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Международная организация по стандартизации

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Ref. ISO/TMB IWA 35

2020-03-19

Invitation to an international workshop on "Quality of clinical learning environments for healthcare professionals – requirements" (IWA 35)

Dear ISO Members,

Following approval by the Technical Management Board of a proposal from the British Standards Institute (BSI), we are pleased to enclose the draft schedule and registration information for a workshop to develop an International Workshop Agreement on "Quality of clinical learning environments for healthcare professionals – requirements".

Workshop dates and times

Workshop #1: 22nd June 2020 – 07:00-10:30 GMT - 15:00-18:30 GMT
Workshop #2: 29th June 2020 – 07:00-10:30 GMT - 15:00-18:30 GMT

All meetings will be conducted via Zoom.

We ask that you register for the workshop by completing the attached form no later than 1st June, using the instructions included in the attached invitation.

We would be grateful if you could publicize this event in your country.

Yours sincerely,

Antoine Morin

Secretary to the Technical Management Board

Encl.:

- Invitation, including registration instructions and schedule for the workshop
- Background information on the proposal from BSI
- Draft outline of the ISO/IWA 35

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IWA 35 Quality of clinical learning environments for healthcare professionals – requirements

INVITATION TO INTERNATIONAL WORKSHOP

You are invited to attend a series of virtual workshops to develop a new ISO Workshop Agreement (IWA) on the quality of clinical learning environments for healthcare professionals.

Attendance at these meetings is free
All relevant stakeholders are permitted to participate.

NOTE: An ISO IWA is developed outside of the normal ISO system to enable the fast development of an international agreement that can be used by any organization to which it applies. IWAs indicate the organizations which were involved in their development in the published document and are typically used for six years or less before being withdrawn or developed into a full ISO international standard.

Background

This proposal is to develop a requirements document to assure the quality of clinical learning environments for healthcare trainees across the world. Whilst applying to a wide range of healthcare courses, this proposal and the attached draft document mostly uses the example of nursing and midwifery, as the largest provider of health care globally.

In some regions work has advanced to assure quality and consistency of clinical learning environments for healthcare education, but there is currently nothing at a global level. Consequently, it is not currently possible to assure that trainee placements are of appropriate quality prior to student attendance.

Additionally, no organization has yet been found with a complete and consistent approach to placement audit (including steps from the preparation of auditors through to completion of an effective audit outcome). Even where standard requirements do exist, these are varied in the extent and nature of their existence (e.g. US and UK) and colleagues from these countries identify the benefits of having international standards, even where national or local tools exist.

To address these issues within Europe, the European Commission funded an applied research project to develop a system for assuring the quality of clinical traineeships (see www.healint.eu). The HEALINT consortium encountered interest from non-European countries and recognized that increasing the geographical range could support learning for trainees within the country of origin and mobile students across the world. An agreed requirements' document relating to standards expected for clinical practice experience can also help improve quality globally.

The European document will be used as the preliminary draft for this IWA and is attached to this invitation. Experts are invited to use an ISO Commenting table to comment on the draft and propose changes or new text to ensure it is globally applicable.

Meeting details

Dates: **1st meeting:** 22nd June
2nd meeting: 29th June

Times: 07:00-10:30 GMT
15:00-18:30 GMT

Note: The same work will be covered at both meeting times on each date, to enable people in different parts of the world to contribute.

Location: All meetings will be via Zoom. Links below.

Join from PC, Mac, Linux, iOS or Android: https://iso.zoom.us/j/810662855
Meeting ID: 810 662 855
International numbers available: https://iso.zoom.us/u/adVGMvq87K
Or Skype for Business (Lync): https://iso.zoom.us/skype/810662855

TC Secretariat Sally Swingewood (BSI) sally.swingewood@bsigroup.com
Tel: + 44 7843 112599

Convenors

Carol Hall (University of Nottingham) C.Hall@nottingham.ac.uk

Dr Carol Hall is a Registered Nurse and Professor in Nursing Education with extensive experience in design, delivery and quality assurance of nursing and healthcare education, within the UK and internationally. Carol contributed to new nurse education competencies for the European Directive on Mutual Recognition of Professional Qualifications as Education Forum Chair, UK Royal College of Nursing (2006 - 2015) and as Vice President of the Federation of European Nurse Educators (FINE 2012 - 2018). She chaired subject pilot panels for Medicine and Health Sciences during development of the UK Teaching Excellence Framework (TEF 2018, 2019). Carol was awarded Principal Fellowship by the UK Higher Education Academy in November 2014 and received a team award for Collaboration in Teaching Excellence (CATE Award) in 2018.

