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Class II biological safety cabinets

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Foreword

This Japanese Industrial Standard has been revised by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Air Cleaning Association (JACA)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS K 3800** : 2009), which has been technically revised.

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Class II biological safety cabinets

Introduction

This Japanese Industrial Standard was established in 1994 with reference to **NSF/ANSI 49 Biosafety Cabinetry : Design, Construction, Performance, and Field Certification**. This revision was initiated to update the contents of this Standard in keeping with the advance in testing technique and in light of the importance of in-site verification of the cabinet performance, as well as to respond to the revision of **NSF/ANSI 49** in 2014.

No corresponding International Standard has been established at this point.

1 Scope

This Standard specifies the performance, structure and material requirements, as well as the test methods of Class II biological safety cabinets. A Class II biological safety cabinet includes an exhaust duct and a remote blower connected to it, if any. This Standard is not applicable to classic type Class II cabinets in which the positive pressure contaminated plenum is directly in contact with the outer wall.

WARNING 1 Users of Class II biological safety cabinets shall have sufficient knowledge regarding the handling of pathogenic microorganisms and the handling of Class II biological safety cabinets, and in operating the cabinet, shall follow the directions given by a person in charge of or responsible for biohazard safety. This Standard is not intended to address all the safety problems associated with its use.

WARNING 2 The clean work station, in contrast with Class II cabinet, is an apparatus designed to send clean air to the work space and to prevent the treated sample from being contaminated, and is not intended for ensuring personnel or environmental safety against biohazards. Although the two apparatuses resemble each other in appearance, air-flow and structure, a clean work station should never be used in works requiring biohazard safety measures.

NOTE 1 The Class II biological safety cabinets, as referred to in this scope, are the safety cabinets satisfying the requirements established by the Minister of Health, Labour and Welfare based on the Regulation for Enforcement of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases [Order of the Ministry of Health and Welfare No. 99 of 1998, 2 of Article 31, item (x)]. They are also safety cabinets stipulated in the Regulation for Enforcement of the Act on Domestic Animal Infectious Diseases Control (Order of the Ministry of Agriculture and Forestry No. 35 of 1951, 8 of Article 56) and also the research purpose safety cabinets stipulated in the Act on the Conservation and Sustainable Use of Biological Diversity through Reg-

ulations on the Use of Living Modified Organisms (Act on “Cartagena”) (Act No. 97 of 2003) and the Ministerial Order Providing Containment Measures to be Taken in Type 2 Use of Living Modified Organisms for Research and Development (Order of the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of the Environment No. 1 of 29 January 2004), Attached Table 2.

NOTE 2 **JIS K 3800** : 2009 may be applied until 19 January 2023.

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 7505-1 *Aneroid pressure gauges — Part 1 : Bourdon tube pressure gauges*

JIS B 8330 *Testing methods for turbo-fans*

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

JIS C 1302 *Insulation resistance testers*

JIS C 1509-1 *Electroacoustics — Sound level meters — Part 1 : Specifications*

JIS C 1609-1 *Illuminance meters Part 1 : General measuring instruments*

JIS C 4034-30 *Rotating electrical machines — Part 30 : Efficiency classes of single-speed, three-phase, cage-induction motors (IE-code)*

JIS G 4304 *Hot-rolled stainless steel plate, sheet and strip*

JIS G 4305 *Cold-rolled stainless steel plate, sheet and strip*

JIS K 0557 *Water used for industrial water and wastewater analysis*

JIS T 7322 *High-pressure steam sterilizers for medical use*

JIS T 7324 *High-pressure steam sterilizers for medical use (Small size)*

JIS T 8202 *Anemometer for general use*

JIS Z 8122 *Contamination control — Terminology*

JIS Z 8731 *Acoustics — Description and measurement of environmental noise*

JIS Z 8901 *Test powders and test particles*

3 Terms and definitions

For the purpose of this Standard, the terms and definitions given in **JIS Z 8122**, and the following apply.

3.1

biological safety cabinet

work equipment used for the purpose of protecting the worker and the environment

from hazards caused by infectious organisms or their components (see Clause 5)

3.2

decontamination

complete removal of a specific pathogen, etc.

3.3

sterilization

complete removal of all pathogens, etc.

3.4

disinfection

procedure of reducing the coexisting pathogenic microorganisms down to a degree where they are harmless

3.5

blower

device used for air intake from the front opening, air supply to the work space and exhaust of the Class II biological safety cabinet

3.6

remote blower

device used for Class II biological safety cabinets connected to a duct, which is installed at the end of the duct to exhaust air to the outdoors

3.7

HEPA and ULPA filters

HEPA filter (High Efficiency Particulate Air filter) or ULPA filter (Ultra-Low Penetration Air filter) specified in **JIS Z 8122**, at no point on which the penetration efficiency exceeds 0.01 % as guaranteed by a scanning test performed by the manufacturer

Either HEPA filter or ULPA filter may be used.

3.8

front panel

transparent panel provided at the front of the Class II biological safety cabinet (see Figure 1)

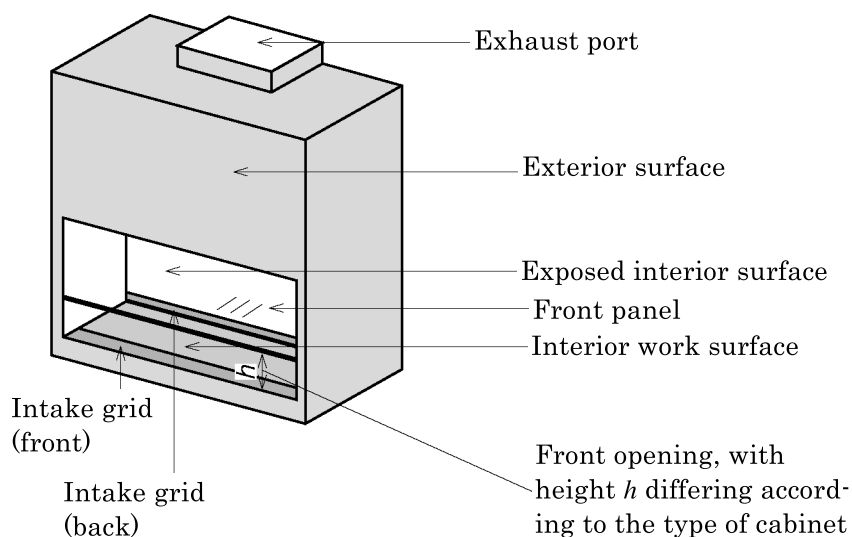


Figure 1 Parts of Class II biological safety cabinet and their names

3.9

front opening

work access opening provided at the front of the Class II biological safety cabinet (see Figure 1)

