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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of an identical text or by endorsement, at the latest by May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.

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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**

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Foreword

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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).

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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.

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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.

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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.

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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.

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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.

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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/

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