Sandra Feliciano (Knowledge Innovation Centre) sandra@knowledgeinnovation.eu

Sandra Feliciano graduated in Social Sciences and post-graduated in Evaluation in Education. She has over 20 years of experience with quality management and is an experienced international consultant and trainer as well as a qualified assessor for several accredited certification schemes. She is a Research Associate at KIC, working with projects dealing with quality in education and a Lecturer at the Porto Polytechnic, where she teaches Standardization, Quality, and Management Systems Audits at Master level. She represented Portugal and Angola at ISO/TC176 during the last revision of ISO 9001 and, as Convenor of ISO/PC 288/WG 1, led the development of ISO 21001:2018, the first ISO management system standard for educational organizations. More information at www.linkedin.com/in/felicianosandra

Process:

1. Please **circulate this calling notice** to any relevant stakeholders and invite them to join the meetings. Experts do not need to be a member of a technical committee to join this workshop.

2. Each participant should **register** their intention to join the workshop by completing the attached form and returning it to the Secretariat no later than 1st June.

3. Participants should review the attached draft document and **submit comments** (guidance below) to the Secretariat no later than 1st June.

4. The Secretariat will collate the comments into one document and suggest whether each comment is likely to be accepted or not and give reasons. This **updated document will be sent to all registrants** to consider before we meet.

5. At the first meeting the **comments will be reviewed,** and the **draft will be revised** based on the consensus reached.

6. The second meeting each day will review the outcome of the earlier meeting and any decisions which are not agreed by the 2nd group, or further suggestions to resolve issues, will be shared with everyone.

7. The **combined outputs of both meetings will be circulated** to everyone for review and a second commenting period before the meetings on the 29th June.

8. Further remote meetings will be planned to finalize the document as required.

Registration: Please ensure you register for the specific dates and times you wish to attend by filling in the form below and returning it to the Secretariat.
Registration closes 1 June 2020.

NAME EMAIL COUNTRY	
INTEREST/EXPERTISE IN THIS TOPIC	
JOB TITLE/ORGANIZATION	
JUNE 22 07:00-10:30 GMT/UTC 15:00-18:30 GMT/UTC	**YES / NO** **YES / NO**
JUNE 29 07:00-10:30 GMT/UTC 15:00-18:30 GMT/UTC	**YES / NO** **YES / NO**

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IWA 35 Quality of clinical learning environments for healthcare professionals – requirements

DRAFT AGENDA
INTERNATIONAL WORKSHOPS 22 and 29 June

22 June	
07:00/15:00	Introductions & welcome
07:10/15:10	Background to the project
07:25/15:25	Discussion on general topics identified through the comments
08:25/16:25	**Break**
08:55/16:55	Discussion of specific comments received on draft
10:15/18:15 end	Review of proposed decisions made on comments NOTE: the results of both meetings will be circulated to everyone for review and to resolve any areas of difference before June 29

29 June	
07:00/15:00	Introductions & welcome
07:10/15:10	Review of agreed decisions made on 22 June
07:25/15:25	Discussion of remaining specific comments received on draft
08:25/16:25	**Break**
09:30/17:30	Discussion of specific comments received on draft
10:00/18:00	Review of revised text
10:15/18:15 end	Next steps and date of next meeting (s)

ISO IWA 35-2020

Secretariat: BSI

Quality of clinical learning environments for healthcare professionals – requirements

Preliminary working draft

Warning for WDs and CDs

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

GUIDANCE FOR COMMENTS

1. Please send comments on the ISO commenting template ONLY to: sally.swingewood@bsigroup.com
2. Please always use the **line number** to identify the text you are commenting on
3. Please provide **one** comment per line/sentence/paragraph.

