# TECHNICAL SPECIFICATION

# ISO/TS 16975-1

First edition

# Respiratory protective devices — Selection, use and maintenance —

# Part 1:

Establishing and implementing a respiratory protective device programme

Appareils de protection respiratoire — Choix, utilisation et entretien —

Partie 1: Élaboration et mise en oeuvre d'un programme pour les appareils de protection respiratoire

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Reference number ISO/TS 16975-1:2016(E)

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## Foreword

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

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

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For an explanation on 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: <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

The committee responsible for this document is ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 15, *Respiratory protective devices*.

ISO 16975 consists of the following parts, under the general title *Respiratory protective devices* — *Selection, use and maintenance*:

- Part 1: Establishing and implementing a respiratory protective device programme [Technical Specification]
- Part 2: Condensed guide to establishing and implementing a respiratory protective device programme [Technical Specification]
- Part 3: Fit testing procedures

# Introduction

This part of ISO 16975 contains the essential requirements for establishing and implementing a complete respiratory protective device (RPD) programme for respiratory protective devices that meet the requirements of the performance standards. It contains information on risk assessment, selection procedure, training, use and maintenance.

Informative Annexes provide additional guidance on how to implement such a programme.

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# Respiratory protective devices — Selection, use and maintenance —

# Part 1:

# Establishing and implementing a respiratory protective device programme

# 1 Scope

This part of ISO 16975 specifies detailed information to assist persons responsible for establishing and implementing a programme for respiratory protective devices (RPD) that meet the performance requirements of the performance standards.

This part of ISO 16975 does not apply to RPD programmes for RPD used exclusively under water, for use in aircraft, and medical life support respirators and resuscitators.

NOTE The information contained in this part of ISO 16975 can be used to assist in the preparation of national or local regulations; however, this part of ISO 16975 does not supersede national or local regulations.

WARNING — Failure to select, use and maintain RPD correctly can result in injury, illness or death.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 16900-1, Respiratory protective devices — Methods of test and test equipment — Part 1: Determination of inward leakage

ISO 16972, Respiratory protective devices — Terms, definitions, graphical symbols and units of measurement

ISO/TS 16975-2,<sup>1)</sup>Respiratory protective devices — Selection, use and maintenance — Part 2: Condensed guide to establishing and implementing a respiratory protective device programme

ISO 16975-3,<sup>2)</sup>Respiratory protective devices — Selection, use and maintenance — Part 3: Fit testing procedures

ISO 17420-3, Respiratory protective devices — Performance requirements — Part 3: Thread connection

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16972 and the following apply.

## 3.1

## adequate RPD

RPD (3.8) capable of reducing the inhalation exposure to an acceptable level

- 1) To be published.
- 2) To be published.

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### 3.2

## assigned protection factor

## **APF**

anticipated level of respiratory protection that would be provided by a properly functioning *RPD* (3.8) or class of RPD within an effective RPD programme (3.10)

### 3.3

## competent person

person with suitable and sufficient experience and with practical and theoretical knowledge of the elements of an *RPD programme* (3.10) for which (s)he is responsible

#### 3.4

### hazardous substance

substance that presents a potential to cause injury or ill health if it is inhaled, ingested or comes into contact with, or absorbed through, the skin.

Note 1 to entry: A hazardous substance may be a pure substance or generated as by-products during work activities; for example, wood dust and stone dust welding fume.

Note 2 to entry: Hazardous substances can be present in the atmosphere in a number of physical states as

- a) gases, such as ammonia and chlorine,
- b) vapours, such as from solvents, and
- c) particles, such as dust, mist, smoke, fumes, fibres, fog and bioaerosols.

## 3.5

## hazardous atmospheres

the level atmosphere that is oxygen-deficient and/or of substances in the atmosphere is at a concentration deemed to be hazardous

## 3.6

## protection class

## PC

numerical designation from PC1 to PC6 allocated to individual RPD (3.8) based upon laboratory testing indicating its relative protection

## 3.7

## protection level

degree of respiratory protection allocated to an RPD (3.8) for the purposes of selection and use that is expected to be provided to wearers when used within an effective RPD programme (3.10)

### 3.8

# respiratory protective device

personal protective equipment designed to protect the wearer's respiratory tract against inhalation of hazardous atmospheres (3.5)

## 3.9

## risk assessment

process of hazard, adequacy and suitability assessments relating to the selection of *RPD* (3.8)

### 3.10

## **RPD** programme

process of selecting, using and maintaining RPD (3.8) to ensure adequate protection to the wearer

## 3.11

2

## suitable RPD

RPD (3.8) that is adequate and is matched to the requirements of the wearer, the task and the working environment

## 3.12

## work rate class

numerical designation from W1 to W4 allocated to individual *RPD* (3.8) based upon laboratory testing indicating its relative ability to meet the wearer's demand for breathable gas at different activity levels

Note 1 to entry: Further information on work rate is given in 7.3.3.4.

