

DRAFT International Standard

# **ISO/DIS 18706**

## ISO/TC 304

Secretariat: ANSI

Voting begins on: 2024-10-10

Voting terminates on: 2025-01-02

ICS: 11.020.01

Healthcare organization

specimen collection

management – Pandemic response

quality evaluation of test booth for

(respiratory) — Functions and

This document is circulated as received from the committee secretariat.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

© ISO 2024



## **COPYRIGHT PROTECTED DOCUMENT**

#### © ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Email: copyright@iso.org Website: <u>www.iso.org</u> Published in Switzerland

#### Contents Foreword Introduction v 1 Scope 1 2 Normative references \_\_\_\_\_1 3 Terms and definitions 1 4 Negative pressure booth 3 4.1 Principle \_\_\_\_\_ 3 4.2 Structure 3 421 General 3 4.2.2 Main body..... .3 4.2.3 Filtration Glove and work shelf 4.2.4 4 4.2.5 Control unit .5 4.2.6 Option for outdoor usage..... .5 4.3 Function 5 4.3.1 General .5 4.3.2 HEPA filter leak .5 4.3.3 Noise level .5 4.3.4 Light intensity..... .5 4.3.5 Differential pressure .5 4.3.6 Air velocity..... .6 Positive pressure booth 5 6 5.1Principle ..... .6 5.2 Structure .6 5.2.1 General .6 5.2.2 Main body..... .7 5.2.3 Filtration 7 5.2.4 Glove and work shelf..... .8 5.2.5 Control unit .8 5.2.6 Option for outdoor usage 8 5.3 Function 8 5.3.1 General .8 5.3.2 HEPA filter leak 8 5.3.3 Noise level .8 5.3.4 Lighting intensity 9 5.3.5 Differential pressure 9 5.3.6 Annex A (normative) Performance Evaluation 10 Bibliography 17

#### Page

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

This document was prepared by Technical Committee ISO/TC 304, Healthcare organization management.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <u>www.iso.org/members.html</u>.

## Introduction

Globally, as the movement of population have been active, infectious diseases that have occurred locally have spread throughout the world and are now becoming a pandemic.

Over the past 20 years, infectious diseases such as Severe Acute Respiratory Syndrome (SARS, in 2002), H1N1 Influenza (H1N1, in 2009), and Middle East Respiratory Syndrome (MERS, in 2012) appear to be surfacing with increased intensity and shorter cycle times. Experts are concerned that occurrence of disease continues to increase and the cycle tends to be shorter.

When an infectious disease spreads on a large scale such as pandemic, if screening treatment is carried out inside a hospital, hospital workers, treatment, inpatients, and patient caregivers are exposed to the risk of infection. To reduce the risk of such cross-infection, sample collection methods such as drive-through screening station (DTSS) and walk-through screening station (WTSS) are being developed.

The specimen collection booth is a facility that physically separates medical staff and walking visitors in WTSS to reduce the risk of cross-infection and enable quick testing.

This standard considered structural elements, functions, and evaluation methods to be equipped for the safe use of a specimen collection booth to quickly collect samples from suspected respiratory diseases.

## Healthcare organization management — Pandemic response (respiratory) — Functions and quality evaluation of test booth for specimen collection

## 1 Scope

This document specifies the functions and quality evaluation of specimen collection booth as part of pandemic response management by respiratory diseases.

NOTE COVID-19 is an example of a disease for which such a specimen collection booth is developed.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5472, Healthcare organization management — Pandemic response (respiratory) — Walk-through screening station

## 3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <u>https://www.iso.org/obp</u>
- IEC Electropedia: available at <u>https://www.electropedia.org/</u>

#### 3.1

#### air change rate

rate expressing number of air changes per unit of time and calculated by dividing the volume of air delivered in the unit of time by the volume of the cleanroom or clean zone

[SOURCE: ISO 14644-3:2019, 3.4.1]

#### 3.2

#### chemical resistance

properties of substances that retain their original surface properties under conditions of prolonged contact with cleaning compounds, decontamination agents and under normal environmental conditions of use

#### 3.3

#### differential pressure

difference in absolute (static) pressure between two points in a system

Note 1 to entry: Resistance to air flow is measured in Pa.

