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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 <u>documents_document</u> 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 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 the Technical Committee 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

Improving hand hygiene remains the most important measure to prevent the spread of infections in healthcare settingsfacilities, yet compliance with hand hygiene is globally low. The goal of this document is to provide scientific knowledge, evidence-based implementation guidance for best practices to achieve targeted hand hygiene outcomes that can enhance patient safety.

An essential practice in the prevention or control of the spread of infections in the healthcare environment is the effective and continuous act of hand hygiene. In healthcare settingsfacilities, hand hygiene is mainly performed via hand washing or hand rubbing at the points of care, with the purpose of protecting patients and healthcare workers alike from acquiring healthcare-associated infections (HAIs).

Hand hygiene is the process of reducing potentially harmful microorganisms (pathogens) on the hands for the purpose of preventing the spread of infections. Hand hygiene is supported by three pillars:

- behavioural hand hygiene: which contains all active behaviours intended to keep hands uncontaminated;
- —hand washing which requires water, the cleansing agent, and drying material and is mainly intended to clean hands from visible contaminations and remove microorganisms;
- —hand rubbing which requires a disinfecting substance to be absorbed/evaporate until completely dry and is intended to reduce and inactivate microorganisms.

The daily execution of an infection prevention and control system, including hand hygiene, is a responsibility of all healthcare related personnel and stakeholders.

This document builds on the top of existing national and international laws, regulations and recommendations supporting patient safety, and assumes that there are infection prevention and control personnel in each healthcare settingfacility to ensure its implementation.

This document is intended to address specifically all environments that provide healthcare services and can be tailored wherever care is given. Furthermore, fields outside of healthcare can adopt this document or components of it as needed if they provide proper documentation and reasoning behind any modifications.

Adopters of this document may perform an initial assessment of hand hygiene practices as a foundation for the organizational hand hygiene performance and compliance program.

An evaluation and continued assessment of hand hygiene practices is the corner stone of an organization's hand hygiene performance and compliance program.

The key differences between this document and those listed in the bibliography are:

- a) a) increased emphasis on the design and implementation of an institutional-level hand hygiene policy for hospitals and other healthcare settingsfacilities called the "hand hygiene system;
- b) b) extensive, coherent and comprehensible instructions regarding every aspect of a hand hygiene program (requirements, feedback methods, documentation, validation) within the hand hygiene system;
- c) e)—aggregation of current evidence-based resources, know-how and best practices to facilitate the implementation and maintenance of an efficient hand hygiene program.

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d)	d) customizable and adaptable framework of operation, stretching over national and geographical
	houndaries

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Healthcare organization management — Hand hygiene performance and compliance

1 Scope

This document specifies hand hygiene training, compliance benchmarking, performance/feedback, and facility requirements for healthcare settings.facilities that operate hand hygiene systems. This document covers facility readiness, hand hygiene education and training, monitoring, performance, promotion and identifying key issues that require attention for improvement. Procedures for surgical hand preparation are not addressed in this document.

Furthermore, this document does not take into consideration, surface disinfection, instrument disinfection, ultraviolet irradiation (UV-C), heat sterilization, room fogging or electrostatic spraying devices and any other methods typically not designed or suitable for human hand hygiene purposes.

This document details the requirements for a healthcare setting that operates a hand hygiene system. This includes facility readiness, hand hygiene education and training, monitoring, performance, promotion and identifying key issues that require attention for improvement.

It is important to note that excluding <u>Excluding</u> surgical hand preparation, this document applies specifically to clinical healthcare workers, patients, and visitors as well.

2 Normative references

The following standardsdocuments are referred to in this document in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 22886, Healthcare organization management — Vocabulary $\frac{1}{2}$ $\frac{1}{$

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 22886 and the following 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

hand hygiene adherence

general act of conforming to the adequate hand hygiene (3.2(3.2)) guidelines and requirements

Note 1 to entry: The term *hand hygiene compliance* (3.19(3.22)) shall only be used as defined in the context of this standarddocument. For all generic use, the word adherence is suitable.

3.2

hand hygiene

HH

act of mechanical and chemical techniques including sustained friction (scrubbing) with clean water or a liquid, gel, or foam chemical formula that effectively reduces, neutralizes and/or inactivates microorganisms on the hands, temporarily removing the transient flora-

Note 1 to entry: Hands are considered as the palmar and dorsal surfaces of the human hand, following the anatomy to the line of the ulnar styloid process.

