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ISO 23328-1

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Breathing system filters for anaesthetic and respiratory use —

Part 1: Salt test method to assess filtration performance

Filtres pour matériel d'anesthésie et de réanimation respiratoire —

Partie 1: Méthode d'essai saline pour l'évaluation de l'efficacité de filtration

Reference number
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Contents

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 23328-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

ISO 23328 consists of the following parts, under the general title *Breathing system filters for anaesthetic and respiratory use*:

— *Part 1: Salt test method to assess filtration performance*

— *Part 2: Non-filtration aspects*

Introduction

This part of ISO 23328 gives a method of test for assessing the filtration performance of breathing system filters (BSF).

BSF are used to reduce the number of particulates, including microorganisms, in gases delivered to, and exhaled from, patients.

BSF are exposed to various levels of humidity during clinical use. Exposure of the BSF to humidified air to simulate clinical use forms part of this method (see Annex A), as it is possible that such exposure can influence the filtration performance of the BSF.

In the test, the BSF is challenged with sodium chloride particles of the most penetrating size range, i.e. 0,1 µm to 0,3 µm (see Annex C).

It is recognized that transmission of microorganisms across a filter can occur due to “channeling” and “grow-through”. There are at present no accepted methods to quantify these occurrences. This test method is for comparison purposes only, and has no proven clinical relevance. The results are specific to the test method and no risk factor should be derived from it.

Breathing system filters for anaesthetic and respiratory use —

Part 1:
Salt test method to assess filtration performance

1 Scope

This part of ISO 23328 gives a short-term airborne sodium chloride particle challenge test method for assessing the filtration performance of breathing system filters (BSF) intended for the filtration of respired gases.

This part of ISO 23328 is applicable to BSF used with a clinical breathing system. It is not applicable to other types of filter, e.g. those designed to protect vacuum sources or gas sample lines, to filter compressed gases, or to protect test equipment for physiological respiratory measurements.

NOTE Non-filtration aspects of BSF are addressed in ISO 23328-2.

2 Terms and definitions

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

2.1
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in breathing systems

2.2
challenge concentration
concentration of sodium chloride particles in the airstream as it reaches the BSF

NOTE Challenge concentration is expressed in milligrams per cubic metre.

2.3
penetration concentration
concentration of sodium chloride particles in the airstream flowing out of the BSF

NOTE Penetration concentration is expressed in milligrams per cubic metre.

2.4
penetration value
concentration of sodium chloride particles passing through the BSF as a percentage of the concentration in the challenge

2.5
percent filtration efficiency
100 minus the penetration value

3 Method

3.1 Principle

3.1.1 The ability of a BSF to remove particles is measured by nebulizing a sodium chloride solution into an airstream and passing the sodium chloride particles produced by the nebulizer through the BSF. Annexes B and C give further explanation.

3.1.2 The generation of aerosols from a nebulizer produces particles that are charged electrostatically. The magnitude of the charge is reduced by mixing the airstream containing the particles with a flow of ionized air so that, when the two flows are mixed, the particles are neutralized to the Boltzmann equilibrium state.

3.1.3 The flows chosen for testing represent the typical flows likely to be encountered during the intended use of the BSF.

3.1.4 The performance of the BSF is assessed by measuring the penetration concentration of sodium chloride particles in the airstream leaving the BSF and comparing this with the challenge concentration in the airstream entering the BSF. BSF are tested in the unused state as removed from the packaging and after conditioning to simulate clinical use.

3.2 Test conditions

The ambient conditions during the tests shall be:

— temperature: (23 ± 2) °C;

— relative humidity: (60 ± 15) % RH; and

— pressure: (96 ± 10) kPa.

3.3 Apparatus

3.3.1 **Flowmeter**, with an accuracy of ± 5 % of the actual value to be measured.

3.3.2 **Sodium chloride aerosol generator**[1)], capable of generating an aerosol at (25 ± 5) °C and relative humidity of (30 ± 10) % with a concentration between 10 $mg \cdot m^{-3}$ and 20 $mg \cdot m^{-3}$ which has been neutralized to the Boltzmann equilibrium state.