[SOURCE: ISO 29464:2017, 3.1.36]

## 3.4

downstream

direction to where the air flow discharges

[SOURCE: ISO 5801:2017, 3.4]

#### 3.5

#### high efficiency particulate air filter HEPA filter

retentive matrix having a minimum particle-collection efficiency of 99,97 % (that is, a maximum particle penetration of 0,03 % for 0,3  $\mu$ m particles)

[SOURCE: ISO 13408-1:2008, 3.23]

#### 3.6

#### negative pressure booth

a specimen collection booth with internal pressure less than that of the ambient atmosphere to allow the outside air into the booth

#### 3.7

**pandemic** worldwide spread of a disease

[SOURCE: ISO/PAS 45005:2020, 3.5]

3.8

## personal protective equipment PPE

device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards

[SOURCE: ISO 15384:2018, 3.12]

#### 3.9

#### positive pressure booth

specimen collection booth with internal pressure greater than that of the ambient atmosphere

#### 3.10

pre-filter

air filter fitted upstream of another filter to reduce the challenge on that filter

[SOURCE: ISO 14644-16:2019, 3.1.6]

#### 3.11

#### specimen collection booth

facility for specimen collection which protects healthcare workers and test subject

#### 3.12

upstream

direction from where the air flow comes

[SOURCE: ISO 5801:2017, 3.3]

#### 3.13

## walk-through screening station WTSS

screening station with disinfected, single or multiple, mobile or fixed booths with negative, positive or an adaptable pressure which enables minimized consumption of personal protective equipment

[SOURCE: ISO 5472:2022, 3.14]

## 4 Negative pressure booth

#### 4.1 Principle

A test subject (the person being sampled) goes inside a negative pressure booth while healthcare worker stays outside. The internal negative pressure is maintained to prevent cross infection between the test subject and healthcare worker as well as between the test subjects.

It requires time to disinfect and ventilate inside of the booth after each sampling. Disinfection and ventilation time are dealt with in ISO 5472:2022, 6.2.5 and 6.2.6. Healthcare workers should confirm whether the booth is operated properly before use.



Figure 1 — A Front and side view of negative pressure booth

#### 4.2 Structure

#### 4.2.1 General

Negative pressure booth shall be designed and constructed to keep potentially harmful particles within the booth by preventing the internal air from leaving the booth, operate in a safe manner, minimize contamination and be capable of being cleaned and decontaminated.

Materials of negative pressure booth shall withstand normal abrasion, corrosive action of gases or liquids, cleaning compounds, and disinfectant solution. Exposed burrs and sharp edges shall be eliminated from surfaces of the negative pressure booth.

#### 4.2.2 Main body

#### 4.2.2.1 Wall

The interior surface of the booth shall be readily accessible and easily cleanable as assembled or when removed.

#### 4.2.2.2 Glove wall

The glove wall has the glove port towards the inside of the negative pressure booth. If there is the window, the window shall be optically clear and not adversely affected by accepted cleaning methods and disinfectant solution. The materials of the window can be laminated glass, tempered glass, safety plastic, or equivalent.

#### 4.2.2.3 Frame

The frame of the negative pressure booth is the skeleton supporting the booth structure.

#### 4.2.2.4 Door

The door shall be fit properly and closed completely. Horizontal sliding doors shall not be used for the booth. Handles shall be designed and installed to eliminate sharp edges or unnecessary projections.

#### 4.2.3 Filtration

#### 4.2.3.1 Fan module

Ventilation part for sending purified air through a filter from the negative pressure booth to the outside and prevents cross-infection. Fan module shall be variable speed and shall have controls that can be secured. To maintain the airstream effectively, there may be a supply air inlet. If there is a supply air inlet, its location and the exhaust air outlet should be nearly opposite each other.

#### 4.2.3.2 Pre-filter

Pre-filter is a component that filters relatively large dust with a particle size of 50  $\mu m$  or more, primarily preventing intrusion of various harmful substances.

#### 4.2.3.3 HEPA filter

HEPA filters for the booth shall conform to the materials, construction and aerosol efficiency requirements. Refer to ISO 29463-1 and other related documents for details of requirements for HEPA filters. Receipt of HEPA filters shall be accompanied by a supplier's certificate that indicates the filter has an efficiency of not less than 99,97 % for the retention of 0,3  $\mu$ m or larger particles. The HEPA filter shall be leak tight when it is installed on the booth.

