



JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS B 9920-1 : 2019

(JACA/JSA)

**Cleanrooms and associated
controlled environments—Part 1:
Classification of air cleanliness by
particle concentration**

ICS 13.040.35

Reference number : JIS B 9920-1 : 2019 (E)

Date of Establishment: 2019-03-20

Date of Public Notice in Official Gazette: 2019-03-20

Investigated by: Japanese Industrial Standards Committee
Standards Board for ISO area

JIS B 9920-1:2019, First English edition published in 2020-03

Translated and published by: Japanese Standards Association
Mita MT Building, 3-13-12, Mita, Minato-ku, Tokyo, 108-0073 JAPAN

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

© JSA 2020

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan

Contents

	Page
Introduction	1
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Classification	5
4.1 Occupancy state(s)	5
4.2 Particle size(s)	5
4.3 Air cleanliness class number	5
4.4 Designation	6
4.5 Intermediate decimal cleanliness classes and particle size thresholds	7
5 Demonstration of compliance	7
5.1 Principle	7
5.2 Testing	7
5.3 Airborne particle concentration evaluation	7
5.4 Test report	8
Annex A (normative) Reference method for classification of air cleanliness by particle concentration	9
Annex B (informative) Examples of classification calculations	14
Annex C (informative) Counting and sizing of airborne macroparticles	18
Annex D (normative) Sequential sampling procedure	24
Annex E (normative) Specification of intermediate decimal cleanliness classes and particle size thresholds	28
Annex F (informative) Test instruments	30
Annex JA (normative) Handling of large-volume space on classification of air cleanliness and measures for measurement reliability improvement	31
Annex JB (informative) Calculation examples of measures for measurement reliability improvement and handling of large-volume space	33
Annex JC (informative) Classification examples using sequential sampling procedure	37
Annex JD (informative) Comparison table between JIS and corresponding International Standard	42

Foreword

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

Consequently **JIS B 9920:2002** has been withdrawn and partially replaced with this Standard.

This **JIS** document is protected by the Copyright Law.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, applications for a patent after opening to the public or utility model rights. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, applications for a patent after opening to the public or utility model rights.

JIS B 9920 series consists of the following 2 parts under the general title *Cleanrooms and associated controlled environments*:

Part 1: Classification of air cleanliness by particle concentration

Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 14644-1:2015**, Edition 2, with some modifications of the technical contents.

The dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JD.

1 Scope

This Standard specifies the classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones, and separative devices as defined in **JIS B 9917-7**.

Only particle populations having cumulative distributions based on threshold (lower limit) particle sizes ranging from 0.1 μm to 5 μm are considered for classification purposes.

The use of light scattering airborne particle counters (LSAPCs) is the basis for determination of the concentration of airborne particles at designated sampling locations. Concentrations of ultrafine particles (particles smaller than 0.1 μm) will be addressed in a separate standard. An M descriptor (see Annex C) may be used to quantify populations of macroparticles (particles larger than 5 μm).

This Standard cannot be used to characterize the physical, chemical, radiological, viable or other nature of airborne particles.

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

ISO 14644-1:2015 *Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

2 Normative references

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

JIS B 9917-3 *Cleanrooms and associated controlled environments—Part 3: Test methods*

JIS B 9917-7 *Cleanrooms and associated controlled environments—Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

NOTE Corresponding International Standard: ISO 14644-7 *Cleanrooms and associated controlled environments—Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)* (MOD)

JIS B 9920-2 *Cleanrooms and associated controlled environments—Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

NOTE Corresponding International Standard: ISO 14644-2:2015 *Cleanrooms and associated controlled environments—Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

JIS B 9921 *Light scattering airborne particle counter for clean spaces*

3 Terms and definitions

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

3.1 General

3.1.1

cleanroom

room within which the concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

NOTE 1 The class of concentration of airborne particles is specified.

NOTE 2 Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, chemical, viable or nanoscale concentrations might also be specified and controlled.

NOTE 3 Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

3.1.2

clean zone

defined space within which the concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the space

NOTE 1 The class of concentration of airborne particles is specified.

