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Respiratory protective devices — Selection, use and maintenance —

Part 3: Fit-testing procedures

Appareils de protection respiratoire — Choix, utilisation et entretien —

Partie 3: Modes opératoires d'essais d'ajustement

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Contents

Page

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Foreword

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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 www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 15, *Respiratory protective devices*.

A list of all parts in the ISO 16975 series can be found on the ISO website.

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Introduction

This document contains the essential requirements for establishing and implementing a fit-testing programme for tight-fitting respiratory protective devices (RPD) that meet the requirements of the performance standards. It provides requirements with regard to RPD fit-testing procedures in an effective RPD programme.

The RPD fit testing itself is simply one facet of fit-testing procedures. An effective RPD programme requires much more, including a competent fit-test operator to perform the fit test. This document provides guidance on what knowledge and skills are necessary in order to perform as a competent fit-test operator.

This document contains information to aid RPD programme administrators and competent fit-test operators in preparing to perform a proper fit test. This includes guidance regarding potential interference from other personal protective equipment with the RPD, detailed information on RPD used for fit testing, selection of RPD prior to fit testing, and other considerations that should be met if the fit test is to be effective.

The information contained in this document can be used to assist in the preparation of national or local regulations; however, this does not supersede national or local regulations.

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Respiratory protective devices — Selection, use and maintenance —

Part 3: Fit-testing procedures

1 Scope

This document specifies guidance on how to conduct fit testing of tight-fitting respiratory protective device (RPD) and on appropriate methods to be used. Fit testing is only one element of a complete RPD programme. The intention of fit testing is to evaluate the effectiveness of the seal between the wearer's face and the respiratory interface (RI). A complete RPD programme is defined in ISO/TS 16975-1.

This document specifies requirements for conducting RPD fit testing and includes

— qualifications/competences of fit-test operators,

— specific fit-testing procedures,

— interpretation of fit-test results, and

— record keeping.

A fit test is not required for escape-only RPD.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
face-seal leakage
leakage between the wearer's face and the *respiratory interface* (3.11)

[SOURCE: ISO 16972:2010, 3.72, modified — "wearer's" has been added.]

3.2
fit test
use of a challenge agent and specific protocol to qualitatively or quantitatively determine the effectiveness of the seal between the wearer's face and *respiratory interface* (3.11) with a specific make, model, and size of an *RPD* (3.12)

[SOURCE: ISO 16972:2010, 3.76, modified — "the effectiveness of the seal between the wearer's face and respiratory interface" has been inserted.]

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3.3
competent fit-test operator
person with suitable and sufficient experience and with practical and theoretical knowledge of fit-test methods that conducts the fit-testing procedures

3.4
force-fitting
practice of repeating a failed *fit test* (3.2) with the same *RPD* (3.12) more than three times re-donning, or otherwise adjusting the RPD (e.g. over-tightening the straps), until a passing fit test is finally achieved

3.5
protection level
degree of respiratory protection allocated to an *RPD* (3.12) for the purposes of selection and use that is expected to be provided to *wearers* (3.14) when used within an effective RPD programme as described in ISO/TS 16975-1 and ISO/TS 16975-2

[SOURCE: ISO 16972:2010, 3.148, modified — reference to ISO/TS 16975-1 and ISO/TS 16975-2 has been added.]

3.6
qualitative fit factor
QLFF
qualitative estimate of the minimum fit of a particular tight-fitting RPD to a specific individual when a qualitative fit test is passed, i.e. the test agent is not detected by the subject's senses

[SOURCE: ISO 16972:2010, 3.151, modified — minimum assured (C_o/C_i) has been deleted.]

3.7
qualitative fit test
QLFT
pass/fail test method that relies on the subject's sensory response to detect a challenge agent in order to assess the adequacy of RPD fit

[SOURCE: ISO 16972:2010, 3.152]

3.8
quantitative fit factor
QNFF
numeric value of the fit of a particular *tight-fitting respiratory interface* (3.13) to a specific individual

Note 1 to entry: It represents only respiratory interface to face leakage. Leakage from other sources (e.g. air-purifying elements, exhalation valve) should be significantly lower than the measured face-seal leakage. The QNFF is measured with specialized instrumentation.

[SOURCE: ISO 16972:2010, 3.153, modified — the definition and Note 1 to entry have been changed.]

3.9
quantitative fit test
QNFT
test method that uses an instrument to assess (quantify) the amount of *face-seal leakage* (3.1) into the *RPD* (3.12) in order to assess the adequacy of its fit

[SOURCE: ISO 16972:2010, 3.154]

3.10
required fit factor
RFF
numeric value established as a pass/fail point or acceptance criterion for *quantitative fit testing* (3.9)

[SOURCE: ISO 16972:2010, 3.159]

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3.11
respiratory interface
RI
part of an *RPD* (3.12) that forms the protective barrier between the wearer's respiratory tract and the ambient atmosphere

Note 1 to entry: The RI is connected to the filtering part of the RPD, or the part managing the supply of breathable gas

[SOURCE: ISO 16972:2010, 3.162]

3.12
respiratory protective device
RPD
personal protective equipment designed to protect the wearer's respiratory tract against inhalation of hazardous atmospheres

[SOURCE: ISO 16972:2010, 3.163]

3.13
tight-fitting respiratory interface
respiratory interface (3.11) that forms a protective barrier between the wearer's respiratory tract and the ambient atmosphere by forming a seal to the wearer's skin

[SOURCE: ISO 16972:2010, 3.189]

3.14
wearer
person who actually wears the *RPD* (3.12)

[SOURCE: ISO 16972:2010, 3.200]

3.15
wearer-seal check
action conducted by the RPD wearer to determine if the tight fitting *RPD* (3.12) is properly donned and sealed on the face

[SOURCE: ISO 16972:2010, 3.201, modified — the definition has been slightly amended.]

4 General

Fit testing is an essential part of an effective RPD programme. All wearers of tight-fitting RPD shall pass an appropriate qualitative fit test (QLFT) or quantitative fit test (QNFT) as described in this document, see also Annex C. A fit test shall be performed prior to first use of the RPD and shall be conducted by a competent fit-test operator. Tight-fitting RIs, those that have a face or neck seal (classes bT, cT and dT as defined in ISO/TS 16973), will not provide optimum performance if they do not fit and therefore need to be fit tested on the individuals who will wear the RPD. All other RIs (classes bL, cL, and dL as defined in ISO/TS 16973) do not require a fit test. A fit test is not required for escape-only RPD.

