This document is a preview generated by EVS

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

This document is a preview generated by EVS

See Eesti standard EVS-EN IEC 81001-5-1:2022 sisaldab Euroopa standardi EN IEC 81001-5-1:2022 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 81001-5-1:2022 consists of the English text of the European standard EN IEC 81001-5-1:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.02.2022.	Date of Availability of the European standard is 11.02.2022.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.01, 35.240.80

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autoriõiguse kaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about standards copyright protection, please contact the Estonian Centre for Standardisation and Accreditation: Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 81001-5-1

February 2022

ICS 11.040.01; 35.240.80

English Version

Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle (IEC 81001-5-1:2021)

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)

Gesundheitssoftware und Gesundheits-IT-Systeme Sicherheit, Effektivität und Security - Teil 5-1: Security - Aktivitäten im Produktlebenszyklus
(IEC 81001-5-1:2021)

This European Standard was approved by CENELEC on 2022-01-20. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2022 CENELEC All rights of exploitation in any form and by any means reserved worldwide for CENELEC Members.

This document is a preview generated by EVS

European foreword

The text of document 62A/1458/FDIS, future edition 1 of IEC 81001-5-1, prepared by SC 62A "Common aspects of electrical equipment used in medical practice" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 81001-5-1:2022.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2022-10-20
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2025-01-20

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 81001-5-1:2021 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 62304:2006	NOTE Harmonized as EN 62304:2006 (not modified)
IEC 62443-3-2	NOTE Harmonized as EN IEC 62443-3-2
IEC 62443-3-3	NOTE Harmonized as EN IEC 62443-3-3
IEC 62443-4-1:2018	NOTE Harmonized as EN IEC 62443-4-1:2018 (not modified)
IEC 62443-4-2:2019	NOTE Harmonized as EN IEC 62443-4-2:2019 (not modified)
IEC 62740:2015	NOTE Harmonized as EN 62740:2015 (not modified)
IEC 82304-1:2016	NOTE Harmonized as EN 82304-1:2017 (not modified)
ISO/TS 14441	NOTE Harmonized as CEN ISO/TS 14441
ISO 14971:2019	NOTE Harmonized as EN ISO 14971:2019 (not modified) +A11:2021
ISO/IEC 27000:2018	NOTE Harmonized as EN ISO/IEC 27000:2020 (not modified)
ISO 27789	NOTE Harmonized as EN ISO 27789
ISO 27799	NOTE Harmonized as EN ISO 27799
ISO/IEC 29147	NOTE Harmonized as EN ISO/IEC 29147
ISO/IEC 30111	NOTE Harmonized as EN ISO/IEC 30111

This document is a preview generated by EVS

ISO 13485:2016	NOTE Harmonized as EN ISO 13485:2016 (not modified) +A11:2021
IEC 62366-1:2015	NOTE Harmonized as EN 62366-1:2015 (not modified)
IEC/TR 63069	NOTE Harmonized as CLC IEC/TR 63069
ISO 9000:2015	NOTE Harmonized as EN ISO 9000:2015 (not modified)

This document is a preview generated by EVS

IEC 81001-5-1

Edition 1.0 2021-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

This document is a preview generated by EVS

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 81001-5-1:2021-12(en-fr)

THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2021 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC online collection - oc.iec.ch
Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 18 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC - webstore.iec.ch/advsearchform
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, …). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC online collection - oc.iec.ch
Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org
Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

This document is a preview generated by EVS

IEC 81001-5-1

Edition 1.0 2021-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

This document is a preview generated by EVS

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01; 35.240.80

ISBN 978-2-8322-1053-7

Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.

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

This document is a preview generated by EVS

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

This document is a preview generated by EVS

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

This document is a preview generated by EVS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

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

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

This document is a preview generated by EVS

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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. 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.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

This document is a preview generated by EVS

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.

This document is a preview generated by EVS

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).

