SLOVENSKI STANDARD
oSIST prEN IEC 62304:2021

01-marec-2021

Programska oprema v zdravstvu - Procesi v življenjskem ciklu programske opreme

Health software - Software life cycle processes

Gesundheits-Software - Software-Lebenszyklus-Prozesse

Logiciels de santé - Processus du cycle de vie du logiciel

Ta slovenski standard je istoveten z: **prEN IEC 62304:2021**

ICS:

13.020.60	Življenjski ciklusi izdelkov	Product life-cycles
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

oSIST prEN IEC 62304:2021 **en**

62A/1422/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 62304 ED2	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2021-01-01	**2021-03-26**
SUPERSEDES DOCUMENTS:	
62A/1349/CDV, 62A/1383B/RVC	

IEC SC 62A : COMMON ASPECTS OF ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE	
SECRETARIAT: United States of America	SECRETARY: Ms Hae Choe
OF INTEREST TO THE FOLLOWING COMMITTEES: TC 62,SC 62B,SC 62C,SC 62D,TC 65,TC 66,TC 76,TC 106,TC 108	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

IEC 62304 Ed. 2: Health software - Software life cycle processes

PROPOSED STABILITY DATE: 2024

NOTE FROM TC/SC OFFICERS:

Please note that this draft is a joint project between IEC/SC 62A and ISO/TC 215 and is IEC led. During the last CDV stage, this project was approved on the IEC side but not approved in ISO and CENELEC. A task group was assigned to develop proposed resolutions to the comments and to the draft which were reviewed by the 62304 Project Team and the IEC/ISO Joint Working Group. Attached is the result of that extensive work. Some comments did not offer specific changes but provided ideas that may be better utilized during the next maintenance cycle for this document.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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HEALTH SOFTWARE –

SOFTWARE LIFE CYCLE PROCESSES

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.

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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 62304 has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice,in cooperation with ISO Technical Committee 215, Health informatics. Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and systems engineering.

It is published as a dual logo standard.

This second edition cancels and replaces the first edition published in 2006 and Amendment 1:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) the scope of this document has been expanded to HEALTH SOFTWARE;

b) Clause 4 related to general requirements has been updated to assure that this document would meet the state of art of the use-environment and the way that HEALTH SOFTWARE is being used.

The text of this International Standard is based on the following documents:

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

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

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: smaller type. Normative text of tables is also in a smaller type;
– TERMS USED THROUGHOUT THIS DOCUMENT THAT HAVE BEEN DEFINED IN CLAUSE 3: SMALL CAPITALS.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2:2018. For the purposes of this document, the verb:

– "shall" means that compliance with a requirement is mandatory for compliance with this document;
– "should" means that compliance with a requirement is recommended but is not mandatory for compliance with this document;
– "may" is used to describe a permissible way to achieve compliance with a requirement;
– "establish" means to define, document and implement.

Where this document uses the term "as appropriate" in conjunction with a required PROCESS, ACTIVITY, TASK or output, the intention is that the MANUFACTURER shall use the PROCESS, ACTIVITY, TASK or output unless the MANUFACTURER can document a justification for not so doing.

An asterisk (*) as the first character of a title or at the beginning of a paragraph indicates that there is guidance related to that item in Annex B.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://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.

NOTE The attention of users of this document is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication 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.

INTRODUCTION

Software is becoming increasingly important in healthcare. The use of software can help contribute to more efficient and safe care of patients. Thus, HEALTH SOFTWARE needs to be developed with appropriate controls to ensure its safe, effective and secure use.

Users of software in the care environment have expanded from clinical users (nurses, technicians, dieticians, physicians, etc.) to include non-clinical users (patients, consumers, laypersons, family care givers, etc.). IEC 62304:2006 and IEC 62304:2006/AMD1:2015 focused on software life cycle activities for MEDICAL DEVICE SOFTWARE that was primarily used by clinical users. For this reason, the scope of this document has been expanded to HEALTH SOFTWARE.

As software becomes more dependent on network connectivity and integral to clinical workflows, additional considerations need to be made for SECURITY and USABILITY. HEALTH SOFTWARE is being used more commonly in the home and outside of the hospital, so it becomes even more important to develop these products with the user and use environment in mind. For these reasons, Clause 4 related to general requirements has been updated to assure that this document would meet the state of art of the use-environment and the way that HEALTH SOFTWARE is being used.

