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Quality of learning environments for students in healthcare professions – requirements for healthcare education providers in care setting

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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).

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.

International Workshop Agreement IWA 35 was approved at a workshop hosted by the British Standards Institution (BSI), in association with Nottingham University and the Knowledge Innovation Centre, held via a video conferencing meeting, in June 2020.

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

In healthcare studies which include professional regulation, student learning in care settings is an essential part of the curriculum. This education occurs when an organization provides structured arrangements, such as student teacher relationships and/or interactions, in care settings. Curricula are designed with close input from national health services and, when they graduate, students are expected to have sufficient experience to practice independently within their profession. Simultaneously, a shortage of healthcare professionals in certain countries is stimulating mobility. However, healthcare professionals who are educated or trained in the systems in which they intend to work are more likely to be capable of immediate integration into that system, unlike professionals from other systems who can require extra time and resources for a similar integration.

The intent of this document is, therefore, to provide a set of requirements that support educational and healthcare institutions in offering and directing high-quality international learning opportunities and in simplifying the processes involved in organizing these for students.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Quality of learning environments for students in healthcare professions – requirements for healthcare education providers in care setting

1 Scope

This document specifies requirements for operational practices in care settings when a provider wishes to demonstrate its ability to consistently provide and improve healthcare education or training that meets the learning requirements of educational organizations.

All the requirements in this document are intended to be applicable to any provider, regardless of its type, size or the healthcare services it offers.

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 terminological databases for use in standardization at the following addresses:

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

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

3.1
legal requirements and other requirements
legal requirements that an *organization* (3.8) has to comply with and other requirements that an organization has to, or chooses to, comply with

Note 1 to entry: Legal requirements and other requirements can arise from mandatory requirements, such as applicable laws and regulations, or voluntary commitments, such as organizational and industry standards, contractual relationships, codes of practice and agreements with community groups or non-governmental organizations.

[SOURCE: ISO 45001:2018, 3.9, modified — The original notes to entry have been removed and a new note to entry has been added.]

3.2
documented information
information required to be controlled and maintained by an *organization* (3.8) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: Documented information can refer to:

— management systems and related processes;

— information created in order for the organization to operate (documentation);

— evidence of results achieved (records).

Note 3 to entry: This constitutes one of the common terms and core definitions of the high level structure for ISO management system standards. The original definition has been modified by replacing “the management system, including related processes” with “management systems and related processes” in Note 2 to entry.

3.3
infrastructure
<organization> system of facilities, equipment and services needed for the operation of an *organization* (3.8)

[SOURCE: ISO 9000:2015, 3.5.2]

3.4
interested party
person or *organization* (3.8) that can affect, be affected by, or perceive itself to be affected by a decision or activity

Note 1 to entry: Customers, owners, people in an organization, *providers* (3.11), bankers, regulators, unions, partners or society that can include competitors or opposing pressure groups.

Note 2 to entry: This constitutes one of the common terms and core definitions of the high level structure for ISO management system standards. The original definition has been modified by deleting the admitted term "stakeholder" and by adding the Example.

3.5
nonconformity
non-fulfilment of a requirement

Note 1 to entry: This constitutes one of the common terms and core definitions of the high level structure for ISO management system standards.

3.6
incident
occurrence arising out of, or in the course of, work that could or does result in injury and ill health

Note 1 to entry: An incident where injury and ill health occurs is sometimes referred to as an “accident”.

Note 2 to entry: An incident where no injury and ill health occurs, but has the potential to do so, may be referred to as a “near-miss”, “near-hit” or “close call” and can also include omission of care.

Note 3 to entry: Although there can be one or more *nonconformities* (3.5) related to an incident, an incident can also occur where there is conformity to requirements.

[SOURCE: ISO 45001:2018, 3.35, modified — Notes 2 and 3 to entry have been modified.]

3.7
healthcare educator
person responsible for providing learning experiences in a care setting

Note 1 to entry: Depending on the context, there can be one or more healthcare educators.

Note 2 to entry: Depending on the context, other terms can be used in place of “healthcare educator”, e.g. practice supervisor, clinical instructor, preceptor, monitor, mentor, tutor.

Note 3 to entry: Depending on the context, healthcare educators can originate from a care setting, an education *organization* (3.8), or both.

3.8
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: This constitutes one of the common terms and core definitions of the high level structure for ISO management system standards. The original definition has been modified by deleting the original Note to entry.

3.9
service user
person to which the care service is delivered

Note 1 to entry: Depending on the nature and culture of the *organization* (3.8), other terms can be used in place of "service user", e.g. patient, customer, client, among others.

3.10
healthcare education
learning facilitated by a *provider* (3.11) that is part of a recognized qualification

Note 1 to entry: Healthcare education is sometimes referred to as healthcare training.

3.11
provider
organization (3.8) offering *healthcare education* (3.10) or training in a care setting

Note 1 to entry: The provider can differ substantially according to the services offered (hospital, clinic, care home, hospice, etc.); their financial nature (public, private, etc.) and their size (micro, small or large), among other characteristics.

4 Governance

4.1 Organizational culture

The provider shall determine its purpose, scope and aspirations for healthcare education and maintain this as documented information. This documented information shall be communicated to relevant interested parties.

The provider shall determine, implement and promote a positive culture that demonstrates knowledge of the service users' needs and expectations and reflects cultural sensitivity, effective practice and continual improvement.

When identifying this culture, the provider should consider elements including, but not limited to:

a) person-centred approach and care;

b) anti-discrimination;

c) cultural integration;

d) data protection;

e) ethical practice;

f) occupational health and safety;

g) dedication to healthcare professional development;

h) digital literacy;

i) innovation;

j) sustainability;

k) commitment to continuous improvement supported by evidence-based practice and reflection on lessons learned.

NOTE 1 Cultural integration can include the recognition, respect and fulfilment of cultural and language needs of service users as appropriate.

NOTE 2 A positive culture can include sensitivity towards all cultures; mutual respect; empathy; compassion; motivation; confidence; patient safety.

4.2 Healthcare policy

The provider shall establish, implement and periodically review a healthcare policy that reflects its purpose, scope, aspirations and culture through a set of organizational commitments for the delivery of care.

The healthcare policy shall be maintained as documented information and available to interested parties.

4.3 Legal requirements and other requirements

The provider shall identify the applicable legal requirements and other requirements for delivery of safe and effective care, and for safe and effective education within that care setting, considering, as a minimum:

a) clinical practice;

b) data protection;

c) occupational health and safety;

d) appropriate insurance arrangements to protect patients and their care providers, employees, visitors and students in the workplace (this can include group or individual insurance for students).

The provider shall maintain documented information on the above requirements and retain documented information that compliance has been verified.

NOTE 1 Legal requirements and other requirements can be stated in proprietary or formal standards, policies, procedures and other similar technical documents.

NOTE 2 Verification of legal requirements and other requirements can be performed through self-assessment practices such as internal audits, an inspection from a regulatory body or an audit from an accredited certification body.

4.4 Risk management

The provider shall establish and implement one or more processes for risk management related to the healthcare education programme within the care setting, which enables:

a) identification of risks;

b) evaluation of risks;

c) determination of actions to address relevant risks;

d) evaluation of the effectiveness of the actions implemented.

The provider shall ensure that people working on its behalf are adequately trained in the adopted risk management process(es).

Documented information regarding risk management shall be maintained and communicated to relevant interested parties in a timely manner.

