TECHNICAL SPECIFICATION

ISO/TS 16975-4

First edition
2022-11

Respiratory protective devices — Selection, use and maintenance —

Part 4: Selection and usage guideline for respiratory protective devices under pandemic/epidemic/outbreak of infectious respiratory disease

Appareils de protection respiratoire — Choix, utilisation et entretien —

Partie 4: Choix et lignes directrices d'utilisation des appareils de protection respiratoire en cas de flambée/épidémie/pandémie de maladie respiratoire infectieuse

Reference number
ISO/TS 16975-4:2022(E)

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

Published in Switzerland

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.

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).

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

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

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

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

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

Introduction

National and international health organisations such as the World Health Organization (WHO) recommend respiratory protective devices (RPDs) and/or other forms of face coverings such as surgical masks and barrier masks as part of a strategy for the prevention and control of infection and to limit the spread of infectious respiratory diseases. Depending on the type, RPDs and other mask forms, like face coverings, can be used either for individual protection such as for healthcare workers or in the case of the general public to reduce infectious transmission, i.e. as source control.

This document contains information on risk assessment, on the selection of adequate and suitable RPD and provides essential guidance on its use, care and maintenance. This document details the requirements for adjusting or establishing and implementing a programme for the use of RPD during a pandemic/epidemic/outbreak of an infectious respiratory disease.

Infectious respiratory disease can be transmitted in several ways. Transmission modes can include:

a) “droplets”, which are relatively large airborne particles containing the pathogen;

b) “aerosols” or airborne transmission, which consists of smaller particles with effective transport over distance and longer residence time in the air;

c) “contact”, whereby the pathogen is transmitted to the nose, mouth or eyes via a contaminated surface.

Exposure via all routes to an infectious respiratory disease should be eliminated or effectively controlled and reduced to a minimum by the application of adequate protective measures. Aerosols and smaller droplets can be significant airborne inhalation hazards.

Due consideration of other occupational hygiene controls and infection prevention measures such as engineering and administrative controls like ventilation, social distancing, environmental cleaning and hand hygiene should be given in conjunction with the selection and deployment of RPD by way of a sufficient and suitable risk assessment.

The informative annexes provide an explanation of the difference in performance and purpose of RPD and their various national and jurisdictional standards, as well as an explanation of the role and uses of surgical/medical masks and face coverings (barrier masks).

Respiratory protective devices — Selection, use and maintenance —

Part 4: Selection and usage guideline for respiratory protective devices under pandemic/epidemic/outbreak of infectious respiratory disease

1 Scope

This document specifies detailed information to assist the responsible person to select, use and maintain respiratory protective devices (RPD) in the context of a pandemic/epidemic/outbreak of infectious respiratory disease at the workplace. This document is intended for workplace applications and to guide those developing pandemic-related respiratory protection programs.

The guidance contained in this document is not intended to be exhaustive but highlights important aspects to which attention is given. It is used in conjunction with ISO/TS 16975-1, ISO/TS 16975-2 and ISO 16975-3 for all workplaces, including healthcare.

This document focuses on particle filtering RPD only, as respiratory protection against pathogens.

This document does not apply to RPD programmes for RPD used exclusively for medical life support respirators and resuscitators.

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

This document is not applicable to non-workplace situations.

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 terminology databases for use in standardization at the following addresses:

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

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

3.1
aerosol
suspension of solid, liquid, or solid and liquid particles in a gaseous medium, having a negligible falling velocity (generally considered to be less than 0,25 m/s)

[SOURCE: ISO 16972:2020, 3.6]

3.2
airborne transmission
spread of an infectious disease through infectious particles that remain suspended in the air over long distances and time (as *aerosols*) (3.1)

Note 1 to entry: Infection can also be transmitted through the air by larger droplets that are carried by airflow to the breathing zone of other persons.

3.3
aerosol generating procedure
AGP
medical procedures that generate higher concentrations of infectious respiratory aerosols than coughing sneezing, talking or breathing

Note 1 to entry: These aerosol generating procedures (AGPs) potentially put healthcare personnel and others at an increased risk for pathogen exposure and infection. There is neither expert consensus, nor sufficient supporting data, to create a definitive and comprehensive list of AGPs for healthcare settings.

Commonly performed medical procedures that are often considered AGPs, or that can create controlled or uncontrolled respiratory secretions, include:

— open suctioning of airways;

— sputum induction;

— cardiopulmonary resuscitation;

— endotracheal intubation and extubation;

— non-invasive ventilation;

— bronchoscopy.

3.4
asymptomatic
not showing signs or symptoms of the associated disease

3.5
community face covering
barrier mask
barrier face covering
face covering
product worn on the face, covering at least the wearer's nose and mouth, with the primary purpose to reduce the release of *droplets* (3.6) and particulate matter from the wearer into the immediate environment

Note 1 to entry: These products are not classed as RPD.

