

STN	Zdravotnícka informatika Služby zdravotnej starostlivosti na diaľku Usmernenie na plánovanie kvality (ISO 13131: 2021)	STN EN ISO 13131 84 8119
------------	---	--

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/23

Obsahuje: EN ISO 13131:2022, ISO 13131:2021

136270

EUROPEAN STANDARD

EN ISO 13131

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2022

ICS 35.240.80

English Version

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

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

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

This European Standard was approved by CEN on 14 November 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN ISO 13131:2022 (E)

Contents	Page
European foreword.....	3
Endorsement notice	3

European foreword

The text of ISO 13131:2021 has been prepared by Technical Committee ISO/TC 215 "Health informatics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 13131:2022 by Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 13131:2021 has been approved by CEN as EN ISO 13131:2022 without any modification.

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*



Reference number
ISO 13131:2021(E)

© ISO 2021

ISO 13131:2021(E)**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

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.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN