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Processing of health care products—Quality management systems for processing in health care facilities

AAMI
Advancing Safety in Health Technology

Processing of health care products—Quality management systems for processing in health care facilities

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Abstract: This document specifies minimum requirements for quality management systems (QMSs) to effectively, efficiently, and consistently process (transport, clean, decontaminate, disinfect, inspect, package, sterilize, and store) medical devices to prevent adverse patient events and non-manufacturer-related device failures.

Keywords: sterilization, medical device processing, quality systems, documentation, monitoring, measurement, communication, resources

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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

Committee representation

Association for the Advancement of Medical Instrumentation

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This standard was developed by the AAMI Quality Systems for 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 Quality Systems for Device Processing Working Group of the AAMI Sterilization Standards Committee. The purpose of this document is to provide guidelines for procedures and records designed and planned to support quality management systems (QMSs) for processing of medical devices in hospitals and other health care facilities. These guidelines are intended to promote quality processes and methods and to assist health care personnel in their proper application to achieve acceptable and reproducible results.

This standard reflects the conscientious efforts of health care professionals, in cooperation with medical device and equipment manufacturers, to develop recommendations for quality systems for the processing of medical devices. It is not intended that these recommendations be construed as universally applicable in all circumstances. Also, it is recognized that in many cases these recommendations might not be immediately achievable. Therefore, the document should be used to guide personnel towards desirable performance objectives, and all of its provisions should be considered and applied in the light of professional judgment and experience.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the standard. “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 standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The provisions of this standard should be reviewed routinely by departmental managers and quality management representatives and adapted to the needs of their particular institutions. Written policies, procedures, and work instructions should be developed and implemented in consultation with appropriate hospital committees (e.g., safety, infection prevention and control, and hazardous materials).

The concepts incorporated in this standard should be considered flexible and dynamic. The recommendations set forth in this document are reviewed and updated periodically to assimilate progressive technological developments. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every five years.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of the American National Standard, *Processing of health care products—Quality management systems for processing in health care facilities* (ANSI/AAMI ST90), but it does provide important information about the development and intended use of the document.

Processing of health care products—Quality management systems for processing in health care facilities

Introduction

General

This standard specifies requirements for a quality management system that can be used by an organization that processes medical devices.

It can also be used by internal and external parties to assess the organization's ability to meet customer and regulatory requirements.

It is emphasized that the quality management system requirements specified in this standard are complementary to technical requirements specified in other ANSI/AAMI standards and technical information reports.

The adoption of a quality management system should be a strategic decision of an organization/department. The design and implementation of an organization's quality management is influenced by varying needs, particular objectives, the products provided, the processes employed, and the size and structure of the organization. It is not the intention of this standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

Process approach

This standard is based on a process approach to quality management.

Any activity that receives inputs and converts them to outputs can be considered a process.

For an organization/department to function effectively, it has to identify and manage numerous linked processes.

Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes and their management, can be referred to as the "process approach."

Relationship with other standards

Although this is a stand-alone standard, it is based on ANSI/AAMI/ISO 13485:2016.

Compatibility with other management systems

This standard follows the format of ANSI/AAMI/ISO 13485:2016.

This standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management.

However, this standard enables an organization/department to align or integrate its own quality management system with related management system requirements. It is possible for an organization/department to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this standard.