FINAL
DRAFT

INTERNATIONAL STANDARD

ISO/FDIS 23447

ISO/TC **304**

Secretariat: **ANSI**

Voting begins on:
2023-07-20

Voting terminates on:
2023-09-14

Healthcare organization management — Hand hygiene performance

Reference number
ISO/FDIS 23447:2023(E)

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Published in Switzerland

Contents

Page

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 document 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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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 facilities, 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 facilities, 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 facility 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) increased emphasis on the design and implementation of an institutional-level hand hygiene policy for hospitals and other healthcare facilities – called the "hand hygiene system;

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) aggregation of current evidence-based resources, know-how and best practices to facilitate the implementation and maintenance of an efficient hand hygiene program.

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

Healthcare organization management — Hand hygiene performance

1 Scope

This document specifies hand hygiene training, compliance benchmarking, performance/feedback, and facility requirements for healthcare 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.

Excluding surgical hand preparation, this document applies specifically to clinical healthcare workers, patients and visitors.

2 Normative references

The following documents are referred to in the text 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*

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) guidelines and requirements

Note 1 to entry: The term *hand hygiene compliance* (3.19) shall only be used as defined in the context of this document. 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.

Note 2 to entry: This may include the physical removal of soil and debris from the hand.

Note 3 to entry: Hand hygiene acknowledges two types of *hand hygiene actions* (3.11) which are not mutually interchangeable:

a) hand washing which requires water, product, and drying material;

b) *hand rubbing* (3.20) which requires a cleaning substance to be absorbed/evaporated until completely dry.

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

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

3.3
alcohol-based hand rub product
ABHR product
chemical formula in liquid, gel, or foam format, containing at least 60 % mass fraction of C2- to C3-alcohols designed to perform *hand hygiene* (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: It is presupposed that users comply with all current local and national requirements.

3.4
handwashing
act of cleaning an individual's hands using water, *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) activities when hands are visibly soiled, 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 facilities* (3.6).

3.6
healthcare facility
healthcare setting
physical infrastructure of a healthcare organization

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

3.11
hand hygiene action
hand hygiene event
conscious act of performing *hand washing* (3.4) or *hand rubbing* (3.20)

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), and regarded as complete when it meets the standard of quality as stated in 4.3.3.

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* (3.6) 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].

3.15
hand hygiene indication
theoretical point(s) in the workflow of the *clinical stakeholders* (3.10), where there is an increased risk of pathogen transmission for which a *hand hygiene action* (3.11) can be performed to decrease risk

Note 1 to entry: *Hand hygiene* (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 five 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 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 *healthcare facilities* (3.6)

Note 1 to entry: Healthcare professionals are those 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) are a key subgroup of the *clinical stakeholders* (3.10) within the scope of this document.

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) observers, by automatically registering hand hygiene opportunities

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

3.19
hand hygiene compliance
adherence to *hand hygiene* (3.2) related rules and regulations, particularly in terms of method, frequency, and documentation of *hand hygiene* (3.2)

3.20
hand rubbing
process of using *ABHR product* (3.3) product to conduct *hand hygiene action* (3.11)

4 Hand hygiene quality policy and requirements

4.1 General

4.1.1 Conformity

To conform to this document, adopters shall meet all the requirements. Healthcare facilities shall establish policies and procedures for assessing and accomplishing requirements and recommendations. Healthcare facilities should ensure that each clinical stakeholder of the healthcare organization conforms to this document. If the adopter aims to deviate from any of the requirements, peer-reviewed evidence and proof shall 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 document

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 document

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

A hand hygiene system comprises a plurality of hand hygiene programs, preferably one for every healthcare department (e.g. surgery, intensive care, paediatrics), addressing its needs. Hand hygiene thus can be viewed as a component or an element of a larger system for patient safety (Figure 2). This system includes the incorporation of people required to develop, produce, test, distribute, operate, train and support people to accomplish their roles within the healthcare organization. This generic hierarchy represents the necessary components of the system. Figure 1 provides a simple hierarchy of names for the elements that should make up the hand hygiene system. Globally, the hierarchy of leadership and names of leadership may vary, however it is important to recognize necessary components to manage the hand hygiene system. While providing background on the science behind hand hygiene, this document provides practical advice about how to implement this approach.

