ISO/TS 16975-4:2022(E)

Date: 2022-~~09-07~~xx

ISO TC 94/SC 15~~/WG 6~~

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

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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~~www.iso.org

Published in Switzerland

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Contents

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~~www.iso.org/directives).

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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~~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~~www.iso.org/members.html.

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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:

~~1~~a) "droplets", which are relatively large airborne particles containing the pathogen;

~~2~~b) "aerosols" or airborne transmission, which consists of smaller particles with effective transport over distance and longer residence time in the air;

~~3~~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 ~~standard~~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 ~~should be~~is given. It ~~should be~~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~~https://www.iso.org/obp

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

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~~**aerosol generating procedure**~~
~~**AGP**~~
~~medical procedures that generate high concentrations of respiratory aerosols~~

~~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.~~

~~3.3~~
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.~~4~~3
asymptomatic
not showing signs or symptoms of the associated disease

3.~~5~~4
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~~5) and particulate matter from the wearer into the immediate environment

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

3.~~6~~5
droplet
very small drops of liquid such as a particle of moisture discharged from the mouth during coughing, sneezing, or speaking

3.~~7~~6
droplet transmission
infection spread through exposure to respiratory *droplets* (3.~~6~~5) exhaled by an infectious source

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3.~~8~~7
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~~8
extended use
use/reuse of a "single use" respirator product over multiple or longer periods than intended

3.~~10~~9
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~~17).

[SOURCE: ISO 16972:2020, 3.91]

~~Note 1 to entry: *See also wearer seal check* (3.24).~~

~~**3.11**~~
3.10
general public
all individuals in society who are not conducting work activities

3.~~12~~11
healthcare worker
HCW
healthcare professional involved in the direct provisions of healthcare

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

3.~~13~~12
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~~13
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~~7).

3.~~15~~14
pandemic
epidemic (3.~~8~~7) that has spread over several countries or continents, usually affecting a large number of people

3.~~16~~15
pathogen

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infectious ~~microorganism~~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~~12)

3.~~17~~16
respiratory interface
RI
~~Part~~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~~17
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~~18
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*~~/~~ (3.14)/*epidemic*~~/~~ (3.7)/*outbreak* (3.13) of an infectious disease to minimize exposure and reduce the transmission of infection

3.~~20~~19
source control
intervention to reduce release of *aerosols* (3.1) and *droplets* (3.5) at or close to the point of origin or release into the atmosphere

3.~~21~~20
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~~21
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~~22
tight-fitting respiratory protective device
tight-fitting RPD

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respiratory protective device (3.17) 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**~~
~~**wearer seal-check**~~
~~action conducted by the wearer to determine if *tight fitting respiratory protective device* (3.23) is properly donned and sealed on the face~~

~~[SOURCE: ISO 16972:2020, 3.258]~~

~~**3.25**~~
3.23
workplace
designated area or areas (static or mobile) in which the work activities are carried out

4 Situations ~~where~~recommending protection from airborne hazards ~~may be required~~

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~~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.

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