The purpose of RPD fit testing is to verify that the selected make, model and size of a tight-fitting RPD adequately fits the wearer. Before being fit tested, the wearer being fitted should be trained to obtain the required level of (proficiency/ competency) as well as on the purpose and procedures for the fit test. Fit testing serves as a validation that the wearer knows how to correctly inspect, don, doff and perform a wearer-seal check on the RPD on a specific make, model and size of RPD. The wearer being fit tested shall be free from hair or jewellery in the RI sealing surface area.

NOTE National or local regulations can require periodic repeat fit testing, e.g. annually.

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5 Competent fit-test operator

5.1 General

Fit-test operators shall be properly trained and demonstrate a proficiency in the fit-test method(s) being used. The RPD programme administrator is responsible for evaluating and verifying the training and qualification of operators. An example of an evaluation form to assess the competency of fit-test operators is given in Annex A.

NOTE Programme administrators can consider the benefits of formal training programmes from outside providers for competent fit-test operators.

5.2 Qualifications

5.2.1 General

Fit-test operators should have adequate knowledge, understanding and practical skills required to conduct a fit test. Fit-test operators shall be familiar with this document along with the appropriate sections of the RPD programme concerning RPD fit testing, purpose and applicability, specific roles and responsibilities, interference concerns, inspection, cleaning, maintenance and storage in ISO/TS 16975-1 and ISO/TS 16975-2.

5.2.2 Knowledge of RPD used for the fit test

Fit-test operators shall demonstrate a general knowledge of RPD used by the wearer in the workplace by:

a) a basic understanding of the selection of adequate and suitable RPD;

b) identifying RPD components and their functions;

c) demonstrating RPD inspection, cleaning, and maintenance procedures;

d) identifying different makes, models, styles, and size RPD as alternatives;

e) discussing RPD capabilities and limitations as related to RPD fit testing;

f) demonstrating and evaluating correct donning and doffing procedures including wearer-seal checks.

5.2.3 Knowledge of the fit-test method

Fit-test operators shall demonstrate knowledge and application of the fit-test method(s) being used, by:

a) explaining the purpose of fit testing;

b) explaining fit-testing procedures;

c) explaining the capabilities and limitations of the fit-test method;

d) identifying indications of erroneous fit-test results (e.g. quantitative fit factors that are unusually low or high);

e) demonstrating knowledge of the health and safety hazards associated with the chemicals and/or equipment used in the fit test.

5.2.4 Ability to set up and monitor the function of fit-test equipment

Fit-test operators shall demonstrate the ability to set up all applicable equipment and monitor its function for the fit-test method(s) being used, by:

a) selecting the proper RPD filters for the fit-test method;

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b) preparing, inspecting and performing operational checks of fit-testing equipment and materials;

c) proper assembly and use and positioning of probes and adapters for quantitative fit-test methods;

d) identifying possible issues with the fit-test equipment.

5.2.5 Ability to conduct the fit test

Fit-test operators shall demonstrate the ability to conduct the fit test(s) being used, by:

a) properly evaluating persons being fit tested and understanding when to refuse to conduct a fit test by recognizing interference concerns (such as/ due to) facial characteristics, facial hair or other problems that may interfere with RPD fit or the fit test;

b) explaining the fit-test purpose and procedures to persons being fit tested;

c) observing that the correct donning procedure is used without assisting the person being fit tested;

d) observing that wearer-seal checks are performed according to the procedures recommended by the RPD manufacturer;

e) observing the person being fit tested throughout the entire fit-test procedure to ensure it is performed correctly;

f) conducting the chosen fit-test method according to the procedures specified in 8.5 and 8.6;

g) evaluating and recording the results of the fit test;

h) explaining the result of the fit test and the meaning of the result to the wearer;

i) performing RPD cleaning and disinfection according to the information supplied by the manufacturer;

j) removing the fit-test adapter and reassembling valves, etc., if applicable prior to use in the workplace.

5.2.6 Ability to identify likely causes of fit-test failure

Fit-test operators shall demonstrate the ability to identify causes of fit-test failure such as:

a) improperly donned or adjusted RPD;

b) incorrectly assembled or damaged RPD;

c) incorrect size, shape or style RPD.

6 General fit-test considerations

6.1 Medical clearance

Persons being fit tested shall be medically cleared to wear the RPD prior to fit testing. Refer to ISO/TS 16975-1, ISO/TS 16975-2 or other applicable national or local regulations.

6.2 Training for RPD wearers

Persons to be fit tested shall receive training prior to the fit test.

A mirror can be helpful to assist with positioning and adjusting the RPD. The wearer shall be informed of the identity of the challenge agent and any potential health and safety hazards of challenge agents used.

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The wearer shall be able to:

a) properly inspect the RPD and recognize conditions that may compromise its integrity, such as missing components or deformations;

b) properly don the RPD without assistance;

c) perform a wearer-seal check.

Instruction in proper donning may occur immediately prior to the fit test or earlier and may involve assistance. After training, the fit test shall be conducted only after the RPD is donned without any physical or verbal assistance. If assistance is provided, the person being fit tested shall completely remove the RPD and don it again.

This does not fulfil the training requirements for the use of RPD. For further information, refer to ISO/TS 16975-1 and ISO/TS 16975-2.

6.3 Interference concerns

6.3.1 Facial hair

Skin contacting respiratory-interface sealing surfaces shall be shaved within 24 h of testing, preferably within 12 h.

A person shall not be fit tested if:

a) hair comes between the sealing surface of the RI and the face or neck; and

b) hair interferes with valves and/or RPD function.

6.3.2 Foreign material

A fit test shall not be conducted if there is any foreign material or substance between the sealing surface of the respiratory interface and the face or neck. Examples include temple bars or straps for eyewear, gels and creams.

6.3.3 Personal protective equipment (PPE) and other items that may interfere with fit

When any PPE and/or RPD accessory has the potential to interfere with the seal, it shall be worn during the fit test to ascertain compatibility with the RPD. For example, eye glasses, goggles, face shield, head protection, skull cap, hearing protection, welding helmet, hoods or other protective devices can potentially interfere with the seal of the RPD. This applies to all tight-fitting RPD.

The competent fit-test operator should record the make and model of PPE and/or RPD accessory worn during the fit test. Subsequently, if the make/model of PPE and/or RPD accessory changes, the RPD programme administrator will need to decide whether a new fit test is required in order to assess compatibility of the new combination.

6.3.4 Other conditions that can adversely affect fit

The fit test should be conducted with the RPD worn in the manner in which it is used. Not every individual may be able to obtain a satisfactory fit. For example, certain facial characteristics may interfere with RPD fit, such as hollow temples, excessively protruding cheekbones, deep skin creases, scars, the absence of teeth or dentures, injury to the face and swelling of the mouth or face.

RPD wearers who have dentures shall be fit tested:

a) with dentures, if they wear them while wearing the RPD in the workplace; or

b) without dentures, if they do not wear them while wearing the RPD in the workplace.

