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# INTERNATIONAL STANDARD

**Health software and health IT systems safety, effectiveness and security - Part 2-2: Coordination - Guidance for the implementation, disclosure and communication of security needs, risks and controls**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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## FOREWORD

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IEC TS 81001-2-2 has been prepared by subcommittee 62A: Common aspects of electrical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems and ISO technical committee 215: Health informatics. It is a Technical Specification.

This document withdraws and replaces:

– IEC TR 80001-2-2, *Application of risk management for IT-networks incorporating medical devices – Part 2-2: Guidance for the communication of medical device security needs, risks and controls*
– IEC TR 80001-2-8, *Application of risk management for IT-networks incorporating medical devices – Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2*

This document includes the following significant changes:

a) Combines and updates the contents of IEC TR 80001-2-2 and IEC TR 80001-2-8;
b) Extends the scope to *health software* instead to only *medical device* software;
c) Aligns contents and definitions to ISO 81001-1:2021 and the updated IEC 80001-1;
d) Removed the Configuration of Security Features (CNFS) capability, as any configurable *security capability* shall be clearly communicated.
e) Provide *security control* mappings to several new standards, e.g. IEC TR 60601-4-5, IEC 62443-4-2, ISO/IEEE 11073-40102 and the recent versions of previous standards, e.g. ISO/IEC 27002 and NIST 800-53 version 5.

The text of this Technical Specification is based on the following documents:

| Draft | Report on voting |
|---|---|
| 62A/1668/DTS | 62A/1690/RVDTS |

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Technical Specification is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

A list of all parts in the IEC 81001 series, published under the general title *Health software and health IT systems safety, effectiveness and security*, can be found on the IEC website.

Terms used throughout this document that have been defined in Clause 3 and the terms referenced in the alphabetical index at the end of the document appear in *italics.*

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

– reconfirmed,
– withdrawn, or
– revised.

# INTRODUCTION

ISO 81001-1 provides the principles, concepts, terms and definitions for *health software* and *health IT system*s, *key properties* of *safety*, *effectiveness* and *security* across the life cycle. ISO 81001-1 and all parts of the ISO 81001 and IEC 81001 series are applicable to all relevant stakeholders including *health software manufacturer*s (including *medical device manufacturer*s) and *healthcare delivery organization*s (*HDOs*). This document provides guidance on the implementation, disclosure and communication of *health software security* needs, *risks* and controls for both *health software manufacturers* (including *medical device manufacturer*) and *HDOs*.

For this document, the term "*manufacturer*" refers to the *health software manufacturer* which includes the *medical device manufacturer*. The term "user" typically refers to the *HDOs* for whom the information exchange resulting from using this document can be applied for their *risk assessments* and to establish a common understanding of the products *security* capabilities, and to further support the shared responsibility between *HDOs* and *manufacturers*.

The informative set of *security capabilities* presented are intended to be the baseline for a *security*-centric discussion between all stakeholders, including *manufacturers*, vendors, *HDOs*, procurements, etc. The level of effort is scalable across organizations of all sizes and it is crucial that it is adapted to the *risk* tolerance and the organizational goals. This document can be used across the life cycle of the *health IT system* and *health IT Infrastructure* into which the *health software* is incorporated, including:

a) administrative and technical *security control*s to protect and maintain the confidentiality, integrity, availability, authenticity, accountability and non-repudiation of data and systems,

b) documentation,

c) *risk management*,

d) shared responsibility,

e) procurement, and

f) agreements.

A *security capability* represents broad categories of technical, administrative and organizational *security controls* which are used to manage *risks* to confidentiality, integrity, availability, authenticity, accountability, non-repudiation and other characteristics, such as authorization, auditing, privacy, resilience, compliance and revocability, which are important for a comprehensive *security* of data and systems. This document presents these categories of *security controls* prescribed for a system and the operational environment to establish *security capabilities* that protect, maintain, and ensure the confidentiality, integrity and availability of data and systems. It is important to note that *security controls* for each *security capability* can be added as the need arises. Controls are intended to protect both data and systems but special attention is given to the protection of personal data and health data. Both special terms have been defined to carefully avoid any law-specific references (e.g. European special categories of personal data or sensitive data and *Personal Health Information* (PHI) in the USA).

The list is not intended to constitute or to support rigorous IT *security* standards-based controls and associated programs of certification and assurance like other ISO/IEC documents (e.g. ISO/IEC 15408 with its Common Criteria for Information Technology Security Evaluation and IEC 62443 for Security for industrial automation and control systems). This document does not contain sufficient detail for exact specification of requirements. However, the classification and structure can be used to organize such requirements with underlying detail sufficient for communication during the life cycle of *health software* or IT equipment component.