## 3.13

# immediately dangerous to life or health

## **IDLH**

atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere

## 4 Abbreviated terms

**AB** Abrasive Blasting (Special Application Class)

**ADE ASM** Adequacy Assessment

**APF** Assigned Protection Factor

**CBRN** Chemical, Biological, Radiological, and Nuclear (Special Application Class)

**ES** Escape (Special Application Class

**FF** FireFighting (Special Application Class)

**HAZ-ASM** Hazard Assessment

**HHG** Health Hazard Group

HR Hazard Ratio

IDLH Immediately Dangerous to Life or Health

MA Marine (Special Application Class)

MN Mining (Special Application Class)

**NPF** Nominal Protection Factor

**OEL** Occupational Exposure Level

**OEL-TWA** Occupational Exposure Level-Time Weighted Average

**PC** Protection Class

PL Protection Level

**PPE** Personal Protective Equipment

**QLFT** Qualitative Fit Test

**QNFF** Quantitative fit factor

**QNFT** Quantitative Fit Test

**RFF** Required Fit Factor

**RI** Respiratory interface

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**RPD** Respiratory Protective Devices

**S** Breathable gas capacity

**SU ASM** Suitability Assessment

**SY** Breathable gas capacity Class of airline supplied RPD

W Work rate Class

**WE** Welding (Special Application Class)

# 5 Situations for using RPD

RPD is considered to be at the bottom of the hierarchy of control measures and should only be used after an acceptable case for its use has been established by way of an appropriate risk assessment. RPDs are used to further reduce inhalation exposures to hazardous atmospheres:

- when sufficient engineering and administrative controls are lacking;
- when these controls are not reasonably practical (maintenance, escape or rescue work);
- prior to implementing or improving a control measure.

# 6 RPD programme

## 6.1 General

The RPD programme includes processes for selecting, using and maintaining RPD to ensure adequate protection to the wearer.

Prior to using RPD, it is essential to establish a written RPD programme. The RPD programme needs to be understood by all persons within the organization, as appropriate.

# 6.2 RPD programme elements

The RPD programme consists of the following elements:

- a) roles and responsibilities (see <u>6.3</u>);
- b) RPD programme implementation (see <u>6.4</u>);
- c) risk assessment (see <u>Clause 7</u>);
- d) selection procedures (see <u>Clause 7</u>);
- e) medical assessment (see 7.3.3.2);
- f) fit testing (see 7.4);
- g) training (see 7.5);
- h) use (see <u>7.6</u>);
- i) maintenance procedures (see 7.7);
- j) storage (see  $\frac{7.8}{1.8}$ );
- k) programme review (see 7.9);
- l) records and record keeping (see 7.10).

5

# 6.3 Roles and responsibilities

## 6.3.1 General

All persons involved in the respiratory protection programme shall be competent in their area of responsibility within the RPD programme and maintain the appropriate knowledge, experience and training to effectively carry out their duties.

# 6.3.2 Employer

The employer shall

- be responsible for the entire RPD programme,
- define, implement and document the RPD programme,
- provide adequate resources and organization to ensure the programme's continued effectiveness, and
- assign an RPD programme administrator.

The employer and the programme administrator may be the same person.

# 6.3.3 RPD Programme administrator

The programme administrator shall be responsible for effective management of the entire RPD programme.

## 6.3.4 Wearer

The wearer shall be responsible for

- using the RPD in accordance with the instructions and training received,
- reporting of any damage, defects or non-function of the RPD provided, and
- reporting any physical or medical limitations or changes that can impact their ability to wear and use the RPD correctly.

## 6.4 RPD programme implementation

The RPD programme shall be implemented, evaluated and updated as necessary to reflect those changes in workplace conditions that affect RPD use.