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Other factors can alter the seal of a RPD. Examples include cosmetics, facial jewellery and certain hair styles.

6.4 Frequency of fit testing

6.4.1 After completing health surveillance, persons wearing a tight-fitting RPD shall be fit tested prior to initial use of the RPD and whenever a different RI (size, style, model, material or make) is used.

National or local regulations can require periodic repeat fit testing. It is recommended that it be done at least annually.

6.4.2 A fit test shall also be repeated when a person has experienced a change that may affect the RI seal, such as:

a) a significant change in body weight;

b) a change to the face in the sealing area (e.g. scarring, facial surgery);

c) dental changes;

d) wearer discomfort.

6.5 RPD used for fit testing

6.5.1 General

Fit testing of tight-fitting RPD shall be done using either:

— the wearer's individually assigned RPD; or

— a surrogate or test RI having sealing surfaces, materials and head straps that are the same as the RPD to be assigned to the wearer.

RPD used for fit testing shall be equipped with filters and/or adapters appropriate for the selected fit-test method. The filter used for fit testing may be different than those used in the workplace. The weight of filters, and/or fit-test adapters used for fit testing can affect fit. Where possible, the RPD assembly used during the fit test should be representative of the RPD used in the workplace. For example, the weight of combination gas/particle filters may be significantly higher than a particle filter alone. RPD modifications made to accommodate fit testing shall not alter the fit of the RPD.

All tight-fitting respiratory interfaces shall be fit tested in the negative-pressure mode regardless of the mode of operation in which the RPD is used. For positive-pressure breathable gas RPD and assisted RPD, this can be accomplished by:

— temporarily converting the RI into a negative-pressure RPD by using appropriate adapter and filters; or

— using a negative-pressure RPD with an identical RI sealing surface.

6.5.2 RPD used for QLFT

RPD used for QLFT do not require modifications beyond those discussed above. (In-RI sampling instrumentation is not used for QLFT.)

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6.5.3 RPD used for QNFT

6.5.3.1 General

RPD used for QNFT shall permit in-RI sampling. This can be accomplished by either:

a) using a fit-test sampling adapter on an individually assigned RI,

b) using a fit-test sampling adapter on a surrogate RI, or

c) using a permanently-probed surrogate RI.

6.5.3.2 RPD temporarily modified with adapters

Fit-test sampling adapters used for QNFT shall be completely removed and the RPD restored to its original configuration before that RPD is used for respiratory protection.

6.5.3.3 Permanently-probed surrogate RIs

RPD used for QNFT may be permanently probed to provide a sampling port for the purpose of obtaining an in-respiratory interface sample. Permanently-probed RPD shall not be used for respiratory protection, unless the probed RPD meets the applicable requirements of the performance standards.

6.5.4 Sampling for aerosol systems

In-RI aerosol sampling devices shall be designed and used such that the sample is drawn at a point close to the face, midway between the nose and mouth. The sample probe should extend into the RPD cavity, but not close enough to be blocked by the face. The in-RI sampling point shall not be isolated from the nose or mouth by a physical partition. For example, if a nose cup is used on a full facepiece, the sample point shall be inside the nose cup. Care shall be taken to ensure that sample tubing is not extended beyond that which is necessary to take a sample from the breathing zone.

6.5.5 Maintenance of equipment and RPD used for fit testing

Fit testing equipment such as fit-test adapters, qualitative fit-test hoods and sampling tubing shall be kept in a clean and sanitary condition consistent with manufacturer's recommendations. RPD used for fit testing shall be properly inspected, tested and maintained according to the RPD manufacturer's recommendations.

RPD shall be cleaned and disinfected before being donned by different individuals. See the RPD manufacturer's instructions for recommended practices. Surrogate RI that cannot be sanitized (e.g. filtering facepiece) shall not be used by more than one individual.

6.6 Selecting RPD

6.6.1 General

No one size or model of RPD can be expected to fit all faces. Different sizes and models will accommodate more individuals. If fit is unsatisfactory, a different model or size of RI should be selected and the test repeated. Therefore, an appropriate number of sizes and models to accommodate the wearers shall be made available. Factors that should be considered in determining the number of RPD to be made available include the number of wearers and wearer acceptance.

If there is no make or model of tight-fitting RI to be found that fits satisfactorily, other RPD alternatives should be considered. Changing the model or size of potentially-interfering PPE may also be considered.

Fit-test operators shall not force-fit the RPD being fit tested but should inspect to make sure that there were no donning issues that might compromise the seal. Offering a reasonable assortment of RPD types and/or sizes should eliminate the inclination to force-fit.

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The selection should be based on comfort and results of wearer-seal checks, as well as personal preferences. Other factors that influence wearer acceptance include breathing resistance, impairment of vision, impairment of communications and RPD weight. RPD with greater wearer acceptance are more likely to be worn.

Repeat fit testing can be accomplished on the same make, model, style and size RPD without repeating the selection process if the wearer still finds that RPD acceptable. If fit testing shows that a person can obtain an acceptable fit with two or more models of the selected class of RPD, then the person should be permitted to use their preferred RPD model, provided that it is adequate and suitable for the intended use.

6.6.2 Comfort-assessment period

IMPORTANT — All RPD wearers shall don and adjust their RPD in accordance with the manufacturer's instructions.

RPD comfort is an important factor in wearer acceptance. Initial RPD wearers and anyone who changes the model or brand of RPD shall wear the RPD for a comfort-assessment period of approximately five minutes immediately prior to the fit test. If necessary, the person being fit tested may make adjustments to achieve a comfortable fit during this period.

The comfort period will also allow purging of any particles which have become trapped inside the RPD upon donning. This is important for QNFT methods which use particle-counting technology.

The comfort-assessment period allows the RPD wearer time to determine if the RPD is truly comfortable or not, and to make any necessary adjustments. Discomfort may become apparent only after the RPD is worn for a period of time. For example, over-tightened straps may not be noticed immediately. If the RPD wearer finds the comfort of the RPD to be unacceptable at any time, they shall be given the opportunity to try another RPD.

6.6.3 Required fit factor

Either qualitative or quantitative fit-testing methods may be used where appropriate. Qualitative fit testing shall only be used where a required fit factor (RFF) of 100 or less is needed. When performing quantitative fit testing, the overall quantitative fit factor (QNFF) measured shall be equal to or greater than the RFF.

Table 1 and Table 2 summarize the RFF needed for tight-fitting RPD and the acceptable fit-testing methods.

Table 1 — Required fit factors

Protection Class (PC)	Required fit factor[a]	
	GA[b] and CNC[c]	CNP[d]
1	100	100
2	100	100
3	100	100
4	2 000	500
5	2 000	500
6	2 000	500

[a] Required fit factor is dependent on method of QNFT performed. See Annex B for further information.