3.3.3 **Scanning mobility particle sizer**[2)], or equivalent instrument.

3.3.4 Suitable **forward-light-scattering photometer**[3)], or equivalent instrument.

3.4 Conditioning of BSF

Condition the BSF in accordance with Annex A.

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1) Model 8118A sodium chloride aerosol generator is an example of a suitable product available commercially from TSI Inc., PO Box 64394, St. Paul, MN 55164, USA. This information is given for the convenience of users of this part of ISO 23328 and does not constitute an endorsement by ISO of this product.

2) Model 3936 scanning mobility particle sizer is an example of a suitable product available commercially from TSI Inc., PO Box 64394, St. Paul, MN 55164, USA. This information is given for the convenience of users of this part of ISO 23328 and does not constitute an endorsement by ISO of this product.

3) Model AFT 8130 forward-light-scattering photometer is an example of a suitable product available commercially from TSI Inc., PO Box 64394, St. Paul, MN 55164, USA. This information is given for the convenience of users of this part of ISO 23328 and does not constitute an endorsement by ISO of this product.

3.5 Sample size

It is the responsibility of the BSF manufacturer to document the rationale for the test BSF sample size chosen in order to demonstrate the filtration efficiency of the BSF.

3.6 Procedure

NOTE Rationales for various aspects of this method are given in Annex C.

3.6.1 Set the flowrate through the test apparatus (see Figure 1) to the appropriate value for the intended use of the BSF given in Table 1, using the flowmeter (3.3.1).

3.6.2 Using the aerosol generator (3.3.2), generate a sodium chloride aerosol at (25 ± 5) °C and relative humidity of (30 ± 10) %, with a concentration between 10 mg·m^{-3} and 20 mg·m^{-3}, that has been neutralized to the Boltzmann equilibrium state.

3.6.3 Using the scanning mobility particle sizer (3.3.3), confirm that the sodium chloride test aerosol has a particle size distribution with a count median diameter of (0,075 ± 0,020) µm and a geometric standard deviation not exceeding 1,86 at the specified test conditions.

NOTE 1 A particle size distribution with a count median diameter of 0,075 µm and a geometric standard deviation of 1,86 has a mass median aerodynamic diameter (MMAD) of 0,26 µm. See Annex B.

NOTE 2 This is a calibration step of the aerosol generator and only needs to be performed as recommended by the manufacturer.

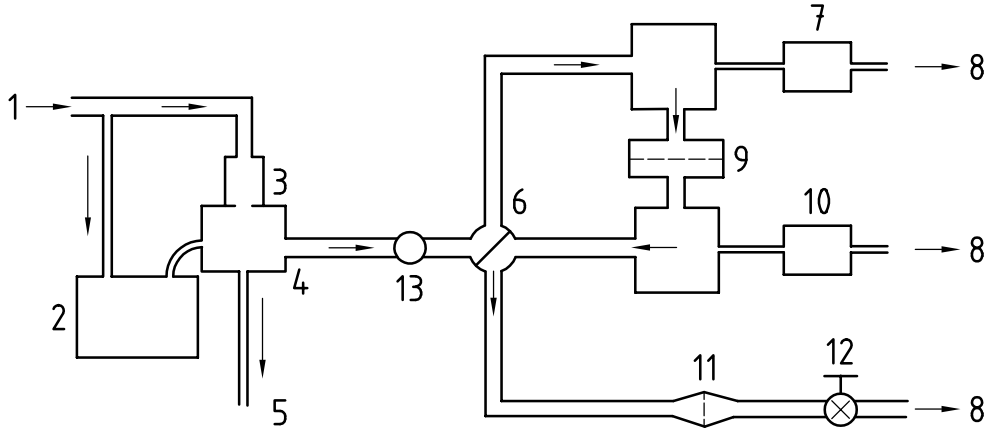
3.6.4 Without a BSF attached, interconnect the two photometers (3.3.4) and measure the challenge concentration at the upstream photometer. Check that the challenge concentration at the downstream photometer is ± 2,5 % of this value each time the apparatus is switched on, when the airflow is changed and after the BSF sample size (3.5) has been tested.