3.10

baffle board

permeable board installed for the purpose of making the downflow air uniform

3.11

interior work surface

table used for performing works (see Figure 1)

3.12

exposed interior surface

inside walls of the Class II biological safety cabinet with which the instruments, sample and the worker may come into direct contact during working (see Figure 1)

3.13

frontage

distance between the internal surfaces of the Class II biological safety cabinet

3.14

intake grid

grid which sucks air in from the work area, normally located before and behind the interior work surface

3.15

contaminated plenum

space reached by an airflow containing droplets and contaminated aerosols

3.16

indirect duct connection

duct connection where there is a gap between the Class II biological safety cabinet and the duct, and the duct is connected to the remote blower

3.17

direct duct connection

duct connection where the gap between the Class II biological safety cabinet and the duct is sealed, and the duct is connected to the remote blower

3.18

static pressure of duct connecting part

static pressure in a duct measured with a differential pressure gauge at a distance of approximately two times the duct diameter downstream from the connecting part between the cabinet and the duct when a duct is connected to the Class II biological safety cabinet

3.19

concurrent balance value (CBV) of remote blower

value used for duct design of direct duct connection and selection of a remote blower

NOTE It is used for compensating the air volume reduction due to clogging of HEPA and ULPA filters by maintaining the static pressure of the duct connecting part at zero or at a negative value.

3.20

inflow air

air which flows through the front opening into the Class II biological safety cabinet

3.21

downflow air

clean air supplied to the work area from the upper direction of the cabinet

3.22

inspection body

third-party organization provided with the capability and the system adequate for inspecting the conformity of Class II biological safety cabinet to this Standard

3.23

type inspection

inspection performed by an inspection body to judge acceptance of a model of Class II biological safety cabinet designed and manufactured by a manufacturer by testing a representative cabinet

3.24

100 % inspection

shipping inspection and site inspection of Class II biological safety cabinets

3.25

shipping inspection

inspection performed at the time of factory shipment

3.26

site inspection

inspection of Class II biological safety cabinets installed at a laboratory, etc. performed at the site of installation, immediately after installation, and at regular intervals or as required for maintenance and control purposes

3.27

average inflow velocity

average velocity of air flowing in from the front opening

3.28

average inflow velocity alternative test

alternative test of average inflow velocity approved by the inspection body

3.29

conversion factor

factor used to multiply the result of the average inflow velocity alternative test to calculate the average inflow velocity

For the variable symbol of this factor, the lower case letter “*k*” and the capital letter “*K*” are used for the value before and after approval by the inspection body, respectively.

3.30

inflow volume

volume of air which flows through the front opening into the Class II biological safety cabinet

3.31

selected air velocity

average downflow velocity and average inflow velocity approved by the inspection body
For the type inspection, it is the value proposed by the manufacturer.

3.32

polydisperse aerosol

aerosol of approximately 0.5 μm in mass median diameter (approximately 0.3 μm in particle number median diameter) specified in **JIS Z 8901** used for the penetration efficiency test of HEPA and ULPA filters

4 Symbols

Symbols used in this Standard are shown in Table 1.

Table 1 Symbols

Symbol	Definition	Unit
B	height of sinusoidal waveform (one side)	μm
c	DOP aerosol concentration when operating one Laskin nozzle at 140 kPa	$\mu\text{g/L}$
d	power of tenfold serial dilution rate	—
C_d	PAO concentration in the downstream side	$\mu\text{g/L}$
C_u	PAO concentration in the upstream side	$\mu\text{g/L}$
k	conversion factor (before approval)	—
K	conversion factor (after approval)	—
n	number of measuring points, or number of agar plates of each dilution	popint (count)
N_0	spore concentration	cfu/mL
N_i	colony count of each agar plate	count
P	penetration efficiency of HEPA and ULPA filters	—
Q_d	exhaust volume in duct	m^3/s
Q_e	exhaust volume	m^3/s
Q_f	downflow volume	m^3/s
Q_i	inflow volume	m^3/s
Q_{if}	inflow volume measured by an air flow meter installed at the front opening	m^3/s
Q_{im}	average of inflow volume	m^3/s
Q_w	exhaust volume per 1 m of frontage	m^2/s
S_b	area of the downflow volume measuring plane	m^2
S_d	duct cross-sectional area	m^2
S_e	effective exhaust port area	m^2
S_f	front opening area	m^2
V_d	average exhaust velocity in duct	m/s
V_e	average exhaust velocity	m/s
V_{em}	average of average exhaust velocity	m/s
V_f	downflow velocity of each measuring point	m/s
V_i	average inflow velocity	m/s
V_p	air velocity of each measuring point	m/s
V_q	average of air velocity of each measuring point	m/s
V_{qm}	average of opening average inflow velocity	m/s
w	spraying amount	mL
W	frontage	m
NOTE “—” indicates a unitless number.		

5 Biological safety cabinet

5.1 Classification of biological safety cabinets

Biological safety cabinets are classified into Class I, Class II and Class III according to the basic structure.

For reference, basic structures of Class I and Class III biological safety cabinets are described in Annex E.

A Class II biological safety cabinet is designed to protect the worker and the environment from contaminated aerosol produced in handling of pathogens etc., protect samples from contaminants existing in the laboratory environment, and prevent cross-contamination between samples.

5.2 Classification of Class II biological safety cabinets

5.2.1 Types of Class II biological safety cabinets

Class II biological safety cabinets (hereafter referred to as cabinets) are classified into Type A1, Type A2, Type B1 and Type B2 according to the purpose of work (see Table 2). The structures and the features of respective types are exemplified in Figure 2. Considerations for introduction and purchase of a cabinet suitable for the intended purpose are provided in Annex D.

5.2.2 Type A1 and Type A2

Type A1 and Type A2 cabinets are suitable for works handling biological materials and non-volatile hazardous materials [see Table 2, and **a)**, **d)** and **e)** of Figure 2]. These cabinets basically perform exhaust within the laboratory, but can perform exhaust to the outdoors through indirect duct connection (see 7.15) in the case of handling low concentrations (Type A1 and Type A2), or gaseous or volatile radioactive materials (Type A2) (see Table 2).

Type A1 and Type A2 cabinets shall not be used for works handling gaseous or volatile hazardous materials if the working environment of the laboratory exceeds the specified limit. For Type A1 and Type A2 cabinets, direct duct connection shall not be used.

NOTE 1 “Type A cabinet” specified in the standard prior to **JIS K 3800 : 2009** is included in Type A1 cabinet of this Standard and “Type B3 cabinet” specified in **JIS K 3800 : 2000** is included in Type A2 cabinet of this Standard.

NOTE 2 In the controlled area based on the Radiation Hazards Prevention Act, compounds having radioactive isotopes are included in hazardous material.