Template for comments and secretariat observations

Date:	Document: **Preliminary**	Project: IWA35

MB/NC[1]	Line number (e.g. 17)	Clause/ Subclause (e.g. 3.1)	Paragraph/ Figure/ Table/	Type of comment[2]	Comments	Proposed change	Observations of the secretariat
your intials	Line number you wish to change	Clause number	Specific place in clause e.g. bullet b	Tech/ editorial/ general	Why you want to change something	Exact proposed changes or new text	LEAVE THIS COLUMN BLANK

Contents

Foreword THIS IS STANDARD TEXT – DO NOT COMMENT ON THIS

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.

This document was prepared by XXX

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 clinical practice is an essential part of the curriculum. Curricula are designed with close input from the national health services, and on graduation, 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 trained within the system they intend to work in, are able to immediately integrate to deliver care, unlike other professionals coming from abroad, who require extra time and resources to integrate them with national specificities of the health system.

The intent of this document is, therefore, to provide a set of requirements that support higher education and healthcare institutions to offer and direct high-quality cross-border traineeships and simplify the processes involved in organizing these for trainees.

This document uses the below four verbs with the following intentions:

Used in requirements:

'Shall' indicates an obligation.

'Should' indicates a recommendation.

'May' indicates a permission.

'Can' indicates a possibility.

Quality of clinical learning environments for healthcare professionals – requirements

1 Scope

This document specifies requirements for operational practices when a traineeship host organization wishes to demonstrate its ability to consistently provide and improve traineeship placements that meet the requirements of the educational organizations as well as the applicable legal requirements.

All the requirements of this document are intended to be applicable to any traineeship host organization, regardless of its type, size or the healthcare services provided

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

compliance obligations (preferred term)

legal requirements and other requirements (admitted term)

legal requirements that an organization has to comply with and other requirements that an organization has to, or chooses to, comply with

Note to entry: Compliance obligations 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: Adapted from ISO 14001:2015 Environmental management – Requirements – Note 1 to entry was deleted and Note 2 to entry was kept without numbering]

3.2

documented information

information required to be controlled and maintained by an organization 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:

- the management system, including related processes;

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

- evidence of results achieved (records).

[Source: ISO/IEC Directives, Part 1 - Consolidated ISO Supplement - Procedures specific to ISO – Annex SL - Proposals for management system standards – Appendix 2 - High level structure, identical core text, common terms and core definitions]

3.3

credit transfer and accumulation system (CTS)

credit system designed to make it easier for students to move between different countries.

Note to entry: CTS are based on the learning achievements and workload of a course and a student can transfer CTS credits from one university to another, to contribute to an individual's degree programme or training.

[Source: European Commission - modified]

3.4

credit transfer for vocational education and training (CVET)

system designed to facilitate the transfer, recognition and accumulation of assessed learning outcomes of individuals who are aiming to achieve a qualification

[Source: European Commission - modified]

3.5

qualification framework (QF)

common reference framework to make qualifications more readable and understandable across different countries and systems

Note to entry: Covering qualifications at all levels and in all sub-systems of education and training, the QF provides a comprehensive overview over qualifications in the countries currently involved in its implementation.

[Source: CEDEFOP - modified]

3.6

formal education

education that is institutionalised, intentional and planned through public organizations and recognised private bodies and constitutes the formal education system of a country

Note 1 to entry: Formal education programmes are recognised by the relevant national education or equivalent authorities, e.g. any other institution in cooperation with the national or sub-national education authorities. Formal education consists mostly of initial education. Vocational education, special needs education and some parts of adult education are often recognised as being part of the formal education system.

Note 2 to entry: Institutionalised education occurs when an organization provides structured educational arrangements, such as student-teacher relationships and/or interactions, that are specially designed for education and learning.