3.6.5 Fit a BSF in the unconditioned state to the test apparatus. Test the BSF using the flow direction stated by the manufacturer. If the flow direction is not stated, perform the test with the airstream entering the BSF at the machine port.

3.6.6 Repeat the generation of aerosol as described in 3.6.2.

3.6.7 Measure the challenge concentration (c_C) and penetration concentration (c_P) whilst continuing the test until an aerosol mass of (0,2 ± 0,1) mg for adult BSF and (0,1 ± 0,05) mg for paediatric BSF has contacted the BSF.

3.6.8 Repeat 3.6.5 to 3.6.7 using a BSF in the conditioned state (see 3.4).



Key

1	compressed gas	8	to vacuum
2	aerosol generator	9	BSF under test
3	neutralizer	10	downstream photometer
4	mixing chamber	11	flowmeter
5	exhaust	12	flow control valve
6	switching valve	13	location for scanning mobility particle sizer,
7	upstream photometer		when used; see 3.3.3

Figure 1 — Apparatus for testing BSF

4 Calculation and expression of test results

For the BSF tested, calculate the penetration value (PV) from the following expression:

$$PV = (c_P/c_C) \times 100$$

where

c_P is the penetration concentration, in milligrams per cubic metre, determined in accordance with 3.6;

c_C is the challenge concentration, in milligrams per cubic metre, determined in accordance with 3.6.

Table 1 — Flowrates for testing BSF

BSF intended use	Flowrate $l \cdot min^{-1}$
Paediatric	15
Adult	30

5 Test report

The test report shall include the identification of the BSF, including lot number or date of manufacture and location of manufacturer, the quantity of BSF tested under each condition and the filtration efficiencies of each BSF in the unconditioned and conditioned states.

Annex A
(normative)

Conditioning of BSF

A.1 Principle

BSF are exposed to humidified air in a conditioning apparatus to simulate a period of clinical use before they are tested for filtration efficiency. The conditioning apparatus consists of a humidity-generating patient model connected to a breathing system with or without an inspiratory limb humidity generator. The BSF can be positioned at various points in the breathing system, to simulate clinical use or as recommended by the manufacturer.

A.2 Test conditions

The ambient conditions during the conditioning shall be:

— temperature: (23 ± 2) °C;

— relative humidity: (60 ± 15) % RH;

— pressure: (96 ± 10) kPa.

A.3 Apparatus

A.3.1 Inspiratory limb humidity generator [see Figure A.1 a)], to increase the temperature and relative humidity of the inspired air if required (see A.4).

A.3.2 Breathing system [see Figure A.1 b)], consisting of an inspiratory limb, a Y-piece with a patient connection port, and an expiratory limb, having one-way valves placed at the ends of the breathing system limbs to ensure unidirectional flow through the breathing system.

A.3.3 Humidity-generating patient model [see Figure A.1 c)].

The model shall consist of the following:

a) an insulated chamber, the internal temperature of which is maintained at (37 ± 1) °C;

b) a heated water bath, maintained at (37 ± 1) °C, through which air is bubbled in both directions;

c) a rigid reservoir containing a 2 l reservoir bag;

d) a reciprocating piston/bellows pump.

A.4 Positioning of BSF

A.4.1 General

The positioning of BSF for conditioning shall be as shown in Figure A.1 and as described in A.4.2 and A.4.3.

A.4.2 With the inspiratory limb humidity generator in place in the breathing system

A.4.2.1 To simulate use in a circle breathing system with a carbon dioxide absorber, set the mean temperature at the inlet to the Y-piece to (26 ± 1) °C and the relative humidity to > 90 % RH and place the BSF at position A.

A.4.2.2 To simulate use with a hot water humidifier, set the mean temperature at the inlet to the Y-piece to (38 ± 1) °C and the relative humidity to > 90 % RH and place the BSF at position B.

