DRAFT INTERNATIONAL STANDARD

IEC/DIS 62304

ISO/TC **215**	Secretariat: **ANSI**
Voting begins on: **2019-10-04**	Voting terminates on: **2019-12-27**

Health software — Software life cycle processes

Logiciels de santé — Processus du cycle de vie du logiciel

ICS: 11.040.01; 35.240.80

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IEC/DIS 62304:2019(E)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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HEALTH SOFTWARE –
SOFTWARE LIFE CYCLE PROCESSES

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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 and 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) the general requirements section 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.

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

FDIS	Report on voting
62A/XXXX/FDIS	62A/XXXX/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 STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3: SMALL CAPITALS.

The verbal forms used in this standard 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;

The term "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 National Committees and Member Bodies 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.

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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.

In the past, software in the care environment was used primarily by clinical users (nurses, technicians, dieticians, physicians, etc.) and previous versions of this document addressed product development activities focused on the use of MEDICAL DEVICE SOFTWARE by clinical users. There are now software products that are being used by non-clinical users to measure, manage, maintain, or improve the health of individual(s), or for the delivery of care. For these reasons, 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, the general requirements section 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. The addition of USABILITY and SECURITY to this document followed the same approach as RISK MANAGEMENT and quality management PROCESSES of previous versions of this document (i.e. editions 1.0 and 1.1).

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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.

The MANUFACTURER of HEALTH SOFTWARE is responsible for determining and complying with the appropriate SAFETY, SECURITY, environmental, health, and interference protection practices and the applicable laws and regulations. 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 is required to adhere to privacy and SECURITY rules. This can require 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).

Whether software is a contributing factor to a HAZARDOUS SITUATION is determined during the HAZARD identification ACTIVITY of the RISK MANAGEMENT PROCESS. However, software may also be used to control RISK. The decision to use software to control RISK is made during the RISK CONTROL ACTIVITY of the RISK MANAGEMENT PROCESS.

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 life cycle ACTIVITIES are shown in Figure 1 and described in Clause 5. Some incidents in healthcare delivery are related to HEALTH SOFTWARE SYSTEMS, including

inappropriate software updates and upgrades. The SOFTWARE MAINTENANCE PROCESS is therefore as important as the software development PROCESS. It is shown in Figure 2 and described in Clause 6.