This document creates a framework for the disclosure of *security*-related capabilities necessary for managing the *risk* when implementing *health software* as a component of *health IT system*s operating on *health IT infrastructure*s and *IT Infrastructure* for *security* dialog that supports *key properties* of *safety*, *effectiveness* and *security* as conceptualized in ISO 81001-1 and other relevant *security* standards.

In addition to providing a basis for discussing *risk* and respective roles and responsibilities toward *risk management*, this document is intended to supply:

a) *HDOs* with a catalogue of management, operational and administrative *security controls* to maintain the *effectiveness* of a *security capability* for a product as a component of a *health IT system* being implemented on an organization's *health IT Infrastructure*;

b) *manufacturers* with a catalogue of technical *security controls* for the establishment of each of the *security capabilities*;

c) guidance on the communication of information on *security* capabilities between manufactures and *HDOs* as described in a sample scenario showing the exchange of *security* information (Annex A).

This document presents the *security capabilities*, their respective "requirement goal" and "user need" with a corresponding mapping of *security controls* from a number of *security* standards in Annex C.

This document remains agnostic as to the underlying controls framework. It only proposes a structure for the implementation, disclosure and communication among the *manufacturers* and other stakeholders. While this document can be used independently, it is best used in conjunction with other documents in the ISO/IEC 80001 and ISO/IEC 81001 series. Furthermore, the *security capabilities* encourage the use of more detailed *security controls* – perhaps those specified in one or more *security* standards as followed by the *HDO* or the *manufacturer*.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

In this document, the following verbal forms are used:

– "shall" indicates a requirement;

– "should" indicates a recommendation;

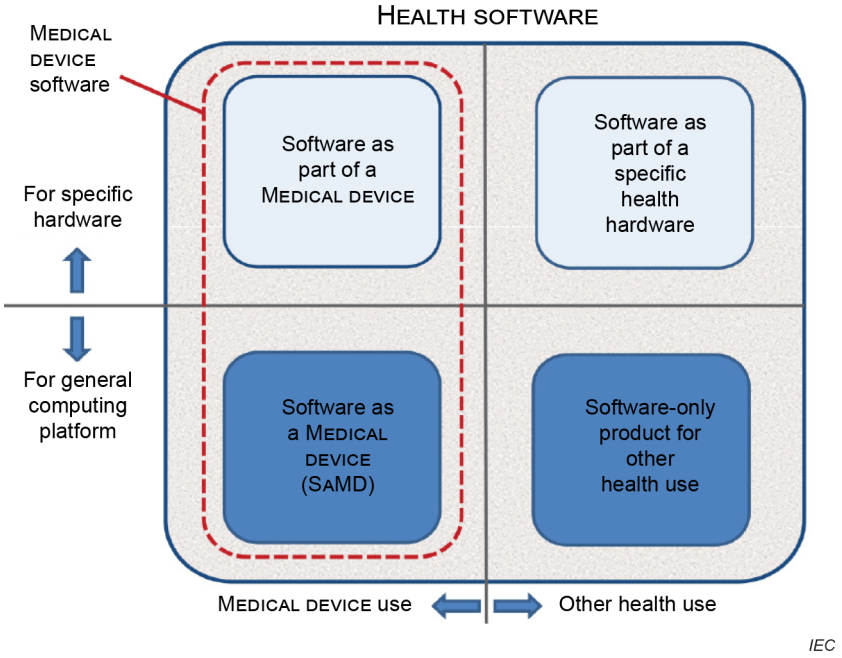
– "may" indicates a permission;

– "can" is used to describe a possibility or capability.

## 1 Scope

This document presents an informative set of common, high-level *security-related capabilities* and additional considerations to be used across the life cycle of *health software* and *health IT systems*, for the information exchange between the *health software manufacturers* (including *medical device manufacturers)*, *healthcare delivery organizations* (*HDOs*) and other stakeholders. It is applicable to *health software* running on any platform and in any environment such as cloud, on premise or hybrid.

Figure 1 provides a graphical representation of the *health software* which fully includes *medical device* software.




SOURCE: IEC 82304-1:2016, Figure A.1 [56]

**Figure 1 – *Health software* Field of Application as shown in IEC 81001-5-1 [3][1]**

While important *security* topics, the following are outside the scope of this document:

a) the *security* policies of the *HDO*,
b) the product and services *security* policies of the *manufacturer*,
c) determinations of *risk* tolerance by the *HDO* or *manufacturer*, and
d) clinical studies where there is a need to secure personal data.

As *security risks* can be caused by any product on *health IT systems* and *health IT Infrastructure*, considerations in this document can be applied for other products that are not *health software*.

[1] Numbers in square brackets refer to the Bibliography.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 81001-1:2021, *Health software and health IT systems safety, effectiveness and security - Part 1: Principles and concepts*