Technical Information Report

AAMI TIR52: 2026

Environmental monitoring for terminally sterilized healthcare products

AAMI

Advancing Safety in Health Technology

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Environmental monitoring for terminally sterilized healthcare products

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AAMI

Abstract: This technical information report primarily addresses routine monitoring for viable particles (i.e., microorganisms) to demonstrate the suitability of microbiological control in controlled environments used to produce healthcare products that are intended to be terminally sterilized. Where applicable, routine monitoring for non-viable particles is addressed, however ISO 14644 series should be used as the main source of information for non-viable particles. As required by the current applicable quality system regulations, if the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to control and monitor the work environment (per clause 6.4.1 in ISO 13485:2016).

Keywords: environmental monitoring, terminal sterilization, terminally sterilized healthcare products, sterility assurance, microbiological monitoring, biocontamination control, cleanrooms, viable particles, non-viable particles

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Contents

Page

Committee representation iv

Foreword vii

Introduction viii

1 Scope 1

2 References 1

3 Terms and definitions 1

4 Establishment of microbiological control 3

5 Demonstration of microbiological control 9

6 Measurement methods 15

7 Water monitoring 18

8 Compressed air or process gasses 20

Annex A (informative) Guidance on qualification of controlled environments 22

Annex B (informative) Guidance on laboratory investigations for environmental monitoring excursions 26

Bibliography 29

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Foreword

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- “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.

Introduction

An environmental monitoring program assists in demonstrating the continued effectiveness of the environmental control measures implemented as part of the sterility assurance program. Environmental monitoring should be performed in those areas where defined controls are in place as determined based on formal risk assessment.

Environmental monitoring is used to assess the current state of the environment which is typically related to the measurement of viable and non-viable particles. During the manufacturing process, changes in activity can affect the environment. Such changes can include the activity level or actions of personnel, operation of equipment, and the introduction of materials, components, packaging, etc. Environmental change can also be brought about by seasonal variation. The culmination of these and other environmental factors can impact the manufacturing area's control systems established to maintain the desired level of control.

The majority of terminally sterilized products are not manufactured using an aseptic process, so the presence of microorganisms in the environment is expected. Therefore, sampling strategies and responses to excursions are significantly different than those of an aseptic processing program in the majority of situations.

Manufacturing environments are typically controlled and, where appropriate, classified based on the control of non-viable particles as specified in ISO 14644-1. The requirements for establishing a monitoring program for non-viable particles are described in ISO 14664-2. The levels of microorganisms and nonviable particles are not typically directly related, but it is understood that any particle could carry microorganisms. Additional information relating to the construction, test methods, operations, and other types of manufacturing environments can be found in ISO 14644-3, ISO 14644-4, ISO 14644-5, ISO 14644-7, and ISO 14644-18.

Standards for biocontamination control such as ISO 14698-1, ISO 14698-2, and EN 17141 have been published, however these standards address all types of cleanrooms and controlled environments, not only those used for terminally sterilized products.

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Environmental monitoring for terminally sterilized healthcare products

1 Scope

This technical information report primarily addresses routine monitoring for viable particles (i.e., microorganisms) to demonstrate the suitability of microbiological control in controlled environments used to produce healthcare products that are intended to be terminally sterilized. Where applicable, routine monitoring for non-viable particles is addressed, however the ISO 14644 series should be used as the main source of information for non-viable particles. As required by the current applicable quality system regulations, if the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to control and monitor the work environment (per clause 6.4.1 in ISO 13485:2016).

NOTE The guidance provided in this document can also be applied to controlled environments used to produce healthcare products that are intended to be non-sterile.

The following types of viable particle monitoring are included in the scope of this technical information report:

a) Air

b) Surfaces

c) Water

d) Compressed gasses

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

For requirements and guidance for establishing classified cleanrooms, refer to the ISO 14644 series.

2 Normative references

The following documents are provided for information.

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

ISO 14644-2, *Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

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

3 Terms and definitions

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

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