



JAPANESE  
INDUSTRIAL  
STANDARD

Translated and Published by  
Japanese Standards Association

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**JIS B 9918-1** : 2008

(ISO 14698-1 : 2003)

(JACA/JSA)

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

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**ICS 13.040.35**

**Reference number : JIS B 9918-1 : 2008 (E)**

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Date of Establishment: 2008-03-20

Date of Public Notice in Official Gazette: 2008-03-21

Investigated by: Japanese Industrial Standards Committee

Standards Board

Technical Committee on Industrial Machinery

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JIS B 9918-1:2008, First English edition published in 2008-10

Translated and published by: Japanese Standards Association  
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

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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.

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**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**.

## 2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this Standard. The most recent edition of the standard (including amendments) indicated below shall be applied.

JIS B 9918-2 *Cleanrooms and associated controlled environments—Biocontamination control—Part 2: Evaluation and interpretation of biocontamination data*

NOTE : Corresponding International Standard: ISO 14698-2:2003 *Cleanrooms and associated controlled environments—Biocontamination control—Part 2: Evaluation and interpretation of biocontamination data* (IDT)

## 3 Terms and definitions

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

### 3.1 General

#### 3.1.1 action level

level set by the user in the context of controlled environments, which, when exceeded, requires immediate intervention, including investigation of cause, and corrective action

#### 3.1.2 alert level

level set by the user in the context of controlled environments, giving early warning of a drift from normal conditions, which, when exceeded, should result in increased attention to the process

#### 3.1.3 bioaerosol

dispersed biological agents in a gaseous environment

#### 3.1.4 biocontamination

contamination of materials, devices, individuals, surfaces, liquids, gases or air with viable particles

#### 3.1.5 cleanroom

room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room, and in which other relevant parameters e.g. temperature, humidity, and pressure, are controlled as necessary

NOTE : It is a limited space where contamination control is performed and cleanliness is controlled so as not to exceed the cleanliness level in which airborne fine particles and bioaerosols are limited. Furthermore, it is a space where the cleanliness level required also for materials, chemicals, water, etc. supplied to the space is maintained and as required, the environmental conditions such as temperature, humidity, and pressure are also controlled.

[See JIS Z 8122 : 2000, 4001 ([28] in Annex H).]

### **3.1.6 contact device**

specialty designed appliance holding an appropriate, sterile, culture medium with an accessible surface used for surface sampling

### **3.1.7 contact plate**

contact device where a rigid dish is filled with aseptic culture medium

### **3.1.8 control point**

point in a controlled environment at which control is applied and a hazard can be prevented, eliminated or reduced to acceptable levels

### **3.1.9 controlled environment**

defined zone in which sources of contamination are controlled by specified means

### **3.1.10 corrective action**

action to be taken when the results of monitoring indicate that alert or action levels are exceeded

### **3.1.11 Formal System**

system of biocontamination control with established and documented procedures

### **3.1.12 hazard**

potential source of harm which can cause impediment due to biocontamination

NOTE : See **JIS Z 8051:1999, 3.5.**

### **3.1.13 impact sampler**

device designed to sample particles in the air, or other gas, through a collision with a solid surface

### **3.1.14 impingement sampler**

device designed to sample particles in the air, or other gas, through a collision with a liquid surface and the subsequent entering into the liquid

### **3.1.15 qualification**

process of demonstrating whether an entity—activity or process, product, organization, or any combination thereof—is capable of fulfilling specified requirements

### **3.1.16 risk**

combination of the probability of occurrence of harm and the severity of that harm

NOTE : See **JIS Z 8051:1999, 3.2.**

### **3.1.17 risk zone**

defined and delimited space where individuals, products or materials (or any combination of these) are particularly vulnerable to contamination

### **3.1.18 settle plate**

suitable container (e.g. a Petri dish) of appropriate size, containing an appropriate, sterile, culture medium, which is left open for a defined period to collect viable particles depositing from the air

NOTE : Modifies the definition in **JIS Z 8122:2000.**

**3.1.19 swab**

sterile collection device for swabbing the sample, such as a cotton bud, non-toxic and non-inhibitory to the growth of the microorganisms being sampled, consisting of a specific matrix of suitable size, mounted on an applicator

(See **JIS Z 8122:2000**.)

**3.1.20 target level**

defined level set by the user as a goal for routine operations, for the user's own purpose

**3.1.21 validation**

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTE : Modifies the definitions in **JIS Z 8122:2000** and **JIS Q 9000**.

**3.1.22 verification**

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

NOTE 1 Monitoring and auditing methods, procedures and tests, including random sampling and analysis, can be used in the verification of the Formal System.

NOTE 2 See **JIS Q 9000**.

