Technical Information Report

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Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces

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Advancing Safety in Health Technology

Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces

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Abstract: Provides guidance on the selection and use of low and intermediate-level disinfectants and disinfection processes for safe and effective use.

Keywords: low-level disinfection, intermediate-level disinfection, environmental surfaces

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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.

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

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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:

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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 was developed by the AAMI Hospital Chemical Sterilants Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this technical information report is to provide guidance on the selection and use of low and intermediate-level disinfectants and disinfection processes for safe and effective use by all healthcare personnel who perform low and intermediate-level disinfection processes on patient care medical devices, medical equipment, and their accessories, and who have responsibility for cleaning and disinfecting environmental surfaces in medical device processing areas.

As used within the context of this document, “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the technical information report; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

This technical information report should be considered flexible and dynamic. As technology advances and as new data are brought forward, the technical information report will be reviewed and, if necessary, revised.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards Dept, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of the AAMI TIR68, *Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces* (AAMI TIR68:2018), but it does provide important information about the development and intended use of the document.

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Low and intermediate-level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces

Introduction

Appropriate, efficacious cleaning and disinfection of noncritical medical devices and equipment surfaces and of critical and semi-critical medical devices prior to high-level disinfection or sterilization by means of intermediate-level disinfection or low-level disinfection are important aspects of infection prevention and control for both patients and healthcare user safety. Cleaning and the various levels of disinfection are intended to help prevent transmission of infectious organisms that can cause disease. Transmissions can include person-to-person transmission (e.g., methicillin resistant *Staphylococcus aureus* (MRSA)*)* and also transmission of environmental pathogens (e.g., *Pseudomonas aeruginosa*). Unfortunately, outbreaks in healthcare facilities are not an uncommon occurrence and numerous published outbreaks have been traced to contaminated medical devices, equipment and even the disinfectants used. The increase in emerging and re-emerging pathogens and drug resistant pathogens presents a higher risk to patients and as a result there is a heightened need for thorough understanding of appropriate disinfection procedures and protocols to help prevent transmission of these microorganisms.

Use of chemical disinfectants was one of the first processes implemented to reduce patient infection risk, beginning in the mid-19th century. Even though disinfectants have been used for a very long period of time and much is known regarding the use and limitations, it is the multitude of available types of products from manufacturers that makes proper use more challenging today than in the past. The same chemical disinfectant from two different manufacturers can have different formulations and use instructions. Some general use disinfectants such as alcohol and chlorine are also used as household antiseptics or disinfectants but with different concentrations and use applications and might not all have hospital appropriate claims or proper registrations. Hospital grade disinfectants require specific knowledge of the appropriate products, claims and use procedures for healthcare applications.

Current AAMI standards appropriately address critical and some semi-critical patient care items that are terminally sterilized or high level disinfected with the information available in ANSI/AAMI ST79, ANSI/AAMI ST41, ANSI/AAMI ST58 and ANSI/AAMI ST91. Existing information and guidelines for processing of non-critical devices from other organizations outside of AAMI are typically very broad and not focused on sterile processing area applications. This document is written to provide relevant information for safely cleaning and appropriately disinfecting medical devices and environmental surfaces. It is intended to provide an easy-to-use format for primary use by healthcare personnel responsible for processing medical devices, as well as by personnel responsible for cleaning and disinfecting the processing area. Historically, disinfection of many of these types of items was not completed by sterile processing staff. However, with the increased awareness of healthcare associated infections (HAIs) and documented outbreaks tied to improper cleaning and disinfection procedures, the role of sterile processing personnel and the need for their recognized expertise has expanded beyond sterilization related procedures and often includes responsibility for medical device disinfection practices throughout the health care facility.

Items requiring low or intermediate-level disinfection may include non-critical patient-contacting medical devices, non-critical patient care equipment, and environmental surfaces. Guidance for cleaning and disinfection of environmental surfaces outside of the sterile processing area, provided in documents from CDC, APIC, ASHE and other professional organizations, is not discussed here. However, information on the appropriate processes for environmental cleaning and disinfection of the sterile processing area is provided in this document and is included to address the specific requirements necessitated by the nature of the work performed (e.g. cleaning and decontamination of used and potentially infectious medical devices) in the area which can require additional considerations compared to other areas within the environment of care in the healthcare facility.

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