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

Part 5-1:
Security — Activities in the product life cycle

This draft is submitted to a parallel vote in ISO and in IEC.

Reference number
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

HEALTH SOFTWARE AND HEALTH IT SYSTEMS SAFETY, EFFECTIVENESS AND SECURITY –

Part 5-1: Security – Activities in the product life cycle

FOREWORD

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International Standard IEC 81001-5-1 has been prepared by a Joint Working Group of IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO technical committee 215: Health informatics.

The text of this document is based on the following documents:

Draft	Report on voting
62A/XX/FDIS	62A/XX/RVD

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 International Standard 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/standardsdev/publications.

In this document, the following print types are used:

– requirements and definitions: roman type;

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

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.

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- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

0.1 Structure

PROCESS standards for HEALTH SOFTWARE provide a specification of ACTIVITIES that will be performed by the MANUFACTURER – including software incorporated in medical devices –as a part of a development LIFE CYCLE. The normative clauses of this document are intended to provide minimum best practices for a secure software LIFE CYCLE. Local legislation and regulation are considered.

PROCESS requirements (Clause 4 through Clause 9) have been derived from the IEC 62443-4-1[11][1] PRODUCT LIFE CYCLE management. Implementations of these specifications can extend existing PROCESSES at the MANUFACTURER's organization – notably existing PROCESSES conforming to IEC 62304[8]. This document can therefore support conformance to IEC 62443-4-1[11].

Normative clauses of this document specify ACTIVITIES that are the responsibility of the MANUFACTURER. The HEALTH SOFTWARE LIFE CYCLE can be part of an incorporating PRODUCT project. Some ACTIVITIES specified in this document depend on input and support from the PRODUCT LIFE CYCLE (for example to define specific criteria). Examples include:

- RISK MANAGEMENT;
- requirements;
- testing;
- post-release (after first placing HEALTH SOFTWARE on the market).

In cases where ACTIVITIES for HEALTH SOFTWARE need support from PROCESSES at the PRODUCT level, Clause 4 through Clause 9 of this document specify respective requirements beyond the HEALTH SOFTWARE LIFE CYCLE.

Similar to IEC 62304[8], this document does not prescribe a specific system of PROCESSES, but Clause 4 through Clause 9 of this document specify ACTIVITIES that are performed during the HEALTH SOFTWARE LIFE CYCLE.

Clause 4 specifies that MANUFACTURERS develop and maintain HEALTH SOFTWARE within a quality management system (see 4.1) and a RISK MANAGEMENT SYSTEM (4.2).

Clause 5 through Clause 8 specify ACTIVITIES and resulting output as part of the software LIFE CYCLE PROCESS implemented by the MANUFACTURER. These specifications are arranged in the ordering of IEC 62304[8].

Clause 9 specifies ACTIVITIES and resulting output as part of the problem resolution PROCESS implemented by the MANUFACTURER.

The scope of this document is limited to HEALTH SOFTWARE and its connectivity to its INTENDED ENVIRONMENT OF USE, based on IEC 62304[8], but with emphasis on CYBERSECURITY.

For expression of provisions in this document,

– "can" is used to describe a possibility or capability; and
– "must" is used to express an external constraint.

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

NOTE HEALTH SOFTWARE can be placed on the market as software, as part of a medical device, as part of hardware specifically intended for health use, as a medical device (SaMD), or as a PRODUCT for other health use. (See Figure 2).

