Technical Information Report

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Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

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Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

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Abstract: This technical information report (TIR) provides guidance to medical device manufacturers, who are required to provide instructions that detail the processing steps from pre-treatment at the point of use through the terminal process and storage to accompany reusable and single-use medical devices that are processed by a health care facility prior to clinical use.

Keywords: cleaning, decontamination, disinfection, instructions for use, medical device design, sterilization

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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Instructions for Reusable Device Reprocessing Working Group

This recommended practice was developed by the AAMI Instructions for Reusable Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the recommended practice does not necessarily mean that all working group members voted for its approval.

At the time this recommended practice was published, the **AAMI Instructions for Reusable Medical Device 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

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;
- “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 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.

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Introduction

Scientific advances in diagnostic and therapeutic medicine have led to the development of new and sophisticated medical devices for use by health care personnel. These devices vary in size, complexity, fragility, and immersibility, as well as sensitivity to cleaning, disinfecting, and sterilizing agents and the processes that are used. Manufacturers of medical devices intended to be processed by facilities have the responsibility to support product label claims by providing complete and comprehensive written instructions for the handling, cleaning, disinfection, testing, packaging, sterilization, as applicable, of their products. Manufacturers also have the responsibility to conduct and document any testing necessary to validate the suitability of these instructions. Manufacturers have these obligations under U.S. Food and Drug Administration (FDA) labeling regulations (21 CFR 801 [67]). Detailed FDA recommendations are provided in the FDA guidance document, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff (FDA, Issued March 17, 2015; Updated June 9, 2017)*. Similarly, ANSI/AAMI/ISO 17664, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices* also applies to manufacturers of medical devices that are intended to be processed by a health care facility to be made ready for use on the next patient.

This Technical Information Report (TIR) is intended to assist medical device manufacturers in designing, testing, and labeling devices intended to be processed by a health care facility and to provide information that complies with the requirements presented in FDA, ISO, and relevant AAMI documents. In addition, greater detail will be provided about the processes and resources that a health care facility can have for processing devices. This should provide further assistance to medical device manufacturers (MDMs) in developing their processing instructions.

Health care personnel have the responsibility to obtain and review manufacturers' data and recommendations and to ensure that they have the necessary resources to follow manufacturers' instructions thoroughly. This TIR can serve as a resource for identifying the questions health care personnel should ask manufacturers when considering a product for purchase or when devising a processing protocol for a product already being used. See also ANSI/AAMI ST40, ANSI/AAMI ST41, ANSI/AAMI ST58, ANSI/AAMI ST79, AAMI TIR55, and ANSI/AAMI ST91.

NOTE This technical information report is not a standard, and the material contained herein is not normative in nature. The committee has used the term "shall" in a few instances, based on their knowledge of requirements contained in relevant standards and regulatory requirements.

Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

1 Scope

This document provides guidance to medical device manufacturers, who are required to provide instructions that detail the processing steps from pre-treatment at the point of use through the terminal process and storage to accompany reusable and single-use medical devices that are processed by a health care facility prior to clinical use.

Textile devices used in patient draping systems or surgical clothing that are covered in ANSI/AAMI PB70 [5], and medical devices specified by the manufacturer as single-use and not to be processed by the health care facility are not included in the scope of this document.

2 Normative references

The following documents are provided for information.

ANSI/AAMI/ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

AAMI TIR55, *Human factors engineering for processing medical devices*

AAMI/ANSI/ISO 11607[31], *Packaging for terminally sterilized medical devices*

ANSI/AAMI/ISO 13485, *Medical devices - Quality management systems - Requirements for regulatory purposes*

ANSI/AAMI/ISO 15223-1:2016, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*

AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*

AAMI TIR30[2], *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*

AAMI ST98[3], *Cleaning validation of health care products — Requirements for development and validation of a cleaning process for medical devices*

ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities*

ANSI/AAMI ST77, *Containment devices for reusable medical device sterilization*

ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

[1] Entire series.
[2] Document is intended to be superseded by AAMI ST98, which is currently under preparation.
[3] Under preparation.