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Health software and health IT systems safety, effectiveness and security —

Part 1: Principles and concepts

Sécurité, efficacité et sûreté des logiciels de santé et des systèmes TI de santé —

Partie 1: Principes et concepts

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Foreword

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This document was prepared jointly by Technical Committee ISO/TC 215, *Health informatics*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62A, *Common aspects of electrical equipment used in medical practice*.

A list of all parts in the ISO 81001 and IEC 81001 series can be found on the ISO and IEC websites.

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Introduction

While the benefits of digital health are widely accepted, the potential for inadvertent and adverse impacts on *safety*, *effectiveness* and *security* caused by *health software* and *health IT systems* is also becoming more apparent. Today's sophisticated *health software* and *health IT systems* provide advanced levels of decision support and integrate patient data between *systems*, across organizational lines, and across the continuum of care. In addition to the patient and healthcare *system* benefits this creates, there is also increased likelihood of software-induced adverse *events* causing harm to both patients and healthcare organizations. Design flaws, coding errors, incorrect *implementation* or configuration, data integrity issues, faults in decision support tools, poor alignment with clinical workflows and improper maintenance and use of *health software* and *health IT systems* are examples of *events* with the potential to cause *harm*.

Managing *safety*, *effectiveness* and *security* for *health software* and *health IT systems* (including *medical devices*), requires a comprehensive and coordinated approach to optimizing these three properties. Many *organizations* and *roles* are involved throughout the *life cycle* of *health software* and *health IT systems* (see Figure 1). Therefore, a common understanding of the concepts, principles and terminology is important in standardizing the *processes* and inter-organizational communications to support a coordinated approach to managing *safety*, *effectiveness* and *security*. This document takes into account the evolving complex internal and external context in healthcare, including people, technology (hardware/software), *organizations*, *processes*, and external environment.

Annex A provides further information on the rationale for this document, the terms and definitions being used and their relationship to other standards addressing various aspects of *health software* and *health IT systems safety*, *effectiveness* and *security*.

In addition to a common set of terms, definitions and concepts, this document describes eight foundational elements in Clause 5, which support the overarching themes articulated in Clause 4. For each foundational element, there is a "statement" describing each element; a "rationale" explaining why it is important; "key concepts and principles" pertinent for managing *safety*, *effectiveness* and *security*; and high-level guidance on the "approach" *organizations* can take to apply the concepts and principles.

Given the importance of communication between the various *organizations*, *roles* and responsibilities involved across the *life cycle* of *health software* and *health IT systems* for the four foundational cross-organizational elements, additional sub-clauses on communication and information sharing at major transition points are also included for 5.3.2, 5.3.3, 5.3.4 and 5.3.5.