[b] GA is the generated aerosol QNFT.

[c] CNC is the condensation nuclei counting QNFT.

[d] CNP is the controlled negative pressure QNFT.

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Table 2 — Acceptable fit-testing methods

PC	QLFT	QNFT
1	Yes	Yes
2	Yes	Yes
3	Yes	Yes
4	No	Yes
5	No	Yes
6	No	Yes

7 Fit-test records

The programme administrator shall ensure that fit-test records are retained and contain the following information:

a) date of the test;

b) identification of the fit-test operator and fit-test operator's employer/company name;

c) name of the person fit tested;

d) details which will uniquely identify the RI such as make, model, size and material;

e) details which will uniquely identify all other potentially interfering PPE worn during the fit test such as spectacles, jewellery, make, model and size;

f) fit-test method used;

g) pass/fail criteria;

h) results: pass/fail, fit factors or other information generated may be documented;

i) corrective actions in case of a failed fit test;

j) overall fit factor achieved;

k) pass level used in the test;

l) serial number or other means of identifying test equipment used in the test;

m) any additional information the RPD programme administrator deems pertinent.

8 Fit-testing procedures

8.1 General

When RPD with tight-fitting RIs have been selected, regardless of their mode of operation, they shall be fit tested on the wearer. Type bT (e.g. quarter or half masks, filtering facepieces), cT (e.g. full facepieces), and dT (e.g. hood with a neck seal) will not provide optimum performance if they do not fit. Based on currently available information, annual fit testing is recommended.

NOTE National or local regulations can require periodic repeat fit testing, e.g. annually.

A fit test shall not be conducted if there is any hair growth such as beard stubble, beard, moustache or long sideburns, any jewellery or other article of clothing that cross between the face or neck and the sealing surface of the tight-fitting RPD.

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Before being fit tested, the wearer being fitted should be trained on correct inspection, donning, doffing, performing a wearer-seal check on the RPD and the purpose and procedures for the fit test. It is essential that the wearer being fit tested is free from hair or jewellery in the RI sealing-surface area.

Fit testing is accomplished by using either a qualitative (QLFT) or quantitative (QNFT) fit test procedure. Proper precautions are necessary to ensure that the RPD being fit tested is configured to remove the test agent ensuring that if the test agent is detected or measured inside the RI, it is because of a leakage via the face/neck seal. Prior to conducting the fit test, the wearer is to be briefed about the test procedure.

8.2 Respiratory interface

It is preferable to be fit tested using the wearer's "personal" RI. Where this is not practicable or pooled equipment is used, then a test RI of the same model, size and material should be used.

When an individual uses more than one type (i.e. different make and model) of tight-fitting RI, that individual is to be fit tested with each RI.

WARNING — Any modifications made to the RI for fit-testing purposes shall be removed, and the RI restored to its original configuration, before it can be used in the workplace.

8.3 Briefing the fit-test subject

Before being fit tested, the person being fitted shall be trained on how to correctly don the RPD and on how to conduct a pre-use check (e.g. wearer-seal check) as described in the information supplied by the manufacturer. The person should be shown how to put on the RI including how it is positioned on the face and how to adjust strap tension; a mirror can be a useful aid in evaluating the positioning of the RI and straps.

Prior to starting the fit test, the person being fitted shall be briefed on the purpose and procedures for the fit test. A description of test exercises that will be used should be provided. The person being fit tested should understand that the purpose of the test is to determine the specific respiratory-interface model and size that provides adequate fit.

8.4 Fit-test exercises

The following test exercises are to be performed for all fit-testing methods prescribed in this document, except for the controlled negative pressure (CNP) method. A separate fit-test exercise regime is contained in the CNP protocol; see 8.6.4.5 b). The wearer shall perform exercises in the following manner.

a) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

b) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

c) Turning head side to side. Standing or sitting, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side. Exhalation shall take place through the return movement of the head.

d) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up and down positions. Exhalation shall take place through the return movement of the head.

e) Talking. The subject shall talk slowly and loud enough so as to be heard clearly by the fit-test operator. The subject can read from a prepared text, count backward from 100 or recite a memorized poem.

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f) Bending over. The wearer shall bend at the waist as if to touch their toes and return to an upright position. This shall be repeated. Jogging in place shall be substituted for this exercise when using test equipment, such as shroud type QNFT or QLFT units, that do not permit bending over at the waist.

g) Normal breathing. Same as exercise a).

Each fit-test exercise shall be performed for at least 60 s. For QNFT, the test exercises should allow for an in-mask sample period of at least 60 s. Instruct the person being fit tested to perform each exercise described above for the entire period. The RPD shall not be adjusted once the fit-test exercises begin. Any adjustment voids the test and the fit test shall be repeated.

8.5 Qualitative fit testing (QLFT)

8.5.1 General

These fit-test methods use test agents with distinctive taste or smell for detecting leakage via the respiratory-interface seal. Three test agents are commonly used: a sweet-tasting aerosol (sodium saccharin CAS# 128-44-9), a bitter-tasting aerosol [(Bitrex®[1] CAS# 3734-33-6)] and a sweet (banana) smelling vapour [isoamyl acetate (IAA) CAS# 123-92-2)]. The fit test is conducted in an atmosphere containing the fit-test agent. Specially adapted enclosures are used for creating a localized test atmosphere. If the wearer detects the taste or smell of the fit-test agent during the fit test then the fit is unsatisfactory; the RI should be re-inspected and/or readjusted and the test repeated. During this test, the wearer will carry out a number of specified exercises (see test exercises in 8.4).

Qualitative fit-tests do not give a numerical indication of fit; no direct measurements of the test and leak concentrations are made. The reliability of the fit test depends upon the wearer's ability to detect and indicate whether the fit-test agent is sensed. Some wearers may not be sensitive enough to the fit-test agent resulting in face-seal leaks that may not be detected. Therefore, before commencing the fit test, it is necessary to establish whether the wearer is able to detect the fit-test agent at low concentrations. This is called threshold screening. With the use of the threshold-screening step, these qualitative fit-test methods are sensitive enough to ensure fit factors of 100. Where a fit factor greater than 100 is required, qualitative fit-test methods are not suitable and a quantitative fit-test method should be selected.

