



SLOVENSKI STANDARD
oSIST prEN ISO 13131:2022
01-september-2022

Zdravstvena informatika - Telezdravstvene storitve – Smernice za načrtovanje kakovosti (ISO 13131:2021)

Health informatics - Telehealth services - Quality planning guidelines (ISO 13131:2021)

Medizinische Informatik - Telemedizinische Dienste - Leitlinien für die Qualitätsplanung (ISO 13131:2021)

Informatique de santé - Services de télésanté - Lignes directrices pour la planification de la qualité (ISO 13131:2021)

<https://standards.iteh.ai/catalog/standards/sist/02f14b28-2e95-41a5-b961-774444444444/sist-pr-en-iso-13131-2022>

Ta slovenski standard je istoveten z: prEN ISO 13131

ICS:

11.020.01	Vodenje kakovosti in ravnanje z okoljem v zdravstvu	Quality and environmental management in health care
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

oSIST prEN ISO 13131:2022

en,fr,de

INTERNATIONAL
STANDARD

ISO
13131

First edition
2021-05

**Health informatics — Telehealth
services — Quality planning
guidelines**

*Informatique de santé — Services de télésanté — Lignes directrices
pour la planification de la qualité*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[oSIST prEN ISO 13131:2022](https://standards.iteh.ai/catalog/standards/sist/02f14b28-2e95-41a5-b961-53a8b71bcba3/osist-pren-iso-13131-2022)

<https://standards.iteh.ai/catalog/standards/sist/02f14b28-2e95-41a5-b961-53a8b71bcba3/osist-pren-iso-13131-2022>



Reference number
ISO 13131:2021(E)

© ISO 2021

iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN ISO 13131:2022](https://standards.iteh.ai/catalog/standards/sist/02f14b28-2e95-41a5-b961-53a8b71bcba3/osist-pren-iso-13131-2022)

<https://standards.iteh.ai/catalog/standards/sist/02f14b28-2e95-41a5-b961-53a8b71bcba3/osist-pren-iso-13131-2022>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 Quality characteristics.....	2
3.2 Actors.....	3
3.3 Care.....	5
3.4 Quality and risk.....	7
3.5 Services.....	10
3.6 Devices.....	10
4 Application of these guidelines	10
5 Quality management of telehealth services	11
5.1 Quality management.....	11
5.1.1 Telehealth service quality planning.....	11
5.1.2 Guidelines for quality and risk management.....	12
5.2 Management of quality characteristics.....	12
5.2.1 General.....	12
5.2.2 Guidelines for quality characteristics.....	13
5.3 Description of service scope and context.....	13
5.3.1 General.....	13
5.3.2 Guidelines for description of services.....	13
5.4 Description of healthcare processes.....	14
5.4.1 General.....	14
5.4.2 Guidelines.....	14
5.5 Evaluation and monitoring.....	14
5.5.1 General.....	14
5.5.2 Guidelines for evaluation and monitoring.....	14
6 Risk management	15
6.1 Telehealth service risk, quality and safety assessment.....	15
6.2 Risk assessment - Identification.....	16
6.2.1 General.....	16
6.2.2 Guidelines for risk assessment.....	16
6.3 Risk assessment - analysis.....	17
6.3.1 General.....	17
6.3.2 Guidelines for risk analysis.....	17
6.4 Risk assessment - evaluation.....	17
6.4.1 General.....	17
6.4.2 Guidelines for risk evaluation.....	17
6.5 Risk treatment.....	18
6.5.1 General.....	18
6.5.2 Guidelines for risk treatment.....	18
7 Financial management	18
7.1 Quality characteristics.....	18
7.1.1 General.....	18
7.1.2 Guidelines for sustainability.....	19
7.1.3 Guidelines for healthcare funds.....	19
7.1.4 Guidelines for service payment.....	19
8 Service planning	19
8.1 Quality characteristics.....	19
8.1.1 General.....	19

ISO 13131:2021(E)