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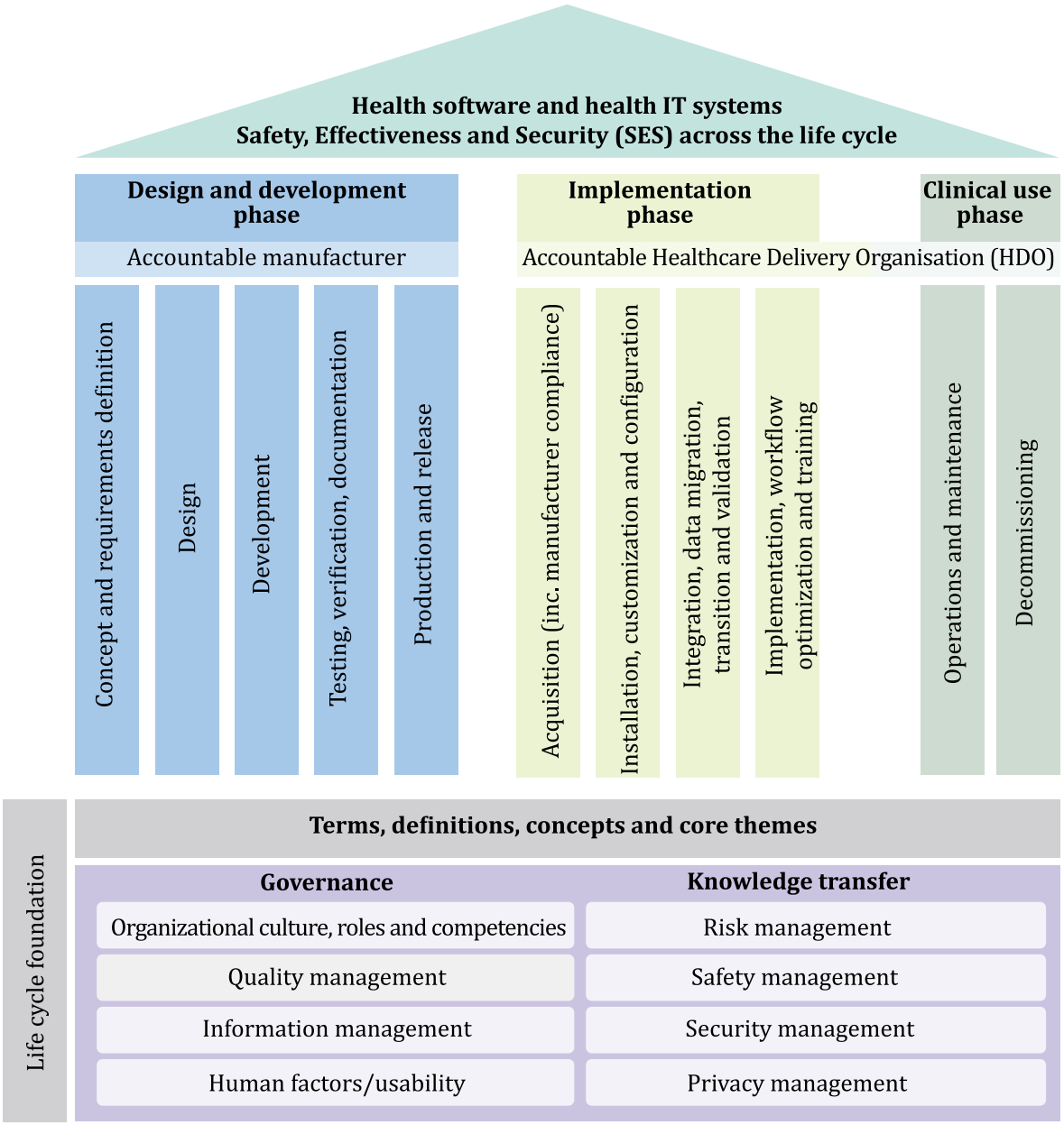

Figure 1 — *Life cycle* framework addressing *safety, effectiveness* and *security* of *health software* and *health IT systems*

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Health software and health IT systems safety, effectiveness and security —

Part 1: Principles and concepts

1 Scope

This document provides the principles, concepts, terms and definitions for *health software* and *health IT systems, key properties* of *safety*, *effectiveness* and *security,* across the full *life cycle*, from concept to decommissioning, as represented in Figure 1. It also identifies the transition points in the *life cycle* where transfers of responsibility occur, and the types of multi-lateral communication that are necessary at these transition points. This document also establishes a coherent concepts and terminology for other standards that address specific aspects of the *safety*, *effectiveness*, and *security* (including *privacy*) of *health software* and *health IT systems*.

This document is applicable to all parties involved in the *health software* and *health IT systems life cycle* including the following:

a) *Organizations*, health informatics professionals and clinical leaders designing, developing, integrating, implementing and operating *health software* and *health IT systems* – for example *health software developers* and *medical device manufacturers*, *system integrators*, *system administrators* (including cloud and other IT service providers);

b) Healthcare service delivery *organizations*, healthcare providers and others who use *health software* and *health IT systems* in providing health services;

c) Governments, health system funders, monitoring agencies, professional *organizations* and *customers* seeking confidence in an *organization's* ability to consistently provide safe, effective and secure *health software*, *health IT systems* and services;

d) *Organizations* and interested parties seeking to improve communication in managing *safety*, *effectiveness* and *security risks* through a common understanding of the concepts and terminology used in *safety*, *effectiveness* and *security* management;

e) Providers of training, assessment or advice in *safety*, *effectiveness* and *security risk management* for *health software* and *health IT systems*;

f) *Developers* of related *safety*, *effectiveness* and *security* standards.

2 Normative references

There are no normative references in this document.

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