A.4.3 With the inspiratory limb humidity generator removed from the breathing system

A.4.3.1 To simulate use in a non-rebreathing system, place the BSF at position A.

A.4.3.2 To simulate use in the expiratory limb of a breathing system, place the BSF at position C.

A.5 Procedure

A.5.1 Set up the apparatus and operate the humidity-generating patient model, ensuring that the water bath temperature has stabilized at (37 ± 1) °C. For the conditioning requirements specified in A.4.2, operate the inspiratory limb humidity generator until the temperature and humidity measured at position 1 of Figure A.1 have reached the specified values. Set the patient model parameters according to the intended use of the BSF, as given in Table A.1.

A.5.2 Fit the BSF in the breathing system at the position required to simulate its intended use, as given in A.4 and Figure A.1.

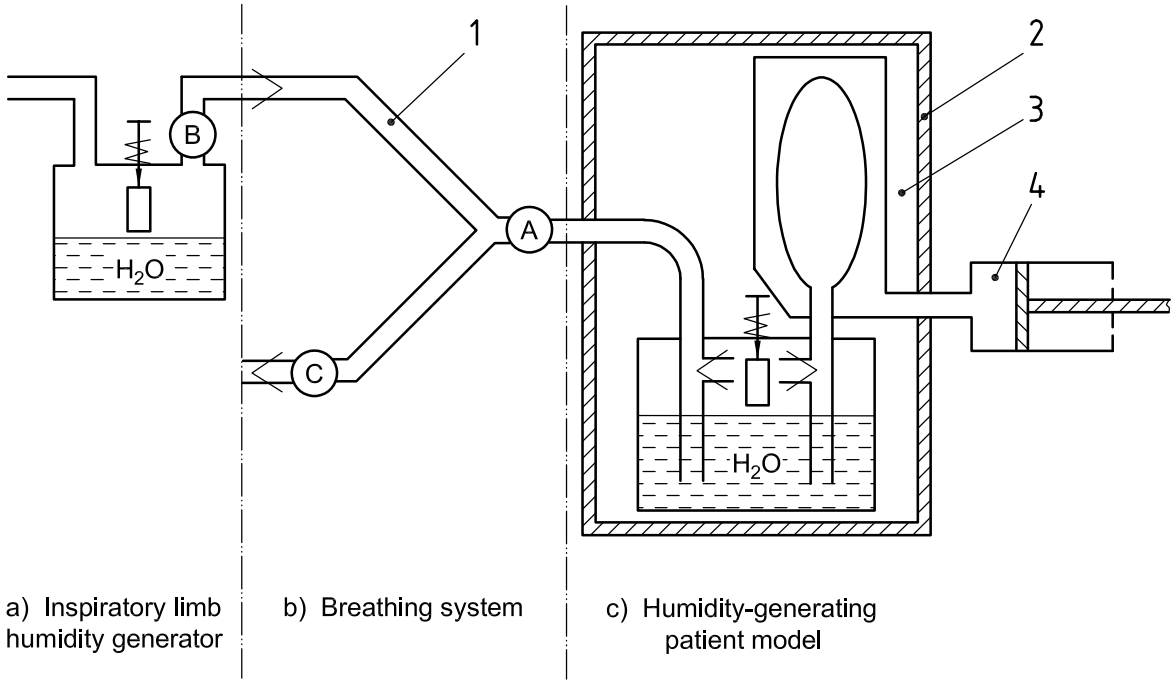
A.5.3 Operate the apparatus to condition the BSF for the maximum period recommended by the manufacturer for clinical use, or for (25 ± 1) h if this is not stated.

A.5.4 Within 5 min of the end of the conditioning period, remove the conditioned BSF and test the BSF in accordance with Clause 3.

Table A.1 — Patient model parameters for conditioning BSF

BSF intended use	**Tidal volume** V_t[a] ml	**Frequency** f min^{-1}	**Ventilation rate** $l \cdot min^{-1}$	**I:E ratio** (inspiration: expiration)
Paediatric	250	20	5	1:1
Adult	500	15	7,5	1:1

[a] Tidal volume is the volume of gas entering or leaving the lungs of the patient in a breath.



