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ISO/PAS 23307

**Healthcare organization
management — Pandemic
response — Guidance for managing
infected patients with respiratory
infectious disease**

*Management des organisations de soins de santé — Réponse
en cas de pandémie — Lignes directrices relatives à la prise
en charge des patients atteints d'une maladie respiratoire
infectieuse*

**First edition
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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 www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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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.

This document was prepared by ISO/TC 304, *Healthcare organization management*.

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

This document concerns patients infected with respiratory infectious diseases with a high transmission risk including Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), and coronavirus disease 2019 (COVID-19), requiring the isolation of patients.

Major infection routes for respiratory infectious diseases include droplets from humans (e.g. droplets produced by the source person during breathing, talking, sneezing, coughing) or contact infection when a person touches one's own eyes, nose or areas surrounding the lips with their contaminated hands or after contacting a contaminated mediator.

Such patients usually experience a high fever of 38 °C or above as the most common symptom; however, no fever can be observed in the early stage. Coughing, dyspnea, fever, malaise, myalgia, headache, chilliness and other symptoms can also be developed.

This document provides standardized guidance for managing infected patients in healthcare organizations and other facilities based on the COVID-19 classification criteria of the World Health Organization (WHO) in classifying patients infected with respiratory diseases with a high transmission risk.

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Healthcare organization management — Pandemic response — Guidance for managing infected patients with respiratory infectious disease

1 Scope

This document provides recommendations for healthcare organizations on how to effectively manage and classifies patients who are infected with respiratory infectious diseases, especially during a pandemic. It covers various aspects of patient care, infection control and healthcare facility management to ensure the safety of both patients and healthcare workers in such 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 confirmed patient

person who is confirmed to be infected with an infectious disease pathogen according to the test criteria for respiratory infectious disease diagnosis

3.2 asymptomatic

not showing signs or symptoms of the associated disease

[SOURCE: ISO/TS 16975-4:2022, 3.4]

3.3 symptomatic case

person who has epidemiological association with the outbreak of respiratory infectious diseases and has associated signs or symptoms following incubation period

3.4 self-quarantine

act of staying away from others, typically at home, after possible exposure to an infectious disease, to prevent the spread of infection

4 Classification of patients with respiratory infectious diseases

4.1 Preliminary patient classification^[1]

4.1.1 A preliminary classification is carried out according to the following procedure:

- a) identifying clinical symptoms and risk factors;
- b) determining treatment priority;
- c) selecting and classifying patients who require in-patient care.

4.1.2 The preliminary system classifies patients based on the details stated in the confirmed patients survey and patient screening questionnaire by referring to the factors considered for hospitalization by the institutions concerned (see [Annex A](#)).

- Altered consciousness presented after the onset of respiratory disease infection symptoms.
- Dyspnea (shortness of breath in daily life).
- Fever goes 38 °C or above and lasts for more than three days, not suppressed with antipyretics.
- Diabetes uncontrolled with drugs.
- Patients with mental illness, presenting symptoms uncontrolled with drugs.
- Bedridden patients (lying in bed for more than half of day time).
- Pregnant women presenting with symptoms (including abdominal pain, pains and vaginal bleeding) and severely ill children.

4.2 Severity classifications based on respiratory infectious disease symptoms^[2]

The severity of patients with respiratory infectious diseases should be classified as shown in [Table 1](#).^[1]

Table 1 — Severity classifications based on respiratory infectious disease symptoms (Example)

| Stage | Definition | Severity |
|-------|---|-------------------------------------|
| 0 | No clinical or virological evidence for infection is found | Noninfectious |
| 1 | Infected with no limit of activities of daily living (ADL) | A mild symptom (Ambulatory care) |
| 2 | Infected with a limit of activities of daily living but no O ₂ | |
| 3 | O ₂ with nasal prong | Mild disorder (hospitalized) |
| 4 | O ₂ with facial mask | |
| 5 | Non-invasive ventilation/high flow O ₂ | Severe disorder (hospitalized) |
| 6 | Invasive ventilation | |
| 7 | Multi-organ failure/Extra membrane oxygenation (ECMO)/Continuous renal replacement therapy (CRRT) | |
| 8 | Death | Death |

5 Control of confirmed patients of respiratory infectious disease

5.1 Control of overseas entrants^[1]

5.1.1 People applicable to control

According to the national strategy for prevention and control, all travellers entering the country are subject to control. They are classified by symptoms (symptomatic or asymptomatic cases), nationality (domestic or foreign) and stay period (long or short term).

