AAMI TIR67: 2018
Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals in health care facilities
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years.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, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

Published by

AAMI
4301 N. Fairfax Dr., Ste. 301
Arlington, VA 22203-1633

© 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 AAMI at 4301 N. Fairfax Dr., Ste. 301, Arlington, VA 22203-1633. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

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 Drosnoke, 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, TSO3 Inc
- Stacey MacArthur
- Jo Ann Maltas, Maltas 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

PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
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, NanoSonic Limited
- Tim Carlson, Becton Dickinson & Company
- Phil Cogdill, Medtronic Inc Campus
- Sean Coswell, 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 Houghtaling, Cosmed Group Inc
- Sue Klack, 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
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 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 on 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, 4301 N. Fairfax Dr., Suite 301, Arlington VA 22203-1633.

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.
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
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