#### 4.2.3.4 Sampling ports

For performing HEPA filter test, two test holes should be considered on the booth design.

- a) A sampling hole towards upstream of the filter for injecting aerosols of dioctyl phthalate(DOP) particles or equivalent fluid.
- b) A sampling hole towards downstream of the filter for scanning leak penetration in percent.

If the negative pressure booth is connected to ductwork, the test hole towards downstream of the filter shall be near a downstream duct.

#### 4.2.4 Glove and work shelf

#### 4.2.4.1 Internal work shelf

Internal work shelf is space for specimen storage, disinfection solution and waste box. It can be mounted on the wall, or adjustable legs, or other acceptable means.

#### 4.2.4.2 Glove port

Glove port is in the form of sealing with chemical-resistant glove. The connection between the wall and the glove including its joints shall not permit leakage of air.

#### 4.2.5 Control unit

#### 4.2.5.1 Differential pressure gauge

A pressure gauge that could check the differential pressure shall be installed in accordance with the manufacturer's instructions.

#### 4.2.5.2 Lighting

Lamps shall be positioned to prevent reflection of light through the wall.

#### 4.2.5.3 Control panel

A computer display offering a number of controls shall be installed in a location easily accessible to healthcare worker.

NOTE Examples of control item are fan speed, lighting, and broadcast, etc.

#### 4.2.6 Option for outdoor usage

The optional items below can be used if the negative pressure booth is operated outdoor.

- Power supply, with a device that supplies power to the fan controller, heating and cooling device.
- Air-conditioning system, with heating and cooling system for temperature control inside the booth.
- Earth leakage breaker, for electric shock, short circuit fire, equipment and electrical device protection
  and prevents electric shock accident to human body, fire caused by short circuit, and damage to electrical
  equipment by arc.
- Caster, with wheels which can be moved and levelled.

#### 4.3 Function

#### 4.3.1 General

All functions shall be tested according to <u>Annex A</u>. All removable parts shall be tested while installed.

#### 4.3.2 HEPA filter leak

HEPA filter, filter housings, and mounting frames shall be tested with dioctyl phthalate(DOP) or equivalent and determined to be leak tight when the negative pressure booth is operating at steady velocities.

#### 4.3.3 Noise level

The noise level shall be determined with the booth operating at steady velocities and maintained to minimize fatigue of healthcare worker and test subject.

NOTE Equipment such as microphone or amplifier can help the communication between healthcare worker and test subject in noisy environments.

#### 4.3.4 Light intensity

A proper intensity of lighting shall be maintained to minimize fatigue of healthcare worker and test subject.

#### 4.3.5 Differential pressure

The differential pressure shall be maintained under negative pressure.

#### 4.3.6 Air velocity

The negative pressure booth shall be designed to achieve recommendations of air change per hour (ACH) of public health agency of each country.

#### **5** Positive pressure booth

#### 5.1 Principle

A healthcare worker stays inside the positive pressure booth, while outside, the test subject (the person being sampled) comes one by one to the glove wall of the positive pressure booth. The internal positive pressure is maintained to prevent cross infection between the test subject and healthcare worker.

It requires only time to disinfect the exposed gloves after each sampling and saves much time without ventilation. Healthcare worker should confirm whether the positive pressure booth is operated properly before use.



Figure 2 — A front and side view of positive pressure booth

#### 5.2 Structure

#### 5.2.1 General

Positive pressure booth shall be designed and constructed to allow for a safe environment that removes the risk of cross-infection between test subjects and healthcare workers.

Materials of positive pressure booth shall withstand normal abrasion, corrosive action of gases or liquids, cleaning compounds, and disinfectant solution. Exposed burrs and sharp edges shall be eliminated from surfaces of the positive pressure booth.

Structural factors of positive pressure booth should be considered ergonomically to prevent musculoskeletal diseases of healthcare workers.

NOTE Examples of the positive pressure booth size design considering ergonomic factors are shown in <u>Annex B</u>.

#### 5.2.2 Main body

#### 5.2.2.1 Wall

The surface that surrounds the outside of the booth shall be readily accessible and easily cleanable as assembled or when removed.

#### 5.2.2.2 Glove wall

The glove wall has the glove port towards the outside of the positive pressure booth. If there is window, the window shall be optically clear and not adversely affected by accepted cleaning methods and disinfectant solution. The materials of the window can be laminated glass, tempered glass, safety plastic, or equivalent.

