American National Standard

ANSI/AAMI ST90:2017

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

AAMI
Advancing Safety in Healthcare Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

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

Approved 11 June 2017 by
Association for the Advancement of Medical Instrumentation

Approved 18 July 2017 by
American National Standards Institute Inc.

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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www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Quality Systems for Device Processing Working Group

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

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

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

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.

1 Scope

This document is intended for sterile processing personnel and specifies minimum requirements for a quality management system (QMS) in a health care organization to effectively, efficiently, and consistently process medical devices to prevent adverse patient events and non-manufacturer-related device failures.

1.1 Inclusions

This standard addresses the major elements of a quality management system as it applies to the processing of health care products performed in a sterile processing area or similar location with the same responsibility. The major elements of a quality management system are as follows:

a) General objectives and documentation requirements

b) Management responsibility

c) Resource management

d) Product realization

e) Measurement, analysis, and improvement

1.2 Exclusions

This standard does not cover

a) the implementation of any specific AAMI standard, recommended practice, or guideline supporting a particular process;

b) the development or implementation of any specific system instruction, work instruction, or policy supporting a particular process and/or piece of equipment;

c) the development or implementation of any specific education, training, or competency test supporting a particular process and/or piece of equipment;

d) the development or implementation of any specific audit process or tool supporting a particular process and/or piece of equipment; or

e) the reprocessing of single-use devices by a health care facility.

2 Normative references

The following documents contain provisions that, through reference in the text, constitute provisions of this standard. At the time of publication, the editions indicated were valid.

Association for the Advancement of Medical Instrumentation. *Medical devices—Quality management systems—Requirements for regulatory purposes.* ANSI/AAMI/ISO 13485:2016. Arlington (VA): AAMI, 2016. American National Standard.

Association for the Advancement of Medical Instrumentation. *Medical devices—Application of risk management to medical devices.* ANSI/AAMI/ISO 14971:2007/(R)2016. Arlington (VA): AAMI, 2007. American National Standard.

Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.* ANSI/AAMI ST41:2008/(R)2012. Arlington (VA): AAMI, 2008. American National Standard.

Association for the Advancement of Medical Instrumentation. *Chemical sterilization and high-level disinfection in health care facilities.* ANSI/AAMI ST58:2013. Arlington (VA): AAMI, 2013. American National Standard.

Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterility and sterility assurance in health care facilities.* ANSI/AAMI ST79:2017. Arlington (VA): AAMI, 2017. American National Standard.

3 Definitions and abbreviations

3.1 calibration: Set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

[SOURCE: AAMI/ISO TIR11139:2006, 2.4]

3.2 correction: Action to eliminate a detected nonconformity.

NOTE—A correction can be made in conjunction with a corrective action.

[SOURCE: AAMI/ISO TIR11139:2006, 2.9]

3.3 corrective action: Action to eliminate the cause of a detected nonconformity or other undesirable situation.

NOTE 1—There can be more than one cause for a nonconformity.

NOTE 2—Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

NOTE 3—There is a distinction between correction and corrective action.

[SOURCE: ANSI/AAMI/ISO 17665-1:2006/(R)2013, 3.9]

3.4 critical business function: Activity or process that ensures the ability of the organization to protect assets, meet organizational needs, and satisfy regulations.

3.5 customer: Recipient of a product or process result.

3.6 document: Set of defined guidelines and steps for performing a process.

3.7 documented: recorded as evidence that a requirement, procedure, activity, or special arrangement has been established, implemented and maintained.

3.8 equipment: Any tool or device used in a process.

3.9 high-risk case: Situation that creates unknown quality requirements and variable outcomes that might require specific risk management protocols or deviations from standard procedures.

3.10 input: Any source of information or material that influences a process or organization.

3.11 installation qualification (IQ): Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

[SOURCE: AAMI/ISO TIR11139:2006, 2.22]

3.12 instructions for use (IFU): Written recommendations provided by the manufacturer of a device that provide instructions for operation and safe and effective processing.

3.13 maintain: To review and update a document or process, on an ongoing basis, to reflect current processes and practices.

3.14 master product: Medical device or procedure set used to represent the most difficult-to-sterilize item in a product family or processing category.

[SOURCE: AAMI/ISO TIR17665-3:2014/(R)2016, 3.1]

3.15 monitoring: Indication of measured values in comparison with specified values for a process.

[SOURCE ANSI/AAMI ST15883-1:2006/A1:2014]

3.16 operational qualification (OQ): Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

[SOURCE: AAMI/ISO TIR11139:2006, 2.27]

3.17 organization: Business, company, or facility that is involved in manufacturing, distributing, transporting, processing, or using a medical device (e.g., a health care facility, manufacturer, or distributor).

[SOURCE: AAMI TIR63, 2.4]

3.18 output: Any result to an organization from a process or action.

3.19 performance qualification (PQ): Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

[SOURCE: AAMI/ISO TIR11139:2006, 2.30]

3.20 preventive action: Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.

NOTE 1—There can be more than one cause for a potential nonconformity.

NOTE 2—Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

[SOURCE: AAMI/ISO TIR11139:2006, 2.32]

3.21 processing category: Collection of different products or product families that can be processed together.

[SOURCE: AAMI/ISO TIR17665-3:2014/(R)2016, 3.2]

3.22 product: Result of a process.

NOTE—For the purposes of sterilization standards, product is tangible and can be raw material(s), intermediate(s), sub-assembly(ies) or health care product(s).

[SOURCE: AAMI/ISO TIR11139:2006, 2.36]

3.23 product family: Group or subgroup of product characterized by similar attributes determined to be equivalent for processing purposes.

3.24 product quality assurance testing (PQA): Quality assurance testing of routinely processed items, representing a product family, intended to verify that the process being used by a particular facility on a particular product family is working as specified.

3.25 qualification: Process to demonstrate the ability to fulfill specified requirements.

3.26 quality management system (QMS): Collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is expressed as the organizational structure, policies, procedures, processes, and resources needed to implement quality management.

3.27 quality manual: Organizational document that defines the scope of the quality management system, including details of and justification for any exclusions, and the documented procedures established for the quality management system or reference to them.

3.28 record (noun): Collection of data and process evidence that is presented in a controlled and identifiable format and that demonstrates compliance to a documented procedure or requirement.

3.29 record: To collect and store data.

3.30 record retention program: System of identifying the duration, archiving, and retrieval of an organization's records.

3.31 requalification: Repetition of part of validation for the purpose of confirming the continued acceptability of a specified process.