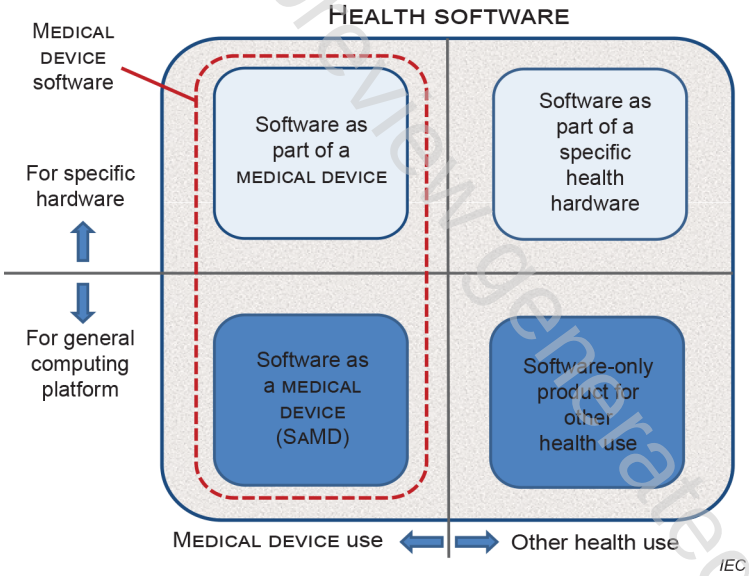
0.2 Field of application

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 a preview generated by EVS

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.

This document is a preview generated by EVS

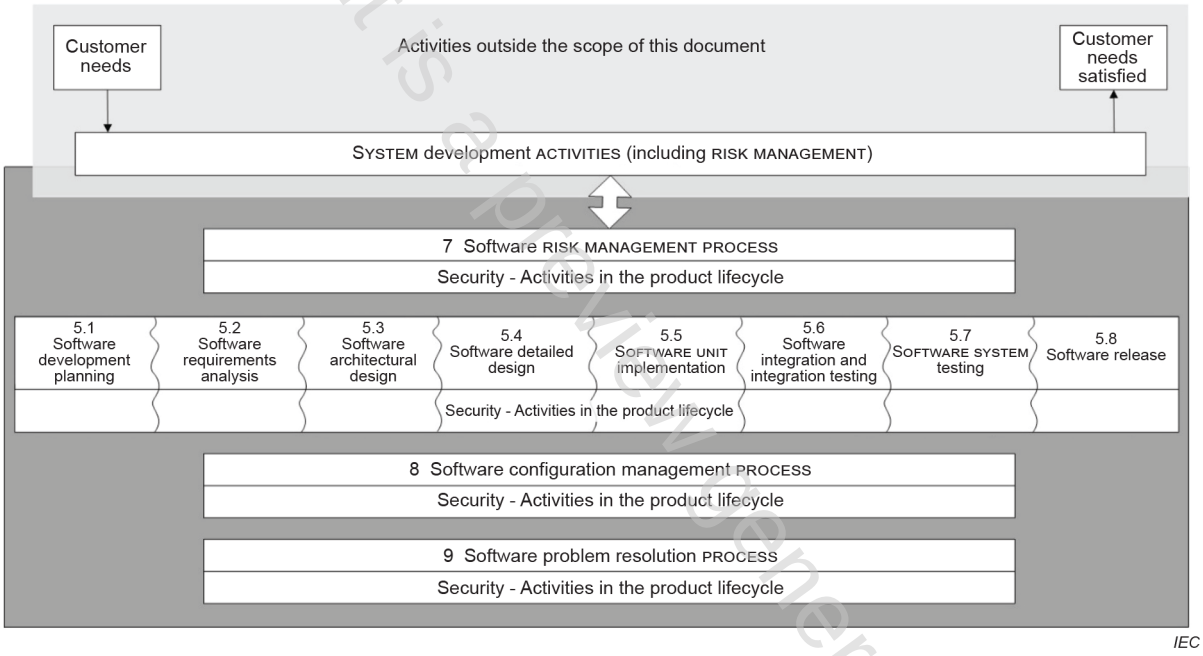
HEALTH SOFTWARE AND HEALTH IT SYSTEMS SAFETY, EFFECTIVENESS AND SECURITY –

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

This document is a preview generated by EVS

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.