8.5.2 Aerosol qualitative fit tests

There are two substances that are used as aerosol (particles) challenges for conducting a qualitative fit test. Because the two fit tests are similar, they are discussed together. The fit test only needs to be done using one of the substances; sodium saccharin solution or Bitrex® (denatonium benzoate) solution. Both fit tests use a person's ability to taste small amounts of the fit-test aerosol to determine RPD face/neck-seal leakage. The wearer being fit tested shall be able to detect a weak concentration of either sweet-tasting saccharin or bitter-tasting Bitrex®, depending on the fit-test agent to be used (threshold-screening). The wearer's ability to taste low concentrations of the fit-test agent is determined by spraying a weak solution of sodium saccharin or Bitrex® into a fit-test hood placed over the person's head while not wearing a RPD. Next, while the person is wearing a RPD, the fit-test hood is placed over the head and a stronger saccharin or Bitrex® solution is sprayed into the fit-test hood at measured intervals, while the wearer conducts fit-test exercises as in 8.4. If the person being fit tested does not detect the taste of saccharin or Bitrex®, the RI fits the person and (s)he has a minimum ensured fit factor of 100. This fit testing procedure is only appropriate for wearers who pass the threshold-screening for the respective fit-test agent and use RPDs that have a particle filter or one that can be fitted with a particle filter for the fit test.

1) Bitrex is the trademark of a product supplied by Macfarlan Smith Limited, part of Johnson Matthey PLC's Fine Chemicals Division. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

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If the person is unable to pass the threshold-screening using one of the fit-test agents, the fit-test operator may choose to do the threshold-screening test using the other fit-test agent. For the fit test, the fit-test solution for the fit-test agent in which the subject passed the threshold-screening shall be used.

Any variation from the procedure specified below can invalidate the results, including changes in solution concentration, how the bulb is squeezed, the number of squeezes, and the size of the fit-test hood.

PRECAUTIONS Because a person's ability to taste the fit-test solution is used to determine whether the RPD fits, he or she should refrain from activities that would affect the sense of taste such as consuming any food or beverage (other than plain water), using tobacco products or chewing gum, for at least 15 min prior to threshold-screening. The fit test shall be done after the threshold-screening, allowing sufficient time for the taste of the threshold fit-test agent to clear. Review the sodium saccharin or Bitrex® safety data sheet (SDS), depending on the chemical being used for the fit-test, for any handling and use precautions.

Fit-test operators should be aware that wearing a fit-test hood will elevate inhaled carbon dioxide levels and decrease inspired oxygen levels. The fit-test operator should inform the person that they may feel hot or experience distress. If this occurs, the person should tell the fit-test operator, and the competent fit-test operator should stop the test and remove the hood and RPD.

8.5.3 Taste-threshold-screening

8.5.3.1 General

Use of either one of the fit-test solutions requires that the person being fit tested demonstrates the ability to taste a low concentration of the fit-test agent being used.

8.5.3.2 Equipment

The following equipment is necessary for conducting the threshold-screening. Kits containing the equipment listed below are sold commercially.

a) A hand-held inhalation nebulizer designed to create fine mists with a 2,5 µm MMAD (mass median aerodynamic diameter) with a 5 ml capacity. Aerosol particle size and concentration are determined by the characteristics of the nebulizer.

b) A fit-test hood with a nominal size of 300 mm in diameter by 355 mm high with at least the front portion clear. The fit-test hood shall allow free movement of the head when a RPD is worn. A hole approximately 25 mm in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle.

c) Threshold-screening solution with 0,83 g sodium saccharin (USP grade) in 100 ml distilled water or with 13,5 mg Bitrex® in 100 ml of a 5 % sodium chloride (NaCl) solution (5 mg NaCl/95 ml distilled water).

CAUTION — If there is evidence of solution contamination, immediately discard the solution. To avoid contamination, always replace the lid of the bottle immediately after use and observe the manufacturer's storage instructions and expiry date.

8.5.3.3 Taste-threshold screening procedure

The following procedure shall be followed to conduct the threshold-screening test.

a) Add a small amount of the selected taste-screening solution (~ 3 ml) into the nebulizer.

b) Place the fit-test hood over the person's head.

c) The person being fit tested shall not be wearing a RPD at this time. Ask the person to breathe through their mouth only.

d) Instruct the person to immediately report if or when the sweet taste of saccharin or the bitter taste of Bitrex® is detected.

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e) Insert the nebulizer nozzle into the opening at the front of the fit-test hood. Direct the nozzle away from the nose and mouth of the person. Be careful not to spray the aerosol onto the surface of the fit-test hood or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

   Determine that the nebulizer is working by observing that a visible mist is produced throughout the procedure.

f) Squeeze the nebulizer bulb up to 10 times. If the person reports the sweet or bitter taste during the 10 squeezes, stop squeezing the bulb; the screening test is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 10.

g) If the person being fit tested is unable to detect the sweet or bitter taste after 10 squeezes, apply up to another 10 squeezes. If the person reports the sweet or bitter taste during the second 10 squeezes, stop squeezing the bulb; the screening is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 20.

h) If the person is unable to detect the sweet or bitter taste after the second 10 squeezes, apply up to another 10 squeezes. If the person reports the sweet or bitter taste during the third set of 10 squeezes, stop squeezing the bulb; the screening is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 30.

i) If the person is unable to detect the sweet or bitter taste after 30 squeezes, he or she is unable to taste saccharin or Bitrex®, respectively, and that fit-test method shall not be used. The competent fit-test operator should recognize that some people may not detect the sweet taste of saccharin or the bitter taste of Bitrex® and therefore should not encourage the person to respond in a falsely positive manner. If the threshold screening to one of the fit-test agents is unsatisfactory, the screening can be repeated with the other fit-test agent.

8.5.4 Fit testing

8.5.4.1 General

Prior to the start of the fit test, the competent fit-test operator should ensure that the wearer's mouth and lips are clear of taste. The person is fit tested while wearing a RPD inside the fit-test hood and the fit-test solution is sprayed into the hood.

8.5.4.2 Equipment

The following equipment is necessary for conducting the fit test.

a) A second nebulizer of the same make and model as that used for the threshold screening.

b) Fit-test solution: 83 g sodium saccharin (CAS# 128-44-9, USP grade) per 100 ml distilled water or 337,5 mg of Bitrex® (CAS# 3734-33-6) per 200 ml of a 5 % sodium chloride (CAS# 7647-14-5) by weight solution in distilled water.

c) RPD used for fit testing shall be equipped with a particle filter(s).

d) A fit-test hood of the same size as the one used during the threshold screening should be used during the fit test. The fit-test hood shall allow free movement of the head when a RPD is worn. A hole, approximately 25 mm in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle (e.g. the same hood used during the threshold-screening).

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8.5.4.3 Fit-testing procedure

The following procedure shall be followed to conduct the fit test.

a) The person being fit tested shall don the RPD and conduct a wearer-seal check. Place the fit-test hood over the person's head positioning the fit-test hood to maximize the space between the front of the fit-test hood and the RPD.

b) Ask the person to breathe through their mouth only. Instruct the person to immediately report if the sweet taste of saccharin or the bitter taste of Bitrex® is detected.

c) Add a small amount of the selected test solution (~ 3 ml) into the nebulizer.