5.1.2 Diagnostic tests

The diagnostic tests for overseas entrants are conducted as follows:

- a) all overseas entrants should receive a respiratory infectious disease test within 24 h after entry;
- b) if necessary, relevant organizations can conduct additional tests on overseas entrants.

5.1.3 General control measures

[Figure 1](#) defines measures for symptomatic cases in the Ports of Entry (POE) screening stage and [Figure 2](#) defines measures for asymptomatic cases in the POE screening stage.

- a) In the stage of POE screening, symptomatic cases should be responded as described in [Figure 1](#).

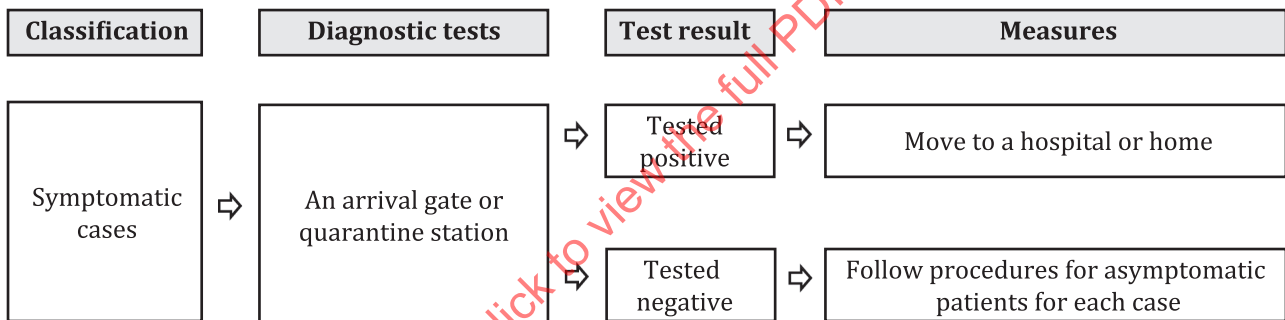


Figure 1 — Measures for symptomatic cases in the POE screening stage (Example)

- b) Asymptomatic cases should be responded as described in [Figure 2](#) in the POE screening stage.

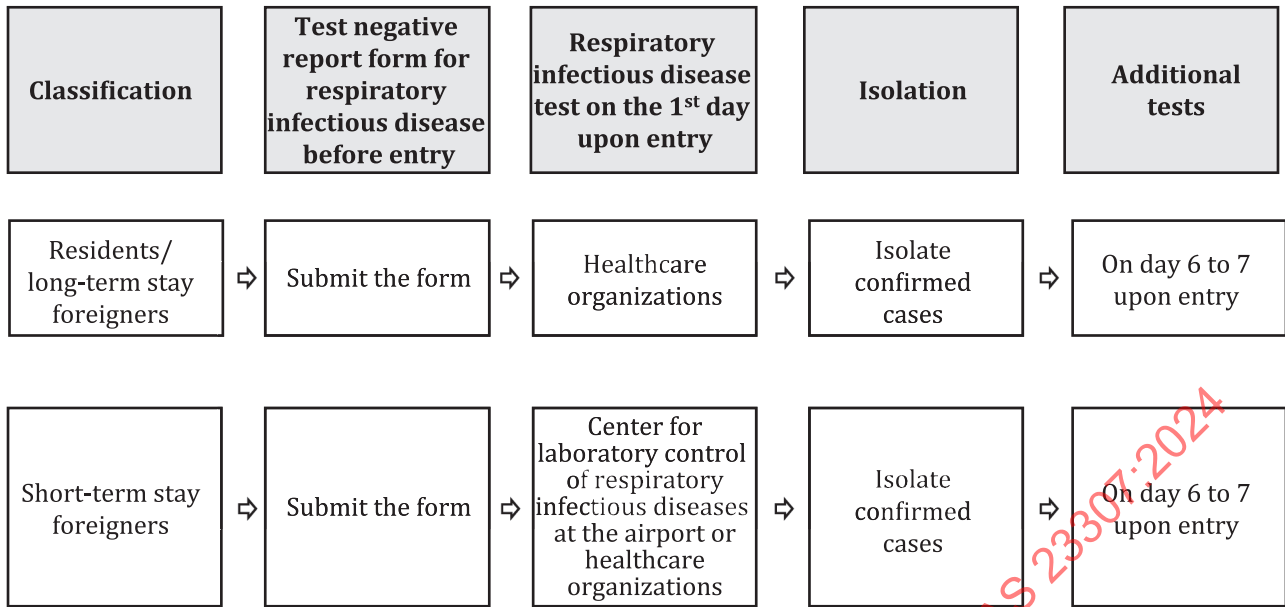


Figure 2 — Measures for asymptomatic cases in the POE screening stage

5.1.4 Control measures for confirmed patients in the POE screening stage^{[1][4]}

Based on the severity of symptoms, it is recommended to implement appropriate control measures for confirmed patients during the POE screening stage as follows:

