Technical Information Report

AAMI TIR106:2024

Microbiological methods—Understanding and use of product bioburden data

AAMI
Advancing Safety in Health Technology

Microbiological methods—Understanding and use of product bioburden data

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AAMI

Abstract: This document provides guidance regarding the understanding and use of product bioburden data including: what bioburden data represent; how to use bioburden data to support a sterilization process; the analysis and characterization of bioburden; establishment and the use of alert and action levels; how to investigate bioburden excursions; trending and maintaining an effective bioburden monitoring program; counting plates and recording results.

Keywords: product bioburden data, microbiological methods, sterilization

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- “shall” and “shall not” are used to express requirements;
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- “can” and “cannot” are used as statements of possibility or capability;
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- “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.

NOTE This foreword does not contain provisions of the AAMI TIR106, *Microbiological methods—Understanding and use of product bioburden data* (AAMI TIR106:2024), but it does provide important information about the development and intended use of the document.

Introduction

This document is intended to supplement guidance in ANSI/AAMI/ISO 11737-1 Sterilization of health care products—Microbiological methods—Part 1: Determination of a population of microorganisms on products to provide information regarding the use of bioburden data. ISO 11737-1 specifies requirements and provides guidance on the methods for enumeration and microbial characterization of the population of viable microorganisms. Understanding of the data obtained is essential when dealing with the sterilization of health care products, and the assessment of their microbiological quality. This document provides guidance on the use of the enumeration and characterization data obtained through laboratory analysis. It explains when such information is critical and when it is supplemental or informative for the most common use cases. Additionally, this document contains guidance on establishing bioburden levels, excursions, and trending.

Because of the broad range of materials employed, manufacturing processes and environments, and intended use of health care products, the guidance found in this technical information report (TIR) is not specific and is designed to allow for inclusion of all types of medical products. Although this document addresses specific processes referenced in the standard, such as validation, the information presented in this document might not be applicable in certain cases.

Microbiology is not an exact science. Its variability due to the many factors influencing microbiological outcomes makes it difficult to evaluate microbiological quality based on the results of a single test. Use of groups of data and data trends is essential to the understanding and use of bioburden data.

Microbiological methods—Understanding and use of product bioburden data

1 Scope

This document provides guidance regarding the understanding and use of product bioburden data including:

- what bioburden data represent;
- how to use bioburden data to support a sterilization process;
- the analysis and characterization of bioburden;
- establishment and the use of alert and action levels;
- how to investigate bioburden excursions;
- trending and maintaining an effective bioburden monitoring program;
- counting plates and recording results.

2 Normative references

ANSI/AAMI/ISO 11737-1:2018, *Sterilization of health care products—Microbiological methods—Part 1: Determination of a population of microorganisms on products*

3 Terms and definitions

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

3.1
bioburden spike
individual bioburden value that is significantly greater than other bioburden values in a set

[SOURCE: ISO 11139:2018, 3.26]

3.2
excursion
data exceeding an established level

NOTE Bioburden results are typically evaluated as averages of a number of individual values.

3.3
microbiological quality
attributes of raw materials, components, finished products, manufacturing processes, and environment that can be impacted by the numbers and types of microorganisms or by-products of microorganisms

3.4
microbiologically significant
a characterization of microbiological data represented by true differences in number or types of microorganisms and are not due to typical microbiological variation

NOTE Among bioburden data, a microbiologically significant difference in number is typically considered to be a factor of 10.