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# Technical Information Report



## AAMI TIR67: 2018

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

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

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Approved 23 February 2018 by

**Association for the Advancement of Medical Instrumentation**

**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.

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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## 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<sub>3</sub> 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<sub>3</sub> 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

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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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*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, Aduvo QS & SA Consulting  
Joel Gorski, NAMS  
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

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## 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, 4301 N. Fairfax Dr., Suite 301, Arlington VA 22203-1633.

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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.

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The AAMI logo consists of the letters 'AAMI' in a bold, blue, sans-serif font. The letter 'A' is the largest and is positioned on the left. The letters 'A', 'M', and 'I' are smaller and positioned to the right of the first 'A'. A small green and blue graphic element is located to the right of the 'I'.  
Advancing Safety in Health Technology

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# 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