8.1.2	Guidelines for service design	19
8.1.3	Guidelines for service availability	20
8.1.4	Guidelines for duration of care	20
8.1.5	Guidelines for service level agreements	20
9	Human resources planning	21
9.1	Quality characteristics	21
9.1.1	General	21
9.1.2	Guidelines for human resources skills and training	21
9.1.3	Guidelines for consultation with human resources	22
10	Care planning	22
10.1	Quality characteristics	22
10.1.1	General	22
10.1.2	Guidelines for healthcare processes	22
10.1.3	Guidelines for care plans	22
10.1.4	Guidelines for healthcare continuity	22
10.1.5	Guidelines for emergency procedures	23
10.1.6	Guidelines for when clinical guidelines and protocols are unavailable	23
10.1.7	Guidelines for adverse event management	23
10.1.8	Guidelines for professional health record management	23
11	Responsibilities	24
11.1	Quality characteristics	24
11.1.1	General	24
11.1.2	Guidelines for healthcare mandates	24
11.1.3	Guidelines for informed consent	24
11.1.4	Guidelines for care recipient preferences	25
11.1.5	Guidelines for care recipients' expenses	25
11.1.6	Guidelines for providing appropriate healthcare services	25
11.1.7	Guidelines for ensuring competence of care recipients	26
11.1.8	Guidelines for design of telehealth services	26
11.1.9	Guidelines for execution of care plans	26
12	Facilities management	27
12.1	Quality characteristics	27
12.1.1	General	27
12.1.2	Guidelines for healthcare organization facilities	27
12.1.3	Guidelines for care recipient facilities	27
13	Technology management	28
13.1	Quality characteristics	28
13.1.1	General	28
13.1.2	Guidelines for safety and quality	29
13.1.3	Guidelines for service support	29
13.1.4	Guidelines for service delivery	29
13.1.5	Guidelines for infrastructure management	30
13.1.6	Guidelines for deployment management	30
13.1.7	Guidelines for operations management	30
13.1.8	Guidelines for technical support	31
13.1.9	Guidelines for device management	31
14	Information management	32
14.1	Quality characteristics	32
14.1.1	General	32
14.1.2	Guidelines for privacy	32
14.1.3	Guidelines to protect care recipient identity	32
14.1.4	Guidelines for confidentiality of health records	32
14.1.5	Guidelines for consultations, ordering and prescribing	33
14.1.6	Guidelines for coordination and scheduling	33
14.1.7	Guidelines for data quality	33

Annex A (informative) Procedures for the implementation of telehealth services by a large organization	35
Annex B (informative) Using quality planning guidelines in real-world telehealth services	37
Bibliography	46

iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN ISO 13131:2022](https://standards.iteh.ai/catalog/standards/sist/02f14b28-2e95-41a5-b961-53a8b71bcba3/osist-pren-iso-13131-2022)

<https://standards.iteh.ai/catalog/standards/sist/02f14b28-2e95-41a5-b961-53a8b71bcba3/osist-pren-iso-13131-2022>

ISO 13131:2021(E)

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.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This first edition cancels and replaces the ISO/TS 13131:2014, which has been technically revised.

The main changes compared to the previous edition are as follows:

- alignment with ISO 9000:2015, ISO 9001:2015, ISO 31000:2018 and ISO 13940:2015;
- addition of informative annexes providing use cases illustrating applications of this document;
- improvement in the clarity of the clauses on quality management and risk 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

Healthcare activities rely on communication between healthcare actors. When the point of care is geographically separated from healthcare resources and healthcare actors are geographically separated, technology enabled services can support healthcare activities. There are diverse forms of healthcare activity, including care by a health professional, self-care activity, treatment, investigation, management, assessment, and evaluation, provision of resources, documentation and education. (For an explanation of these terms, refer to ISO 13940). Health services rely on many technical devices and services including, but not limited to facsimile machines, telephones, cameras, mobile phones, mobile devices, health state monitors, diagnostic scanners and communications services including email, telephony, video conferencing, image transmission and electronic messaging to convey health information and data between healthcare actors.

These services can be described as telehealth services because information and communication technology services are being used to support healthcare activities. Telehealth services can include but are not limited to telemedicine, telecare, mhealth (healthcare supported by mobile devices), remote use of medical applications, tele-monitoring, tele-diagnostics and virtual care^[30]. Examples of health services include but are not limited to tele-pathology, tele-dermatology, tele-cardiology, tele-rehabilitation, tele-oncology, and tele-orthopaedics. Healthcare activities that directly or indirectly support care recipients include but are not limited to teleconsultation, telephone advice, health alarm systems and health status monitoring at home. Telehealth services can support immediate healthcare activities using synchronous communications services such as a telephone or video conversation, or delayed health care activities using asynchronous communications services such as messaging services.