NOTE 2 Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, chemical, viable or nanoscale concentrations might also be specified and controlled.

NOTE 3 A clean zone(s) can be a defined space within a cleanroom or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

NOTE 4 Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

3.1.3

installation

cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services and utilities

3.1.4

classification

method of assessing level of cleanliness against a specification for a cleanroom or a clean zone, or the determined air cleanliness class

NOTE A level of air cleanliness is expressed in terms of a class number, which represents maximum permissible concentrations of particles in a unit volume of air.

3.2 Airborne particles

3.2.1

particle

minute piece of matter with defined physical boundaries

3.2.2

particle size

diameter of a sphere that produces a response, by a given particle-sizing instrument, that is equivalent to the response produced by the particle being measured

NOTE In LSAPC, the light-scattering equivalent particle diameter is used.

3.2.3

particle concentration

number of individual particles per unit volume of air

3.2.4

particle size distribution

cumulative distribution of particle concentration as a function of particle size

3.2.5

macroparticle

particle with an equivalent diameter larger than 5 μm

3.2.6

M descriptor

designation for measured or specified concentration of macroparticles per cubic metre of air, expressed in terms of the equivalent diameter that is characteristic of the measurement method used

NOTE The M descriptor can be regarded as an upper limit for the averages at sampling locations. The M descriptor cannot be used to define the classification, but may be quoted independently or in conjunction with the classification.

3.2.7

unidirectional airflow

controlled airflow through the entire cross-section of a cleanroom or a clean zone with a steady velocity and airstreams that are considered to be parallel

3.2.8

non-unidirectional airflow

air distribution where the supply air entering a cleanroom or a clean zone mixes with the internal air by means of induction

3.3 Occupancy states

3.3.1

as-built

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

3.3.2

at-rest

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

3.3.3

operational

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

3.4 Testing instrumentation (see Annex F)

3.4.1

resolution

smallest change in a quantity being measured that causes a perceptible change in the corresponding indication

NOTE Resolution can depend on, for example, noise (internal or external) or friction. It may also depend on the value of a quantity being measured.

[Source: **ISO/IEC Guide 99:2007, 4.14**]

3.4.2

maximum permissible measurement error

extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system

NOTE 1 Usually, the term “maximum permissible errors” or “limits of error” is used where there are two extreme values.

NOTE 2 The term “tolerance” should not be used to designate the “maximum permissible error”.

[Source: **ISO/IEC Guide 99:2007, 4.26**]

3.5 Instrument specifications

3.5.1

LSAPC (light scattering airborne particle counter, light scattering discrete airborne particle counter)

instrument capable of counting and sizing single airborne particles and reporting particle size data in terms of light-scattering equivalent particle size

NOTE See **JIS B 9921** for the specifications of LSAPC.

3.5.2

discrete-macroparticle counter

instrument capable of counting and sizing single airborne macroparticles

NOTE See Table F.1 for the specifications.

3.5.3

time-of-flight particle sizing apparatus

discrete-particle counting and sizing apparatus that defines the aerodynamic diameter of particles by measuring the time for a particle to accommodate to a change in air velocity

NOTE 1 This is usually done by measuring the particle transit time optically after a fluid stream velocity change.

NOTE 2 See Table F.2 for the specifications.

4 Classification

4.1 Occupancy state(s)

The air cleanliness class by particle concentration of air in a cleanroom or a clean zone shall be defined in one or more of three occupancy states, viz. “as-built,” “at-rest” or “operational” (see **3.3**).

4.2 Particle size(s)

One, or more than one, threshold (lower limit) particle sizes situated within the range from 0.1 μm to 5 μm are to be used to determine air cleanliness particle concentration for classification.

4.3 Air cleanliness class number

Air cleanliness class by particle concentration shall be designated by an air cleanliness number, N. The upper-limit particle concentration for each considered particle size is determined from Table 1.

Particle concentrations for different threshold sizes in Table 1 do not reflect actual particle size and distribution in the air and serve as criteria for classification only. Examples of classification calculations are shown in Annex B.