NOTE 3 See Annex E for details of the classic type Class II cabinets where the positive pressure contaminated plenum is in contact with the outer wall, which were developed several decades ago and described in the standard prior to **JIS K 3800 : 2009**.

5.2.3 Type B1 and Type B2

Type B1 and Type B2 cabinets are used for handling gaseous or volatile hazardous

material of the intermediate concentration which cannot be addressed by Type A1 and Type A2 cabinets using indirect duct connection, as well as for handling biological materials and non-volatile hazardous materials (see Table 2 and Figure 2). For Type B1 and Type B2 cabinets, direct duct connection shall always be used to perform exhaust to the outdoors.

Table 2 Applicable materials of respective cabinet types

Material		Cabinet type			
		Type A1	Type A2	Type B1	Type B2
Biological materials		⊙	⊙	⊙	⊙
Non-volatile hazardous materials (including radioactive materials)		⊙	⊙	⊙	⊙
Gaseous or volatile hazardous materials ^{a)}	Below the specified limit	⊙	⊙	⊙ ^{b)}	⊙
	Low concentration	○	○	⊙ ^{b)}	⊙
	Intermediate concentration	—	—	⊙ ^{b)}	⊙
	High concentration	—	—	—	—
Gaseous or volatile radioactive materials		—	○	⊙ ^{b)}	⊙
⊙: Applicable ○: Applicable if indirect duct connection is used —: Not applicable NOTE 1 It is not very likely that the concentration of gaseous or volatile hazardous material can exceed the low concentration within the normal range of use. NOTE 2 The air circulation rate (rate of downflow air which becomes the circulating air-flow) for each cabinet type is as follows. The lower the air circulation rate is, the quicker the dilution of gaseous material inside the cabinet is. — Type A1 and Type A2 : approximately 70 % — Type B1 : approximately 50 % — Type B2 : zero (0) % Notes ^{a)} The concentrations of gaseous or volatile hazardous materials which may have an adverse effect on the working environment are classified as follows. — Below the specified limit : Concentration where exhaust within the laboratory does not result in the excess of the specified limit for the working environment — Low concentration : Concentration requiring exhaust to the outdoors because exhaust within the laboratory will result in the excess of the specified limit for the working environment — Intermediate concentration : Concentration requiring exhaust to the outdoors using direct duct connection — High concentration : Concentration requiring the use of a gas mask, or concentration potentially resulting in explosion. The related regulations are provided in the Industrial Safety and Health Act (Act No. 57 of 1972), the Offensive Odor Control Act (Act No. 91 of 1971), the Air Pollution Control Act (Act No. 97 of 1968), etc. ^{b)} For Type B1 cabinet, it is desirable to handle gaseous material at the back of the work area.					

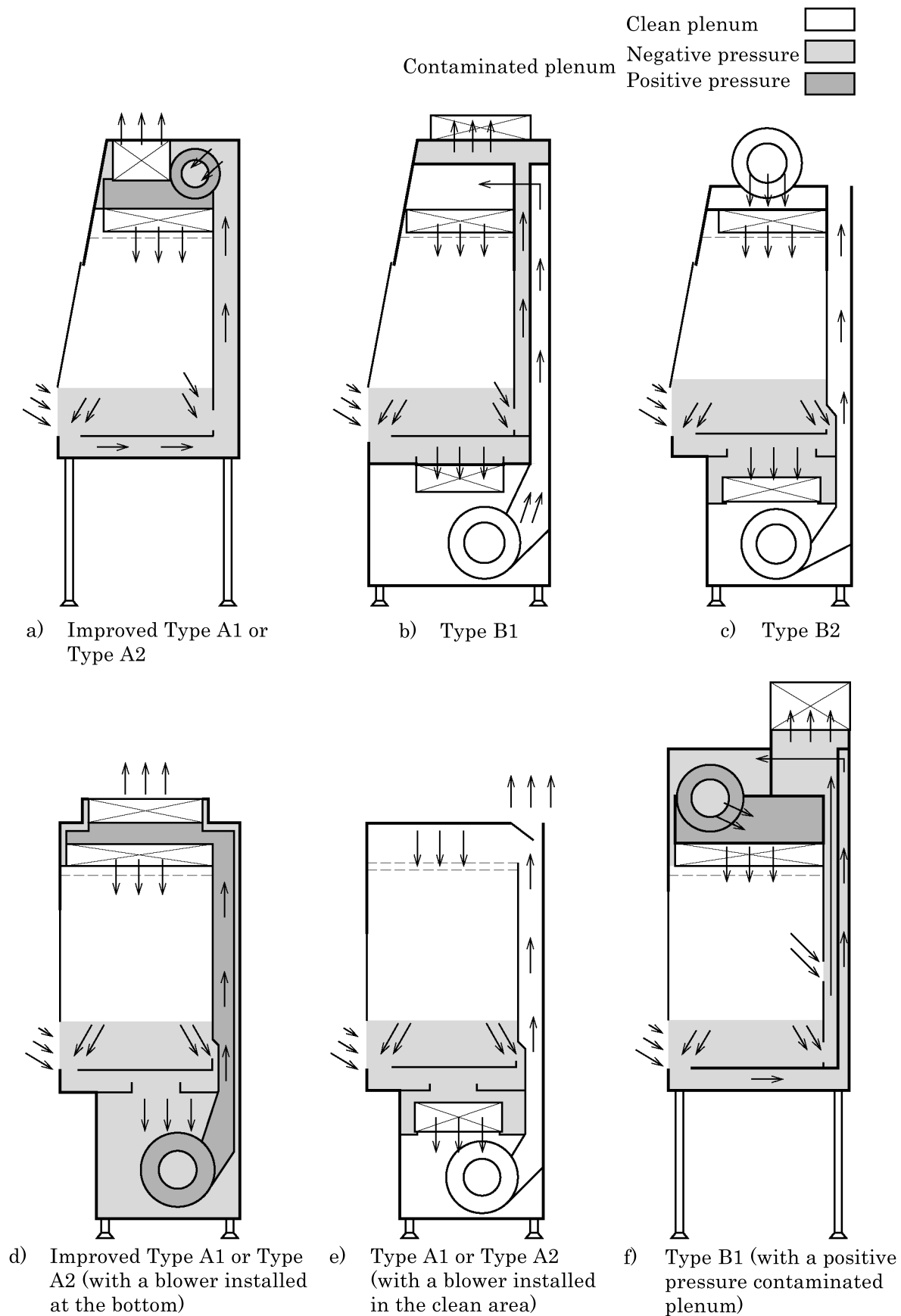


Figure 2 Examples of plenum structure and characteristics of Class II cabinets of respective types

6 Required performance

6.1 Sealing

The sealing performance shall satisfy either of the following.