Within the healthcare industry, these services are described as digital health or ehealth (electronic health) products provided to support healthcare activity. Electronic health information systems are an example of products that support the capture, storage and transmission of healthcare information and data, which may or may not be used for telehealth services. It is expected that telehealth services will improve the quality of health and healthcare. For example, healthcare professionals can have health information about the care recipient available in the right place at the right time, and they will have easier access to support from medical specialists. The care recipient can be monitored in his or her home, and receive advice without the need to travel to consult a health advisor or healthcare professional as well as having easier access to healthcare information and education to support self-care.

Health informatics — Telehealth services — Quality planning guidelines

1 Scope

This document provides processes that can be used to analyze the risks to the quality and safety of healthcare and continuity of care when telehealth services are used to support healthcare activities. Using risk management processes, quality objectives and procedures are derived which provide guidelines for the operations of telehealth services. These include but are not limited to the following domains:

- management of telehealth quality processes by the healthcare organization;
- strategic and operational process management relating to regulations, knowledge management (best practice) and guidelines;
- healthcare processes relating to people such as healthcare activities, planning, and responsibilities;
- management of financial resources to support telehealth services;
- management of information management and security used in telehealth services;
- processes related to the planning and provision of human resources, infrastructure, facilities and technology resources for use by telehealth services.

This document provides a set of example guidelines containing quality objectives and procedures for each domain. Organizations can apply the quality and risk management processes described in [Clauses 5](#) and [6](#) to develop quality objectives and procedures appropriate to the telehealth services they provide.

This document does not provide guidance for the manufacture, assembly, configuration, interoperability or management of devices, products or technical systems.

[Annex A](#) provides procedures for the implementation of telehealth services by a large organization. [Annex B](#) provides use cases for the application of quality planning guidelines in different types of real-world telehealth services.

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/>

ISO 13131:2021(E)

3.1 Quality characteristics

3.1.1

accessibility

usability of a product, service, environment or facility by people within the widest range of capabilities

EXAMPLE Accessibility of healthcare for care recipients.

[SOURCE: ISO 9241-20:2008, 3.1, modified — Notes to entry removed and example added.]

3.1.2

accountability

state of being answerable for decisions and activities to the organization's governing bodies, legal authorities and, more broadly, its stakeholders

[SOURCE: ISO 26000:2010, 2.1]

EXAMPLE Accountability for healthcare activities delivered by a healthcare organization.

3.1.3

appropriateness

extent to which healthcare activities enable care recipients to achieve specified objectives

3.1.4

competence

ability to apply knowledge and skills to achieve intended results

[SOURCE: ISO/IEC 17021-1:2015, 3.7]

EXAMPLE Competence to participate in healthcare activities of care recipients or healthcare professionals.

3.1.5

confidentiality

property that information is not made available or disclosed to unauthorized individuals, entities, or processes

[SOURCE: ISO/IEC 27000:2018, 3.10]

EXAMPLE Confidentiality of information to maintain the privacy of the care recipient in society or social life.

3.1.6

continuity of care

component of patient care quality consisting of the degree to which the care needed by a patient is coordinated among practitioners and across organizations and time

[SOURCE: ISO/TR 18307:2001, 3.42]

EXAMPLE Continuity of healthcare especially when several healthcare professionals or organizations share the delivery of services to a single care recipient.

3.1.7

dependability

ability to perform when and as required

EXAMPLE Dependability of healthcare for care recipients.

[SOURCE: ISO 9000:2015, 3.6.14]

3.1.8 effectiveness

extent to which planned activities are realized and planned results achieved

[SOURCE: ISO 9000:2015, 3.7.11]

EXAMPLE Effectiveness of healthcare activities in improving the quality of life and health outcomes of care recipients and their informal caregivers.

3.1.9 efficiency

relationship between the results achieved and the resources used

[SOURCE: ISO 9000:2015, 3.7.10]

EXAMPLE Efficiency of healthcare activities in improving the quality of life and health outcomes of care recipients.

