

This is a preview of "ISO 13131:2021". [Click here to purchase the full version from the ANSI store.](#)

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



**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](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

This is a preview of "ISO 13131:2021". [Click here to purchase the full version from the ANSI store.](#)

## Contents

	Page
<b>Foreword</b> .....	<b>vi</b>
<b>Introduction</b> .....	<b>vii</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
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
<b>4 Application of these guidelines</b> .....	<b>10</b>
<b>5 Quality management of telehealth services</b> .....	<b>11</b>
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
<b>6 Risk management</b> .....	<b>15</b>
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
<b>7 Financial management</b> .....	<b>18</b>
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
<b>8 Service planning</b> .....	<b>19</b>
8.1 Quality characteristics.....	19
8.1.1 General.....	19

This is a preview of "ISO 13131:2021". [Click here to purchase the full version from the ANSI store.](#)

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
<b>9</b>	<b>Human resources planning .....</b>	<b>21</b>
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
<b>10</b>	<b>Care planning .....</b>	<b>22</b>
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
<b>11</b>	<b>Responsibilities .....</b>	<b>24</b>
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
<b>12</b>	<b>Facilities management .....</b>	<b>27</b>
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
<b>13</b>	<b>Technology management .....</b>	<b>28</b>
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
<b>14</b>	<b>Information management .....</b>	<b>32</b>
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

This is a preview of "ISO 13131:2021". [Click here to purchase the full version from the ANSI store.](#)

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

## 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](http://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](http://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](http://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](http://www.iso.org/members.html).

This is a preview of "ISO 13131:2021". [Click here to purchase the full version from the ANSI store.](#)

## 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<sup>[30]</sup>. 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.