- a) **Positive pressure maintenance method** In the test performed in accordance with **9.2 a)**, the drop in pressure after 30 min shall not exceed 10 %.
- b) **Soap bubble method** In the test performed in accordance with **9.2 b)**, no bubbles of soap due to leakage shall be found.

6.2 HEPA and ULPA filters

The HEPA and ULPA filters shall satisfy the following.

- a) The penetration efficiency of HEPA and ULPA filters shall satisfy either of the following.
 - 1) HEPA and ULPA filters that can be tested by scanning shall be subject to the test specified in **9.3.3.1**, and shall not have a penetration efficiency larger than 0.01 % at any point of the filter.
 - 2) HEPA and ULPA filters that cannot be tested by scanning shall be subject to the test specified in **9.3.3.2**, and shall not have a penetration efficiency larger than 0.005 % at any point during the suction of 28.3 L minimum of the sample.
- b) The separator attached to the HEPA and ULPA filters shall be flame retardant.

6.3 Blower

In the test performed according to **9.14**, the air volume of the blower shall not drop more than 25 % of the initial value when the test pressure is increased by 25 % of the initial positive pressure.

6.4 Airflow balance

6.4.1 General

The airflow balance in the cabinet shall be such that the leakage of the contaminated aerosol generated in the cabinet into the laboratory, the mixing of the aerosol existing in the laboratory into the cabinet and the turbulence of air current on the interior work surface are all sufficiently small.

In 100 % inspection, cabinets are considered to meet this airflow balance if they satisfy the average downflow velocity in **6.5.2** when tested in accordance with **9.5**, and the average inflow velocity in **6.5.3** when tested in accordance with **9.6**.

6.4.2 Personal safety

In the test performed according to **9.4.3**, all of the following requirements shall be met.

- a) The total count of colonies recovered from the collection suspension of all 6 impingers shall not exceed 10 per test.

NOTE The colony refers to the colony of bacteria cultured on a plate and

originates from 1 live bacterium.

- b) The total count of colonies obtained from the 2 slit-type samplers during their operation shall not exceed 5 per test.
- c) The colony count in the positive reference agar plates shall be 300 or more.

6.4.3 Sample protection

In the test performed according to **9.4.4**, all of the following requirements shall be met.

- a) The total count of colonies collected in the tested agar plate shall not exceed 5 per test.
- b) The colony count in the positive reference agar plates shall be 300 or more.

6.4.4 Cross-contamination prevention between samples

In the test performed according to **9.4.5**, the total count of colonies collected in the agar plates, which are positioned such that their centre is at a distance of not less than 360 mm from the side surface of the work space of the cabinet, shall not exceed 2 per test for both the right side test and left side test.

6.5 Air velocity and air volume

6.5.1 Air velocity allowable range

The allowable range of the average downflow velocity and average inflow velocity shall be as follows.

- a) **Air velocity allowable range 1** It shall be ± 0.015 m/s of the selected air velocity and used for the type inspection and evaluation of the average inflow velocity alternative test.
- b) **Air velocity allowable range 2** It shall be ± 0.025 m/s of the selected air velocity and used for the 100 % inspection.

6.5.2 Average downflow velocity

In the test performed according to **9.5**, the measured average downflow velocity shall be as follows.

- a) It shall be within the air velocity allowable range specified in **6.5.1**.
- b) Individual point readings shall be within ± 0.08 m/s from the average downflow velocity when the average downflow velocity is 0.40 m/s or under, or shall be within ± 20 % of the average downflow velocity when the average downflow velocity is above 0.40 m/s.

6.5.3 Average inflow velocity

In the test performed according to **9.6**, the measured average inflow velocity shall be as follows.

- a) For Type A1 cabinets, it shall be 0.40 m/s or greater, and within the air velocity allowable range specified in **6.5.1**

- b) For Type A2, Type B1 and Type B2 cabinets, it shall be 0.50 m/s or greater, and within the air velocity allowable range specified in **6.5.1**.

6.5.4 Exhaust volume per 1 m of frontage

The exhaust volume per 1 m of frontage determined according to **9.7** shall satisfy either of the following.

- a) Not less than 0.066 m²/s for Type A1 cabinets.
- b) Not less than 0.100 m²/s for Type A2, Type B1 and Type B2 cabinets.

6.6 Airflow direction

In the test performed according to **9.8**, the airflow direction shall be as follows.

- a) When the test in **9.8 b) 1)** is carried out, the downward flow shall be such that the smoke shows smooth downward flow with no dead spots or reflux (upward flow).
- b) When the test in **9.8 b) 2)** is carried out, the airflow inside the front panel shall be such that the smoke shows smooth downward flow with no dead spots or reflux (upward flow), and no smoke escapes from the cabinet.
- c) When the test in **9.8 b) 3)** is carried out, the inflow air around the front opening shall be such that no smoke is refluxed out of the cabinet once drawn in and no smoke penetrates into the work space.
- d) When the test in **9.8 b) 4)** is carried out, the tightness of the movable front panel shall be such that no smoke escapes from the cabinet through the upper edge of the front panel or through the side edges and there is no inward airflow which may cause disturbance in the downflow air.

6.7 Noise level

In the test performed according to **9.9**, the measured noise level shall not exceed 67 dB(A).

6.8 Illuminance

In the test performed according to **9.10**, individual readings shall be 430 lx or more, and the average illuminance shall be 650 lx or more. The dark illuminance shall be average 110 lx ± 50 lx. Other lighting intensity requirement may be applied upon agreement between the interested parties.

6.9 Vibration displacement

In the test performed according to **9.11**, the vibration displacement in the three directions (X, Y, Z) of the interior work surface shall be not more than 5 µm RMS.

6.10 Stability and strength

6.10.1 Overturning

In the test performed according to **9.12.1**, the cabinet shall not tumble over to the front or rear direction.

6.10.2 Distortion

In the test performed according to **9.12.2**, the forward or lateral movement of the top front edge of the cabinet shall not be more than 1.6 mm.

6.10.3 Deflection of interior work surface

In the test performed according to **9.12.3**, the interior work surface shall be free from any permanent deflection exceeding 0.1 mm.

6.10.4 Tipping

In the test performed according to **9.12.4**, the rear leg of the cabinet shall not be lifted off the floor by more than 1.6 mm.

6.11 Water leakage of sink

In the test performed according to **9.13**, the sink shall be free from water leakage.

6.12 Stability of air velocity against impact

In the test performed according to **9.15**, the stability of the air velocity against an impact shall be as follows.

- a) The change in the average inflow velocity and average downflow velocity at representative points before and after an impact shall be ± 0.025 m/s.
- b) The cabinet shall not have any visible damage from the impact.

6.13 Insulation resistance

In the test performed according to **9.16**, the measured insulation resistance shall be not less than 1 M Ω .