   If the fit-test solution bottle has crystallized material, do not use it until all of the crystals have been dissolved by gently warming and shaking the solution.

d) Insert the nebulizer nozzle into the opening at the front of the fit-test hood and direct the aerosol into the space between the side of the RPD and the fit-test hood. As an alternative, directing the aerosol to either side of the wearer's RPD is acceptable. Spray fit-test aerosol into the fit-test hood by squeezing the nebulizer bulb 10, 20, or 30 times based on the taste-threshold number assigned during the threshold screening. Be careful not to direct the aerosol spray onto the fit-test hood, RPD or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

   Determine that the nebulizer is working by observing that a visible mist is produced throughout the fit test.

e) Instruct the person to perform the series of fit-test exercises described in 8.4.

f) Replenish the concentration in the fit-test hood every 30 s throughout the remainder of the fit test, by adding half the original number of squeezes (i.e. 5, 10 or 15).

g) The fit is unsatisfactory if the wearer reports tasting the fit-test aerosol at any time while conducting the test exercises. At this point, a decision shall be made, either to retest after re-donning the RPD or select another RPD. In either case, the entire procedure shall be repeated (taste-threshold screening and fit testing). It may take several minutes for the person being fit tested to regain the ability to taste low concentrations of fit-test aerosol. Rinsing the mouth out with plain water and wiping the lips with a wet towel may help. Do not repeat this fit test until the person being fit tested successfully completes the taste threshold screening again.

h) After the completion of all the exercises described in 8.4, if the wearer being fit tested does not report tasting fit-test aerosol during the fit test, instruct them to reach into the fit-test hood and momentarily break the RPD seal while inhaling through their mouth. If the fit-test aerosol taste is not detected after breaking the RPD seal, the fit test is null and void and the reason why the person did not taste the fit-test aerosol shall be identified. If the fit-test aerosol taste is detected after breaking the seal, the fit test is valid and the RI fits the person.

i) If the wearer with the relevant RI has passed, it is assumed to have an equivalent fit factor of at least 100.

IMPORTANT — Since the saccharin test solution has a tendency to clog during use, the competent fit-test operator shall make periodic checks to determine that it is not clogged. If clogging occurs during the fit test and it is not immediately cleared or a new nebulizer used, the fit test is invalid.

8.5.5 Vapour qualitative fit test with isoamyl acetate (banana oil)

8.5.5.1 General

The isoamyl acetate (IAA) fit test uses a person's sense of smell to detect leakage into the RPD. The person being fit tested shall first demonstrate the ability to detect a known, low (~ 1 ppm) concentration

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of IAA. Next, while wearing a RPD, the person enters a fit-test enclosure with a higher (>100 ppm) concentration of IAA. If the banana-like odour of IAA is not detected during the fit test, the RI fits the person and it is assumed to have an equivalent fit factor of 100.

NOTE Any variation from the procedure specified below can invalidate the results, especially changes in solution concentrations, amount of IAA used during the fit test and the size of the fit-test enclosure.

PRECAUTIONS The threshold screening and the fit test shall be done in separate areas that do not allow the transfer of IAA vapours from the fit-test area to the screening area. The sense of smell is diminished temporarily by even brief exposures to IAA. The fit test should be conducted immediately after the screening. Review the isoamyl acetate safety data sheet (SDS) for any handling and use precautions.

8.5.5.2 Odour-threshold-screening

8.5.5.2.1 General

Use of the IAA fit-test method requires that the person being fit tested have the ability to smell low concentrations of IAA. This is determined by completing the odour-threshold-screening.

8.5.5.2.2 Equipment

The following equipment is necessary for conducting the threshold screening. Kits containing the equipment listed below are sold commercially:

a) three or more identical 1-l glass jars with non-porous lids;

b) a 1-ml pipette, syringe or other device capable of dispensing in 0,1 ml increments;

c) odour-free water (e.g. distilled or spring water) at room temperature (about 20 °C to 25 °C);

d) isoamyl acetate (IAA), reagent grade (CAS# 123–92–2).

8.5.5.2.3 Odour threshold-screening solution preparation

The following procedure for the preparation of the IAA odour screening solution shall be followed.

a) Prepare a stock solution by adding 1 ml of reagent grade IAA to 800 ml water in a glass jar labelled “stock solution” and shake for 30 s. This solution shall be prepared at least weekly.

b) Label the remaining jars described below using a switchable identification system (e.g. switchable numbers) so that only the person who conducts the fit test can identify the contents of each jar by sight.

c) Prepare an odour-threshold screening solution by placing 0,4 ml of the stock solution into 500 ml water in a second jar. Close the lid, shake and let the jar stand for 2 min before use. This solution is prepared daily.

d) Prepare a blank jar by adding 500 ml water to one or more jars. More than one blank jar should be used to make it more difficult for someone to guess.

e) Switch the jar-identification labels between tests so that the same numbered jar is not always the one that smells like bananas.

8.5.5.2.4 Odour-threshold screening procedure

The following procedure outlining the necessary steps to conduct the IAA odour-threshold screening shall be followed.

a) Ask the person being fit tested to determine which jar smells like bananas by instructing the person to shake each jar briefly, remove the lid, sniff at the mouth of the jar and recap the lid.

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b) If the person correctly identifies which jar contains IAA, then the person may continue with the odour-threshold screening. If the correct jar cannot be identified, the IAA fit-test method shall not be used.

c) Remarks:

1) Prevent sense of smell fatigue by not allowing IAA vapour to be present in the screening area. The odour-threshold screening shall be done in a separate area (i.e. a different room) to prevent transfer of IAA vapours from the fit-testing area.

2) A card may be prepared with instructions that the person being fit tested can follow to shake the jars, remove the lids, and determine which jar smells like bananas. Example wording: "The purpose of this odour-threshold screening is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight; then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the fit-test conductor which bottle contains banana oil."

3) Take care not to contaminate the blank jar(s) by switching jar lids.

8.5.6 IAA fit-testing procedure

8.5.6.1 General

The person is fit tested while wearing a RPD in a fit-test enclosure containing a controlled concentration of IAA.

Competent fit-test operators should be aware that wearing a RPD within a fit-test enclosure may elevate inspired carbon dioxide levels and decrease inhaled oxygen levels. The competent fit-test operator should inform the person that they may feel hot or experience distress. If this occurs, the person should tell the competent fit-test operator to stop the fit test, exit the enclosure and remove the RPD.

