

INTERNATIONAL STANDARD

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**Health software and health IT systems safety, effectiveness and security –
Part 5-1: Security – Activities in the product life cycle**

**Logiciels de santé et sécurité, efficacité et sûreté des systèmes TI de santé –
Partie 5-1: Sûreté – Activités du cycle de vie du produit**

IEC 81001-5-1:2021

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CONTENTS

FOREWORD..... 5

INTRODUCTION..... 7

 0.1 Structure..... 7

 0.2 Field of application..... 8

 0.3 Conformance 8

1 Scope..... 10

2 Normative references 10

3 Terms and definitions 11

4 General requirements 18

 4.1 Quality management..... 18

 4.1.1 Quality management system..... 18

 4.1.2 Identification of responsibilities..... 18

 4.1.3 Identification of applicability..... 18

 4.1.4 SECURITY expertise 18

 4.1.5 SOFTWARE ITEMS from third-party suppliers..... 19

 4.1.6 Continuous improvement 19

 4.1.7 Disclosing SECURITY-related issues 19

 4.1.8 Periodic review of SECURITY defect management 19

 4.1.9 ACCOMPANYING DOCUMENTATION review 20

 4.2 SECURITY RISK MANAGEMENT 20

 4.3 SOFTWARE ITEM classification relating to risk transfer..... 20

5 Software development PROCESS..... 21

 5.1 Software development planning 21

 5.1.1 ACTIVITIES in the LIFE CYCLE PROCESS..... 21

 5.1.2 Development environment SECURITY 21

 5.1.3 Secure coding standards 21

 5.2 HEALTH SOFTWARE requirements analysis 21

 5.2.1 HEALTH SOFTWARE SECURITY requirements..... 21

 5.2.2 SECURITY requirements review 22

 5.2.3 SECURITY risks for REQUIRED SOFTWARE 22

 5.3 Software architectural design..... 22

 5.3.1 DEFENSE-IN-DEPTH ARCHITECTURE/design..... 22

 5.3.2 Secure design best practices 22

 5.3.3 SECURITY architectural design review..... 23

 5.4 Software design 23

 5.4.1 Software design best practices 23

 5.4.2 Secure design 23

 5.4.3 Secure HEALTH SOFTWARE interfaces 23

 5.4.4 Detailed design VERIFICATION for SECURITY 24

 5.5 Software unit implementation and VERIFICATION..... 24

 5.5.1 Secure coding standards 24

 5.5.2 SECURITY implementation review..... 24

 5.6 Software integration testing 25

 5.7 Software system testing 25

 5.7.1 SECURITY requirements testing..... 25

 5.7.2 THREAT mitigation testing..... 25

5.7.3	VULNERABILITY testing	25
5.7.4	Penetration testing	26
5.7.5	Managing conflicts of interest between testers and developers	26
5.8	Software release	26
5.8.1	Resolve findings prior to release	26
5.8.2	Release documentation	27
5.8.3	File INTEGRITY	27
5.8.4	Controls for private keys	27
5.8.5	Assessing and addressing SECURITY-related issues	27
5.8.6	ACTIVITY completion	27
5.8.7	SECURE decommissioning guidelines for HEALTH SOFTWARE	27
6	SOFTWARE MAINTENANCE PROCESS	28
6.1	Establish SOFTWARE MAINTENANCE plan	28
6.1.1	Timely delivery of SECURITY updates	28
6.2	Problem and modification analysis	28
6.2.1	Monitoring public incident reports	28
6.2.2	SECURITY update VERIFICATION	28
6.3	Modification implementation	29
6.3.1	SUPPORTED SOFTWARE SECURITY update documentation	29
6.3.2	MAINTAINED SOFTWARE SECURITY update delivery	29
6.3.3	MAINTAINED SOFTWARE SECURITY update INTEGRITY	29
7	SECURITY RISK MANAGEMENT PROCESS	29
7.1	RISK MANAGEMENT context	29
7.1.1	General	29
7.1.2	PRODUCT SECURITY CONTEXT	29
7.2	Identification of VULNERABILITIES, THREATS and associated adverse impacts	30
7.3	Estimation and evaluation of SECURITY risk	31
7.4	Controlling SECURITY risks	31
7.5	Monitoring the effectiveness of RISK CONTROLS	31
8	Software CONFIGURATION MANAGEMENT PROCESS	32
9	Software problem resolution PROCESS	32
9.1	Overview	32
9.2	Receiving notifications about VULNERABILITIES	32
9.3	Reviewing VULNERABILITIES	32
9.4	Analysing VULNERABILITIES	33
9.5	Addressing SECURITY-related issues	33
Annex A (informative)	Rationale	35
A.1	Relationship to IEC 62443	35
A.2	Relationship to IEC 62304	36
A.3	Risk transfer	37
A.3.1	Overview	37
A.3.2	MAINTAINED SOFTWARE	37
A.3.3	SUPPORTED SOFTWARE	37
A.3.4	REQUIRED SOFTWARE	37
A.4	Secure coding best practices	38
Annex B (informative)	Guidance on implementation of SECURITY LIFE CYCLE ACTIVITIES	39
B.1	Overview	39
B.2	Related work	39