6.14 Withstand voltage

In the test performed according to **9.17**, no abnormality shall be observed for the duration of 1 min.

6.15 Static pressure of duct connecting part

In the test performed according to **9.18.2**, the static pressure of the duct connecting part shall be zero (0) or negative.

6.16 Performance of remote blower

The performance of remote blower shall satisfy the following.

- a) **Remote blower used for indirect duct connection** In the test performed according to **9.18.3 a)**, the smoke from the smoke canister shall not leak through the gap between the cabinet and the duct.

NOTE 1 The test smoke leaking through the gap indicates that gaseous or volatile hazardous materials in the cabinet will leak out into the laboratory when the cabinet is in use.

NOTE 2 The exhaust capacity of the remote blower used for indirect duct connection is often required to be nearly 150 % of the cabinet exhaust volume.

- b) **Remote blower used for direct duct connection** In the test performed according to

9.18.3 b), the concurrent balance value (CBV) of the remote blower used for direct duct connection shall be as follows.

- 1) CBV of the remote blower for Type B1 cabinet shall be not less than 75 Pa.
- 2) CBV of the remote blower for Type B2 cabinet shall be not less than 175 Pa.

6.17 Gap between cabinet and duct

In the test performed according to **9.18.4**, the average inflow velocity measured with the remote blower stopped shall not drop from the selected air velocity by more than 0.05 m/s.

6.18 Alarm and interlock of duct

The alarm and interlock of the duct shall satisfy the following.

- a) **Indirect duct connection** In the test performed according to **9.18.5 a)** as part of the site inspection (immediately after installation, and for maintenance and control), the alarm shall activate within 15 s, and the blower shall continue operation after the activation of the alarm.
- b) **Direct duct connection** In the test performed according to **9.18.5 b)** as part of the site inspection (immediately after installation, and for maintenance and control), the alarm shall activate within 15 s, and the blower shall stop and the remote blower shall continue operation after the activation of the alarm.

6.19 Installation situation around exhaust port

In the test performed according to **9.18.1** as part of the site inspection immediately after installation, the exchange of HEPA and ULPA filters shall be possible without moving the cabinet.

7 Structure of cabinet

7.1 General

The cabinet has a front opening and an exhaust port (see Figure 1), and the inflow air from the front opening prevents contaminated aerosol from leaking to the outside. At the same time, the clean airflow filtered through the HEPA and ULPA filters is blown into the work area unidirectionally from the upper to downward direction. The downflow air is distributed just above the interior work surface, and sucked into the intake grid (see Figure 1) provided before and behind the interior work surface to minimize the cross-contamination between samples due to a turbulent flow. The exhaust air of the cabinet is filtered through the HEPA and ULPA filters. The cabinet shall be designed to ensure personal safety, sample protection and prevention of cross-contamination between samples, as well as to allow easy cleaning and decontamination. The exposed interior surface that will be exposed during normal works, site inspection and decontamination works shall be free from sharp protrusions, burrs, etc. For the classification of cabinets, see Figure2.

7.2 Considerations for cleaning and decontamination

The considerations for cleaning and decontamination shall be as follows.

The cabinet, or the parts of the cabinet exposed to a contaminated area (e.g. HEPA and ULPA filters) shall be decontaminated before disposal. The decontaminated cabinet or its parts may be disposed of as normal industrial waste.

- a) Any surface which may be contaminated by a sample, its airborne droplets, etc. shall be easy to clean without the use of a tool.
- b) Performing decontamination (see Annex B) with formaldehyde or other gas shall be possible without moving the cabinet.
- c) The cabinet shall be sealable by closing the front opening and exhaust port with a metal plate, plastic sheet, duct tape, etc.
- d) A sealed valve for gas introduction, if used for decontamination, shall be provided at the clean side of the HEPA and ULPA filters.

7.3 Corners of interior work surface and work space

The corners formed by planes at an angle of less than 110° of the interior work surfaces and the work space shall be rounded, smooth and even. An internal corner formed by the intersection of two planes shall have a minimum radius of 3 mm, and that formed by the intersection of three planes shall have a minimum radius of 6 mm (see Figure 3). The corners shall be continuous, where possible, so that they are not prone to accumulation of dust.

Hard solder may be used as a filler for joints on which a load is not applied structurally.

Unit: mm

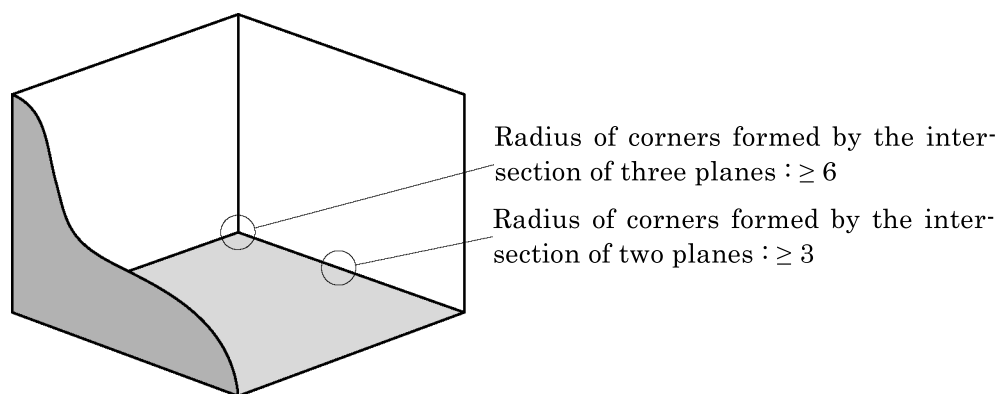


Figure 3 Corners of interior work surface and work space

7.4 Outer corners

All the outer corners shall be smoothly finished so that they do not become an obstacle to works, cleaning and decontamination.

7.5 Internal joint of contaminated plenum

The joint of the sink and the plenum shall be as follows. Other joints than this shall be free from gaps larger than 0.8 mm.

- The joint of the sink and the plenum shall be sealed so that it will be free from leakage when subjected to 500 Pa pressure, and shall be finished smoothly.
- The joint shall be designed to prevent collection of dust.
- The joint with a possibility of being exposed to gaseous or toxic material shall be sealed and finished smoothly.

7.6 Welding

The welds shall be smooth. Solder may be used for parts on which a load is not applied structurally.

7.7 Use of screws

When using screws, the following shall be followed.

- Unless absolutely necessary, the projecting screws shall not be used for the interior work surface or the exposed interior surface (see Figure 1).
- The structure shall be such that there is minimum unevenness.

WARNING A projecting screw may come into contact with the arm or hand of the worker, or an instrument, and increase the danger of work.