Key

1 position of temperature and humidity sensor for use with inspiratory limb humidity generator
2 insulated enclosure
3 rigid reservoir
4 pump
A, B, C Positions of BSF for testing (see A.4)

NOTE Symbols are in accordance with ISO 8835-2.

Figure A.1 — Conditioning apparatus for BSF

Annex B
(informative)

Aerosol particle size distribution

B.1 The test apparatus described in 3.3 detects the mass of aerosol particles. Hence, aerosol particle size distribution is defined in terms of the mass median aerodynamic diameter (MMAD) and the geometric standard deviation (GSD).

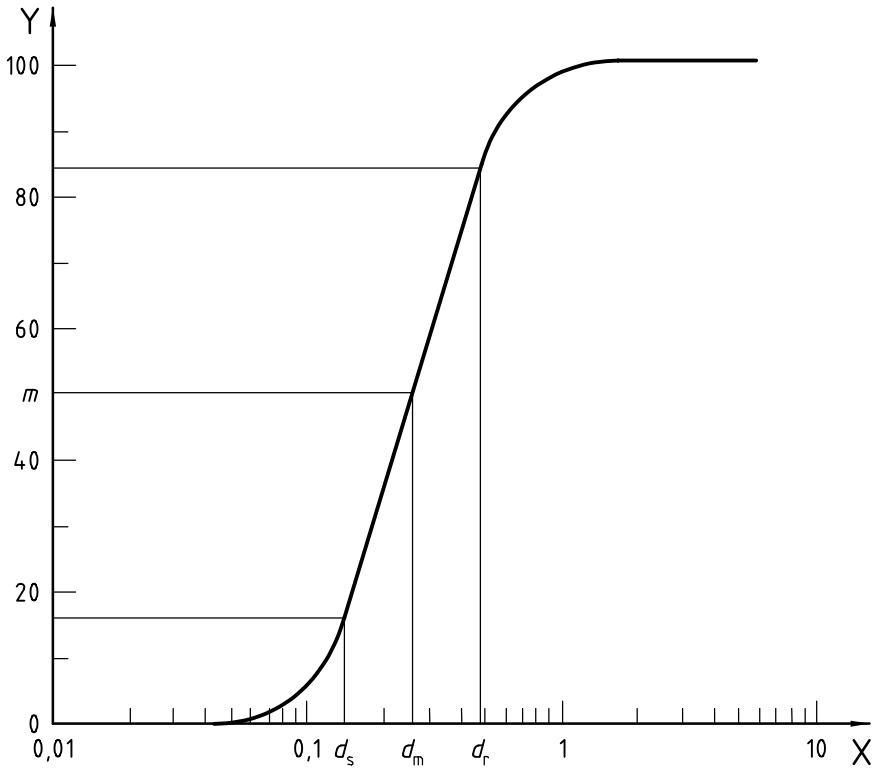
B.2 A typical particle size distribution is shown in Figure B.1.

B.3 It can be seen that at 50 % of the total mass (m), the median particle size (d_m) is 0,26 µm. One standard deviation from 50 % of the total mass is at 84,13 % and 15,87 % cumulative mass distribution on the Y-axis. GSD is calculated by noting the particle sizes d_r and d_s at these points and using the expression:

$$\text{GSD} = \sqrt{d_r / d_s}$$

NOTE This calculation can be made provided the curve is effectively straight between 90 % and 10 % cumulative mass distribution.

The GSD should have a maximum value of 1,86, for the purposes of this part of ISO 23328.



Key

Y cumulative mass distribution, %

X aerodynamic particle size, µm (logarithmic scale)

Figure B.1 — Typical aerosol particle size distribution

Annex C
(informative)

Rationale for chosen test method

C.1 NIOSH test method (42 CFR Part 84)

During the development of this part of ISO 23328, the committee considered a variety of test methods specified in European and other standards for particulate filters for respiratory protective devices and other applications.