8.5.6.2 Equipment

The following equipment is necessary for conducting the IAA fit test.

a) Fit-test enclosure: A clear plastic bag approximately 60 cm in diameter and 150 cm long, (e.g. a 200 l plastic drum liner) equipped with a frame to hold the bag open and a suitable device or clip for holding the absorbent paper.

b) A piece of absorbent paper (e.g. a paper towel), approximately 15 cm × 12 cm. A new piece of absorbent paper is needed for each fit test.

c) A quantity of 0,75 ml of IAA (reagent grade) is needed for each fit test.

d) RPDs used for fit testing shall be equipped with gas filters that remove organic vapours. Gas filters should be replaced before breakthrough occurs.

8.5.6.3 Conducting the IAA fit test

The following steps outline the procedure for conducting the IAA fit test.

a) Instruct the person being fit tested to don the RPD, equipped with a filter capable of removing organic vapours, as trained. Adjust the ceiling of the enclosure to a distance about 15 cm above the person's head.

b) Apply 0,75 ml of reagent grade IAA to one piece of absorbent paper, which is folded in half. Hand it to the person in the enclosure, who then attaches it to the inside top of the enclosure. A freshly wetted piece of absorbent paper shall be used for each fit test.

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c) Wait two minutes for the IAA concentration to stabilize in the enclosure.

d) Instruct the person that any detection of the smell of IAA (banana-like odour) during the fit test is to be reported immediately.

e) Instruct the person to perform the series of test exercises described in 8.4.

f) The fit is unsatisfactory if the person reports smelling IAA at any time while conducting the fit-test exercises. The subject shall quickly exit from the fit-test chamber and leave the test area to avoid olfactory fatigue. At this point, a decision shall be made, either to retest the same RPD after re-donning or select another RPD. In either case, the entire procedure shall be repeated (odour screening and fit testing). It can be useful to inspect the RPD for possible leaks before re-donning. It can take several minutes for the person being fit tested to regain the ability to smell low concentrations of IAA. Do not repeat the fit test until the person being fit tested successfully completes the odour-threshold screening again.

g) After completion of all the fit-test exercises described in 8.4, if the person being fit tested does not report smelling the IAA, instruct the person to momentarily break the RPD seal and inhale. If IAA is not detected after breaking the RPD seal, the fit test is null and void and the reason why the person did not smell the IAA shall be identified. If the IAA is detected after breaking the seal, the RI fits the person.

h) If the wearer with the relevant RI has passed, it is assumed to have an equivalent fit factor of at least 100.

i) At the end of a passed or failed fit test, have the person remove the absorbent paper and seal it in a small plastic bag or similar container to lessen the build-up of IAA vapour in the fit-testing area.

The absorbent paper shall not be re-used for other IAA fit tests.

8.6 Quantitative fit testing (QNFT)

8.6.1 General

Quantitative fit testing provides a numerical indicator of fit called a fit factor (FF). The tests given in 8.6.2 to 8.6.4 provide a measure of RPD fit. This subclause contains three QNFT methods that have been proven for field use and readily available.

8.6.2 Generated aerosol quantitative fit-test procedure

8.6.2.1 Operating principles

The RPD used for the fit test shall be equipped with particle filters that do not allow the challenge aerosol to significantly penetrate into the RPD. The aerosol detection instrument cannot differentiate between body-generated particles, face-seal particle penetration, exhalation valve leakage and filter leakage. Leakage from all sources other than face-seal leakage can result in erroneously low fit factors. To minimize leakage from the sources other than face-seal leakage:

— the RPD shall be inspected for proper function prior to fit testing;

— the RPD shall be equipped with particle filters that do not allow the challenge aerosol to penetrate significantly (particle filter class F3, F4 or F5);

— care shall be taken to minimize body-generated particles inside the RPD. (For example, particles may be released from the lungs for a period of time after smoking cigarettes or e-cigarettes. Therefore, fit testing should not be conducted within 30 min of smoking.)

An aerosol challenge agent is introduced into a fit-test chamber that surrounds the head and shoulders, or the entire body, of the RPD wearer. An instrument is used to measure concentrations of the challenge aerosol outside, C_{out}, and inside, C_{in}, the RPD, while the person being fit tested performs a series of fit-

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test exercises designed to stress the face/neck seal in ways that approximate anticipated workplace movements.

The RPD used for the fit test shall be equipped with particle filters that do not allow the challenge aerosol to significantly penetrate into the RPD. Thus, it is assumed that the aerosol inside the RPD has entered through a face/neck-seal leak.

The quantitative fit factor (QNFF) is calculated as the ratio of the two aerosol concentrations measurements as shown in Formula (1):

$$QNFF = \frac{C_{\text{out}}}{C_{\text{in}}} \tag{1}$$

where

C_{out} is the challenge aerosol concentration outside the RI;

C_{in} is the challenge aerosol concentration inside the RI.

8.6.2.2 Equipment

The equipment needed for the generated aerosol QNFT includes:

a) aerosol generation and distribution system. The challenge aerosol shall have a mass median aerodynamic diameter (MMAD) less than 1 µm;

b) aerosol detection system, typically flame or forward light scattering photometry;

c) fit-test chamber to contain challenge aerosol;

d) selected RPD equipped with sampling probe or fit-test sampling adapter and appropriate RPD filters (particle filter class F3, F4 or F5) (where practical, the weight of the particle filter should approximate the one used in the workplace);

e) other accessories and supplies as required by the equipment manufacturer.

8.6.2.3 Equipment setup

The fit-testing equipment can vary widely depending on its manufacturer. The manufacturer's instructions shall be followed for equipment set-up, inspection and operation.

8.6.2.4 Conducting the fit test

The following steps outline the general procedure for conducting the generated aerosol QNFT.

a) Instruct the person being fit tested to don the RPD as trained.

b) Have the person being fit tested enter the test chamber and connect the RPD used for the fit test to the sample line.

c) Perform fit test according to the instrument manufacturer instructions using the exercises described in 8.4.

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8.6.2.5 Interpretation of results

Leakage (C_{in}/C_{out}) is measured for each exercise. The average leakage, Pen_{ave}, is the arithmetic mean of the measured leakage (Pen) for each exercise as shown in Formula (2):

$$Pen_{ave} = \frac{Pen_1 + Pen_2 \ldots + \ldots Pen_n}{N} \quad (2)$$

where

Pen_1 is the first measured leakage;

Pen_2 is the second measured leakage;

Pen_n is the nth measured leakage;

N is the number of exercises.