[Source: ISCED - modified]

3.7

human resources

people working within or contributing to the organization

[Source: ISO 30400:2016 Human resource management -- Vocabulary]

3.8

infrastructure

<organization> system of facilities, equipment and services needed for the operation of an organization

[Source: ISO 9000:2015 Quality management – Fundamentals and vocabulary]

3.9

interested party (preferred term)

stakeholder (admitted term)

person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

Note to entry: Examples of interested parties are: Customers, owners, people in an organization, providers, bankers, regulators, unions, partners or society that can include competitors or opposing pressure groups.

[Source: ISO 9000:2015 Quality management – Fundamentals and vocabulary]

3.10

nonconformity (preferred term)

incident (admitted term)

non-fulfilment of a requirement

[Source: Adapted from ISO/IEC Directives, Part 1 - Consolidated ISO Supplement - Procedures specific to ISO – Annex SL - Proposals for management system standards – Appendix 2 - High level structure, identical core text, common terms and core definitions]

3.11

mentor

person(s) primarily concerned with the learning development of the trainee during the time they are within the traineeship

Note 1 to entry: depending of the context, there might one or more mentors per trainee – e.g. academic mentor, clinical mentor, among others.

Note 2 to entry: Depending on the context/culture, a mentor may be called a practice supervisor, a director, or any other job role' name which responsibilities match the above definition.

3.12

mission

reason for being, mandate and scope of an organization, translated into the context in which it operates

[Source: ISO 21001:2018 – Educational organizations – Managements systems for educational Organizations – Requirements with guidance for use]

3.13

organization

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

[Source: ISO/IEC Directives, Part 1 - Consolidated ISO Supplement - Procedures specific to ISO – Annex SL - Proposals for management system standards – Appendix 2 - High level structure, identical core text, common terms and core definitions]

3.14

organization culture

values, beliefs and practices that influence the conduct and behaviour of people and organizations

[Source: ISO 30400:2016 Human resource management – Vocabulary / ISO 30401:2018 Knowledge management systems -- Requirements]

3.15

organizational policy

intentions and direction of an organization as formally expressed by its top management

[Source: ISO/IEC Directives, Part 1 - Consolidated ISO Supplement - Procedures specific to ISO – Annex SL - Proposals for management system standards – Appendix 2 - High level structure, identical core text, common terms and core definitions]

3.16

professional higher education

form of higher education that offers a particularly intense integration with the world of work in all its aspects, including teaching, learning, research and governance, ~~and at all levels of the overarching qualifications framework of the European Higher Education Area (EHEA).~~

[Source: EURASHE]

3.17

service user

person to which the health care service is delivered.

Note to entry: Depending on the nature and culture of the organization, a service user might be known as patient, customer, client, among others.

3.18

traineeship (preferred term)

apprenticeship (admitted term)

learning that alternates between a workplace and an education or training institution; that is part of formal education and training; and that on successful completion, learners acquire a qualification and receive an officially recognized certificate.

(Source: Adapted from CEDEFOP)

3.19

traineeship host organization

organization offering the traineeship placement

Note to entry: The host organization can differ in 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.

3.20

vision

aspirations of an organization in relation to its desired future condition and duly aligned with its mission

[Source: ISO 21001:2018 – Educational organizations – Managements systems for educational Organizations – Requirements with guidance for use]

4 Governance

4.1 Mission and vision

The traineeship host organization shall identify its mission and determine its vision and maintain it as documented information.

4.2 Organizational culture

The traineeship host organization shall identify, implement and maintain a culture that demonstrates the organization's knowledge of service users' needs and expectations and reflects cultural sensitivity, effective practice and continual improvement.

When identifying this culture, the traineeship host organization should consider:

a) anti-discrimination;

b) cultural integration;

c) a positive working attitude;

d) data protection;

e) ethical practice;

f) occupational health and safety;

g) dedication to healthcare professional development;

h) promotion and use of evidenced-based practice;

i) commitment to continuous improvement based on best practice and reflections 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 working attitude can include sensitivity of all cultures; mutual respect; empathy; compassion; motivation; confidence; patient safety.

4.3 Organizational policy

The traineeship host organization shall establish, implement and periodic review an organizational policy that reflects the organizational culture, through a set of organizational commitments.