**3.1.23 viable particle**

particle that consists of, or supports, one or more live microorganisms

**3.1.24 viable unit (VU)**

one or more viable particles which are enumerated as a single unit

NOTE : When viable units are enumerated as colonies on agar media, it is common usage to name them colony forming units (CFU). One CFU might consist of one or more VU.

**3.2 Occupancy states****3.2.1 as-built**

condition where the installation is complete with all services connected and functioning, but with no production equipment, materials or personnel present

NOTE : Modifies the definition in **JIS B 9920:2002**.

**3.2.2 at-rest**

condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present

NOTE : Modifies the definition in **JIS B 9920:2002**.

**3.2.3 operational**

condition where the installation is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon

NOTE : Modifies the definition in **JIS B 9920:2002**.

## 4 Principles of biocontamination control

**4.1** A formal system of biocontamination control (Formal System) shall be established, implemented and maintained within cleanrooms and associated environments. The Formal System will assess and control factors that can affect the microbiological quality of the process and product.

There are a number of accepted methods for achieving this goal by risk assessment (see [4], [5] in Annex H). The hazard analysis critical control point (HACCP) system (see [6], [7], [8], [9] in Annex H) is commonly used. Fault tree analysis (FTA) (see [10] in Annex H), or the failure mode and effect analysis (FMEA) (see [11] in Annex H), or any other validated equivalent system can be used.

In many such methods, any type of hazard can be considered. Within this Standard, only microbiological hazards are addressed.

**4.2** To assess and control the microbiological hazards, any selected system shall address the following principles:

- a) identification of potential hazard(s) to the process or product, assessment of the likelihood of occurrence of these hazard(s), and identification of measures for their prevention or control;
- b) designation of risk zones and, in each zone, determination of the points, procedures, operational steps and environmental conditions that can be controlled to eliminate the hazard(s) or minimize the likelihood of their occurrence;
- c) establishment of limits to ensure control;
- d) establishment of a monitoring and observation schedule;
- e) establishment of corrective actions to be taken when monitoring results indicate that a particular point, procedure, operational step or environmental condition is not under control;
- f) establishment of procedures, which may include supplementary tests and procedures, to verify that the chosen Formal System is working effectively;
- g) establishment of training procedures;
- h) establishment and maintenance of appropriate documentation.

## 5 Establishing the Formal System

### 5.1 General requirements

It is the responsibility of the user to develop, initiate, implement and document and Formal System for biocontamination control that allows detection of adverse conditions in a timely fashion. It is imperative that such a programme be tailored to the field of application, to the specific facility and to specified conditions, and that this system be an integral part of a quality management system. The quality management system shall include an appropriate training programme for the selected Formal System.

In addition, it is essential that a monitoring programme (see **5.3**) be designed and implemented in a manner that minimizes the possibility of the sampling activities themselves contributing to the contamination of the product or risk zone or both.

Risk zones shall be classified according to relevant guidelines, regulations (where these exist) and the chosen Formal System. Risk zones may also be classified according to the level of aerial and surface biocontamination, for example, low, medium, high or very high risk.

NOTE : The first two parts of a Formal System, as given in **4.2 a)** and **b)**, are not discussed in detail in this Standard, but information on how to identify, assess and control hazards is given in other sources. See, for example, [12] in Annex H.

## **5.2 Alert, action and target levels**

The user of a cleanroom or controlled environment shall set microbiological alert and action levels. These levels shall be appropriate to the field of application, to the classification of the risk zones and to what is achievable using current technology. Microbiological target levels may be used as an alternative to microbiological alert and action levels in some specific fields of application.

During initial start-up and at intervals established according to the Formal System, data on biocontamination levels should be reviewed to establish or confirm a baseline for the determination of alert and action levels. Alert and action levels may be related to the target levels in any specific applications where these are set. Alert and action levels should be reviewed and adjusted as appropriate.

## **5.3 Monitoring of biocontamination**

### **5.3.1 General**

Detection and monitoring of biocontamination in risk zones shall be carried out by sampling and enumerating viable units with appropriate methods in accordance with a sampling plan.

Examples of sources of biocontamination that can constitute a hazard (see **3.1.12**) are air, surfaces, textiles and liquids (see Annexes A, C, D and F).

Microbiological sampling may be useful for providing baseline data as new installations are constructed and commissioned, including, as relevant, in the as-built state. Monitoring in risk zones shall be performed when the installation is in the as-built and at-rest states. Monitoring shall also be performed routinely in the operational state according to the selected Formal System.

### **5.3.2 Sampling**

#### **5.3.2.1 General**

The appropriate sampling method and related procedures shall be selected and performed to reflect the complexity and variety of situations. Sampling shall be carried out using a device and method selected in accordance with the written procedure and in accordance with the instructions provided by the device manufacturer.