- a) for severely ill and high-risk group patients;
 - regardless of residents or foreigners, nationally-designated beds should be requested to a state-run central healthcare organization;
- b) for asymptomatic or mild confirmed patients;
 - 1) in principle, the airport should make residents or foreigners use a car or an epidemic control vehicle to return home and get treated at home;
 - 2) if beds should be arranged in the ports regardless of residents or foreigners, a quarantine station should contact a relevant healthcare organization located in the jurisdiction of residence of confirmed patients.

5.2 Control of people in self-quarantine^{[1][5]}

5.2.1 Individuals subject to self-quarantine

Individuals subject to self-quarantine are classified as follows:

- a) of confirmed patients (limited to people treated at home), those receiving a notice of isolation;
- b) those applying for cohort quarantine and received a notice of quarantine to take care of those subject to self-quarantine;
- c) if a confirmed patient is a member of infection-vulnerable facilities (e.g. nursing hospital or sanatorium, mental health care facility, welfare facility for the disabled), those receiving a notice of isolation and identified as a close contact.

5.2.2 Quarantine area and method^[6]

The quarantine area and method are as follows and should be applied according to the country or regional situation:

- a) In principle, the quarantine area should be the individual's current residence. In cases where the individual is a short-term visitor without a fixed residence or where it is difficult to practice quarantine in their current residence, he or she will be housed in a designated accommodation or reserved facility run by a relevant organization for quarantine.
- b) A shower room and toilet should be prepared within the quarantine area. The applicable person should stay in a separate zone to avoid contact with roommates.
- c) If a person in quarantine requires care from others due to severe disability, infants or children (up to the age of 11 or under elementary school age), their applicable roommates may also be quarantined together to provide care.

5.2.3 Recommendations on the prevention of leaving quarantine areas after quarantine release

During the quarantine period and after quarantine release, individuals are advised to follow the following recommendations:

- a) During the quarantine period, individuals subject to quarantine are not permitted to leave their designated quarantine area or make changes to their quarantine location without the approval of the relevant healthcare organization within their jurisdiction.
- b) Upon release from quarantine, individuals are permitted to leave their homes, including returning to work or school, however, it is mandatory to wear a N95 mask or equivalent for at least three days after discharge. Additionally, to minimize the risk of contracting or spreading infections, it is recommended to avoid visiting high-risk facilities and participating in private gatherings.

5.2.4 Temporarily leaving the quarantine area^[3]

Individuals under quarantine are permitted to temporarily leave their quarantine area for the purpose of visiting healthcare organizations related to respiratory infectious diseases and to obtain necessary medication. They should return to their quarantine area within limited time.

5.2.5 Quarantine

If a respiratory infectious disease is confirmed, or it is considered that there is a risk of infection through contact with a confirmed person, self-quarantine is conducted according to the period set by the government.

5.3 Control of severely ill patients at the hospital

5.3.1 Criteria for entering treatment beds for severely ill patients

Severe patients should follow the provided guidance for possible admission to the intensive care unit (ICU), based on their condition.

- a) Those requiring O₂ with facial mask or above level of treatment or expected to require such treatment, should be quickly moved to an intensive care unit (ICU), and may enter a hospital isolation room.
 - 1) Patients requiring treatments including O₂ with facial mask, ECMO or CRRT.
 - 2) For example, for a patient requiring high flow O₂ or above level of treatment, in which O₂ with facial mask or above level of treatment is soon considered necessary.

- 3) For example, for a patient confirmed with pneumonia where oxygen demand keeps increasing more than 5 l/min, those considered necessary to be carried to a hospital isolation room.^[3]
- b) The decision on the admission of a hospital isolation room should be made comprehensively by considering a patient's condition, medical judgment of an attending physician, conditions of a hospital room and others.

5.3.2 Bed allocation^[7]

Hospital beds can be allocated based on the following assignment principles and recommended guidance.