Table 1 Air cleanliness class by upper-limit particle concentration

Air cleanliness class (N)	Upper-limit concentrations for particles equal to and greater than the considered particle sizes, shown below ^{a)} (particles/m ³)					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
1	10	c)	c)	c)	c)	d)
2	100	24	10	c)	c)	d)
3	1 000	237	102	35	c)	d)
4	10 000	2 370	1 020	352	83	d)
5	100 000	23 700	10 200	3 520	832	e), [c), d)]
6	1 000 000	237 000	102 000	35 200	8 320	293
7	b)	b)	b)	352 000	83 200	2 930
8	b)	b)	b)	3 520 000	832 000	29 300
9 ^{f)}	b)	b)	b)	35 200 000	8 320 000	293 000

Notes ^{a)} The number of maximum permissible particles in the table are cumulative, e.g. for air cleanliness class 5, the 10 200 particles shown at 0.3 µm include all particles equal to and greater than this size.

^{b)} Concentration limits are not applicable in this region of the table due to very high particle concentration.

^{c)} Sampling and statistical limitations for particles in low concentrations make classification inappropriate.

^{d)} Sample collection limitations for both particles in low concentrations and sizes greater than 1 µm make classification at this particle size inappropriate, due to potential particle losses in the sampling system.

^{e)} In order to specify this particle size in association with Class 5, the macroparticle descriptor M may be adopted and used in conjunction with at least one other particle size.

^{f)} This class is only applicable for the in-operation state.

4.4 Designation

The designation of air cleanliness according to concentration of airborne particles for cleanrooms and clean zones shall include the following.

- Air cleanliness class number, expressed as “Class N”
- Cleanroom occupancy state
- Considered particle size(s)

If measurements are to be made at more than one considered particle size, each larger particle diameter (D_2) shall be at least 1.5 times the next smaller particle diameter (D_1), i.e. $D_2 \geq 1.5 \times D_1$.

Example: Class number, occupancy state, considered particle sizes

Class 4: at-rest, 0.2 µm, 0.5 µm

4.5 Intermediate decimal cleanliness classes and particle size thresholds

Where intermediate classes, or intermediate particle size thresholds are required, see Annex E.

5 Demonstration of compliance

5.1 Principle

Compliance with air cleanliness (air cleanliness class) requirements specified by the customer is verified by performing specified testing procedures and by providing documentation of the results and conditions of testing.

At-rest or operational classification may be performed periodically based upon risk assessment of the application, typically on an annual basis.

For monitoring cleanrooms, clean zones and separative devices, **JIS B 9920-2** shall be used.

NOTE Where the installation is equipped with instrumentation for continuous or frequent monitoring of air cleanliness by particle concentration and other parameters of performance as applicable, the time intervals between classification may be extended provided that the results of the monitoring remain within the specified limits.

5.2 Testing

The reference test method for demonstrating compliance is given in Annex A. Alternative methods having at least comparable performance may be specified. If no alternative is specified or agreed upon, the test method specified in Annex A shall be used. See Annex JA for the evaluation of large-volume space if the area is greater than 729 m². Also, in the evaluation of clean air cleanliness class in which the concentration is under 500 particles/m³, sequential sampling procedure specified in Annex D may apply.

Tests performed to demonstrate compliance shall be conducted using instruments which are in compliance with calibration requirements at the time of testing.

5.3 Airborne particle concentration evaluation

Upon completion of testing in accordance with Annex A, the particle concentration (expressed as number of particles per cubic metre) in a single sample volume at each sampling location shall not exceed the upper-limit particle concentration given in Table 1 or Table E.1 for the considered particle size(s). The upper-limit particle concentrations shall be as given in Table 1 for decimal classes, and Table E.1 for intermediate decimal classes. For the intermediate particle sizes, Formula (E.1) shall apply. If multiple single sample volumes are taken at a sampling location, the concentrations shall be averaged. If the number of sampling locations of a cleanroom or a clean zone is two or over up to and including nine, measures to improve the measurement reliability should be taken according to the evaluation of the 95 % upper confidence limit of spatial average particle concentration in accordance with Annex JA.

