direct and vital impact on patient care. They are essential to the sterilization or disinfection of heat-sensitive devices such as flexible endoscopes. At the same time, these chemicals can pose various levels of risk for health care personnel that handle them.

Often, sterilant and high-level disinfectant (HLD) chemicals are used within equipment such as sterilizers, automatic endoscope reprocessors, and similar equipment that has been designed by the manufacturers to be as safe as possible for the operators. Proper use of such equipment by well-trained operators who have a good knowledge of safe use of the sterilant and disinfectant chemicals and how to mitigate those risks is an important aspect for the safe use of these chemicals.

However, the injury rate in health care is higher than in almost all other industries. In 2009, the Healthcare and Social Assistance (HCSA) Sector Council of the National Occupational Research Agenda (NORA) (in partnership with the Centers for Disease Control and Prevention [CDC]) examined the health care sector for the causes of the high accident rate, and the following conclusion was drawn:

> "The HCSA sector is burdened by the historical and entrenched belief that patient care issues supersede the personal safety and health of workers and that it is acceptable for HCSA workers to have less than optimal protections against the risks of hazardous exposures or injuries." [NORA, 2009]

As far as chemical safety was concerned, the NORA report went on to say:

> "HCSA workers are also at increased risk for many of the types of adverse health effects potentially caused by hazardous chemical exposures, including cancer, adverse reproductive outcomes, and work-related asthma and dermatitis. Although a wide range of hazards exists, a key barrier to addressing them is the misconception that HCSA work is safer than other work involving exposure to chemical and physical hazards. Improved health and hazard surveillance could help to address this issue, as would epidemiological studies to better evaluate relationships between hazardous exposures in the HCSA sector and development of work-related health outcomes such as cancer, adverse reproductive outcomes, asthma, and skin disorders."

The purpose of this TIR is to assist health care facilities that use sterilant and disinfectant chemicals in improving their occupational safety by providing relevant regulatory and general advice about the safe use of these chemicals.

In the United States, there is an extensive network of overlapping regulations that control the use of chemical sterilants and disinfectants and that are intended to protect workers from exposure in the workplace and in the environment. Although these various regulations are available on the websites of the respective local and federal government agencies, they can be difficult to find, especially if the reader is unaware of which regulations apply.

Another problem for readers is that chemical safety regulations are often written to apply across all or at least many very diverse industries and so are broadly written and often contain considerable matter that is not relevant to chemical sterilization in a health care facility. Thus, the same Occupational Safety and Health Administration (OSHA) regulations apply to the use of hydrogen peroxide in a hospital sterile processing department as to a titanium foundry pickling titanium ingots in an acidified hydrogen peroxide bath to remove mill scale. Therefore, this TIR is written to clarify the

© 2018 Association for the Advancement of Medical Instrumentation ■ AAMI TIR67:2018