This document does not duplicate well-established requirements from standards for USABILITY and SECURITY.

Establishing the SAFETY and EFFECTIVENESS of HEALTH SOFTWARE requires knowledge of what the HEALTH SOFTWARE is intended to do and demonstration that the use of the HEALTH SOFTWARE fulfils those intentions without causing any unacceptable RISKS. To demonstrate the EFFECTIVENESS, software VALIDATION is required, which is outside of the scope of this document.

The MANUFACTURER of HEALTH SOFTWARE is responsible for determining and complying with the appropriate SAFETY, SECURITY, environmental, health, and interference protection practices. Many laws, regulations, and other rules from authorities having jurisdiction have a direct impact on the way SOFTWARE SYSTEMS are developed, tested, and maintained. From a software development perspective, MANUFACTURERS consider these laws, regulations, and other rules as inputs into the requirements that the HEALTH SOFTWARE supports. This means that the requirements of some laws or regulations can translate into specific HEALTH SOFTWARE product requirements. For example, if HEALTH SOFTWARE is going to send or share health data to a doctor, hospital, or other covered entity, it has an obligation to adhere to privacy and SECURITY rules. This can involve authentication and SECURITY mechanisms to protect patient information saved in an electronic format. Other requirements of the laws or regulations can impact the PROCESS used during the development of the HEALTH SOFTWARE product. For example, many national regulations and quality systems standards have design control requirements that translate into specific procedures to confirm that the product is designed, verified, and validated in a systematic manner and per proven software engineering practices.

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

This document provides a framework for a life cycle PROCESS. It defines the ACTIVITIES and TASKS necessary for the safe design, development and maintenance of HEALTH SOFTWARE. The development and maintenance life cycle ACTIVITIES are shown in Figure 1 and described in Clause 5 and Clause 6. Some incidents in healthcare delivery are related to HEALTH SOFTWARE SYSTEMS, including failures that can occur or be injected when software is modified.