If two or more particle sizes are considered, the particle concentration used for the compliance judgement of air cleanliness class shall be measured by the same method for all the considered particle sizes.

5.4 Test report

The results from testing each cleanroom or clean zone shall be recorded and submitted as a comprehensive report, along with a statement of compliance or non-compliance with the specified designation of air cleanliness class by particle concentration. Also, the following shall be included in a test report.

- a) Name and address of testing organization, and test date
- b) Numbers and years of publication of **JIS** and **ISO**
Example: **JIS B 9920-1:2019 (ISO 14644-1:2015)**
- c) Clear identification of physical location of cleanroom or clean zone tested (including reference to adjacent areas if necessary), and specific designations for coordinates of all sampling locations
- d) Specified designation criteria agreed between the customer and the supplier, for cleanroom or clean zone, including air cleanliness class number, occupancy state(s), and considered particle size(s)
- e) Details of the test method used, with any special conditions relating to the test, or departures from the test method, and identification of the test instrument and its current calibration certificate

If the test methods described in Annex D and Annex JA are used, the purport shall be described in the test report.

- f) Test results, including particle concentration data for all sampling locations

If concentrations of macroparticles are quantified in accordance with Annex C, the relevant information should be included with the test report.

Annex A (normative)

Reference method for classification of air cleanliness by particle concentration

A.1 Principle

A discrete-particle-counting instrument is used to determine the concentration of airborne particles, equal to and greater than the considered particle sizes, at designated sampling locations.

A.2 Apparatus requirements

A.2.1 Particle-counting instrument

The instrument shall have a means of displaying or recording the count and size of discrete particles in air with a size discrimination capability to detect the total particle concentration in the appropriate particle size ranges for the class under consideration.

NOTE 1 LSAPC is commonly used for undertaking air cleanliness classification.

NOTE 2 LSAPC not discharging particles should be used.

A.2.2 Instrument calibration

The particle counter shall have a valid calibration certificate. The frequency and method of calibration should be in accordance with **JIS B 9921**.

NOTE Some particle counters cannot be calibrated to all of the required tests specified in **JIS B 9921**. If this is the case, record the decision to use the counter in the test report.

A.3 Preparation for particle count testing

Prior to testing, verify that all relevant aspects of the cleanroom or clean zone that contribute to its integrity are complete and functioning in accordance with its performance specification.

Care should be taken when determining the sequence for performing supporting tests for cleanroom performance. Annex A of **JIS B 9917-3** provides a checklist.

A.4 Establishment of sampling locations

A.4.1 Deriving the number of sampling locations

Derive the minimum number of sampling locations, N_L , from Table A.1. Table A.1 provides the number of sampling locations related to the area of each cleanroom or clean zone to be classified and provides at least 95 % confidence that at least 90 % of the cleanroom or clean zone area does not exceed the upper-limit particle concentrations.

When classified according to Annex JA, the minimum number of sampling locations shall be obtained in accordance with JA.2.

Table A.1 Minimum number of sampling locations related to area of cleanroom

Area of cleanroom (m ²)	Minimum number of sampling locations N_L (points)
≤ 2	1
≤ 4	2
≤ 6	3
≤ 8	4
≤ 10	5
≤ 24	6
≤ 28	7
≤ 32	8
≤ 36	9
≤ 52	10
≤ 56	11
≤ 64	12
≤ 68	13
≤ 72	14
≤ 76	15
≤ 104	16
≤ 108	17
≤ 116	18
≤ 148	19
≤ 156	20
≤ 192	21
≤ 232	22
≤ 276	23
≤ 352	24
≤ 436	25
≤ 636	26
≤ 1 000	27
1 000 >	See Formula (A.1).
In the case of unidirectional airflow, the area may be considered as the cross section of the moving air perpendicular to the direction of the airflow. In all other cases the area may be considered as the floor area of the cleanroom or clean zone.	

