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

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from the Japan Air Cleaning Association (JACA)/ Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

JIS B 9918 consists of the following 2 parts under the general title "*Cleanrooms and associated controlled environments—Biocontamination control*":

Part 1: General principles and methods

Part 2: Evaluation and interpretation of biocontamination data

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

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of **ISO 14698-1** published in 2003, without modifying the technical contents or the construction of the corresponding International Standard.

The portions underlined with dots in this Standard are the matters in which the contents of the corresponding International Standard have been modified.

The principles described here are intended to promote appropriate hygienic practices. This Standard is one of a number of standards considering factors important for the creation of clean, controlled environments.

Hygiene has become increasingly important in many areas of modern society. In such areas, hygiene or biocontamination control methods are, or will be, used to create safe and stable products. International trade in hygiene-sensitive products has greatly increased. At the same time, the use of antimicrobial agents has been reduced or forbidden, creating a need for increased biocontamination control.

This Standard is the first general standard for biocontamination control. However, many factors besides cleanliness must be considered in the design, specification, operation and control of cleanrooms and associated controlled environments.

In some circumstances, relevant regulatory agencies could impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures might be required.

1 Scope

This Standard establishes the principles and basic methodology of a formal system of biocontamination control (Formal System) for assessing and controlling biocontamination when cleanroom technology is applied for that purpose. This Standard specifies the methods required for monitoring risk zones in a consistent way and for applying control measures appropriate to the degree of risk involved. In zones where risk is low, it can be used as a source of information.

Application-specific requirements are not given. Neither are fire and safety issues addressed; for these, see regulatory requirements and other national or local documentation.

NOTE : The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows:

ISO 14698-1 : 2003 *Cleanrooms and associated controlled environments—Biocontamination control—Part 1: General principles and methods* (IDT)

The symbols which denote the degree of correspondence in the contents between **JIS** and the relevant International Standard are IDT (identical), MOD (modified) and NEQ (not equivalent) according to **ISO/IEC Guide 21**.