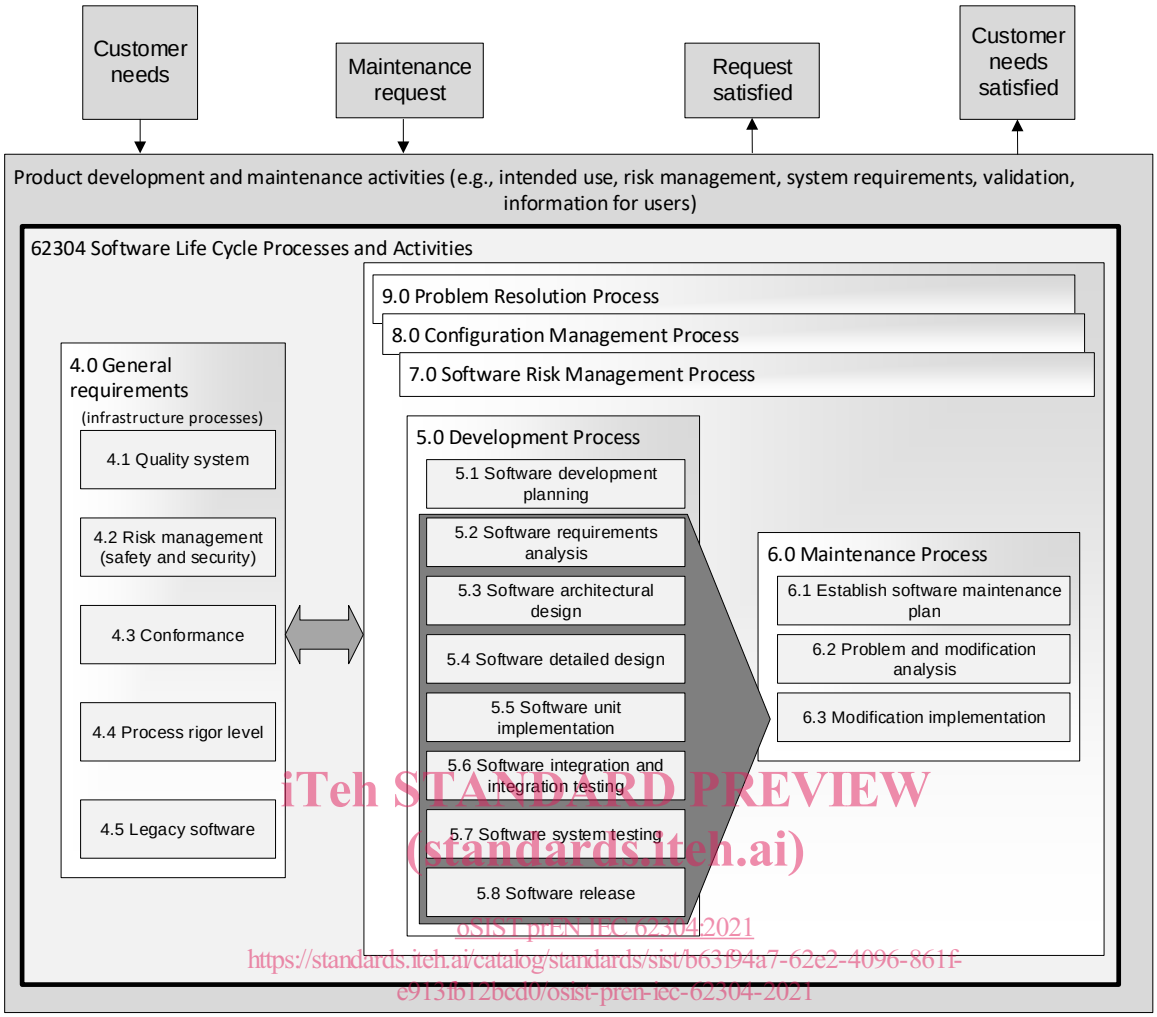

Figure 1 – Overview of software development and maintenance PROCESSES and ACTIVITIES

This document identifies two additional supporting PROCESSES considered essential for developing safe HEALTH SOFTWARE. They are the software configuration management PROCESS (Clause 8) and the software problem resolution PROCESS (Clause 9).

This document does not specify a specific organizational structure nor responsibilities within the organization of the MANUFACTURER to perform PROCESSES, ACTIVITIES, and TASKS. This document specifies planning of software development, maintenance and supporting PROCESS ACTIVITIES, and the completion of the ACTIVITIES or TASKS for conformance with this document.

This document does not prescribe the name, format, or explicit content of the documentation to be produced. This document calls for adequate evidence of required ACTIVITIES and TASKS by documentation. Regardless how content is structured and packaged, it is expected that a controlled documentation PROCESS is in place. This document does not prescribe a specific life cycle model. The users of this document are responsible for selecting a life cycle model for the software project and for mapping the PROCESSES, ACTIVITIES, and TASKS in this document onto that model.Annex A provides rationale for the clauses of this document. Annex B provides guidance on the provisions of this document.

HEALTH SOFTWARE –

SOFTWARE LIFE CYCLE PROCESSES

1 Scope

1.1 * Purpose

This document defines the development and maintenance life cycle requirements for HEALTH SOFTWARE. The set of PROCESSES, ACTIVITIES, and TASKS described in this document establishes a common framework for HEALTH SOFTWARE life cycle PROCESSES.

1.2 * Field of application

This document applies to the development and maintenance of HEALTH SOFTWARE by a MANUFACTURER. MEDICAL DEVICE SOFTWARE is a subset of HEALTH SOFTWARE (see Figure 2). Therefore, this document applies to:

– software as part of a MEDICAL DEVICE;

– software as part of specific health hardware;

– software as a MEDICAL DEVICE (SaMD);

– software-only product for other health use.

Figure 2 provides a graphical representation of the health software this document applies to.

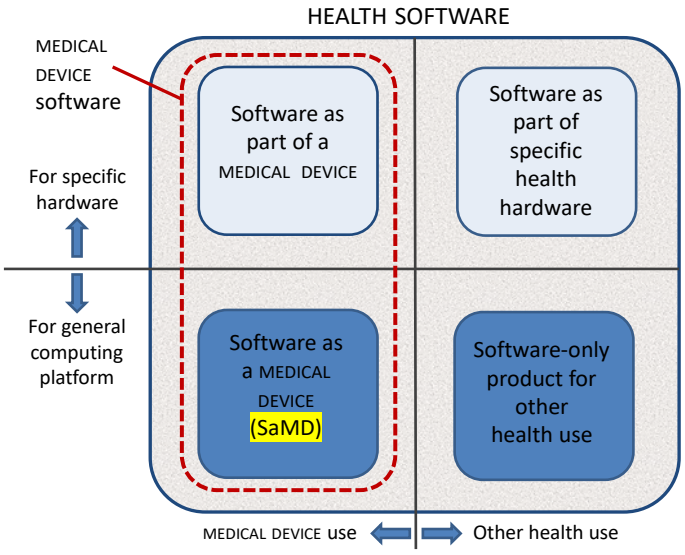

Figure 2 – HEALTH SOFTWARE field of application

NOTE 1 Examples of HEALTH SOFTWARE include the following:

1) software as a part of a MEDICAL DEVICE: software that is an integral part of a device such as an infusion pump or dialysis machine.

