Technical Information Report

AAMI TIR52:2014/(R)2017

Environmental monitoring for terminally sterilized healthcare products

AAMI
Advancing Safety in Healthcare Technology

Environmental monitoring for terminally sterilized healthcare products

Approved 10 March 2014 and reaffirmed 19 October 2017 by
AAMI

Abstract: This TIR assists in establishing an environmental monitoring program that is meaningful, manageable and defendable, and provides guidance to avoid adverse environmental conditions during the manufacture of terminally sterilized healthcare products.

Keywords: sterilization, microbiological, particulate, sampling

AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633

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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

Microbiological Methods Working Group

This AAMI technical information report was developed and approved by the AAMI Microbiological Methods Working Group under the auspices of the AAMI Sterilization Standards Committee.

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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

This technical information report (TIR) was developed by the Microbiological Methods Working Group under the purview of the AAMI Sterilization Standards Committee.

Quality systems regulations require that an appropriate environment must be established, maintained, and monitored for the manufacture of medical devices.

The objective of this TIR is to provide guidance on the routine monitoring for viable and non-viable particulates in controlled environments used to produce healthcare products that are intended to be terminally sterilized.

References to bibliography entries appear throughout the document in brackets, e.g. [1].

As used within the context of this document, “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 TIR. “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.

Suggestions for improving this technical information report 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 AAMI TIR52:2014, *Environmental Monitoring for Terminally Sterilized Healthcare Products* (AAMI TIR52:2014), but it does provide important information about the development and intended use of the document.

Environmental monitoring for terminally sterilized healthcare products

1 Scope

This technical report addresses routine monitoring for viable (i.e. microorganisms) and non-viable particulates in controlled environments used to produce healthcare products that are intended to be terminally sterilized. As required by the current applicable quality system regulations, an appropriate environment must be established, maintained, and monitored for the manufacture of medical devices. The following types of viable and non-viable particulate monitoring are included in the scope of this technical report:

a) Air (viable and non-viable particulates)

b) Surfaces (viable particulates)

c) Water (viable particulates)

d) Compressed gasses (viable and non-viable particulates)

Personnel monitoring, product monitoring, differential pressures, and the effects of temperature and humidity on the manufacturing process are outside the scope of this technical report.

For requirements and guidance for establishing classified cleanrooms see ISO 14644.

2 Normative references

The following standards are indispensable for the application of this document. For dated references, only the edition cited applies.

ISO 14644-1, *Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness*

ISO 14644-2, *Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*

ISO 14644-5, *Cleanrooms and associated controlled environments – Part 5: Operations*

ISO 14698-1:2003, *Cleanrooms and associated controlled environments – Biocontamination control – Part 1: General principles and methods*

ISO 14698-2:2003, *Cleanrooms and associated controlled environments – Biocontamination control – Part 2: Evaluation and interpretation of biocontamination data*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14698-1, ISO 14698-2 and the following apply.

3.1 Action level*:* level set by the user in the context of controlled environments, which, when exceeded, requires immediate action.

[ISO 14644-7:2004]

3.2 Alert level*:* level set by the user in the context of a controlled environment, giving early warning of a drift from normal conditions, which, when exceeded, should result in increased attention in the process

[ISO 14644-7:2004]

3.3 Bioburden*:* the population of viable microorganisms on or in product.

[ISO/TS 11139:2006]