Technical Information Report

AAMI TIR68: 2018

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

AAMI
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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AAMI

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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

AAMI Technical Information Report

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Contents

Page

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www.aami.org/standards/glossary.pdf

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

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.

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.

Low and intermediate-level chemical disinfectants are biocidal solutions applied to inanimate objects such as medical devices used for patient care (e.g., tonometers, stethoscopes) and environmental surfaces. There are several different categories of chemical disinfectants with various performance characteristics and considerations for use as described in this document. Chemical disinfectants are available in a range of formats including liquids, impregnated wipes, sprays, concentrated powders and gases or vapors. Considerations in choosing the correct disinfectant for the task includes: degree of microbicidal activity required, the characteristics of the item to be disinfected, the device manufacturer's IFU, the disinfectant manufacturer's IFU, and the cost and ease of use of the available products.

Chemical disinfectants are classified as biocides and are intended to destroy and inhibit growth of microorganisms and can be ineffective or harmful to the user if not handled according to regulations and the manufacturer's IFU. Efficacy of chemical disinfectants, also referred to as germicides, can be impacted by multiple factors related to the process. Factors such as presence of organic soil on the item, design of the device, disinfectant dilution, contact time and temperature, mode of action, and microbial load in reusable solutions can all have a significant impact on efficacy. User knowledge of the proper use of a disinfectant is critical for rendering the item safe for use in patient care. All chemical disinfectants must be properly disposed of after use (Block).

Cleaning and disinfection terms are often used in conjunction with each other to describe the process of rendering a medical device or environmental surface safe for use and handling. In some cases, the same chemical solution can be used to complete both cleaning and disinfection (e.g. environmental surfaces) but for other applications, e.g. medical devices, it is typically two separate steps (or three, if the surface requires rinsing prior to subsequent processing). The appropriate process is dependent on the specific product being used and the surface being disinfected. It is often required for a surface or item to be free of visible organic matter, dirt or dust prior to use of a chemical disinfectant to achieve efficacy.

Low-level and intermediate-level disinfectants are regulated in the U.S. by the United States Food and Drug Administration (FDA). However, they are under dual regulation also by the Environmental Protection Agency (EPA) as antimicrobial pesticides. Regulation sets requirements for both manufacturers and users for intermediate and low-level chemical disinfectants. The product manufacturer's IFU must be followed to safely and effectively use these categories of products. When chemical disinfectants are used for liquid chemical sterilization or high level disinfection or sterilization of reusable medical devices, the sterilant or disinfectant chemistry and any related systems are regulated solely by the FDA.

1 Scope

This Technical Information Report (TIR) is intended for reference and 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. This TIR provides guidance on the selection and use of low and intermediate-level disinfectants and disinfection processes for safe and effective use.

1.1 Inclusions

This TIR includes:

a) cleaning and disinfection of non-critical patient care items, devices and patient care equipment and accessories, cleaning and disinfection of electronic accessories for devices, and other non-critical devices (e.g., MR coils, MR/CT tables, X-ray detector plates, NICU incubators, cables, smaller console equipment, IV pumps and poles);

b) processes for categories of items that are terminally processed with low or intermediate disinfection;

c) chemical disinfection of items that are made safe to handle through low or intermediate disinfection to proceed to further processing, e.g. critical medical devices that will be terminally sterilized or semi-critical items that will be high-level disinfected;

d) recommendations for cleaning and disinfection of environmental surfaces in the sterile processing area; and

e) guidance on use of disinfectants and disinfection processes intended for items that:

   1) undergo final processing prior to reuse

   2) items that undergo processing to be made safe to handle prior to further processing (high-level disinfection or sterilization)

   3) environmental surfaces in medical device processing areas.