



**SLOVENSKI STANDARD**  
**oSIST prEN IEC 62304:2021**  
**01-januar-2021**

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**Programska oprema v zdravstvu - Procesi v življenjskem ciklu programske opreme**

Health software - Software life cycle processes

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**Ta slovenski standard je istoveten z: prEN IEC 62304:2019**

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**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

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# 62A/1349/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

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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: <input type="checkbox"/> Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: <input type="checkbox"/> EMC <input type="checkbox"/> ENVIRONMENT <input type="checkbox"/> QUALITY ASSURANCE <input checked="" type="checkbox"/> SAFETY	
<input checked="" type="checkbox"/> SUBMITTED FOR CENELEC PARALLEL VOTING <input type="checkbox"/> NOT SUBMITTED FOR CENELEC PARALLEL VOTING	
<p><b>Attention IEC-CENELEC parallel voting</b></p> <p>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.</p> <p>The CENELEC members are invited to vote through the CENELEC online voting system.</p>	

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TITLE:

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

PROPOSED STABILITY DATE: 2024

NOTE FROM TC/SC OFFICERS:

Please note that IEC 62304 was circulated to IEC/SC 62A and ISO/TC 215 as a CDV/DIS in February, 2018. However, the document did not receive the approval to move forward. Therefore, the draft was

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revised, based on the comments received and other input, and was circulated as a 3rd Committee Draft in January 2019. The document was also circulated for information/comment to ISO/TC 210.

The comments submitted on the 3rd Committee Draft were resolved by the IEC 62304 Project Team (see 62A/1319A/CC).

The document is being circulated for ballot as a 2nd CDV/DIS in IEC/SC 62A and ISO/TC 215. The document will also be circulated for information to ISO/TC 210.

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**NOTE DES RESPONSABLES DU TC/SC:**

Please note that IEC 62304 was circulated to IEC/SC 62A and ISO/TC 215 as a CDV/DIS in February, 2018. However, the document did not receive the approval to move forward. Therefore, the draft was revised, based on the comments received and other input, and was circulated as a 3rd Committee Draft in January 2019. The document was also circulated for information/comment to ISO/TC 210.

The comments submitted on the 3rd Committee Draft were resolved by the IEC 62304 Project Team (see 62A/1319A/CC).

The document is being circulated for ballot as a 2nd CDV/DIS in IEC/SC 62A and ISO/TC 215. The document will also be circulated for information to ISO/TC 210.

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**HEALTH SOFTWARE –  
SOFTWARE LIFE CYCLE PROCESSES**

## FOREWORD

- 97 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising  
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99 co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and  
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124 Publications.
- 125 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is  
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- 127 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent  
128 rights. IEC shall not be held responsible for identifying any or all such patent rights.

129 International Standard IEC 62304 has been prepared by a joint working group of subcommittee  
130 62A: Common aspects of electrical equipment used in medical practice, of IEC technical  
131 committee 62: Electrical equipment in medical practice and ISO Technical Committee 215,  
132 Health informatics. Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and systems  
133 engineering.

134 It is published as a dual logo standard.

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

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

- 139 a) the scope of this document has been expanded to HEALTH SOFTWARE;
- 140 b) the general requirements section has been updated to assure that this document would  
141 meet the state of art of the use-environment and the way that HEALTH SOFTWARE is being  
142 used.



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

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

144

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

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

148 In this document, the following print types are used:

- 149 – requirements and definitions: roman type;  
150 – informative material appearing outside of tables, such as notes, examples and references: smaller type.  
151 Normative text of tables is also in a smaller type;  
152 – TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3: SMALL  
153 CAPITALS.

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

- 156 • "shall" means that compliance with a requirement is mandatory for compliance with this  
157 document;  
158 • "should" means that compliance with a requirement is recommended but is not mandatory  
159 for compliance with this document;  
160 • "may" is used to describe a permissible way to achieve compliance with a requirement;

161 **The term** "establish" means to define, document, and implement.

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

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

167 The committee has decided that the contents of this document will remain unchanged until the  
168 stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to  
169 the specific document. At this date, the document will be

- 170 • reconfirmed,  
171 • withdrawn,  
172 • replaced by a revised edition, or  
173 • amended.