3.6
droplet
very small drops of liquid such as a particle of moisture discharged from the mouth during coughing, sneezing, or speaking

3.7
droplet transmission
infection spread through exposure to respiratory *droplets* (3.6) exhaled by an infectious source

3.8
epidemic
increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area

3.9
extended use
use/reuse of a “single use” respirator product over multiple or longer periods than intended

3.10
fit test
use of a challenge agent and a specific protocol to qualitatively or quantitatively determine the effectiveness of the seal between the wearer's face and respiratory interface of a specific make, model and size of a *respiratory protective device* (3.18).

[SOURCE: ISO 16972:2020, 3.91]

3.11
general public
all individuals in society who are not conducting work activities

3.12
healthcare worker
HCW
healthcare professional involved in the direct provisions of healthcare

[SOURCE: ISO/TR 19231:2014, 3.11]

3.13
infectious respiratory disease
disease caused by a pathogen that is either transmitted via inhalation or contact with the nose or mouth or causes clinically significant pathologic changes in the respiratory tract

Note 1 to entry: They can be caused by viruses, bacteria, fungi or spores. Many, but not all, can be transmitted from human to human. For simplicity, the general term “pathogen” is used throughout this document.

3.14
outbreak
greater-than-anticipated increase in the number of endemic cases in an area. It can also be a single case in a new area

Note 1 to entry: If not quickly controlled, an outbreak can become an *epidemic* (3.8).

3.15
pandemic
epidemic (3.8) that has spread over several countries or continents, usually affecting a large number of people

3.16
pathogen
infectious micro-organism or agent, such as a virus, bacterium, protozoan, prion, viroid, or fungus that can cause disease

Note 1 to entry: See also *infectious respiratory disease* (3.13)

3.17
respiratory interface
RI
part of a respiratory protective device (RPD) 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 16972:2020, 3.202]

3.18
respiratory protective device
RPD
personal protective equipment designed to protect the wearer's respiratory tract against the inhalation of hazardous atmospheres

[SOURCE: ISO 16972:2020, 3.203]

3.19
social distancing
practice of maintaining a greater than usual physical distance from other people or of avoiding direct contact with people or objects in public places during the *pandemic* (3.15)/*epidemic* (3.8)/*outbreak* (3.14) of an infectious disease to minimize exposure and reduce the transmission of infection

3.20
source control
intervention to reduce release of *aerosols* (3.1) and *droplets* (3.6) at or close to the point of origin or release into the atmosphere

3.21
surgical mask
medical mask
product that covers the wearer's nose and mouth and provides a physical barrier to fluids and particulate materials

Note 1 to entry: These products are not classed as RPD.

3.22
surgical respirator
tight fitting RPD designed and tested for respiratory protection performance for compliance with an applicable national standard e.g. rated as N95, FFP2, KN95 etc. as well as having performance for fluid resistance and other parameters

3.23
tight-fitting respiratory protective device
tight-fitting RPD
respiratory protective device (3.18) which forms a protective barrier between the wearer's respiratory tract and the ambient atmosphere by forming a seal to the wearer's skin

3.24
workplace
designated area or areas (static or mobile) in which the work activities are carried out

4 Situations recommending protection from airborne hazards

Infectious respiratory diseases can be transmitted through the air via respiratory exhaled or expelled droplets and aerosols, and through contact with contaminated surfaces. RPD, together with other occupational hygiene control measures can form part of the overall control strategy. Selection and deployment of RPD in a pandemic/epidemic/outbreak situation should be by way of a sufficient and suitable risk assessment and managed by an effective RPD programme based on ISO/TS 16975-1 and ISO/TS 16975-2 and this document.

The use of a device by persons who are potential sources of pathogens needs to be considered in addition to ventilation control and other measures. Intention is to reduce the risk of transmitting or acquiring a respiratory infectious disease.

In some instances, the primary purpose is to prevent the individual from inhaling the pathogen (e.g. a HCW treating a patient), whereas in others, the primary purpose is to prevent an infected person from releasing the pathogen into the air, exposing others nearby. The devices used fall into several groups

including respiratory protective devices, surgical/medical masks, and face coverings (see Clause 3 for definitions). See Annex A for more information.

5 Situations for using RPD in the workplace

5.1 General

Under pandemic situations, additional risk assessments might be needed.

5.2 Healthcare

While there are situations in normal activities where a HCW may need to wear an RPD, in a pandemic/epidemic/outbreak situation this requirement can become much broader and many more HCWs will be required to wear a RPD routinely during their work shift. HCWs carrying out tasks with an identified risk should follow recommended national and local infection prevention and control procedures, including those associated specifically with the pandemic/epidemic/outbreak. These can include exposure control actions such as isolation, triaging, specialised air management, work practices (hygiene, respiratory etiquette strategies, distancing, administration actions, etc.) and use of RPD or other protective products to reduce the risk of infection.