The organizational policy should be maintained as documented information and be available to interested parties.

4.4 Compliance obligations

The traineeship host organization shall identify the applicable local, regional and national requirements for delivery of safe and effective care, considering:

a) clinical practice;

b) data protection;

c) occupational health and safety;

d) appropriate insurance arrangements to protect patients and their carers, employees, visitors and students/trainees in the workplace.

The traineeship host organization shall maintain documented information of the identification of the above requirements and retain documented information that the compliance has been verified.

Note 1: Local, regional and national requirements can be stated in proprietary or formal standards, policies, procedures and other similar technical documents.

Note 2: Verification of compliance obligations 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.

4.5 Risk management

The traineeship host organization shall adopt a methodology for risk management related to the traineeship placements, 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 traineeship host organization shall ensure its staff is adequately trained in the adopted risk management methodology.

Documented information regarding the adopted risk management methodology and evidence of its implementation shall be maintained and retained, respectively.

4.6 Control of nonconformities

The traineeship host organization shall establish a methodology to deal with nonconformities related to the traineeship placements, which enables:

a) description of the nonconformity;

b) root cause investigation;

c) determination of appropriate actions to address the nonconformity, the responsible persons for its implementation and deadlines;

d) evaluation of the effectiveness of the actions implemented.

Documented information regarding the methodology and evidence of its implementation shall be maintained and retained, respectively and communicated to the educational organization without undue delay.

Note: Appropriate actions to address nonconformities can include any corrections and support measures needed as well as any actions to avoid nonconformities recurrence.

5 Resources

5.1 Human resources

The traineeship host organization shall determine, provide and maintain sufficient human resources for the traineeship placement, including:

a) adequate staffing ratios and skills;

b) clear job descriptions and leadership styles;

c) support for staff life-long learning and career development.

5.2 Infrastructure

The traineeship host organization shall determine, provide and maintain an adequate infrastructure for the traineeship placement.

5.3 Financial resources

The traineeship host organization shall determine, provide and maintain sufficient financial resources to allow:

a) conformity with the requirements of 5.1 and 5.2;

b) adequate investment into the continuous development of the healthcare services provided.

5.4 Documented information

The organizational scope in which this protocol is implemented, as well as justifications for any non-applicable requirements, shall be maintained as documented information.

To the extent necessary, the traineeship host organization shall also:

a) maintain documented information to support the operation of the traineeship placements offered;

b) retain documented information to have confidence that the traineeship placements are being carried out as planned.

Documented information maintained and retained shall be easily available to staff, students and representatives of the educational organization, as appropriate.

Note 1: Examples of documented information maintained can be: Induction plans, placement desired learning outcomes, documented job descriptions, health and safety documented procedures, among others.

Note 2: Examples of documented information retained can be: Staff rotation records, insurance records, among others.

6 Traineeship planning and control

6.1 Allocation of trainees to traineeship placements

The traineeship host organization shall assure the requirements for the traineeship placement are defined and that the trainee meets those requirements before starting the traineeship.

When the selected trainee does not meet a given requirement, the traineeship host organization shall make sure adequate actions are implemented that lead to the acquisition of the required competences during the induction phase of the traineeship.

The traineeship placement requirements, as well as evidence that the trainee meets them shall be maintain and retained, respectively.

Note: Examples of requirements not usually met in advance by a trainee can include competences related to specific procedures of the organization (e.g. health and safety, security) or to specific resources (e.g. medical devices, software applications or other equipment), among others.

6.2 Assignment of mentors

The traineeship host organization shall assign a mentor to each trainee who is adequately prepared to support the professional development of trainees in their placement. This shall include:

a) pedagogical competence to mentor;

b) professional qualification adequate to the characteristics of the traineeship;

c) knowledge of relevant information regarding the traineeship, including characteristics of the placement and of the trainee being allocated.

The minimum mentorship contact time shall be defined in number of hours and its distribution across the duration of the traineeship.

The identification and contacts of the assigned mentor shall be made available to the trainee and hers/his educational organization.