B.3	THREAT / RISK ANALYSIS	39
B.4	THREAT and RISK MANAGEMENT	40
B.5	Software development planning	40
B.5.1	Development	40
B.5.2	HEALTH SOFTWARE requirements analysis	41
B.5.3	Software architectural design	41
B.5.4	Software unit implementation and VERIFICATION	41
B.5.5	Secure implementation	42
B.5.6	Not used	42
B.5.7	Software system testing	42
Annex C (informative)	THREAT MODELLING	44
C.1	General	44
C.2	ATTACK-defense trees	44
C.3	CAPEC / OWASP / SANS	44
C.4	CWSS	44
C.5	DREAD	45
C.6	List known potential VULNERABILITIES	45
C.7	OCTAVE	45
C.8	STRIDE	45
C.9	Trike	45
C.10	VAST	45
Annex D (informative)	Relation to practices in IEC 62443-4-1:2018	46
D.1	IEC 81001-5-1 to IEC 62443-4-1:2018	46
D.2	IEC 62443-4-1:2018 to IEC 81001-5-1	47
Annex E (informative)	Documents specified in IEC 62443-4-1	48
E.1	Overview	48
E.2	Release documentation	48
E.2.1	PRODUCT documentation	48
E.2.2	HEALTH SOFTWARE DEFENSE-IN-DEPTH documentation	49
E.2.3	DEFENSE-IN-DEPTH measures expected in the environment	49
E.2.4	SECURITY hardening guidelines	49
E.2.5	SECURITY update information	50
E.3	Documents for decommissioning HEALTH SOFTWARE	50
Annex F (normative)	TRANSITIONAL HEALTH SOFTWARE	51
F.1	Overview	51
F.2	Development assessment and gap closure activities	51
F.3	Rationale for use of TRANSITIONAL HEALTH SOFTWARE	52
F.4	Post-release ACTIVITIES	52
Annex G (normative)	Object identifiers	53
Bibliography	54
Figure 1	– HEALTH SOFTWARE field of application	8
Figure 2	– HEALTH SOFTWARE LIFE CYCLE PROCESSES	10
Table A.1	– Required level of independence of testers from developers	36
Table G.1	– Object identifiers for conformance concepts of this document	53

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**HEALTH SOFTWARE AND HEALTH IT SYSTEMS SAFETY,
EFFECTIVENESS AND SECURITY –****Part 5-1: Security –
Activities in the product life cycle**

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It is published as a double logo standard.

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

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62A/1458/FDIS	62A/1466/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.

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

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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).