2) software as part of specific health hardware: patient wristband printer software, healthcare scanner software, health app on specific wearable hardware (i.e. watch, wristband, chestband).

3) software as a MEDICAL DEVICE (SaMD): software that is itself a MEDICAL DEVICE, such as a software application that performs diagnostic image analysis for making treatment decisions. A definition of software as a MEDICAL DEVICE is provided in [46][1].

4) software-only product for other health use: hospital information systems, electronic health records, electronic medical records, mobile applications running on devices without physiologic sensors or detectors, software as a service, i.e. software executed in an external environment, providing calculation-results that fulfil the definition of a MEDICAL DEVICE.

NOTE 2 This document can be used in the development and maintenance of HEALTH SOFTWARE. Before any type of software can be placed into service, activities are necessary before the software product is integrated into the SYSTEM. These SYSTEM activities are not covered by this document (see Figure 1), but can be found in related product standards (e.g., IEC 60601-1 [1] or IEC 82304-1 [15]). For software as a MEDICAL DEVICE (SaMD) additional guidance on ACTIVITIES at a system level (e.g. clinical EVALUATION) can be found in regulatory authority guidance documents.

This document describes PROCESSES that are intended to be applied to software which executes on a processor or which is executed by other software (for example an interpreter) which executes on a processor.

This document applies regardless of the persistent storage device(s) used to store the software (for example: hard disk, optical disk, permanent or flash memory).

This document applies regardless of the method of delivery of the software (for example: transmission by network or email, EEPROM, Smart Drive, Cloud). The method of software delivery itself is not considered HEALTH SOFTWARE.

This document does not cover the means of VALIDATION, even when the product consists entirely of software. It also does not cover software life cycle steps after release for INTENDED USE of the product, including implementation, configuration, integration (with other systems), go-live, clinical use, operations, decommissioning or disposal, other than ACTIVITIES involving maintenance of the software.

This document does not cover the VALIDATION of software tools used in the design of medical devices (e.g. computer aided design (CAD) software), software used in MEDICAL DEVICE quality systems or software for regulated processes (see ISO/TR 80002-2 [20] and AAMI TIR 36 [40]).

NOTE 3 If a product incorporates embedded software intended to be executed on a processor, the requirements of this document apply to the software, including the requirements concerning SOFTWARE OF UNKNOWN PROVENANCE (SOUP) – see 8.1.2).

Data quality and VALIDATION of emergent characteristics or functionality of artificial intelligence (AI) HEALTH SOFTWARE are not within the scope of this document.

NOTE 4 Users of this document may need to utilize other standards and technical sources to supplement this document in addressing the unique performance characteristics of their AI HEALTH SOFTWARE. As AI is a rapidly developing field and as further insights are gained, new updates may need to be incorporated into IEC 62034 via an amendment or a future new edition.

1.3 Relationship to other standards

This HEALTH SOFTWARE life cycle document is written in a way that it can be used together with referencing standards when developing and maintaining a product that includes HEALTH SOFTWARE (see Annex C).

2 * Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies.

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1 Numbers in square brackets refer to the Bibliography.

For undated references, the latest edition of the referenced document (including any amendments) applies.

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 standardisation at the following addresses:

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

3.1
ACTIVITY

set of one or more interrelated or interacting TASKS

3.2
ANOMALY

condition that deviates from expectations based on requirements specifications, design documents, standards, etc. or from someone's perceptions or experiences

[SOURCE: ISO/IEC 25051:2014, 4.1.2]

3.3
ARCHITECTURE

[SYSTEM] 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 Std 24765-2017, 3.216, definition 1]

3.4
CHANGE REQUEST

documented specification of a change to be made to HEALTH SOFTWARE

3.5
CONFIGURATION ITEM

entity that can be uniquely identified at a given reference point

3.6
DELIVERABLE

required result or output (includes documentation) of an ACTIVITY or TASK

3.7
EVALUATION

systematic determination of the extent to which an entity meets its specified criteria