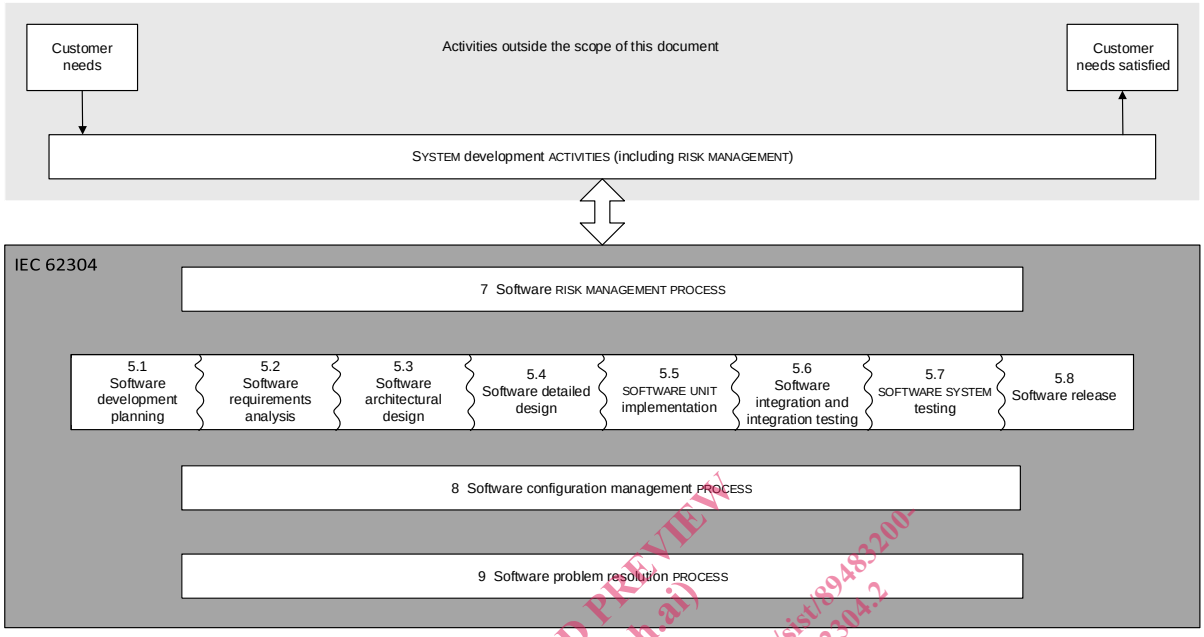

Figure 1 – Overview of software development PROCESSES and ACTIVITIES

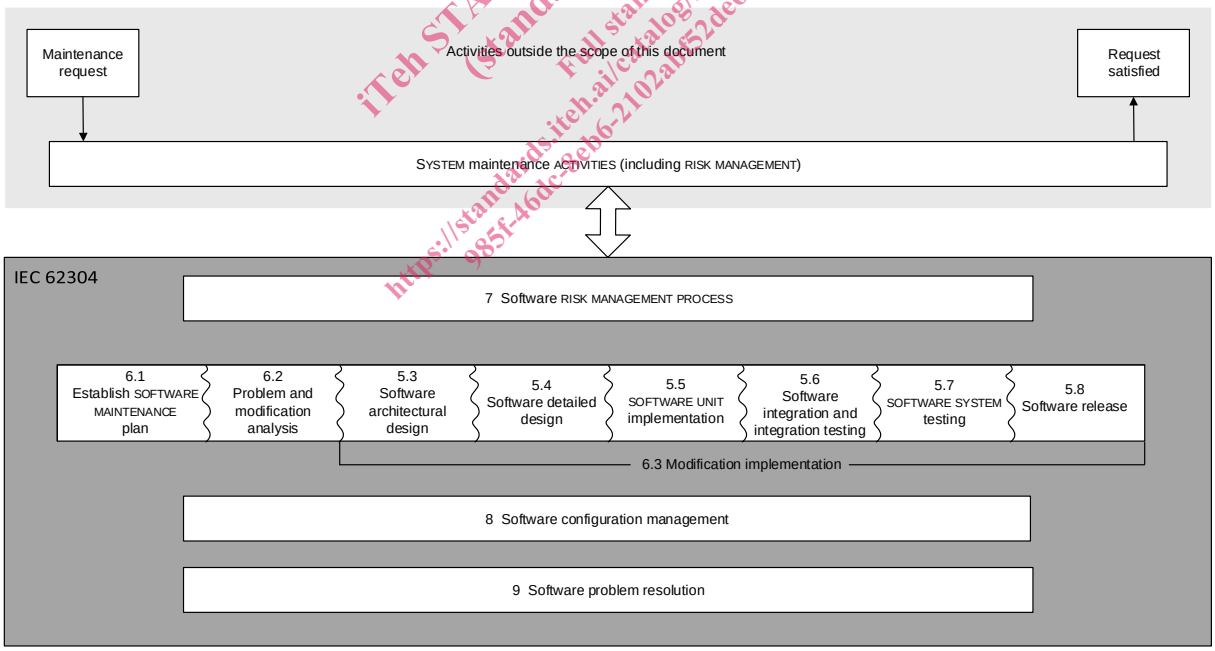

Figure 2 – Overview of SOFTWARE MAINTENANCE PROCESSES and ACTIVITIES

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.

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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.

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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 3). 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.

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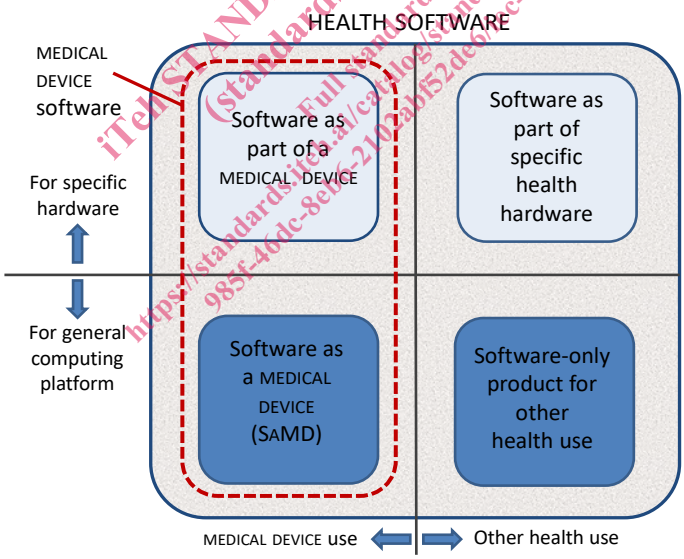