Currently, there are no national or international standards that challenge a BSF with microorganisms. Whilst tests have been described using a microbiological challenge, it was the view of the committee that these methods neither offered any advantages over, nor had any greater clinical relevance than, the already well established particulate methods. However, the committee decided that the EN 1822 series was unsuitable, as it is intended for HEPA and ULPA filters for cleanroom and other similar applications.

EN 143, intended for testing respiratory protective devices, was considered but the particulate range used (0,4 µm to 0,6 µm) is somewhat larger than the currently recognized most penetrating particle size (MPPS) range for typical BSF of 0,1 µm to 0,3 µm.

It was decided to use the NIOSH test method as the basis for testing because:

— it uses particles with a mass median diameter of 0,3 µm, which is closer to the MPPS for typical breathing system filters;

— it has a greater sensitivity than EN 143;

— minimum changes are needed for the method to be used to test BSF;

— test equipment suitable for carrying out the NIOSH test is commercially available.

C.2 Aerosol test material

NIOSH 42 CFR Part 84 specifies two types of aerosol for testing filters, namely a mildly degrading particulate, sodium chloride, and a highly degrading one, dioctyl phthalate (DOP). Testing with DOP is intended to simulate conditions in which the filter would be required to function in an atmosphere contaminated with oils or other toxic and degenerative particles. Clearly, this is not the case for BSF and therefore the Committee agreed that testing would only be with sodium chloride.

C.3 Electrostatically neutral aerosol

There are two fundamental types of particulate filter, mechanical and electrostatic.

The efficiency of a mechanical filter is determined by its physical features, for example diameter, orientation and arrangement of fibers.

The efficiency of an electrostatic filter is enhanced by its ability to retain charged particles. However, the efficiency is reduced for uncharged particles.

Although in reality many particles challenging a BSF have a charge, the test conditions specify an aerosol neutralized to the Boltzmann equilibrium state in order to provide a reproducible challenge to all types of BSF.

C.4 Flowrate

The efficiency of a filter increases with decreased flowrate. Flowrates typically encountered in the clinical environment have been chosen for the test, taking into account both spontaneously breathing and ventilated patients.

C.5 BSF occlusion

Other standards for respiratory protection equipment included tests to determine the performance following loading with a quantity of dust or other material.

As the loading of BSF increases, the filtration efficiency changes. It is important to choose a challenge concentration which differentiates between, but does not unreasonably overchallenge, the BSF. In clinical use, there would not normally be an excessive load of particles or microorganisms on the BSF. Therefore, it would be unreasonable to test the BSF when loaded with a large mass of sodium chloride. The commercially available test apparatus that has been used during the development of this part of ISO 23328 has set challenge concentrations and it has been possible to demonstrate differences between BSF with a load in the range of 0,05 mg to 0,3 mg. However, the effect of moisture on the resistance to airflow of the BSF is an important aspect, and is covered in ISO 23328-2.

Annex D
(informative)

Clauses of this part of ISO 23328 addressing the essential principles of ISO/TR 16142

This part of ISO 23328 supports the essential principles of ISO/TR 16142 as given in the clauses listed in Table D.1.

Other requirements and other standards may be applicable to the product(s) falling within the scope of this part of ISO 23328.

Compliance with the clauses of this part of ISO 23328 provides one means of conforming with the specific essential principles of ISO/TR 16142:1999.

Table D.1 — Correspondence between this part of ISO 23328 and ISO/TR 16142:1999

Clause/subclause of this part of ISO 23328	Corresponding essential principle of ISO/TR 16142:1999
All	1, 8.1

Bibliography

[1] ISO 8835-2, *Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems for adults*

[2] ISO/TR 16142:1999, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[3] ISO 23328-2, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

[4] EN 143, *Respiratory protective devices — Particle filters — Requirements, testing, marking*

[5] EN 1822, *High efficiency air filters (HEPA and ULPA)*

[6] National Institute for Occupational Safety and Health (NIOSH*). Respiratory Protective Devices. Code of Federal Regulations, Title 42, Part 84*[4)]

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