#### 5.2.2.3 Frame

The frame of the positive pressure booth is the skeleton supporting the booth structure.

#### 5.2.2.4 Door

The door shall be fit properly and closed completely. Horizontal sliding doors shall not be used for the booth. Handles shall be designed and installed to eliminate sharp edges or unnecessary projections.

#### 5.2.3 Filtration

#### 5.2.3.1 Fan module

Ventilation part for sending purified air through a filter from the outside to the positive pressure booth and prevents cross-infection. Fan module shall be variable speed and shall have controls that can be secured. To maintain the airstream effectively, there may be an exhaust air outlet. If there is an exhaust air outlet, its location and the supply air inlet should be nearly opposite each other.

#### 5.2.3.2 Pre-filter

Pre-filter is a component that filters relatively large dust with a particle size of 50  $\mu m$  or more, primarily preventing intrusion of various harmful substances.

#### 5.2.3.3 HEPA filter

HEPA filters for the booth shall conform to the materials, construction and aerosol efficiency requirements. Refer to ISO 29463-1 and other related documents for details of requirements for HEPA filters. Receipt of HEPA filters shall be accompanied by a supplier's certificate that indicates the filter has an efficiency of not less than 99,97 % for the retention of 0,3  $\mu$ m or larger particles. The HEPA filter shall be leak tight when it is installed on the booth.

#### 5.2.3.4 Sampling ports

For performing HEPA filter test, two test holes should be considered on the booth design.

- a) A sampling hole towards upstream of the filter for injecting aerosols of dioctyl phthalate (DOP) particles or equivalent fluid.
- b) A sampling hole towards downstream of the filter for scanning leak penetration in percent.

#### 5.2.4 Glove and work shelf

#### 5.2.4.1 External work shelf

External work shelf is space for specimen storage, disinfection solution and waste box. It can be mounted on the outer wall of the positive pressure booth, adjustable legs, or other acceptable means.

#### 5.2.4.2 Glove port

Glove port is in the form of sealing with chemical-resistant glove. The connection between the wall and the glove including its joints shall not permit leakage of air.

#### 5.2.5 Control unit

#### 5.2.5.1 Differential pressure gauge

A pressure gauge that could check the differential pressure shall be installed in accordance with the manufacturer's instructions.

#### 5.2.5.2 Lighting

Lamps shall be positioned to prevent reflection of light through the wall.

#### 5.2.5.3 Control panel

A computer display offering a number of controls shall be installed in a location easily accessible to healthcare workers.

NOTE Examples of control item are fan speed, lighting, and broadcast, etc.

#### 5.2.6 Option for outdoor usage

The optional items below can be used if the positive pressure booth is operated outdoor.

- Power supply, with a device that supplies power to the fan controller, heating and cooling device.
- Air-conditioning system, with heating and cooling system for temperature control inside the booth.
- Earth leakage breaker, for electric shock, short circuit fire, equipment and electrical device protection
  and prevents electric shock accident to human body, fire caused by short circuit, and damage to electrical
  equipment by arc.
- Caster, with wheels which can be moved and levelled.

#### 5.3 Function

#### 5.3.1 General

All functions shall be tested according to <u>Annex A</u>. All removable parts shall be tested while installed.

#### 5.3.2 HEPA filter leak

HEPA filter, filter housings, and mounting frames shall be tested with dioctyl phthalate (DOP) or equivalent and determined to be leak tight when positive pressure booth is operating at steady velocities.

#### 5.3.3 Noise level

The noise level shall be determined with the booth operating at steady velocities and maintained to minimize fatigue of healthcare worker and test subject at steady state.

#### 5.3.4 Lighting intensity

A proper intensity of lighting shall be maintained to minimize fatigue healthcare worker and test subject.

#### 5.3.5 Differential pressure

The Differential pressure shall be maintained under positive pressure.

#### 5.3.6 Air velocity

The positive pressure booth shall be designed to achieve recommendations of air change per hour (ACH) of public health agency of each country.

## Annex A (normative)

## **Performance Evaluation**

Before any performance tests are run, the specimen collection booth shall be properly installed and levelled. These tests are intended for the quality evaluation of the booth.