Figure 3 – HEALTH SOFTWARE field of application

NOTE 1 Examples of HEALTH SOFTWARE include the following:

1) HEALTH SOFTWARE not part of a MEDICAL DEVICE: mobile applications running on devices without physiologic sensors or detectors, hospital information systems;

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

3) software as a MEDICAL DEVICE (SaMD): Software that is itself a MEDICAL DEVICE, such as a software application that reviews images generated by an MRI. For definition of software as a MEDICAL DEVICE see IMDRF/SaMD/WG/N10Final:2013 [33].

4) 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 at the SYSTEM level. 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

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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 VALIDATION and release for INTENDED USE, even when the product consists entirely of software. It also does not cover software lifecycle 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.

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).

1.3 Relationship to other standards

This HEALTH SOFTWARE life cycle document is written in a way that it may be used together with referencing standards when developing and maintaining a product that includes HEALTH SOFTWARE.

1.4 Conformance

Conformance with this document is defined as implementing all of the PROCESSES, ACTIVITIES, and TASKS identified in this document in accordance with the software safety class.

NOTE 1 The software safety classes assigned to each requirement are identified in the normative text following the requirement.

Conformance is determined by inspection of all documentation required by this document including the RISK MANAGEMENT FILE, and assessment of the PROCESSES, ACTIVITIES and TASKS required for the software safety class.

Conformance of LEGACY SOFTWARE may be demonstrated by implementing subclause 4.5.

NOTE 2 This assessment could be carried out by internal or external audit.

NOTE 3 The assessment allows for flexibility in the methods of implementing the PROCESSES and performing the ACTIVITIES and TASKS..

NOTE 4 Where any requirements contain "as appropriate" and were not performed, documentation for the justification is necessary for this assessment.

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

ISO 14971, *Medical devices – Application of risk management to medical devices*

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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 http://www.iso.org/obp

3.1
ACTIVITY
set of one or more interrelated or interacting TASKS

3.2
ANOMALY
any 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]

3.3
ARCHITECTURE
organizational structure of a SYSTEM or component

[SOURCE: IEEE Std 24765-2010, 3.150, definition 2]

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

3.8
HARM
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO 81001-1:—[1], 3.15]

3.9
HAZARD
potential source of HARM

Note 1 to entry: Potential sources of HARM include breach of SECURITY and reduction of effectiveness.

[1] Under preparation. Stage at the time of this CDV: ISO/DIS 81001-1:2019.

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[SOURCE: ISO 81001-1:—, 3.16, modified — Note 1 to entry has been added.]

3.10
HAZARDOUS SITUATION
circumstance in which people, property or the environment is/are exposed to one or more HAZARD(S)

[SOURCE: ISO 81001-1:—, 3.17]

3.11
HEALTH SOFTWARE
SOFTWARE SYSTEM 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:—, 3.22, modified — In the definition, the term "software" has been replaced by "SOFTWARE SYSTEM".]

3.12
INTENDED USE
use for which a product, PROCESS or service is intended according to the specification, instructions and information provided by the MANUFACTURER

[SOURCE: ISO 81001-1:—, 3.26]

3.13
LEGACY SOFTWARE
HEALTH SOFTWARE placed on the market before the publication of this document for which the MANUFACTURER seeks conformance retrospectively.

3.14
MANUFACTURER
natural or legal person with responsibility for designing, manufacturing, packaging, or labelling of HEALTH SOFTWARE product, or adapting HEALTH SOFTWARE product before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

Note 1 to entry: Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of MANUFACTURER.

Note 2 to entry: For a definition of "labelling", see ISO 13485:2016, 3.8.

Note 3 to entry: "Developer" or "developer organization" are commonly used terms and are synonymous with the term "MANUFACTURER" in the context of health information technology.

3.15
MEDICAL DEVICE
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the MANUFACTURER to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of

– diagnosis, prevention, monitoring, treatment or alleviation of disease,
– diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
– investigation, replacement, modification, or support of the anatomy or of a physiological PROCESS,
– supporting or sustaining life,

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