6.3 Learning environment

The traineeship host organization shall determine, provide and maintain a supportive learning environment for the traineeship placement, including an organizational behaviour which reflects the commitments expressed in the organizational policy (see 4.3).

The traineeship host organization shall assure the availability of a learning environment where:

a) the learning opportunities match the learning objectives and level of the trainee and any exceptions justified;

b) the trainee experiences the delivery of patient care based on contemporary evidence-based practice;

c) there is a positive learning culture which embraces and supports diversity;

d) the trainee is not included in the work force and the mentor remains accountable for the trainee activity;

e) there is a system in place for trainees and mentors to raise concerns;

f) the role and responsibilities of the trainee are clearly identified;

g) the wellbeing of the trainee is supported

h) the trainee has access to relevant documented information;

i) trainee feedback is used for continuous improvement of the traineeship placement.

Note 1: Examples of embracing and supporting diversity can include:

a) support acclimatization to new cultures;

b) the implementation of plans to address language barriers such as translation of common medical and healthcare terms;

c) the use of transcultural nonverbal communication to establish professional relationships with patients and others.

Note 2: Concerns raised can include those related to the trainees' experience or care provided to service users;

Note 3: Examples of relevant documented information can include policies, procedures and guidance, among others.

6.4 Assessment of learning

The traineeship host organization shall assure coordination with the higher education institution regarding the assessment of learning of the trainees and retain documented information of any relevant communications held.

Note: Coordination regarding assessment of learning may include:

a) instruments used and its grading system;

b) moments in which the assessment occurs;

c) system to support and assist student by giving continuous feedback on student´s commitment;

d) system to support and recover failing students.

7 Recognition of traineeships

7.1 Establishment of partnerships

The traineeship host organization shall establish a partnership with an education organization that enables continued cooperation and support regarding the traineeship.

The partnership shall ensure:

a) a responsible teacher is nominated for the traineeship and her/his direct contact details are available;

b) the education organization is aware of the host organization's culture (see 4.2) and commits to it;

c) clear insurance arrangements (see 4.4 d)).

Documented information shall be retained as evidence of the partnership and of any relevant communication regarding the traineeships hosted.

Note: A partnership can be evidenced through a documented agreement describing the rights and obligations of the parties involved.

7.2 Certification of traineeship

The partnership established shall ensure that the traineeship is recognised as education.

The traineeship host organization shall ensure that the education organization:

a) complies with national and European applicable legal requirements related to the educational curriculum for clinical traineeships;

b) is accredited under the European Higher Education Area (EHEA) if providing education at EQF levels 5 and above;

c) certifies the traineeship in European credit units, such as European Credit Transfer System (ECTS) or European Credit Transfer System for Vocational Education and Training (ECVET).

Both the accreditation status of the educational organization and the certification status of the traineeship shall be retained as documented information.

Note: The compliance with national and European applicable legal requirements may be evidenced through a self-declaration from the education organization.

Annex A
(informative)

Annex title e.g. Example of a figure and a table

A.1 Clause title autonumber

Use subclauses if required e.g. A.1.1 or A.1.1.1. For example:

A.1.1 Subclause autonumber

A.1.1.1 Subclause autonumber

Type text.

Bibliography

[1] ISO 21001:2018 *Educational organizations – Management systems for educational organizations – Requirements with guidance for use*

[2] ISO/IEC Directives, Part 1 - *Consolidated ISO Supplement - Procedures specific to ISO*

[3] ISO 30400:2016 *Human resource management - Vocabulary*

[4] ISO 14001:*2015 Environmental management – Requirements*

[5] ISO 9001:2015 *Quality management – Fundamentals and vocabulary*

[6] CEDEFOP *European Qualifications Framework (EQF)*

[7] CEDEFOP 2010 *Terminology of European education and training policy: A selection of 100 Key Terms*

[8] EURASHE 2014 *Professional Higher Education in Europe - Characteristics, Practice, Examples and National Differences*

[9] European Commission *he European Credit system for Vocational Education and Training (ECVET). In Education and Training -Supporting education and training in Europe and beyond*

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[11] HEALINT *Healint: The project – Our mission and vision*

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