- a) The medical judgment of a physician having treated an applicable patient should determine hospitalization and the classification of a bed. If a major cause of hospitalization is respiratory infectious disease symptoms, an applicable patient should be allocated to a designated isolation bed.
- b) The criteria for admission to designated isolation beds are applied considering the following factors:
 - 1) in case of a negative pressure, an isolation room is needed due to a high risk of aerosol transmission;
 - 2) hospitalization is needed to treat respiratory infectious disease symptoms;
 - 3) individuals who have underlying respiratory conditions, comorbidities such as diabetes and hypertension, and are at risk of exacerbating respiratory infections within a short period due to factors that worsen respiratory infections.

6 Resource management and bed operation^{[1][3][8][9]}

6.1 Operation of designated isolation bed^[9]

Designated isolation beds should be operated based on the following principles:

- a) If a negative pressure isolation room or hospitalization is required to treat respiratory infectious disease symptoms, an isolation bed should be allocated, and medical personnel should conduct treatment based on the designated isolation bed criteria.
- b) In case of using an isolation bed for the respiratory infectious disease treatment, a single-bed, negative pressure room should be used to block air circulation from the room where confirmed patients stay.
- c) If no negative pressure room is available, medical personnel should prevent the air of the room where confirmed patients stay from being circulated throughout the entire hospital.
 - The requirement for air conditioning facilities is converting from a mixed circulation type of outdoor air (30 %) and indoor air (70 %) to an exhaust type (100 %) to prevent the spreading of infection caused by air circulation.^[10]
- d) In assigning a negative pressure room for high-risk patient groups, those requiring medical operations and others should be assigned first. The high-risk groups are defined as follows.
 - 1) Patients requiring supplemental oxygen whose oxygen saturation is under 90.
 - 2) Patients with underlying health conditions (chronic obstructive pulmonary disease (COPD), cardiovascular disease, etc.).

6.2 Operation of general isolation bed^[11]

General isolation beds should be operated according to the following guidance.

- a) If hospitalization is required to treat underlying health conditions, it is possible to completely separate the location history of confirmed and general patients by adopting the voluntary hospitalization of confirmed patients. Thus, it is possible to operate a ward unit independently.

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- b) A healthcare organization in an applicable region should establish and run a consultation system to respond to those waiting for in-patient care.

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Annex A (informative)

Survey on patients with respiratory disease^[3]

Table A.1 — Confirmed patients survey (Example)

| | | | | | |
|--|---|--|---|---|---|
| Investigator | City/Province | | Contact number | (Work) | -- |
| | Investigation health center | | | (Mobile) | -- |
| | Name of investigator | | Date of survey | ____Year ____Month ____Date | |
| 1. Personal information (Mark the checkbox and/or provide the details) | | | | | |
| 1.1 Name | | | 1.2 Resident registration number | 1.3 Gender | |
| | | | | <input type="radio"/> M <input type="radio"/> F | |
| 1.4 Nationality | Nationality, passport or registration number | | 1.5 Residence address | | |
| 1.6 Contact number | (Patient) | 1.7 Are you a member (employee, user, or resident) of infection-vulnerable facilities? <input type="radio"/> Yes, name of facility (), contact number of facility in charge () <input type="radio"/> No | | | |
| | (Guardian) | 1.8 Types of infection-vulnerable facilities (Select only if you answered "Yes" in Question 1.7.) <input type="radio"/> Nursing hospital <input type="radio"/> Nursing facility (including congregate nursing homes) <input type="radio"/> Day care centre (including temporary care centre) <input type="radio"/> Mental health facility <input type="radio"/> Mental health care facility <input type="radio"/> Psychiatric rehabilitation centre <input type="radio"/> Welfare facility for the disabled | | | |
| 1.9 Registered disabled | <input type="radio"/> Yes <input type="radio"/> No | 1.10 Disability types | <input type="checkbox"/> Physical <input type="checkbox"/> Mental, etc. | 1.11 Disability class | <input type="checkbox"/> Severe disability <input type="checkbox"/> Mild disability |
| 2. Symptoms and underlying diseases (Mark the checkbox and/or provide the details.) | | | | | |
| 2.1 Existing symptoms | <input type="radio"/> Yes <input type="radio"/> No | 2.2 Onset date of symptoms | ____Year ____Month ____Date | | 2.3 The latest date of the PCR test (date of sample collection) |
| | | | | ____Year ____Month ____Date | |
| 2.4 Underlying disease | <input type="radio"/> Yes (name of the underlying disease_____) <input type="radio"/> No | | 2.5 Height/Weight | ____ cm / ____ kg | |