

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**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**



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**Health software and health IT systems safety, effectiveness and security –  
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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 .....	12
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 updates 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**

## 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.

It is published as a double logo standard.

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

Draft	Report on voting
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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications](http://www.iec.ch/standardsdev/publications).

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- 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 A NOTE: 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.

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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]<sup>1</sup> 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 conformity 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.

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<sup>1</sup> 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).

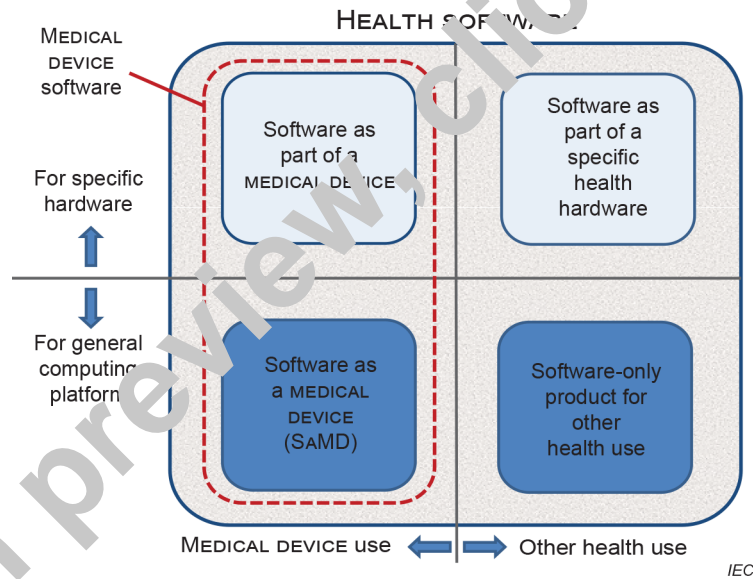
**0.2 Field of application**

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 accesses 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].

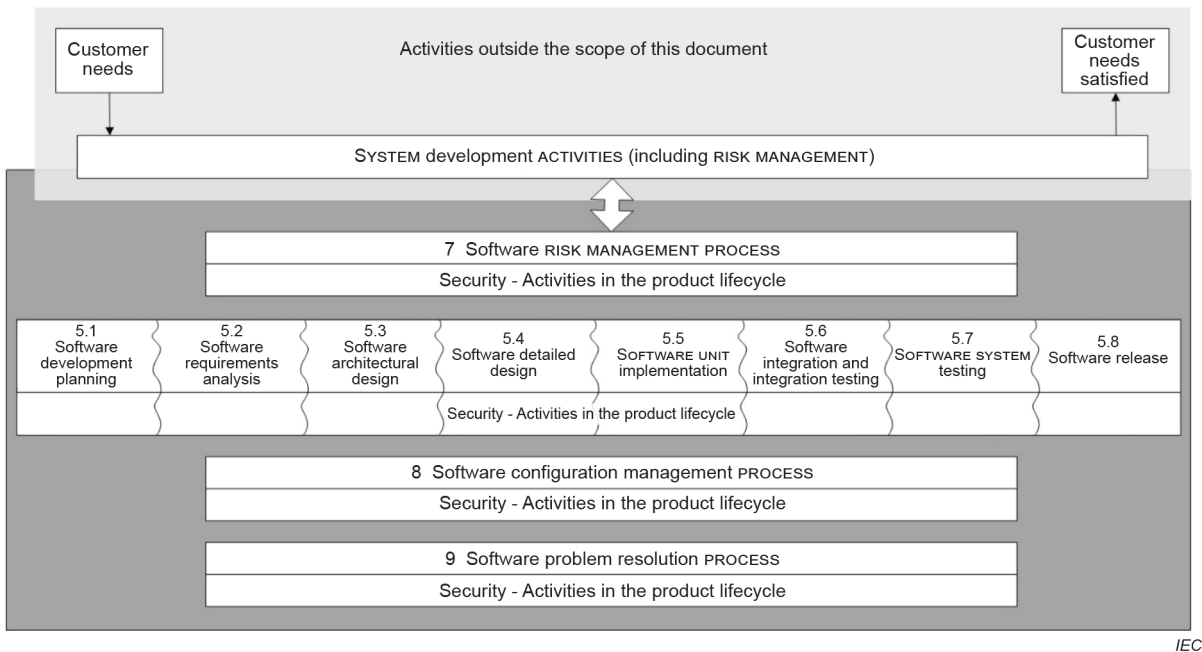
Clause 4 through Clause 9 of this document require establishing one or more PROCESSES that include identified ACTIVITIES. Per these normative parts of this document, the LIFE CYCLE PROCESSES implement these ACTIVITIES. None of the requirements in this document requires to implement these ACTIVITIES as 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.



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[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.