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Note <u>4-2</u> to entry: This may include the physical removal of soil and debris from the hand.

Note $\frac{2-3}{2}$ to entry: Hand hygiene acknowledges two types of *hand hygiene actions* (3.11(3.11)) which are not mutually interchangeable:

- a) a) hand washing which requires water, product, and drying material.
- b) b) hand rubbing (3.20) which requires a cleaning substance to be absorbed/evaporated until completely dry.

Note <u>3–4</u> to entry: Other related but not used terms covering sub-domains of hand hygiene include: hand disinfection, hand cleansing, hand antisepsis, hand decontamination.

Note 4-5 to entry: This definition overrules the one articulated in ISO 22886.

3.3

alcohol-based hand rub product

ABHR product

chemical formula in liquid, gel, or foam format, containing at least $60 \% \frac{(w/w) mass fraction}{(w/w) mass fraction}$ of C2- to C3-alcohols designed to perform *hand hygiene* (3.2(3.2)) activities when hands are not visibly soiled and do not require subsequent rinsing with water and drying of the hands.

Note 1 to entry: C2- to C3-alcohols are ethanol, n-propanol, isopropyl alcohol, or a mixture of these.

Note 2 to entry: ABHR product can also contain other antimicrobial active ingredients with excipients, and humectants.

Note 3 to entry: Users It is presupposed that users comply with all current local and national requirements.

3.4

handwashing

the act of cleaning an individual's hands using water, handwashing handwash product (3.5) and a drying material

3.5

handwash product

soap in liquid, gel, or foam form, that is designed to perform hand hygiene (3.2(3.2)) activities when hands are visibly soiled, that including subsequent rinsing with water and drying of the hands

Note 1 to entry: Such products may contain other antimicrobial active ingredients with humectants and excipients.

Note 2 to entry: In the context of this document solid format soaps are not regarded suitable for *healthcare* <u>facilities</u> <u>[3.6settings.].</u>

3.6

healthcare facility

healthcare setting

HCF

physical infrastructure of a healthcare organization, also called a healthcare setting

Note 1 to entry: This definition is in line with the definition of "healthcare organization" in ISO 22886:2020, 3.2.2.

3.7

healthcare worker

HCW

healthcare professional (3.16(3.18)) involved in the direct provision of healthcare

[SOURCE: ISO/TR 19231:2014, 3.11, modified — The abbreviated term "HCW" has been added.]

3.8

dispenser

wall-mounted, bed-mounted, standalone or personnel-attached container able to provide (dose) ABHR product (3.3(3.3)) or handwash product (3.5)

3.9

audit

systematic and independent process for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines)

Note 2 to entry: An internal audit is conducted by the organization itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

Note 4 to entry: Independence can be demonstrated by the freedom from responsibility for the activity being audited or freedom from bias and conflict of interest.

[SOURCE: ISO 37301:2021, 3.18]

3.10

clinical stakeholder

healthcare worker (3.7(3.7),), visitor, patient, and other individual potentially interacting with the patient or the patient environment related to hand hygiene indications (3.15(3.15)) and expected to practice hand hygiene action(s) (3.11(3.11))

3.11 https://standards.iteh.ai/catalog/standards/sist/6c239e70-403f-4b42-8e11-af7fb7546359/iso-

hand hygiene action

hand hygiene event

conscious act of performing hand washing (3.4(3.4)) or hand rubbing (3.20(20))

Note 1 to entry: A hand hygiene action is considered valid from patient safety point of view when it is performed at the correct time, i.e., there is a *hand hygiene indication* (3.15(3.17),), and regarded as complete when it meets the standard of quality as stated in 4.3.34.2.3.

3.12

point of care

area near the patient where stakeholders may encounter communicable pathogens

3.13

continuous improvement

continuous professional development

recurring activity to enhance performance

[SOURCE: ISO 37301:2021, 3.12, modified — The admitted term "continuous professional development" has been added.]

3.14

healthcare-associated infection

HAI

hospital-acquired infection

DEPRECATED: nosocomial infection

infection acquired in the *healthcare facility* (3.6setting) for which there is no evidence indicating that it was present or incubating during or before the patient's admission

Note 1 to entry: See References [14[14]].