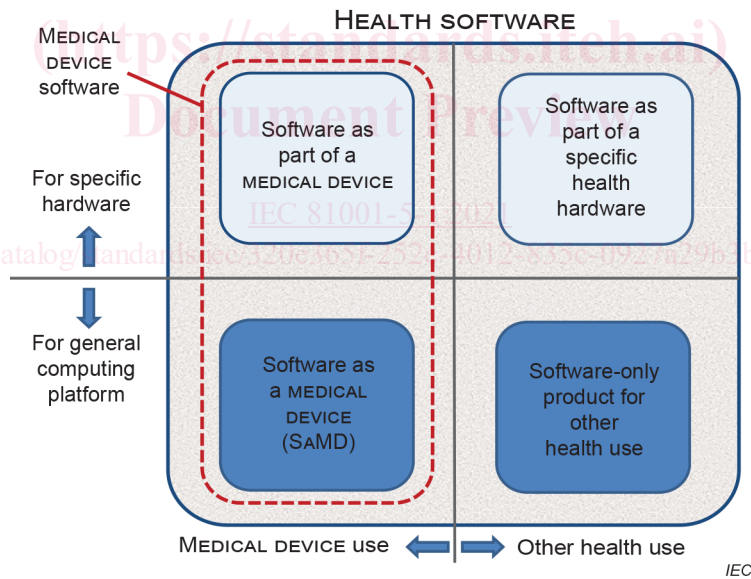
0.2 Field of application

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.

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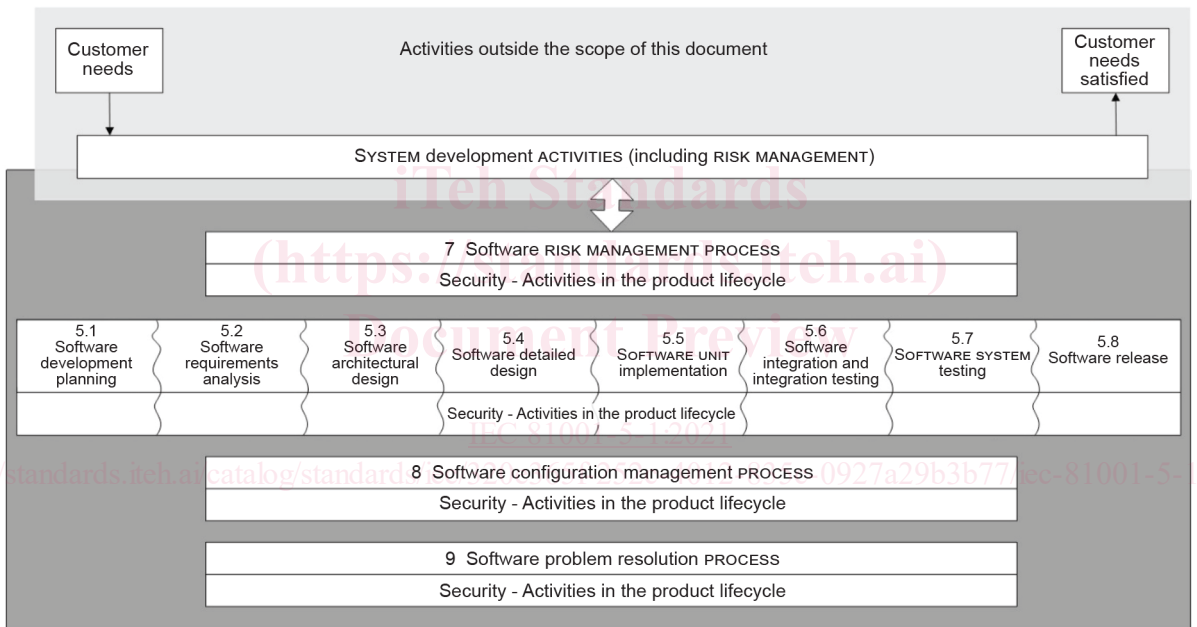
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HEALTH SOFTWARE AND HEALTH IT SYSTEMS SAFETY, EFFECTIVENESS AND SECURITY –

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.



IEC

[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]