A.4.2 Positioning the sampling locations

In order to position the sampling locations:

- use the minimum number of sampling locations N_L derived from Table A.1;
- then divide the whole cleanroom or clean zone into N_L sections of equal area;
- select within each section a sampling location considered to be representative of the characteristics of the section;

- d) at each location, position the particle counter inlet probe in the plane of the work activity (the height of work plane) or another specified point.

Additional sampling locations may be selected for locations considered critical. Their number and positions shall also be agreed and specified.

Sections may be added to facilitate the division.

For non-unidirectional airflow cleanrooms or clean zones, locations may not be representative if they are located directly beneath non-diffused supply air sources.

NOTE The area of section is the area of target cleanroom or clean zone divided by the number of sections.

A.4.3 Number of sampling locations for large cleanrooms or clean zones

When the area of the cleanroom or clean zone is greater than 1 000 m², apply Formula (A.1) to determine the minimum number of sampling locations required.

$$N_L = 27 \times \left(\frac{A}{1000} \right) \dots\dots\dots (A.1)$$

where, N_L : the minimum number of sampling locations required (rounded up to the next whole number)

A : the area of cleanroom (m²)

A.4.4 Establishment of single sample volume and sampling time per location

At each sampling location, sample a volume of air sufficient to detect a minimum of 20 particles if the particle concentration for the largest considered particle size is at the upper-limit particle concentration for the designated air cleanliness.

The single sample volume, V_s , per sampling location is obtained according to Formula (A.2).

$$V_s = \left(\frac{20}{C_{n,m}} \right) \times 1000 \dots\dots\dots (A.2)$$

where, V_s : the minimum single sample volume per location (L)

$C_{n,m}$: the upper-limit particle concentration for the largest considered particle size specified for the relevant air cleanliness class (particles/m³)

20 : the number of particles that could be counted if the particle concentration is at the upper-limit particle concentration (particles)

The volume sampled at each location shall be at least 2 L, with a minimum sampling time of 1 min for each sample at each location. Each single sample volume at each sampling location shall be the same.

NOTE A single sample volume refers to the air volume used in the measurement of one time, which is not less than 2 L, not less than the sample volume during 1 min by an instrument, and not less than V_s .

When V_s is very large, the time required for sampling can be substantial. By using the optional sequential sampling procedure (see Annex D), both the required sample volume and the time required to obtain samples may be reduced.

A.5 Sampling procedure

A.5.1 Set up the particle counter (see **A.2**) in accordance with the manufacturer's instructions including performing a zero count check.

A.5.2 The sampling probe shall be positioned pointing into the airflow. If the direction of the airflow being sampled is not controlled or predictable (e.g. non-unidirectional airflow), the inlet of the sampling probe shall be directed vertically upward.

A.5.3 Ensure normal conditions for the selected occupancy state are established before sampling

A.5.4 Sample the volume of air determined in **A.4.4**, as a minimum, for each sample at each sampling location.

A.5.5 If an out-of-specification count is found at a location due to an identified abnormal occurrence, then that count can be discarded and noted as such on the test report and a new sample taken.

A.5.6 If an out-of-specification count found at a location is attributed to a technical failure of the cleanroom or equipment, then the cause should be identified, remedial action taken and retesting performed of the failed sampling location, the immediate surrounding locations and any other locations affected. The choice shall be clearly documented and justified.

A.6 Processing of results

A.6.1 Recording of results

Record the result of each sample measurement as the number of particles in each single sample volume at each of the considered particle size(s) appropriate to the relevant class of air cleanliness.

NOTE For particle counters with a concentration calculation mode, the manual evaluation may not be necessary.

A.6.1.1 Average concentration of particles at each sampling location

When two or more single sample volumes are taken at a location, calculate and record the average number of particles per location at each considered particle size from the individual sample particle concentrations, according to Formula (A.3).

$$\bar{x}_i = \left(\frac{x_{i,1} + x_{i,2} + \dots + x_{i,n}}{n} \right) \dots\dots\dots (A.3)$$

where, $\bar{x}_i$: the average number of particles at sampling location i