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Water for the processing of medical devices

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Advancing Safety in Health Technology

Water for the processing of medical devices

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Abstract: This standard covers the selection and maintenance of effective water quality suitable for processing medical devices. It provides guidelines for selecting the water quality necessary for the processing of categories of medical devices and addresses water treatment equipment, water distribution and storage, quality control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations.

Keywords: carbon filters, deionization, disinfection, distillation, medical devices, pasteurization, processing, reverse osmosis, rinsing, sediment filters, steam purity, sterilization, ultrafiltration, water filtration, water quality, washing, water softening, water quality, water treatment

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Committee representation

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This standard was developed by the AAMI Water Quality for Medical Device Processing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval.

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Foreword

This standard was developed by the AAMI Water Quality for Medical Device Processing Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to set the quality requirements for the different categories of water used in processing of medical devices and provides guidance as to when and where to use water of each category. In addition, this standard provides information on how to verify that the water continues to meet those minimum requirements. This standard also provides valuable information for the performance qualification of a water treatment/delivery system and a monitoring program to ensure water quality remains within the stated specifications.

This is the first edition of this American National Standard, which revises and replaces AAMI TIR34 [1]. The goal of this standard is to specify the minimum requirements for the water quality and steam purity necessary to effectively process medical devices intended for use on a patient.

The professionals responsible for the processing of medical devices prior to use are experiencing increasing challenges including: the increasing complexity of modern medical devices with hidden, difficult to access areas (e.g., lumens and complex mechanisms) where clinical soil can become lodged; and the emerging and reemerging incidence of "superbugs" that must be removed or inactivated for patient safety but are able to survive processing in situations where soil removal is incomplete. Any limitation on or diminishment of cleaning efficacy can lead to patient morbidity or mortality and decreased device use life. Water of the appropriate quality for the processing of medical devices prior to clinical use is an important part of the solution to these problems.

A common factor in the processing of medical devices is the use of water. While medical devices cleared by the U.S. Food and Drug Administration's (FDA) for sale into the health care market have been provided with validated processing instructions and procedures, these procedures may not be completely effective if water of specified quality is not used. Similarly, cleaning agents work better, and devices are rinsed more thoroughly if the water is of the specified quality. Each health care facility may require a specific approach to treating water for processing needs based on a variety of factors.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
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- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

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

NOTE This foreword does not contain provisions of the ANSI/AAMI ST108, *Water for the processing of medical devices* (ANSI/AAMI ST108:2023), but it does provide important information about the development and intended use of the document.

Introduction

Water quality is an important consideration in all stages of medical device processing, as is the purity or chemical content of the steam that is generated for moist heat sterilization. The health care facility should have a multidisciplinary team in place that develops a strategy to confirm all aspects of water quality that impact the processing of medical devices within this standard. Appropriate water quality and steam purity in device processing requires collaboration between the personnel who process medical devices and the personnel who establish and maintain the water treatment system.

Water treatment and delivery systems can be configured in many ways to achieve the required water quality specifications. Water can be treated by a variety of methods that yield different levels of water quality. Gram-negative bacteria and nontuberculous mycobacteria can grow in water regardless of treatment process. The rate of growth and the microbial levels attained are a function of several factors related to the water (e.g., variety and concentration of organic contaminants, pH, temperature). Water systems that are closely monitored for quality reduce variability of processing conditions and effectiveness of cleaning and disinfection processes as well as reduce the potential of microbial proliferation. The importance of monitoring water quality to prevent problems with microbial proliferation cannot be overemphasized.

This standard defines multiple levels of water quality and steam purity suitable for medical device processing, and it describes the water treatment processes that can be utilized in order to produce water of the quality to meet each of these categories.

Water for the processing of medical devices

1 Scope

1.1 General

This standard establishes minimum requirements for the water quality used at different stages in the processing of medical devices (e.g., reusable devices and single-use devices provided non-sterile requiring processing prior to use such as non-sterile implants and processed single-use devices) to make them ready for use on the next patient. These requirements are established to assist medical device processing professionals in the selection of the appropriate water quality needed for cleaning, rinsing, disinfection, and sterilization of medical devices.

1.2 Inclusions

This standard covers the quality of the water delivered to the point-of-use and used in medical device processing (cleaning, rinsing, disinfection and sterilization). It defines water types based on the qualities possessed and where it will be used. Included in this document are:

a) Responsibility for the water management program;

b) Importance of water quality;

c) Adverse effects of water impurities on medical device processing;

d) Categories and requirements of water quality for medical device processing;

e) Selection of water of the appropriate quality;

f) Purity requirements of water used to generate steam;

g) Effective water treatment and qualification;

h) Considerations for ongoing maintenance, monitoring and quality improvement of the water treatment system;

i) Troubleshooting water quality issues.

This standard also provides definitions of terms and a bibliography.

1.3 Exclusions

This standard does not cover:

a) Water requirements for hemodialysis applications;

b) Water requirements for laboratory use;

c) Steam quality requirements (i.e., physical qualities of steam such as: moisture content, noncondensable gas content and Superheat). See ANSI/AAMI ST79 [8];

d) Water treatment performed within the medical device processing equipment (e.g., washers, washer/disinfectors, or automated endoscope reprocessors (AERs);