3.1.10 inclusivity

intention or policy of including people who might otherwise be excluded or marginalized, such as people with physical disabilities, learning disabilities, or racial and sexual minorities

[SOURCE: The Oxford Pocket Dictionary of Current English, 2009]

EXAMPLE Inclusivity of the care recipient in society or social life

3.1.11 safety

freedom from unacceptable risk or harm

EXAMPLE Safety measures that maintain the health of care recipients.

3.1.12 transparency

openness about decisions and activities that affect society, the economy and the environment, and willingness to communicate these in a clear, accurate, timely, honest and complete manner

[SOURCE: ISO 26000:2010, 2.24]

EXAMPLE Transparency of healthcare activities.

3.1.13 usability

extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use

[SOURCE: ISO 9241-420:2011, 3.42]

EXAMPLE Usability of the systems providing healthcare for care recipients and healthcare professionals.

3.2 Actors

3.2.1 carer caregiver

person who provides care

Note 1 to entry: A carer can be a healthcare professional or an informal caregiver.

ISO 13131:2021(E)**3.2.2****care recipient
patient
client****subject of care**

service user

subject of healthcare

healthcare actor with a person role; who seeks to receive, is receiving or has received healthcare

Note 1 to entry: In applying this document it is possible that the subject of care is considered to be a group of people

[SOURCE: ISO 13940:2015, 5.2.1]

3.2.3**care team**

group of collaborating carers who provide care to a care recipient

EXAMPLE A group of caregivers who collaborate to support a diabetic child; the care team includes his parents (informal caregivers), a primary healthcare professional, a community nurse (healthcare professionals), a teacher and a sport coach (other professionals).

3.2.4**healthcare actor**

organization or person participating in healthcare

Note 1 to entry: An individual person may be regarded as a legal entity in some situations depending on the service being delivered and the relevant national legislation.

[SOURCE: ISO 13940:2015, 5.2]

3.2.5**healthcare organization**

healthcare provider having an organization role

[SOURCE: ISO 13940:2015, 5.2.3.1]

EXAMPLE A care team, a group practice, a hospital department, a hospital care unit, a self-employed healthcare professional, a service providing healthcare advice.

3.2.6**healthcare third party**

healthcare actor other than a healthcare provider or the subject of care

[SOURCE: ISO 13940:2015, 5.2.4]

3.2.7**healthcare personnel**

individual healthcare actor having a person role in a healthcare organization

[SOURCE: ISO 13940:2015, 5.2.3.3]

3.2.8**healthcare professional**

healthcare personnel having a healthcare professional entitlement recognized in a given jurisdiction

[SOURCE: ISO 13940:2015, 5.2.3.3.1]

3.2.9**informal caregiver**

person, other than healthcare professional, who provides care

EXAMPLE A family member, a neighbour.

3.2.10**organization**

persons or groups of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: An organization may in some cases be a single health professional

[SOURCE: ISO 9000:2015, 3.2.1, modified — Note 1 to entry replaced and note 2 to entry removed.]

3.2.11**subject of care proxy**

healthcare third party having a person role with the right to take decisions on behalf of the subject of care

[SOURCE: ISO 13940:2015, 5.2.4.3]

3.2.12**supporting organization**

organization that provides services to healthcare organization but that does not provide healthcare services

EXAMPLE Healthcare financing bodies such as insurance institutions, suppliers of pharmaceuticals and other goods. Internet and application service providers. Manufacturers and suppliers of devices not related to the health of an individual.

3.3 Care

iTeh STANDARD PREVIEW

3.3.1**adverse event**

unintended event that has a negative influence on healthcare processes

[SOURCE: ISO 13940:2015, 8.2.4] [oSIST prEN ISO 13131:2022](https://standards.iteh.ai/catalog/standards/sist/02f14b28-2e95-41a5-b961-53a8b71bcba3/osist-pren-iso-13131-2022)

3.3.2**authorization by law**

provision in legislation that in certain circumstances can overrule the need for informed consent

[SOURCE: ISO 13940:2015, 11.2.9]

3.3.3**care**

interactions between a care recipient and a healthcare actor to benefit the health state of the care recipient

Note 1 to entry: The term 'care' is frequently used in combination with other words, such as 'healthcare' or 'care recipient'.

Note 2 to entry: Care also includes interactions between carers who are not healthcare professionals such as informal caregivers.

3.3.4**care plan****healthcare plan**

dynamic, personalized plan including identified needed healthcare activities, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process

[SOURCE: ISO 13940:2015, 9.2]