3.15

hand hygiene indication

theoretical point(s) in the workflow of the *clinical stakeholders* (3.10(3.10),), where there is an increased risk of pathogen transmission for which a *hand hygiene action* (3.11(3.11)) can be performed to decrease risk

Note 1 to entry: *Hand hygiene* (3.2(3.2)) moment is a term employed by WHO for hand hygiene indication, as a critical point in care to perform hand hygiene.

Note 2 to entry: WHO's My"my five (5) moments of hand hygiene" are considered a widely accepted approach for determining the ideal number of hand hygiene indications in a particular setting.

Note 3 to entry: See Figure 1 Figure 1 for the relationship to this definition.

3.16

healthcare professional

HCP

licensed and unlicensed, clinical, and administrative, remote, and onsite, paid and without compensation, full- and part-time healthcare stakeholders, intermittent healthcare stakeholders, fee basis healthcare stakeholders, contractors, researchers, volunteers and health professions trainees (HPTs)/pre-licensure or certification who are expected to perform any or all of their work at these healthcare facilities (3.6)

Note 1 to entry: <u>healthcare professional (3.18) Healthcare professionals are those</u> involved in the direct provision of healthcare, in particular those with patient contact or access to patient near areas.

Note 2 to entry: HPTs may be paid or unpaid and include residents, interns, fellows, and students. HCP also includes personnel providing care to patients and drivers and other personnel whose duties put them in contact with patients.

Note 3 to entry: $Healthcare\ workers\ (3.7(3.7))$ are a key subgroup of the *clinical stakeholders* (3.10(3.10)) within the scope of this document.

Note 4: These persons include all licensed and unlicensed, clinical, and administrative, remote, and onsite, paid and without compensation, full- and part-time healthcare stakeholders, intermittent healthcare stakeholders, fee basis healthcare stakeholders, contractors, researchers, volunteers and health professions trainees (HPTs)/pre-licensure or certification who are expected to perform any or all of their work at these facilities.

3.17

noncompliance

non-fulfilment of compliance obligations

[SOURCE: ISO 37301:2021, 3.27]

3.18

hand hygiene monitoring system

HHMS

digital technology platform enabling the partial or complete replacement of human *hand hygiene* (3.2(3.2)) observers, by automatically registering hand hygiene opportunities

Note 1 to entry: The term *hand hygiene compliance* (3.19(3.19)) monitoring shall only be used in the restricted meaning defined within this document.

3.19

hand hygiene compliance

adherence (3.1) to hand hygiene (3.2(3.2)) related rules and regulations, particularly in terms of method, frequency, and documentation of hand hygiene (3.2(3.2))

3.20

hand rubbing

process of using ABHR product (3.3(3.3)) product to conduct hand hygiene action (3.11(3.11))

4 Hand hygiene quality policy and requirements

4.1 General

4.1.1 Conformity

To conform withto this document, adopters shall meet all the requirements. To conform, healthcare settings shouldHealthcare facilities shall establish policies and procedures for assessing and accomplishing mandatory clause and, recommended clauses requirements and then recommendations. Healthcare facilities should ensure that each clinical stakeholder of the healthcare organization conforms. Therefore, conformance to this document requires the healthcare organization to establish policies and procedures for accomplishing clauses and processes. If the adopter aims to deviate infrom any of the requirements, peer_reviewed evidence and proof mustshall be provided in the hand hygiene system document or hand hygiene quality policy regarding that aspect. Deviations shall not compromise patient safety.

4.1.2 Prerequisites for the use of this standarddocument

Adopting facilities shall develop, communicate, and enforce their own hand hygiene system in a manner that conforms to the requirements and reflects the guidelines that are stated in this document.

Organizational leadership shall actively support the implementation of this hand hygiene system through hand hygiene program(s) and shall enlist the involvement of key healthcare workers in its development and administration. These healthcare workers shall include, but not be limited to, the organization's risk management, quality management, and infection prevention and control (IPC) staff.

The adopter shall provide capability and resources to develop, implement and evaluate the hand hygiene program guided by this document. The healthcare organization is responsible for resources such as software and products and shall have a set of processes that ensures regulatory requirements are met.

The healthcare organization shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There shall be an active program for the prevention, control, and investigation of infections and communicable diseases.

4.1.3 How to use this **standard**document

The description of the hand hygiene system and its application demands the use of a system paradigm to aid the use of the standard this document. As healthcare organizations familiarize themselves with the this document and application to their practices and work areas, terms that are more familiar may be substituted.