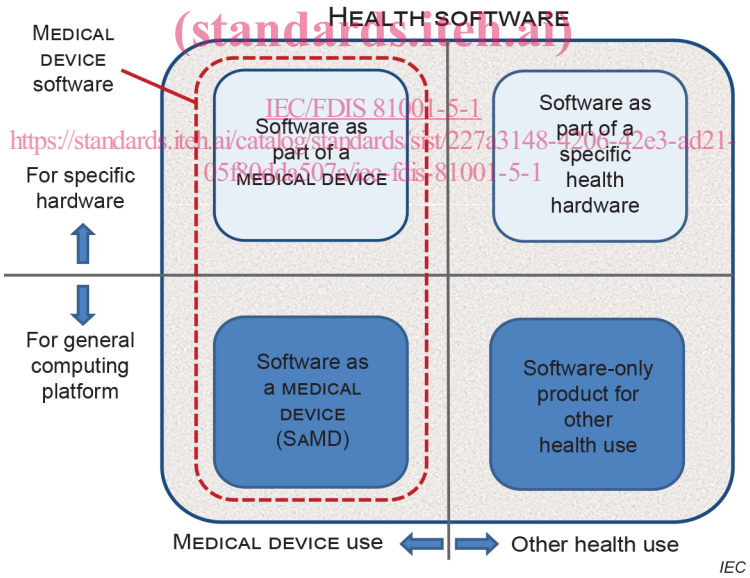
0.2 Field of application

This document applies to the development and maintenance of HEALTH SOFTWARE by a MANUFACTURER, but recognizes the critical importance of bi-lateral communication with organizations (e.g. HEALTHCARE DELIVERY ORGANIZATIONS, HDOs) who have SECURITY responsibilities for the HEALTH SOFTWARE and the systems it is incorporated into, once the software has been developed and released. The ISO/IEC 81001-5 series of standards (for which this is part -1), is therefore being designed to include future parts addressing SECURITY that apply to the implementation, operations and use phases of the LIFE CYCLE for organizations such as HDOs.

A medical device software is a subset of HEALTH SOFTWARE. A practical Venn diagram of HEALTH SOFTWARE types is shown in Figure 1. Therefore, this document applies to:

– software as part of a medical device;
– software as part of hardware specifically intended for health use;
– software as a medical device (SaMD); and
– software-only PRODUCT for other health use.

NOTE In this document, the scope of software considered part of the LIFE CYCLE ACTIVITIES for secure HEALTH SOFTWARE is larger and includes more software (drivers, platforms, operating systems) than for SAFETY, because for SECURITY the focus will be on any use including foreseeable unauthorized access rather than just the INTENDED USE.



[SOURCE: IEC 82304-1[18]]

Figure 1 – HEALTH SOFTWARE field of application

0.3 Conformance

Conformance with this document focuses on the implementation of requirements regarding PROCESSES, ACTIVITIES, and TASKS – and can be claimed in one of two alternative ways:

- for HEALTH SOFTWARE by implementing requirements in Clause 4 through Clause 9 of this document,
- for TRANSITIONAL HEALTH SOFTWARE by only implementing the PROCESSES, ACTIVITIES, and TASKS identified in Annex F.

This document is designed to assist in the implementation of the PROCESSES required by IEC 62443-4-1, however, conformance to this document is not necessarily a sufficient condition for conformance to IEC 62443-4-1[11]. More guidance on coverage can be found in Annex D.

MANUFACTURERS can implement the specifications for Annex E in order to achieve conformance of documentation to IEC 62443-4-1[11].

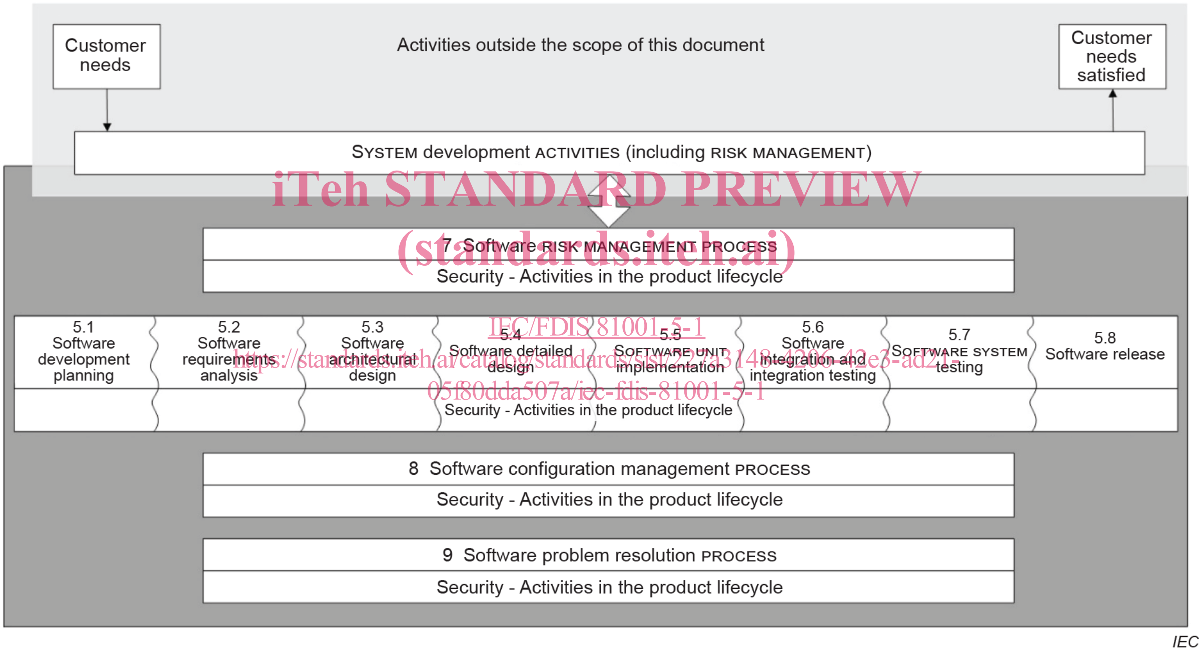
Clause 4 through Clause 9 of this document require establishing one or more PROCESSES that include identified ACTIVITIES. Per these normative parts of this document, the LIFE CYCLE PROCESSES implement these ACTIVITIES. None of the requirements in this document requires to implement these ACTIVITIES as one single PROCESS or as separate PROCESSES. The ACTIVITIES specified in this document will typically be part of an existing LIFE CYCLE PROCESS.