## 7 Risk assessment and RPD selection

## 7.1 General

A risk assessment is essential for the correct selection and use of RPD. It shall be conducted by a competent person before RPD is used for routine work, emergency work, rescue (including response to catastrophic incidents) or escape.

The risk assessment shall be conducted

- prior to the start of all new work processes,
- if the work conditions change,
- for new wearers, not covered by the existing suitability assessments, and
- periodically thereafter, at least annually or in accordance with national or local regulations.

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The RPD selection procedure, shown in the following flow charts in <u>7.2</u> and described in <u>7.3</u>, uses the information gathered from the risk assessment which shall include the following.

- a) The Hazard Assessment flow charts identify the nature of the hazard, e.g. oxygen deficiency, contaminant level, Immediately Dangerous to Life or Health (IDLH).
- b) The Adequacy Assessment flow chart determines the protection level required for the hazard.
- c) The Suitability Assessment flow charts identify the factors to consider when selecting the RPD that meets the needs of the wearer and is appropriate for the task and the environment.
- d) The special application flow chart identifies the minimum work rates and the minimum protection classes of the various classes within the special applications.
- This is an example of a navigation marker. These navigation markers precede text and are cross referenced in the flow charts. All markers are listed sequentially in 7.3. In addition, a flow chart may contain markers out of sequence. Follow the flow charts in the order given above and always begin at the top block. Read the contents of each block in sequence and follow the decision logic.
- The diamond shape indicates that a decision shall be made in order to proceed. Answer each with a "Yes" or "No" response and follow the arrow to the next block.
- The rhomboid shape provides data that leads to the final specification and class of suitable RPD.
- The "wave shape" is an instruction to document the output of the suitability assessment.
- The irregular pentagon is an instruction to go to the next flow chart.
- The cylinder is an indication of the mode of operation.

Record the outcome of the selection procedure in accordance with ISO/TS 16975-2. The example of the selection record sheet can be used (see <a href="Annex J">Annex J</a>).

## 7.2 Selection procedure — Flow charts

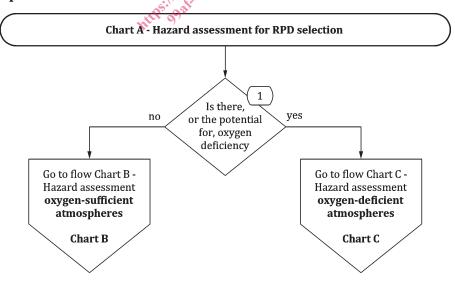


Figure 1 — Chart A Hazard assessment (HAZ-ASM)

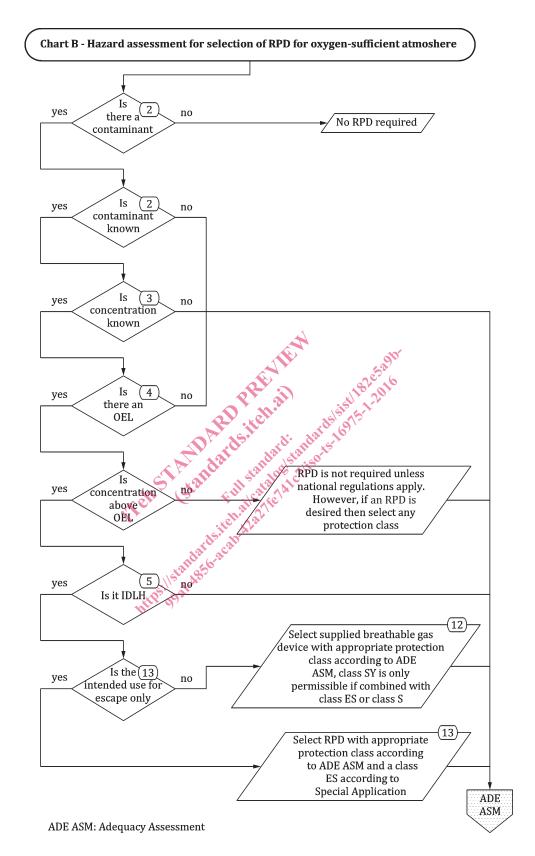


Figure 2 — Hazard ASM — Chart B for oxygen-sufficient atmospheres