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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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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

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 systems*, *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 manufacturers* (including *medical device manufacturers*) and *healthcare delivery organizations* (*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 controls* 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 systems* operating on *health IT infrastructures* 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.