HEALTH SOFTWARE AND HEALTH IT SYSTEMS SAFETY, EFFECTIVENESS AND SECURITY –

Part 5-1: Security – Activities in the product life cycle

1 Scope

This document defines the LIFE CYCLE requirements for development and maintenance of HEALTH SOFTWARE needed to support conformance to IEC 62443-4-1[11] – taking the specific needs for HEALTH SOFTWARE into account. The set of PROCESSES, ACTIVITIES, and TASKS described in this document establishes a common framework for secure HEALTH SOFTWARE LIFE CYCLE PROCESSES. An informal overview of activities for HEALTH SOFTWARE is shown in Figure 2.



[derived from IEC 62304:2006[8], Figure 2]

Figure 2 – HEALTH SOFTWARE LIFE CYCLE PROCESSES

The purpose is to increase the CYBERSECURITY of HEALTH SOFTWARE by establishing certain ACTIVITIES and TASKS in the HEALTH SOFTWARE LIFE CYCLE PROCESSES and also by increasing the SECURITY of SOFTWARE LIFE CYCLE PROCESSES themselves.

It is important to maintain an appropriate balance of the key properties SAFETY, effectiveness and SECURITY as discussed in ISO 81001-1[17].

This document excludes specification of ACCOMPANYING DOCUMENTATION contents.

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:

- IEC Electropedia: available at www.electropedia.org/
- ISO Online browsing platform: available at www.iso.org/obp

3.1
ACCOMPANYING DOCUMENTATION
documentation intended to be used for a HEALTH SOFTWARE or a HEALTH IT SYSTEM or an accessory, containing information for the responsible organization or operator

3.2
ACTIVITY
set of one or more interrelated or interacting TASKS

[SOURCE: IEC 62304:2006[8], 3.1]

3.3
ARCHITECTURE
fundamental concepts or properties of a system in its environment, embodied in its elements, relationships, and in the principles of its design and evolution

[SOURCE: ISO/IEC/IEEE 24765:2017, 3.216, definition1]

3.4
ASSET
physical or digital entity that has value to an individual, an organization or a government

Note 1 to entry: As per the definition for ASSET this can include the following:

a) data and information;

b) HEALTH SOFTWARE and software needed for its operation;

c) hardware components such as computers, mobile devices, servers, databases, and networks;

d) services, including SECURITY, software development, IT operations and externally provided services such as data centres, internet and software-as-a-service and cloud solutions;

e) people, and their qualifications, skills and experience;

f) technical procedures and documentation to manage and support the HEALTH IT INFRASTRUCTURE;

g) HEALTH IT SYSTEMS that are configured and implemented to address organizational objectives by leveraging the ASSETS; and

h) intangibles, such as reputation and image.

[SOURCE: ISO 81001-1:2021[17] 3.3.2, modified – Addition of a new Note 1 to entry.]

3.5
ATTACK
attempt to destroy, expose, alter, disable, steal or gain unauthorized access to or make unauthorized use of an ASSET

[SOURCE: ISO/IEC 27000:2018, 3.2]

3.6
ATTACK SURFACE
physical and functional interfaces of a system that can be accessed and, therefore, potentially exploited by an attacker

[SOURCE: IEC 62443-4-1:2018[11], 3.1.7]

3.7
AVAILABILITY
property of being accessible and usable on demand by an authorized entity

[SOURCE: ISO/IEC 27000:2018, 3.7]

3.8
CONFIDENTIALITY
property that information is not made available or disclosed to unauthorized individuals, entities, or PROCESSES

[SOURCE: ISO/IEC 27000:2018, 3.10]

3.9
CONFIGURATION ITEM
entity that can be uniquely identified at a given reference point

[SOURCE: IEC 62304:2006[8], 3.5]

3.10
CONFIGURATION MANAGEMENT
PROCESS ensuring consistency of CONFIGURATION ITEMS by using mechanisms for identifying, controlling and tracking versions of CONFIGURATION ITEMS

3.11
DEFENSE-IN-DEPTH
approach to defend the system against any particular ATTACK using several independent methods

Note 1 to entry: DEFENSE-IN-DEPTH implies layers of SECURITY and detection, even on single systems, and provides the following features:

- is based on the idea that any one layer of protection, can and probably will be defeated;
- attackers are faced with breaking through or bypassing each layer without being detected;
- a flaw in one layer can be mitigated by capabilities in other layers;
- system SECURITY becomes a set of layers within the overall network SECURITY; and
- each layer is autonomous and not rely on the same functionality nor have the same failure modes as the other layers.

