Technical Information Report

AAMI TIR67: 2018

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

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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

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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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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:

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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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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.

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