## A.1 HEPA filter leak

#### A.1.1 Purpose

This test determines the integrity of downflow and exhaust HEPA filters, filter housings, and filter mounting frames. The booth shall be operated within  $\pm 0,025$  m/s of the nominal set point, with the exception of the downflow HEPA filters on the booth.

#### A.1.2 Apparatus

**A.1.2.1** An aerosol photometer with linear or expanded logarithmic scale shall be used. The instrument shall be capable of indicating 100 % upstream concentration with a minimum aerosol concentration of 10  $\mu$ g/L of polydisperse dioctylphthalate (DOP) particles, or an equivalent fluid that provides the same particle size distribution (e.g., polyalpha olefin [PAO] di[2-ethylhexyl], sebecate, polyethylene glycol, and medicinal-grade light mineral oil) produced by the generator described in <u>A.1.2.2</u> or equivalent. It shall also be capable of detecting an aerosol concentration in the downstream equal to 10<sup>-5</sup> of the upstream concentration of the same particles. The sampling rate of air shall be (28,0 ± 2,8) L/min. Probe area shall have a maximum open area of 1 100 mm<sup>2</sup> and a minimum dimension of 13 mm. The photometer shall be set up in accordance with the photometer manufacturer's instructions or certificate.

**A.1.2.2** An aerosol generator of the Laskin Nozzle type or equivalent shall be used to create an aerosol by flowing air through liquid DOP or an equivalent substitute. When a Laskin nozzle generator is used, the compressed air supplied to the generator should be adjusted to a minimum of 140 kPa, if using DOP or 160 kPa if using PAO, measured at the generator manufacturer's recommended location. The nozzles shall be covered with liquid to a depth not to exceed 31 mm.

**A.1.2.3** A pressure gauge for the generator having a maximum range of 0 to 550 kPa with a resolution and accuracy of 7 kPa calibrated by the manufacturer or in accordance with the manufacturer's instructions shall be used.

#### A.1.3 Method

#### A.1.3.1 Filters that can be scanned

Turn on the booth and lights. Remove the filter diffusers and protective covers if any are present. Place the generator so the aerosol is introduced into each booth fan upstream of the HEPA filter(s). When the manufacturer has not identified the aerosol introduction point(s), introduce the aerosol in a manner to ensure thorough mixing in the booth airflow. For example, a T-connection can be fitted to the aerosol generator output to enable distribution of challenge into both entrances of a single blower or entrances of multiple blowers. The manufacturer shall determine the aerosol introduction point that provides the most uniform distribution.

Turn on the photometer and adjust it in accordance with the manufacturer's instructions.

Determine the aerosol concentration upstream of the HEPA filter:

- when the challenged airflow is not contaminated, sample the aerosol concentration upstream of the HEPA filter;
- when the challenged airflow is contaminated or when measuring the upstream concentration is not practical, the upstream concentration can be calculated. For example, when DOP is used as the challenge aerosol with a Laskin nozzle aerosol generator at 140 kPa, the following formula applies;

 $\mu$ g/L = 13,500 × number of nozzles/CFM

NOTE 1 Use of DOP substitutes will require modification of this formula, unless the photometer is calibrated with the substitutes to yield results equivalent to those of DOP. Use of DOP substitutes will also require pressures different from 140 kPa.

NOTE 2 The volumetric flow rate in this formula is calculated based on 1 CFM (= 472 cm<sup>3</sup>/s, 28,3 l/min or 0,000 472 m<sup>3</sup>/s).

- use an aerosol concentration that is at least equal to the photometric equivalent of 10  $\mu$ g/L of DOP.

Set up the photometer to the upstream challenge in accordance with the photometer manufacturer's instructions to detect leaks greater than or equal to 0,01 % of the upstream concentration.

With the nozzle of the probe held not more than 25 mm from the area being tested, scan the entire downstream side of the HEPA filter(s) and the perimeter of each filter pack by passing the photometer probe in slightly overlapping strokes at a traverse rate of not more than 50 mm/s. Separate passes shall be made around the entire periphery of the filter, along the bond between the filter pack and frame, and around the seal between the filter and the device.

#### A.1.3.2 Filters that cannot be scanned

**A.1.3.3** When a booth is ducted so that the exhaust filter cannot be scanned, it may be leak tested by drilling a hole approximately 8 mm in diameter in the duct at a downstream location that will produce a well-mixed aerosol, and inserting the photometer sampling probe with rigid extension tubing through the hole.