The overall quantitative fit factor (QNFF) is calculated by using Formula (3):

$$QNFF = \frac{1}{Pen_{ave}} \quad (3)$$

EXAMPLE Given the following leakages for a series of six exercises:

Pen_1 = 0,001 5; Pen_2 = 0,000 7, Pen_3 = 0,001 7, Pen_4 = 0,000 5, Pen_5 = 0,000 9, Pen_6 = 0,001 1 and Pen_7 = 0,001 0

$$Pen_{ave} = \frac{0{,}001\,5 + 0{,}000\,7 + 0{,}001\,7 + 0{,}000\,5 + 0{,}000\,9 + 0{,}001\,1 + 0{,}001\,0}{7} = 0{,}001\,057$$

$$QNFF = \frac{1}{0{,}001\,057} = 945$$

When a strip chart is used, the Pen for each exercise is estimated by drawing a line through the midpoint of the trace for that exercise. The midpoint of this line represents the percent leakage taking into account the range to which the instrument is set.

The person with the RI has passed the fit test if the overall fit factor equals or exceeds the required fit factor (see Table 1).

8.6.3 Ambient aerosol condensation nuclei-counting (CNC) instrument quantitative fit-test procedure

8.6.3.1 Operating principles

CNC-counting instruments are capable of measuring the number concentration of particles in a given aerosol sample by counting single particles. When used for QNFT, the particle concentration of the fit-test challenge aerosol around the head and shoulders (C_{out}) and the particle concentration inside the RPD (C_{in}) are both measured while the person being fit tested performs a series of exercises designed to stress the face/neck seal in ways that approximate anticipated workplace movements.

CNC-counting instruments for fit testing typically use the particles in the ambient air as the challenge aerosol. This eliminates the need for aerosol generators and fit-test chambers, however they can be used to augment aerosol concentration when needed (i.e. clean environments like hospitals).

The CNC-counting device cannot differentiate between body-generated particles, face-seal particle leakage, exhalation valve leakage and filter leakage. Leakage from all sources other than face-seal

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leakage can result in erroneously low fit factors. To minimize leakage from the sources other than face-seal leakage:

— the RPD shall be inspected for proper function prior to fit testing to minimize particle leakage;

— the RPD shall be equipped with particle filters that do not allow the challenge aerosol to penetrate significantly (particle filter class F3, F4 or F5);

— care shall be taken to minimize body-generated particles inside the RPD. (For example, particles may be released from the lungs for a period of time after smoking cigarettes or e-cigarettes. Therefore, fit testing should not be conducted within 30 min of smoking.)

It is assumed that all particles sampled from inside the RPD have entered through a face-seal leak.

The quantitative fit factor (QNFF) is calculated from the two fit-test aerosol concentration measurements as given in Formula (1).

8.6.3.2 Equipment

The following equipment is needed to conduct the CNC QNFT:

a) CNC counting-QNFT instrument;

b) filter for diagnostic checks recommended by the instrument manufacturer;

c) other accessories and supplies required by the instrument manufacturer;

d) RPDs equipped with probes or fit-test sampling adapters and RPD particle filters (particle filter class F3, F4 or F5) that do not allow the challenge aerosol to penetrate significantly.

8.6.3.3 Diagnostic checks

All daily diagnostic checks required by the manufacturer shall be performed. The instrument shall pass all required checks before fit testing can begin. Refer to the manufacturer's instructions for specifications and guidance.

8.6.3.4 Prepare to fit test

The manufacturer's instructions shall be followed for the CNC fit-testing equipment set up, inspection and operation.

a) Follow the manufacturer's instructions to set the instrument to perform the required fit-test exercise protocol.

b) Connect the instrument sample hose to the RPD to be tested.

c) Instruct the person being fit tested to don the RPD as trained.

d) Allow the person's breathing to purge ambient particles trapped inside the RPD during donning before testing. A RI type bT will usually purge in a few breaths while a RI type cT may take a full minute.

8.6.3.5 Fit testing

Initiate the instrument's fit-test cycle. During this process, the instrument will sample the particle concentration in the test environment and the concentration of those particles that leak into the RPD. The fit test is completed when all of the described exercises as described in 8.4 have been completed.

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8.6.3.6 Interpretation of results

At the completion of the fit test, the instrument provides a pass/fail indication and/or a numeric overall fit factor result for the entire test calculated according to Formula (4).

The person has passed the fit test if the overall fit factor as calculated in Formula (4) equals or exceeds the required fit factor as given in Table 1:

$$QNFF_{\text{overall}} = \frac{N}{\frac{1}{QNFF_1} + \frac{1}{QNFF_2} + \ldots + \frac{1}{QNFF_n}} \tag{4}$$

where

N is the number of exercises;

$QNFF_1$ is the fit factor for the first exercise;

$QNFF_2$ is the fit factor for the second exercise;

$QNFF_n$ is the fit factor for the n^{th} measured exercise.

EXAMPLE Given the following fit factors for a series of seven exercises:

$QNFF_1 = 666$, $QNFF_2 = 1429$, $QNFF_3 = 588$, $QNFF_4 = 2000$, $QNFF_5 = 1111$, $QNFF_6 = 1018$ and $QNFF_7 = 909$

$$QNFF_{\text{overall}} = \frac{7}{\frac{1}{666} + \frac{1}{1\,429} + \frac{1}{588} + \frac{1}{2\,000} + \frac{1}{1\,111} + \frac{1}{1\,018} + \frac{1}{909}} = 948$$

8.6.4 Controlled negative-pressure (CNP) REDON quantitative fit-test procedure

NOTE REDON is used to distinguish this protocol from earlier CNP protocols. This protocol is called REDON because the respirator is removed and then re-donned two times during the test.

8.6.4.1 Operating principle

During CNP fit testing, in-RI negative challenge pressures are selected that simulate a range of work rates. The primary factors affecting in-RI negative pressure during inhalation are work rate and air flow resistance through the filters. The CNP fit-test method is based on exhausting air from a temporarily sealed RPD. Measurement of the air exhaust rate required to hold the in-RI pressure constant while the air inlets are sealed with leak-tight test adapters yield a direct measure of leakage air flow into the RPD. The rate of air leakage is directly related to the amount of negative pressure created inside the RPD during inhalation.

Air is the fit-test challenge agent for a CNP fit-test. The amount of air that leaks into the RPD is assumed to represent face/neck-seal leakage. The rate of air leakage is directly related to the pressure differential created inside the RPD during inhalation.

The CNP fit-testing system is activated to establish and maintain a negative challenge pressure in the temporarily sealed RPD. The exhaust flow rate required to maintain a constant challenge pressure is averaged over the duration of the measurement, and represents a direct measure of RPD leakage flow rate.

A CNP fit factor is calculated from the ratio of the modelled inspiratory flow rate and measured leakage flow rate. Fit factors cannot be measured during exercises in controlled negative-pressure fit-testing. Therefore, measurements of RI leakage are made at the end of each fit-test exercise while the wearer neither moves nor breathes.

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