American National Standard

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Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices

AAMI
Advancing Safety in Health Technology

Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices

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Abstract: This standard covers the requirements to validate cleaning processes that are developed by the medical device manufacturer for processing medical devices.

Keywords: cleaning, validation

AAMI Standard

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Contents

Page

Tables

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NOTE Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

This standard was developed by the AAMI Cleaning of Reusable Medical Devices Working Group under the auspices of the AAMI Sterilization Standards Committee.

To comply with the U.S. Food and Drug Administration's (FDA) requirements, manufacturers of medical devices must provide validated cleaning instructions for medical devices that are required to be processed prior to each clinical use. More importantly, cleaning validations can help ensure that their medical devices can be effectively cleaned prior to disinfection and/or sterilization (as applicable) in facilities that process medical devices. In addition, single-use device reprocessors, which are regulated as manufacturers, must validate the cleaning of clinically used devices processed at their facilities prior to supplying them to health care facilities.

The objective of this standard is to provide the medical device manufacturer the requirements to validate the cleaning process for their medical device. In addition, this standard also provides valuable information for the development of cleaning protocols, test soil selection, and determination of acceptance criteria.

This document evolved from AAMI TIR30 into a standard. A fundamental problem that exists with the creation of any document of this type is its relevancy and utility after it has been published. The development of a new class of medical device, cleaning agent, or the emergence of an extremely hardy pathogen, could cause enough of a change to invalidate cleaning processes that previously had been used with acceptable results. To address this problem, an attempt has been made to systematically define and categorize the underlying problems and challenges that cleaning processes, test soils, and test methods must overcome to yield a validated cleaning process.

At least two underlying challenges prompted the creation of this document. The first is a significant increase in the complexity of the medical devices being manufactured today. Generally, the complexity of validated cleaning procedures will be proportional to the complexity of the medical devices for which they are designed. Second, new pathogens (e.g., antibiotic-resistant forms of existing microorganisms) continue to emerge. While there has been an increase in the complexity of medical devices and an introduction of new pathogens, there has also been an increase in the scientific advancement of processing medical devices. This document provides requirements for performing validations with consideration of the increased complexity of medical devices, emergence of new pathogens, and the scientific advancement in the processing of medical devices.

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;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Suggestions for improving this document 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 ANSI/AAMI ST98, *Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices,* but it does provide important information about the development and intended use of the document.

Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices

1 Scope

This document specifies the requirements to validate cleaning processes that are developed by the medical device manufacturer for processing medical devices.

1.1 Inclusions

This document applies to all medical devices that require cleaning prior to each clinical use of that device. Clinical uses may be in health care facilities, home uses, or use by first responders, etc.

1.2 Exclusions

This document does not apply to:

— single-use medical devices that are supplied ready for patient use;

— textile devices used in patient draping systems or surgical clothing; or

— devices that might have been exposed to prions, such as those that cause Transmissible Spongiform Encephalopathies (TSE).

2 Normative references

The following document is referred to in the text in such a way that some or all of its content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11139:2018, *Sterilization of health care products—Vocabulary of terms used in sterilization and related equipment and process standards*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
analyte
chemical substance that is the subject of chemical analysis

[SOURCE: ISO 11139, 3.12]