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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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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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).

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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.

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.

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.]

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]

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.