The test report should include the following information:

- a) upstream aerosol challenge concentration;
- b) method used to report concentration (measured or calculated);
- c) maximum leak penetration in percent;
- d) method used (scanned or probe tested);
- e) name of test (HEPA filter leak test).

#### A.2 Noise level

#### A.2.1 Purpose

This test is performed to measure the noise levels produced by the booth as a guide to satisfactory mechanical performance and an aid in minimizing booth operator's fatigue. The procedures can be performed in most acoustically ordinary rooms, such as a factory, where walls are neither sound absorbing nor completely sound reflecting.

#### A.2.2 Apparatus

Sound level meter with a minimum range of at least 50 to 100 db and an A-weighting scale set up in accordance with the manufacturer's instructions.

NOTE A- weighting mode is one of frequency-weighted sound pressure level.

#### A.2.3 Method

**A.2.3.1** Turn on the booth blower and lights.

**A.2.3.2** Booth components that could impact the noise level such as doors, windows, pass through, etc. should be closed. Permanent openings should be kept open during the test.

A.2.3.3 Set the instrument to the A-weighting mode.

**A.2.3.4** Measure the noise level at 0,30 m in front of the booth leading front edge of the access opening and 1,5 m above the floor in the booth.

A.2.3.5 To measure the ambient noise level, turn the booth blower and lights off.

#### A.2.4 Test report

The test report shall include the following information.

- a) sound level reading;
- b) background sound level reading;
- c) acceptance criteria;
- d) name of test (noise level test).

## A.3 Lighting intensity

#### A.3.1 Purpose

This test is performed to measure the light intensity on the work surface of the booth has an aid in minimizing booth operator's fatigue.

#### A.3.2 Apparatus

The portable photoelectric illuminance meter shall be accurate within ±10 %, cosine and colour corrected. The illuminance meter shall be calibrated in accordance with the manufacturer's instructions or certificated.

#### A.3.3 Method

Measure the background lighting intensity along the side-to-side centerline of the work tray on a uniform linear pattern close to but no greater than 300 mm starting 150 mm from the sidewalls.

Turn on the lights and blower, and take readings at the same points again.

#### A.3.4 Test report

The test report shall include the following information.

- a) individual background readings;
- b) individual lighting intensity readings;

- c) average background intensity;
- d) average lighting intensity;
- e) acceptance criteria;
- f) name of test (lighting intensity test).

## A.4 Differential pressure

#### A.4.1 Purpose

The purpose of the test is to verify the capability of the complete installation to maintain the specified pressure difference between the inside and the outside of the booth.

#### A.4.2 Apparatus

An electronic micro-manometer, inclined manometer, or mechanical differential pressure gauge can be used. The apparatus should have a valid calibration certificate.

The minimum requirements for the differential pressure test apparatus are given in <u>Table A.1</u>. This requirement does not prevent the use of improved apparatus. Alternative test apparatus can be appropriate and may be used subject to agreement between customer and supplier.

Item	Minimum requirements		
Measuring limits	N/A		
Resolution	0,5 Pa (0 Pa-49,9 Pa) 1,0 Pa (≥50 Pa)		
Maximum permissible error	The greater of 2 Pa or 5 % of reading (Mechanical gauges can be used for continuous monitoring reference but not for testing due to potential errors)		

Table A.1 — Differential pressure test apparatus

#### A.4.3 Method

**A.4.3.1** Turn on the booth blower.

**A.4.3.2** Booth components that could impact the differential pressure such as doors, windows, pass through, etc. should be closed. Permanent openings should be kept open during the test.

**A.4.3.3** Booth blower should be operated until the conditions have been stabilized.

A.4.3.4 Measure the differential pressure of a steady state.

NOTE To avoid possible erroneous readings, measurements should not be taken near supply air inlets, return air outlets, air movement devices and other localized high air velocity areas that may influence the local pressure at the measuring point.

#### A.4.4 Test report

The test report shall include the following information:

- a) apparatus used and its calibration status;
- b) measuring point locations;
- c) acceptance criteria;

d) name of test (differential pressure test).

## A.5 Air velocity

## A.5.1 Purpose

This test is performed to measure the airflow velocity and used in calculating the air change rate for the booth.