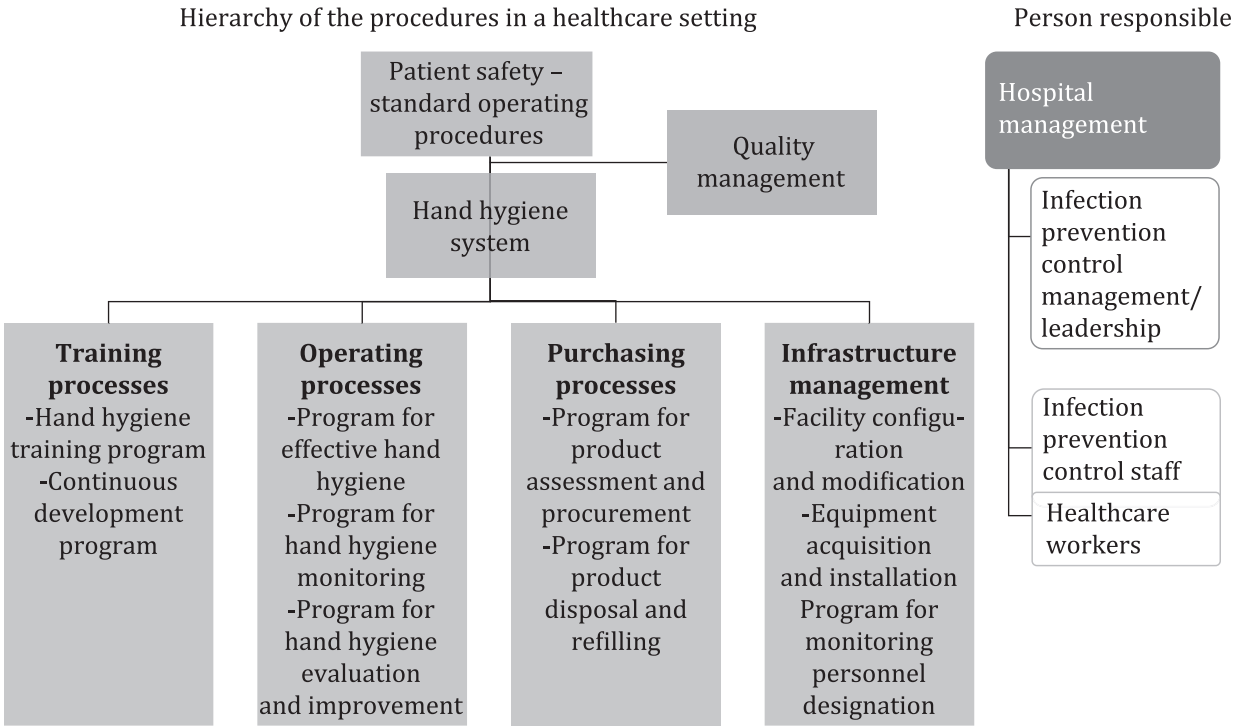

Figure 1 — Breakdown of the key components of a hand hygiene system

Figure 2 provides a general overview of a hand hygiene system from the operational point of view. It depicts the hand hygiene programs implemented to provide an opportunity to collect feedback and improve processes.

