INSTITUTE OF ENVIRONMENTAL SCIENCES AND TECHNOLOGY

Contamination Control Division
Recommended Practice CC023.2

IEST-RP-CC023.2

Microorganisms in Cleanrooms

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1 SCOPE AND LIMITATIONS

1.1 Scope

This Recommended Practice (RP) provides guidelines for the control and quantitative measurement of viable contamination in the air and on surfaces in environments that require control of such contamination. This includes areas designated as aseptic and those considered nonsterile. The procedures and techniques employed to achieve the desired level of microbial control are dependent on the level of bioburden that can be tolerated. This RP presents an introduction to the currently accepted methods for bioburden control and environmental monitoring as well as the devices available for the quantification of airborne and surface viable contamination.

This document also describes disinfectants, their lethality spectrum, and techniques for their application.

1.2 Limitations

Any controlled area designated for the manufacture or storage of a medical device, pharmaceutical product, or food product is subject to regulations imposed by agencies that govern each industry. This document is not intended to supersede or substitute for these regulations. It is intended to provide a framework for meeting the regulatory requirements and to achieve the highest level of bioburden control required for other types of environments.

In selecting a disinfectant, it is the responsibility of the user to consider all factors related to but not necessarily limited to personnel safety, application devices, methods, surface compatibility, residues, and bactericidal or bacteriostatic efficiency.

The selection of testing and disinfection methods varies with the desired level of airborne and surface bioburden.

2 REFERENCES

The cited editions of the following documents are incorporated into this RP to the extent specified herein. Users are encouraged to investigate the possibility of applying the most recent editions of the references.

2.1 Documents

ANSI/AAMI/ISO 11137—1994 Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization

ANSI/AAMI/ISO 11737-1—1995 Sterilization of medical devices—Microbiological methods—Part 1: Estimation of population of microorganisms on products

Association of Official Analytical Chemists. *The Official Methods of Analysis of AOAC International* 18th Ed., Chapter 6, pp. 4, 7, 8.

Guidance for Industry Sterile Drug Products Produced by Aseptic Processing–Current Good Manufacturing Practice. September 2004. US Food and Drug Administration.

IEST-RP-CC003: Garment System Considerations For Cleanrooms and Other Controlled Environments

IEST-RP-CC018: Cleanroom Housekeeping: Operating and Monitoring Procedures

IEST-RP-CC034: HEPA and ULPA Filter Leak Tests

ISO 14644-1 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness

ISO 14644-4 Cleanrooms and associated controlled environments—Part 4: Design, construction and start-up

ISO 14698-1 Cleanrooms and associated controlled environments—Biocontamination control—Part 1: General principles and methods

ISO/DTR 14698-3 Cleanrooms and associated controlled environments—Biocontamination control—Part 3: Measurement of the efficiency of processes of