## A.5.2 Apparatus

For airflow velocity measurements, ultrasonic anemometers, thermal anemometers, vane-type anemometers, or equivalent, can be used. The minimum requirements for the air velocity test apparatus are given in <u>Table A.2</u>. This requirement does not prevent the use of improved apparatus. Alternative test apparatus can be appropriate and may be used subject to agreement between customer and supplier.

Item	Minimum requirements		
Measuring limits	N/A		
Resolution	0,01 m/s (0,20 m/s-0,99 m/s)		
Resolution	0,1 m/s (≥ 1,00 m/s)		
Maximum permissible error	0,1 m/s (0,20 m/s–1,00 m/s)		
	10 % of reading (>1,00 m/s)		

Table A.2 — Air velocity test apparatus

#### A.5.3 Method

**A.5.3.1** Air velocity should be measured at approximately 150 mm to 300 mm from the filter face or entry plane. The minimum number of measuring points (grid cells) should be determined by formula:

 $N = \sqrt{10 \times A}$ 

where

- *N* is the minimum number of measuring points;
- A is the measured area in  $m^2$ .
- **A.5.3.2** Calculate the average of the air velocity.
- A.5.3.3 Measure the size of filter.
- A.5.3.4 Measure the size and volume of the booth.
- A.5.3.5 Calculate Air change per hour (ACH), the following formula applies:

$$ACH = \frac{\overline{v} \times A \times 3\,600}{V}$$

#### where

- *ACH* is Air change rate per hour (cycles/h);
- $\overline{v}$  is Average of Air velocity in m/s;
- A is Area of the filter size in  $m^2$ ;
- V is volume of the booth in m<sup>3</sup>.

#### A.5.4 Test report

The test report shall include the following information:

- a) designations of each measuring apparatus used and its calibration status
- b) measuring locations and the distance from the filter face;
- c) air velocity readings;
- d) average of the air velocity reading;
- e) minimum air velocity reading;
- f) maximum air velocity reading;
- g) dimension of the filter;
- h) size and volume of the booth;
- i) acceptance criteria;
- j) ACH (air change per hour);
- k) name of test (air velocity test).

## Annex B (informative)

## Size information considering ergonomic factors

Structural factors should be considered ergonomically to prevent musculoskeletal diseases of healthcare workers who should be comfortable with the sample collection task, to reduce the fatigue of healthcare workers due to wearing protective clothing for a long time, and to increase work efficiency and convenience of use.

The example of the positive pressure booth size considering ergonomic factors is given in <u>Table B.1</u>

#### Table B.1 — Example of specimen collection booth structure considering ergonomic factors

Size of the specimen collection booth		Anthropometric measurements	
Figure	Description	Figure	Description
	Height of glove port		Elbow Height (Vertical distance from the floor to the lowest bony point of the bent elbow)
	Distance between glove ports		Shoulder breadth (Distance along a straight line from acromion to acromion)
	Height of control board		Overhead Fist Reach (Vertical distance from the floor to grip axis when the arm is maximally extended upward)
	Height of work shelf		Fist height (Vertical distance from the floor to the grip axis of the fist)

## **Bibliography**

- ISO 13408-1:2008, (en), Aseptic processing of health care products Part 1: General requirements
- ISO/PAS 45005:2020, Occupational health and safety management General guidelines for safe working during the COVID-19 pandemic
- ISO 15384:2018, Protective clothing for firefighters Laboratory test methods and performance requirements for wildland firefighting clothing
- [#] Cleanrooms and associated controlled environments Part 16: Energy efficiency in cleanrooms and separative devices
- ISO 29463-1:2017, High efficiency filters and filter media for removing particles from air Part 1: Classification, performance, testing and marking
- ISO 14644-3:2019, Cleanrooms and associated controlled environments Part 3: Test methods
- ISO 7250-1:2017, Basic human body measurements for technological design Part 1: Body measurement definitions and landmarks
- ISO 5801:2017, Fans Performance testing using standardized airways
- [#] IEST-RP-CC-013 IEST-RP-CC013: Calibration Procedures and Guidelines for Select Equipment Used in Testing Cleanrooms and Other Controlled Environments
- [#] Government of the Republic of Korea, How Korea responded to a pandemic using ICT, Flattening the curve on COVID-19, Apr 15

NSF/ANSI 49 - 2020, Biosafety Cabinetry: Design, Construction, Performance, and Field Certification