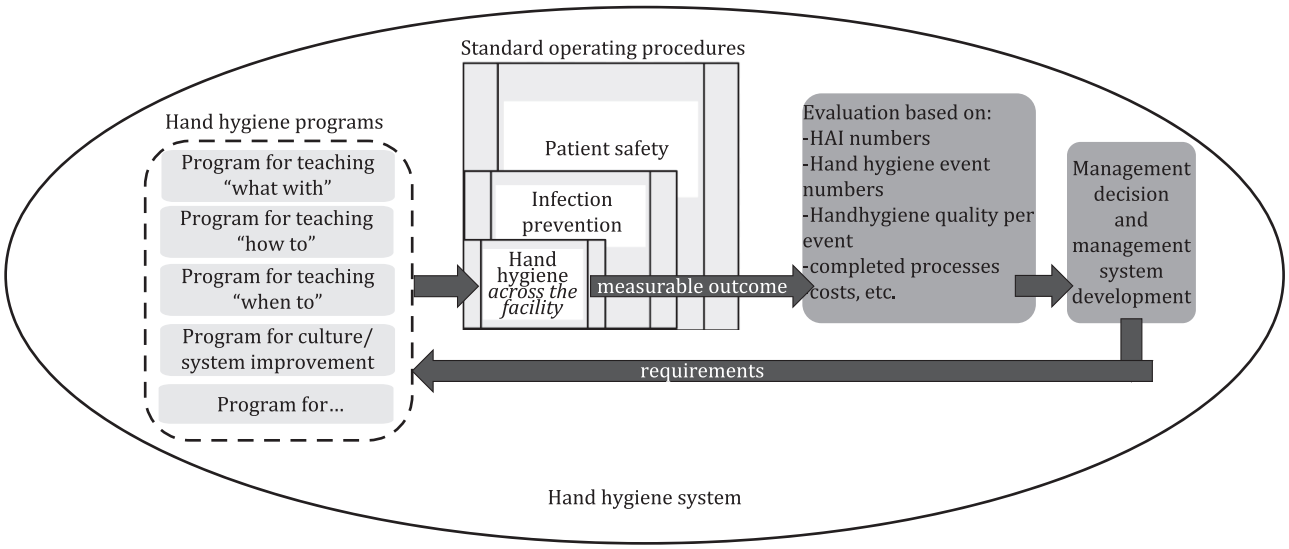

Figure 2 — A hand hygiene system

Hand hygiene systems shall include the hand hygiene programs and procedures targeting the individual elements of patient safety for quality improvement. All procedures applied in line with this document should be based on scientific evidence and target continuous improvement involving in the quality cycle all system components and clinical stakeholder**s.**

4.2 Hand hygiene quality policy

The hand hygiene quality policy is the formalized, documented representation of a healthcare facility's hand hygiene system.

The healthcare facility which choses to conform to this document shall establish and maintain a hand hygiene system (i.e. a quality policy with the objective to provide universal access to hand hygiene with the aim of improving patient safety). A hand hygiene system consists of hand hygiene programs, targeting individual aspects of the quality policy. The quality policy should include, but not be limited to, the following considerations:

a) specific, measurable, actionable, realistic and timely objectives serving the improvement of patient safety;

b) ensuring sufficient resources for the development, implementation, and monitoring of hand hygiene programs;

c) supporting the development and implementation of hand hygiene-related behaviour improvement;

d) facility design, construction, and maintenance requirements of the infrastructure;

e) proper communication within the healthcare organization;

f) periodic review to fit suitable for the purpose of this document;

g) secure sponsorship of the senior management.

The hand hygiene system and quality policy are part of the organization's approach for managing quality.

4.3 Hand hygiene quality policy requirements

4.3.1 Evaluating hand hygiene products for potential use in healthcare facilities

4.3.1.1 General

A risk-based approach should be used to determine the most suitable hand hygiene product.

4.3.1.2 ABHR product - minimal requirements

ABHR product shall contain at least 60 % mass fraction of C2- to C3-alcohols (ethanol, n-propanol, isopropyl alcohol) or a mixture of these, taking international standards and efficacy requirements, such as ASTM E2755 and EN 1500, into consideration.

Administrators or product selection committees shall consider the relative efficacy of antiseptic agents against various pathogens and shall review local guidelines for safety and efficacy before selecting the hand rub products.

4.3.1.3 Handwash product – minimal requirements

Administrators or product selection committees should consider the need to use antimicrobial vs non-antimicrobial handwash products in their healthcare facility based on hygiene risk and review local guidelines for safety before selecting the hand wash products.

For antimicrobial handwash products, administrators and product selection committees should consider the efficacy against various pathogens and take national public policy or regulatory guidelines concerning the efficacy of antimicrobial handwash products into consideration.

The use emollients and hand protection products should be considered for healthcare workers who frequently wash hands in the course of their duties.

4.3.1.4 Other hand hygiene product requirements

Administrators or product selection committees shall provide hand hygiene products that have been tested and shown to have acceptable skin compatibility using internationally recognised standard test methods.

Administrators or product selection committees should consider characteristics of hand hygiene products that can affect personnel acceptance and therefore usage compliance, such as:

— format (i.e. liquid, gel, foam);

— odour;

— colour.

Allergic contact dermatitis due to alcohol-based hand rubs is very uncommon. However, with increasing use of alcohol-based hand rubs by healthcare personnel, it is likely that irritation to such products is occasionally encountered. Healthcare facilities should find alternative solutions to address skin compatibility issues, especially in combination with hand washing, as it is known that increasing hand washing leads more often to skin irritation than hand rubbing.

Healthcare facilities should also consider continuous availability, costs, and a reliable supply that guarantees feasibility and sustainability.

NOTE The effect of antimicrobial active ingredients in hand wash products appears to be negligible.