7.8 Reinforcements

The reinforcements not thoroughly embedded in the wall shall be structured to allow easy wiping with a clean and dry cloth, and shall be as follows.

- Reinforcements provided at places not subject to gas decontamination shall have their cut ends enclosed.
- The joint of the horizontal reinforcement of the contaminated plenum shall be designed to prevent collection of dust.

7.9 Installation of blower and filter

The blower and filter shall be structured to be accessible for maintenance and checks from the front face of the cabinet.

7.10 Contaminated plenum

When there are negative pressure plenums or positive pressure contaminated plenums, all the contaminated plenums shall be structurally surrounded by negative pressure plenums.

NOTE For the cabinet of the type in which the positive pressure contaminated plenums are not surrounded by negative pressure plenums, see Annex E.

7.11 Electrical components and wiring

Electrical components and wiring shall satisfy the following.

- a) No electrical components or wiring, except for ones that are essential for the func-

tion of the cabinet, shall be installed in the contaminated plenums.

- b) All wiring penetrations of the contaminated plenums shall be structured such that they will withstand 500 Pa pressure difference without leakage.
- c) All the outlet circuits shall be provided with fuses or circuit breakers independently of the blower circuit. The outlet provided in the work space shall be of drip proof type. The switch shall be provided at the outside of the cabinet.
- d) The distribution line of single phase shall be of three cores. The earthing conductor shall be connected to the outer jacketing lagging. The electric diagram shall be fixed at the outside of the cabinet plenum for display. The information necessary for power supply such as rated voltage and power consumption shall be given in a specification name plate or instruction manual.
- e) The illumination lamps, sockets, switches and stabilizers shall be installed outside the contaminated plenums in such a way that they are easily accessible for maintenance and checks. The illumination lamps shall be located at positions where the operator's eyes will not be exposed to direct radiation or reflection.
- f) When using sterilization lamps, the illumination lamps and sterilization lamps shall not be turned on at the same time.

7.12 Motor

The motor shall satisfy the following.

- The motor shall be equipped with the overload protection function. Under the normal temperature environment ($23\text{ }^{\circ}\text{C} \pm 10\text{ }^{\circ}\text{C}$) and at the time of maximum loading, the overload protection device for the motor overload protection circuit shall not activate even if 115 % of the rated voltage is reached.
- The overload circuit of the outlet of the motor and lighting, and that of the power supply outlet inside the cabinet shall have different overload circuits.
- If a motor with rated output of 0.75 kW or more is used for the blower and the remote blower, it shall be in accordance with **JIS C 4034-30**.

7.13 Static pressure taps

The cabinet to be supplied for the type inspection shall be equipped with static pressure taps (see Figure 4) for measuring the static pressure of the blower. The positions of the static pressure taps provided in the downflow side and in the inflow side shall be as follows.

- a) The static pressure tap in the downflow side shall be located at the upstream side of HEPA and ULPA filters (see Figure 5), at a position where it is not directly exposed to the downflow air from the blower, and where the pressure measurements are not affected by dynamic pressure.
- b) The static pressure tap in the inflow side shall be located at the centre of the air inlet of the blower, at a distance equal to half the air inlet diameter from the blower air inlet (see Figure 6).

- c) When the blower has two or more air inlets, some of the measuring ports may be connected.
- d) The position of the measuring port shall be such that the pressure measurements are not affected by dynamic pressure.

Unit: mm

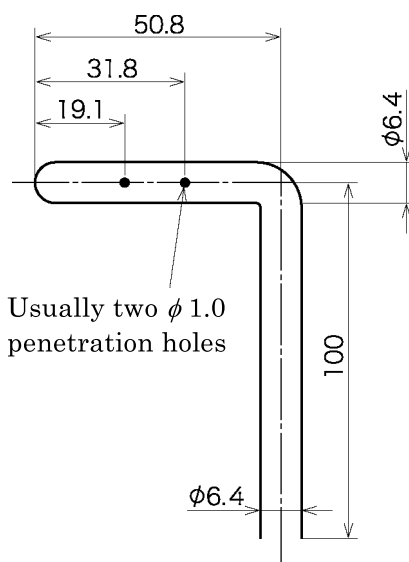


Figure 4 Static pressure taps (example)

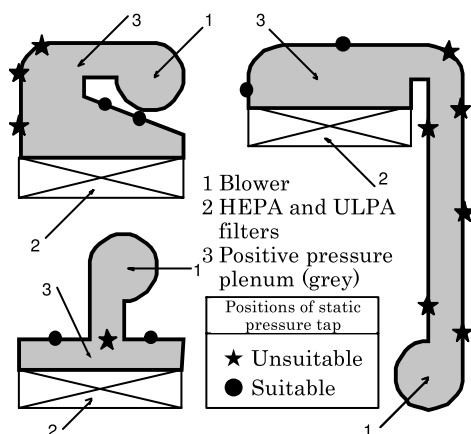


Figure 5 Position of static pressure tap at the downflow side

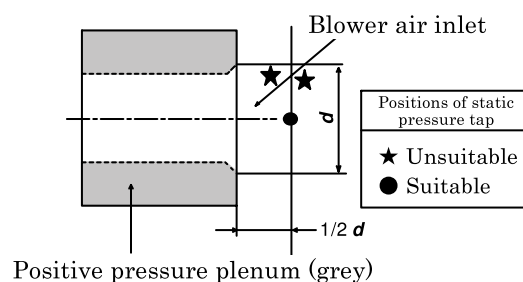


Figure 6 Position of static pressure tap at the inflow side

7.14 Speed regulator

The speed regulator shall satisfy the following.

- a) **Function** The speed regulator shall be capable of regulating the speed of a blower to ensure supply of a specified air volume, fixing the speed at an appropriate level,

and making the change in air volume due to the change of input voltage small. Simple speed regulators using TRIAC or DIAC with a large change in air volume due to change of input voltage shall not be used.

- b) **Location** The speed regulator shall not protrude through the outer surface of the cabinet, and shall be mounted inside the panel with a lid. A display of alert for preventing erroneous operations shall be given.

7.15 Indirect duct connection

The indirect duct connection used for Type A1 and Type A2 cabinets shall be as follows.

- a) **Remote blower** The remote blower shall be installed at the end of the duct.
- b) **Damper for exhaust volume adjustment** For a damper for exhaust volume adjustment, if used, a message such as “DO NOT TOUCH !” shall be displayed to prevent erroneous operations.
- c) **Removable duct** A removable duct which enables the scanning test of exhaust HEPA and ULPA filters shall be provided.
- d) **Alarm and interlock of duct** The alarm and interlock specified in 7.17 shall be provided.
- e) **Reuse of exhaust air** Exhaust air shall not be reused.

7.16 Direct duct connection

The direct duct connection used for Type B1 and Type B2 cabinets shall be as follows.