#### **5.3.2.2 Sampling device**

A sampling device shall be selected according to the area being monitored. The selection for a particular application shall take into consideration the following factors:

- a) type of viable particles for which to sample;
- b) sensitivity of the viable particles to the sampling procedure;
- c) expected concentration of the viable particles;
- d) indigenous microbial flora;
- e) accessibility of the risk zones;
- f) ability to detect low levels of biocontamination;
- g) ambient conditions in the risk zone being sampled;
- h) time and duration of sampling;
- i) sampling method, material and properties of the sampling medium;
- j) effect of the sampling device on the process or environment to be monitored;
- k) collection accuracy and efficiency;
- l) incubation and viable particle detection and evaluation method;
- m) type of information to be obtained (e.g. qualitative or quantitative aspects);
- n) efficiency of extraction/rinse fluids, where appropriate.

#### **5.3.2.3 Sampling plan**

A sampling plan shall be developed through the selected Formal System and shall be documented. A documented sampling plan is essential for accurately assessing and interpreting biocontamination data.

Sampling shall be carried out when the area is in the operational condition and during periods of greatest stress in the system, for example, before the end of a shift or when the greatest amount of activity is taking place. Sampling in the at-rest condition may also provide useful information about the facility design and performance.

The sampling plan shall comprise the following:

- a) initial sampling plan to provide a reference point or baseline within the framework of the chosen Formal System;
- b) routine sampling plan resulting from the implementation of the chosen Formal System.

#### **5.3.2.4 Design of the sampling plan**

The sampling plan shall take into account the cleanliness level of the risk zone and the degree of biocontamination control required for the activity being conducted, to protect individuals, the environment, the process and the product. The following are examples of elements to be considered:

- a) choice of the sampling location, taking account of the location and function of the risk zone;
- b) number of samples (limited or small sample volumes may not provide representative results, although, in some cases, large numbers of samples may compensate for the size of the sample volumes);

- c) frequency of sampling;
- d) methods of sampling, including whether the tests will be qualitative or quantitative;
- e) volume to be taken or the area that should be covered to constitute a sample;
- f) diluents, rinse fluids, neutralizes, etc.;
- g) factors pertinent to a particular situation that could affect culturing results;
- h) impact of operations, personnel and equipment in risk zones which contribute to biocontamination, such as
  - 1) compressed gases,
  - 2) room air,
  - 3) manufacturing equipment,
  - 4) monitoring/measuring devices,
  - 5) storage containers,
  - 6) number of persons present in zone,
  - 7) unprotected surfaces of personnel,
  - 8) personal attire,
  - 9) protective clothing,
  - 10) walls/ceilings,
  - 11) floors,
  - 12) doors,
  - 13) benches,
  - 14) chairs, or
  - 15) air admitted from other sources.

### 5.3.2.5 Frequency of sampling

The frequencies of sampling shall be developed using the selected Formal System and shall be confirmed or modified as necessary in the following cases:

- a) when alert or action levels are exceeded consecutively;
- b) after prolonged shut-down of activities;
- c) on detection of infectious agents in risk zones;
- d) after any significant maintenance work has been undertaken on the ventilation system;
- e) after changes to the process that affect the cleanroom environment;
- f) after recording of unusual results;
- g) after changes to the cleaning or disinfection procedures;
- h) after unplanned incidents that could contribute to biocontamination.

#### 5.3.2.6 Sampling sites

Sampling sites shall be determined through the selected Formal System, and included in the sampling plan.

More than one sample may be taken at each site and different numbers of samples may be taken at different locations.

Sampling shall be carried out at the microbiological control points defined in a written procedure.

#### 5.3.2.7 Identification of samples

The labelling of each sample shall carry the following information or a coding that provides traceability of the information:

- a) collection site;
- b) date and time of collection;
- c) person collecting the sample;
- d) current activity at the time of sampling;
- e) culture medium type;
- f) any deviations from the sampling plan.

#### 5.3.3 Validation

The selected monitoring system shall be used as part of the qualification and validation process for cleanrooms and associated controlled environments in accordance with **JIS B 9918-2** and **JIS B 9919**, Annex C.

NOTE : Information on the validation of some microbiological methods is given in **JIS B 9918-2**.

#### 5.4 Processing of samples

The collection, transport and processing of samples shall not affect the viability and number of the collected organisms. Factors to be considered are

- a) transport/storage conditions and duration,
- b) use of neutralizing agents, and
- c) use of osmotic solutes.

Samples shall be collected in a manner and in containers such as not to add to, or inhibit, biocontamination.

#### 5.5 Culturing of samples

##### 5.5.1 General

Culture media and incubation conditions (e.g. temperature, duration, oxygen tension, relative humidity) shall be selected according to the types of microorganisms expected. This selection will also depend upon the sampling environment and the procedure and equipment used.