[SOURCE: IEC 62443-4-1:2018[11], 3.1.15]

3.12
EXPLOIT (noun)
defined way to breach the SECURITY of information systems through some VULNERABILITY

[SOURCE: ISO/IEC 27039:2015, 2.9]

3.13
HEALTH IT INFRASTRUCTURE
combined set of IT ASSETS available to the individual or organization for developing, configuring, integrating, maintaining, and using IT services and supporting health, patient care and other organizational objectives

[SOURCE: ISO 81001-1:2021[17], 3.3.7, modified – Deletion of the Note 1 to entry.]

3.14
HEALTH IT SYSTEM
a combination of interacting health information elements (including HEALTH SOFTWARE, medical devices, IT hardware, interfaces, data, procedures and documentation) that is configured and implemented to support and enable an individual or organization's specific health objectives

[SOURCE: ISO 81001-1:2021[17], 3.3.8, modified – Addition of "(including HEALTH SOFTWARE, medical devices, IT hardware, interfaces, data, procedures and documentation)".]

3.15
HEALTH SOFTWARE
software intended to be used specifically for managing, maintaining, or improving health of individual persons, or the delivery of care, or which has been developed for the purpose of being incorporated into a medical device

Note 1 to entry: HEALTH SOFTWARE fully includes what is considered software as a medical device.

[SOURCE: ISO 81001-1:2021[17], 3.3.9]

3.16
HEALTHCARE DELIVERY ORGANIZATION
HDO
facility or enterprise such as a clinic or hospital that provides healthcare services

[SOURCE: ISO 81001-1:2021[17], 3.1.4]

3.17
INTEGRITY
property of accuracy and completeness

[SOURCE: ISO/IEC 27000:2018, 3.36]

3.18
INTENDED ENVIRONMENT OF USE
conditions and setting in which users interact with the HEALTH SOFTWARE – as specified by the MANUFACTURER

3.19
INTENDED USE
INTENDED PURPOSE
use for which a PRODUCT, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, INTENDED ENVIRONMENT OF USE, and operating principle are typical elements of the INTENDED USE.

[SOURCE: ISO 81001-1:2021[17], 3.2.7, modified – In Note 1 to entry, replacement of "USE ENVIRONMENT" with "INTENDED ENVIRONMENT OF USE".]

3.20
LIFE CYCLE
series of all phases in the life of a PRODUCT or system, from the initial conception to final decommissioning and disposal

[SOURCE: ISO 81001-1:2021[17], 3.3.12]

3.21
MAINTAINED SOFTWARE
SOFTWARE ITEM for which the MANUFACTURER will assume the risk related to SECURITY

Note 1 to entry: See also A.3.

3.22
MANUFACTURER
organization with responsibility for design or manufacture of a PRODUCT

Note 1 to entry: Responsibility extends to supporting ACTIVITIES during operations.

Note 2 to entry: There is only one MANUFACTURER, but technical responsibility can be with multiple entities along the supply chain, with service providers, or with entities at different stages in the LIFE CYCLE.

Note 3 to entry: Independent of the MANUFACTURER's responsibility, any specific legal accountability is defined by contracts and legislation.

[SOURCE: ISO 81001-1:2021[17], 3.1.7– Addition of the notes to entry.]

3.23
PROCESS
set of interrelated or interacting ACTIVITIES that use inputs to deliver an intended result (outcome)

[SOURCE: ISO 81001-1:2021[17], 3.2.10, modified – Added "(outcome)" after "result".]

3.24
PRODUCT
output of an organization that can be produced without any transaction taking place between the organization and the customer

Note 1 to entry: Production of a PRODUCT is achieved without any transaction necessarily taking place between provider and customer, but can often involve this service element upon its delivery to the customer.

Note 2 to entry: The dominant element of a PRODUCT is that it is generally tangible.

[SOURCE: ISO 81001-1:2021[17], 3.3.15]

3.25
REQUIRED SOFTWARE
SOFTWARE ITEM for which the MANUFACTURER will consider SECURITY-related risks known before release of the HEALTH SOFTWARE

Note 1 to entry: This includes SUPPORTED SOFTWARE. See A.3.

3.26
RESIDUAL RISK
risk remaining after RISK CONTROL measures have been implemented

[SOURCE: ISO 81001-1:2021[17], 3.4.9]