- a) **Duct** Each cabinet shall be provided with its own duct and remote blower.
- b) **Remote blower** The remote blower shall be installed at the end of the duct.
- c) **Damper for exhaust volume adjustment** If a damper for exhaust volume adjustment is used, a message such as “DO NOT TOUCH !” shall be displayed to prevent erroneous operations.
- c) **Removable duct** For the direct duct connection of a Type B1 cabinet, a removable duct which enables the scanning test of exhaust HEPA and ULPA filters shall be provided downstream of the filter. For a Type B2 cabinet, the removable duct is not necessary.
- e) **Alarm and interlock of duct** The alarm and interlock specified in 7.17 shall be provided.
- f) **Reuse of exhaust air** Exhaust air shall not be reused.

7.17 Alarm and interlock of duct

The alarm and interlock of the duct shall satisfy the following.

- a) **Type of alarm** The alarm for abnormality of the duct shall be auditory and visual.
- b) **Activation of alarm** The alarm shall also activate when the blower has stopped.

- c) **Interlock of blower** The blower shall be interlocked so that it will start after the exhaust volume of the remote blower has stabilized.

7.18 Alarm for front panel height position

Cabinets with a vertically sliding front panel shall be provided with an alarm function designed to issue an auditory and visual alarm when it has detected an upward or downward shift of the front panel height of 25 mm or more from the specified height position of the front opening. The alarm may be designed to stop when the front panel is pushed down to the closing position.

7.19 Position of HEPA and ULPA filters

The position of HEPA and ULPA filters shall be as follows.

It is desirable to provide a differential pressure gauge to monitor the pressure loss of HEPA and ULPA filters.

- a) **Mounting position of HEPA and ULPA filters** The HEPA and ULPA filters shall be mounted at a position in the cabinet that will facilitate detachment, testing and sealing.
- b) **Structure of HEPA and ULPA filters case** The HEPA and ULPA filters case shall be positioned such that the airflow will not bypass the filters.
- c) **Upstream aerosol concentration sampling port** One or more upstream aerosol sampling port(s) shall be installed at the upstream side of HEPA and ULPA filters. The sampling part shall be located at the downflow side of the blower where there is sufficient mixing of aerosol. Since this part belongs to a positive pressure contaminated area, sufficient care shall be taken so that the leakage from the aerosol sampling port does not take place. A marking such as “Contamination possible. Decontaminate before opening.” shall be given on the stop cock of the upstream aerosol sampling port installed on the surface of the cabinet.
- d) **Grid for protection of HEPA and ULPA filters for exhaust** The grid for protecting HEPA and ULPA filters from damage due to falling objects, etc. should be provided at the exhaust side of the HEPA and ULPA filters of the cabinet. The alarm capable of detecting the defects related to exhaust volume may be provided.

7.20 Sink

The sink shall be 4 L or more in capacity, and structured to allow easy cleaning. The drain outlet, if provided, shall be capable of being tightly sealed and suitable for connection of a hose, etc.

7.21 Taps of gas, vacuum piping, etc.

When fitting the taps of gas, vacuum piping, etc., the taps shall be located at a more backward position than the centre between both sides of the interior exposed surfaces and the end of its piping shall be suitable for connection to a hose, etc.

7.22 Legs

The legs of the cabinet shall be sturdy and capable of supporting the cabinet stably.

They shall be of a simple and smooth structure so that they are easy to clean, and will not collect dust easily. The material used for the legs shall be such that they will not damage the surface of the floor.

7.23 Installation

The installation shall be in accordance with either of the following so that wiping the cabinet with a clean dry cloth is easy.

- a) The distance between the floor and the lowest surface of the cabinet shall be 80 mm or more.
- b) Where the structure below the interior work surface consists of two front legs and a back panel, or of a back panel and side panels with a thickness of 50 mm or less, the distance between the floor and the lowest surface of the cabinet shall be 50 mm or more.
- c) Where **a)** or **b)** is not applicable, an adhesive sealant shall be applied on the floor or the foundation.

7.24 Height and depth

The height and depth of the cabinet excluding the removable parts such as the container of illumination lamp, the storing box of exhaust filter, protection device and adjustable legs shall be not greater than 2.0 m × 0.9 m.

7.25 Parts

Parts of the cabinet not liable to adversely affect the cabinet performance may be exchanged with new ones of the same type. For any parts recognized to give an adverse influence, a review by an inspection body shall be requested.

8 Materials

8.1 Basic matters

The materials of the cabinet shall be flame retardant, and resistant to corrosion, abrasion and moisture given by gases, liquids, cleaning agents and decontaminating agents.

8.2 Exposed interior surface

The material of the exposed interior surface (excluding front panel) shall be 300 series stainless steel specified in **JIS G 4304** or **JIS G 4305**, or material at least equivalent to these in performance, and shall be smooth in its surface.

8.3 Exterior surfaces

The material of the exterior surfaces shall have an excellent abrasion and corrosion resistance, be resistant to cracking, and smooth in its surface.

8.4 Front panel

The material of the front panel shall be transparent, flame retardant, resistant to breaking and shall not change in quality due to disinfection, decontamination or expo-

sure to irradiation of a sterilizing lamp.

If glass is used for the front panel, it shall be a laminated glass or tempered glass with a thickness of 5 mm or over.

8.5 Gasket and sealants

The material of the gasket and sealant shall be non-hardening and resistant to change in quality due to exposure to gases, liquids, etc. The gasket and sealant shall not be used to supplement the structural strength of the cabinet.

8.6 Sound dampening materials

The sound dampening materials shall be non-hardening and not porous. They shall not be used for contaminated plenums.

9 Test methods

9.1 Test environment

Recommended test environment conditions are temperature of $23\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and humidity of $50\% \pm 20\%$.

9.2 Sealing

The sealing test shall be in accordance with one of the following.

As required, all the removable panels shall be taken off the cabinet prior to the test.

a) Positive pressure maintenance method, as follows.

- 1) Seal the front opening and the exhaust port of the cabinet with a metal plate, plastic sheet, duct tape, etc., and attach necessary measuring instruments such as a differential pressure gauge. Pressurize the inside of the cabinet to 500 Pa to 600 Pa by using compressed air and then close the compressed air supply valve. After 30 min, measure the reduction in pressure. A differential pressure gauge used for this purpose shall be capable of detecting a change of 5 Pa.

In this test, attention shall be paid to the change in pressure due to temperature change.

- 2) For the test results for the inspection report [see 10.4 j) 5)], indicate the initial pressure, final pressure and reduction in pressure.

b) Soap bubble method, as follows.