5.3 Other workplaces

Each workplace shall be assessed appropriately using the latest pandemic/epidemic/outbreak related information available from the health authorities to determine the appropriate RPD or protection needed (if any).

NOTE For guidance on the implementation and use of RPD for the control of exposure to existing workplace hazardous substances see ISO/TS 16975-1. This is an exposure issue that is independent of a pandemic/epidemic/outbreak situation.

Some workplaces may already be using RPD for their work activities. Following a new risk assessment these may also provide them a suitable level of protection from airborne infectious particulates in a pandemic/epidemic/outbreak.

Other workplaces may not normally need RPD, but an additional risk assessment may indicate this step has become necessary to protect the wearer in a pandemic/epidemic/outbreak situation.

Where RPD is also recommended as part of the overall control strategy, the level of protection required or recommended with respect to the types and classes of RPD is often provided by national and international health organisations. The correct selection, use, care and maintenance of the recommended types and classes of RPD is vital to achieve effective protection from this RPD. (See ISO/TS 16975-1 and this document).

Other workplaces may not have any specific extra exposure issues in their activities and should follow the recommendations of the relevant health authorities regarding the need for use of other products such as surgical masks and face coverings as well as other controls like social distancing, cough/sneeze etiquette, etc. See Annex A and Annex C for further information.

6 RPD types and classes

ISO/TS 16975-1:2016, Annex A and Annex H, provide information on RPD types and classes, some of which can be suitable for use during an infectious respiratory disease pandemic/epidemic/outbreak.

Annex B also provides some additional information on current RPD types and classes across different countries/regions.

NOTE Some countries have a national system for assessment/approval/clearance of RPD of various types and all medical devices including surgical masks". Some jurisdictions also require or promote independent certification by a government or independent auditing body to certify the product is made to a certain standard or performance.

7 National (country wide) respiratory protective guidelines/program under a pandemic/epidemic/outbreak of respiratory disease

7.1 General

In a pandemic/epidemic/outbreak (as declared by the relevant health authority), there can be guidance and controls described by a Government or relevant authority to limit the transmission of the disease, including the use of respiratory protection devices and other protective products. The general elements of an RPD programme are described in ISO/TS 16975-1. This document provides information on the extra considerations and decisions that shall be made in a pandemic/epidemic/outbreak regarding some of the elements of the programme.

7.2 Employer responsibility

7.2.1 General

The employer must follow the Government's or relevant health authority's guidelines and directions in respect of protecting their employees at work. The use of RPD for prevention of transmission of infectious disease shall be supported by a respiratory protection programme as described in ISO/TS 16975-1.

During a pandemic/epidemic/outbreak, the employer's responsibility also includes control of potential infection in addition to control of exposure to any industrial inhalation hazard occurring from their work operations.

The employer can appoint an RPD/OSH administrator to be responsible for the operation of the entire RPD programme and provide adequate resources and organization to ensure the programme's continued effectiveness.

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

7.2.2 RPD programme administrator

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

7.3 Public place service provider responsibility

Any service provider or employer located in public places must follow the current Government or relevant authority guidelines in respect of protecting their employees (and the general public) during a pandemic/epidemic/outbreak.

7.4 RPD wearer (general)

The RPD wearer shall be responsible for proper use of their RPD – see ISO/TS 16975-1:2016, 6.3.4, for detail. In a pandemic/epidemic/outbreak situation, there may be extra procedures and controls required and changes to manufacturer's instructions that also shall be followed by all RPD wearers.

7.5 RPD manufacturers' responsibilities

As a pandemic/epidemic/outbreak evolves, provisional or new governmental requirements which are essential for the manufacturer to follow may be published. These new requirements can contain but are not limited to the following aspects:

— provisional changes in requirements on testing, certification and approval;

— additional information to be provided by the manufacturer regarding selection, use (donning, doffing, fitting), cleaning, disinfection, reuse and disposal of the product under a pandemic/epidemic/outbreak context;

— additional record keeping requirement for traceability purposes of the product.

The manufacturer is also responsible for monitoring expiration of any temporary requirements and to stop these when specified.

8 RPD programme

8.1 General

The RPD programme includes processes for selecting, using and maintaining RPD to ensure adequate protection to the wearer. This is described in detail in ISO/TS 16975-1. A pandemic/epidemic/outbreak would additionally involve activities to minimise the risk of infection transmission in activities supporting the deployment of RPD.

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.

The required elements of a RPD programme as given in ISO/TS 16975-1:2016, 6.2, are:

— roles and responsibilities;

— RPD programme implementation;

— risk assessment;

— selection procedures;

— medical assessment;

— respirator fit testing;

— training;

— use of respirators;

— maintenance procedures including cleaning;

— storage;

— programme evaluation and review;

— records and record keeping.

8.2 Roles and responsibilities

See ISO/TS 16975-1:2016, 6.3, and 7.2 to 7.4 in this document for specifics associated with various roles and responsibilities.