- 1) Seal the front opening and the exhaust port of the cabinet with a metal plate, plastic sheet, duct tape, etc. With the inside of the cabinet maintained under the pressure of 500 Pa to 600 Pa by using compressed air, brush or spray soapy water or commercially available leakage detecting test agent on all positions associated with possibility of leakage, such as all the welds or joints constituting the exterior surfaces of the cabinet plenums, to examine if there is any generation of bubbles. The joints of wire and pipe penetrating the plenum and exterior surfaces of the plenums shall be inspected with special attention. The soapy water should be prepared by diluting one part of neutral detergents with ten parts of water. At-

tention should be paid that big leaks may be missed due to bursting of bubbles.

- 2) For the test results for the inspection report [see 10.4 j) 5)], indicate the pressure range maintained during the test, measured results, positions where leakage was observed, and if any leakage was observed, the method of repair.

9.3 Penetration efficiency of HEPA and ULPA filters

9.3.1 Summary

At the time of the type inspection, shipping inspection and site inspection, the filter media, assembly and appropriate mounting accuracy of HEPA and ULPA filters are tested to ensure that the penetration efficiency has not deteriorated at any part of the filters.

9.3.2 Apparatus and aerosol

The apparatus and aerosol used for the penetration efficiency test of HEPA and ULPA filters shall be as follows.

- a) **Polydisperse aerosol generator**, as shown in Figure 7, and equipped with a Laskin nozzle (see Figure 8) and a pressure gauge specified in **JIS B 7505-1** capable of measuring 0 kPa to 550 kPa with an accuracy of 7 kPa.

NOTE 1 Approximately one Laskin nozzle is required per air volume of 0.064 m³/s (3.8 m³/min, 230 m³/h).

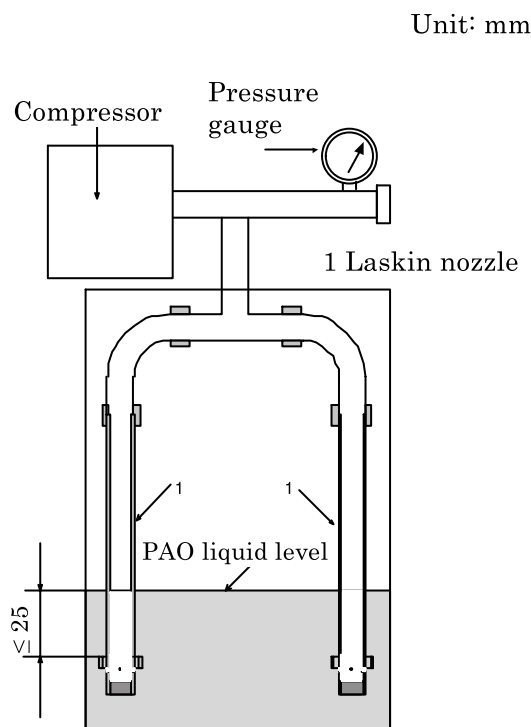


Figure 7 Polydisperse aerosol generator

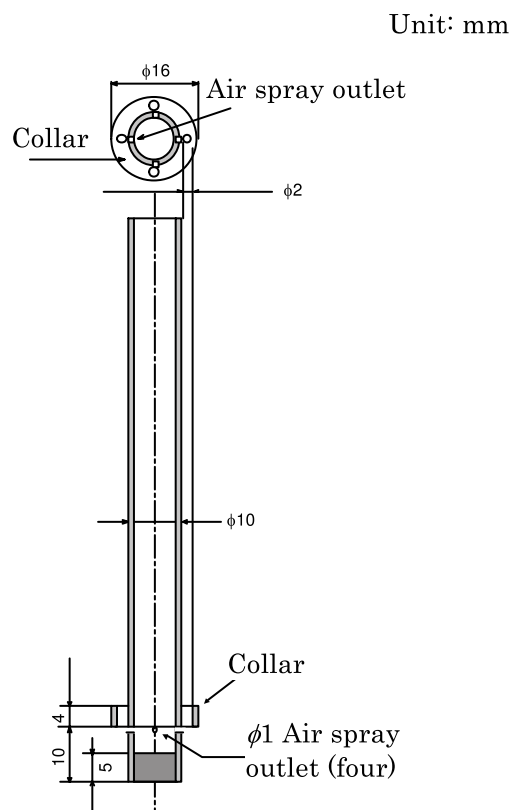


Figure 8 Laskin nozzle

- b) **Polydisperse aerosol** Polyalpha olefin (PAO) aerosol generated by the polydisperse aerosol generator, or aerosol with equivalent performance. Dioctylphthalate (DOP) was previously specified as a standard aerosol to be used, but has been replaced with PAO due to its carcinogenic and hormone-disrupting nature.
- c) **Aerosol photometer**, specified in **JIS B 9917-3**, and satisfying all the following conditions.
 - 1) It shall have a linear scale or a logarithmic scale.
 - 2) The cross-sectional area of the detector tube suction inlet shall be 11 cm² maximum and the short side of the rectangular suction inlet shall be 13 mm minimum.

When there is no aerosol photometer handling standard, the aerosol photometer shall be calibrated in accordance with **IEST RP-CC-013**.

NOTE 2 When the face velocity of HEPA and ULPA filters is 1.00 m/s or 0.43 m/s, the probe cross-sectional area at which the aerosol photometer of a suction amount of 28.3 L/min performs isokinetic sampling is 4.7 cm² (24.5 mm in diameter) or 11 cm² (37.4 mm in diameter), respectively.

- 3) It shall be capable of detecting polydisperse PAO particles with a sensitivity of 1×10^{-3} µg/L or finer at the suction amount of 28.3 L/min or more, and measuring concentrations up to a maximum of 80 µg/L to 120 µg/L. It shall be capable of detecting the concentration in the downstream side of 0.001 % when adjusted to the 100 % concentration in the upstream side.

9.3.3 Test procedure

9.3.3.1 HEPA and ULPA filters that can be tested by scanning (scanning test)

The penetration efficiency test of HEPA and ULPA filters that can be tested by scanning shall be performed according to the following procedure.

- a) When there is biological contamination in the upstream side, perform decontamination treatment (see Annex B).
- b) When there is a connection duct, remove the connecting part between the cabinet and the duct.
- c) Obtain the average downflow velocity and average inflow velocity as specified in **9.5** and **9.6**, and check that both are within Air velocity allowable range 1 for the type inspection, and within Air velocity allowable range 2 for the 100 % inspection.
- d) Remove the baffle board and protection plate in the downstream side of HEPA and ULPA filters, if provided.
- e) Supply polydisperse aerosol to the upstream side of the HEPA and ULPA filters according to the following conditions.
 - 1) Operate the polydisperse aerosol generator. The height of the PAO liquid level in the polydisperse aerosol generator shall not exceed 25 mm above the air spray outlet of the Laskin nozzle.