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

179

**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

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

186 In the past, software in the care environment was used primarily by clinical users (nurses,  
187 technicians, dieticians, physicians, etc.) and previous versions of this document addressed  
188 product development activities focused on the use of MEDICAL DEVICE SOFTWARE by clinical  
189 users. There are now software products that are being used by non-clinical users to measure,  
190 manage, maintain, or improve the health of individual(s), or for the delivery of care. For these  
191 reasons, the scope of this document has been expanded to HEALTH SOFTWARE.

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

199 This document does not duplicate well-established requirements from standards for USABILITY  
200 and SECURITY. The addition of USABILITY and SECURITY to this document followed the same  
201 approach as RISK MANAGEMENT and quality management PROCESSES of previous versions of this  
202 document (i.e. editions 1.0 and 1.1).

203 Establishing the SAFETY and effectiveness of HEALTH SOFTWARE requires knowledge of what the  
204 HEALTH SOFTWARE is intended to do and demonstration that the use of the HEALTH SOFTWARE  
205 fulfils those intentions without causing any unacceptable RISKS.

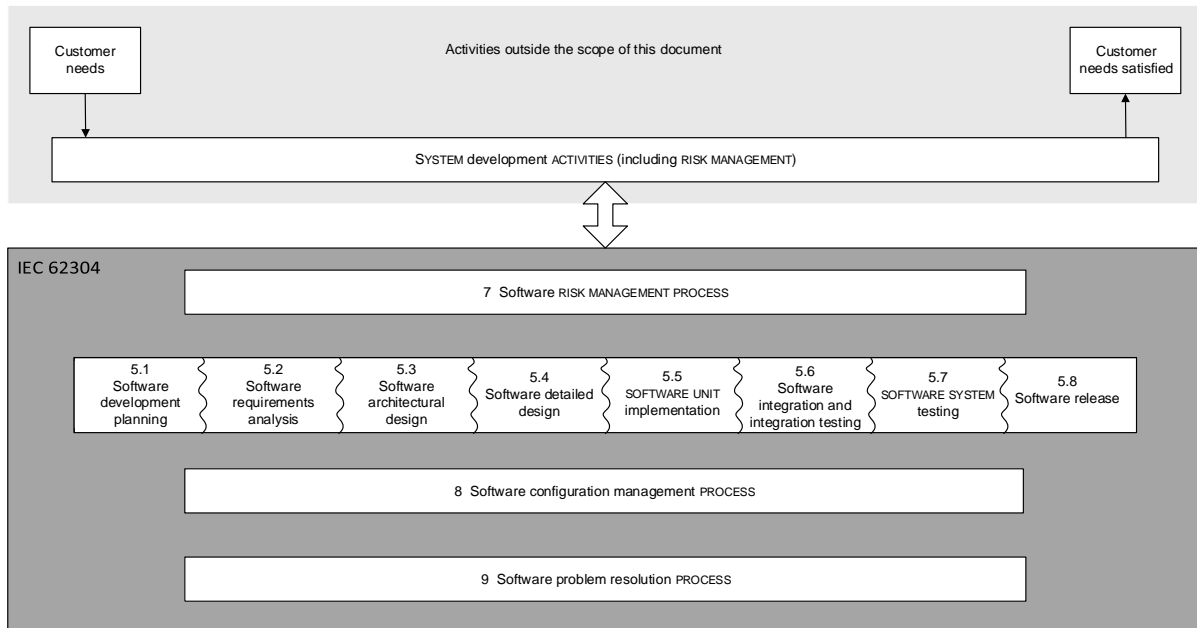
206 The MANUFACTURER of HEALTH SOFTWARE is responsible for determining and complying with the  
207 appropriate SAFETY, SECURITY, environmental, health, and interference protection practices and  
208 the applicable laws and regulations. Many laws, regulations, and other rules from authorities  
209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

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

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

228 This document provides a framework for a life cycle PROCESS. It defines the ACTIVITIES and  
229 TASKS necessary for the safe design, development and maintenance of HEALTH SOFTWARE. The  
230 development life cycle ACTIVITIES are shown in Figure 1 and described in Clause 5. Some  
231 incidents in healthcare delivery are related to HEALTH SOFTWARE SYSTEMS, including

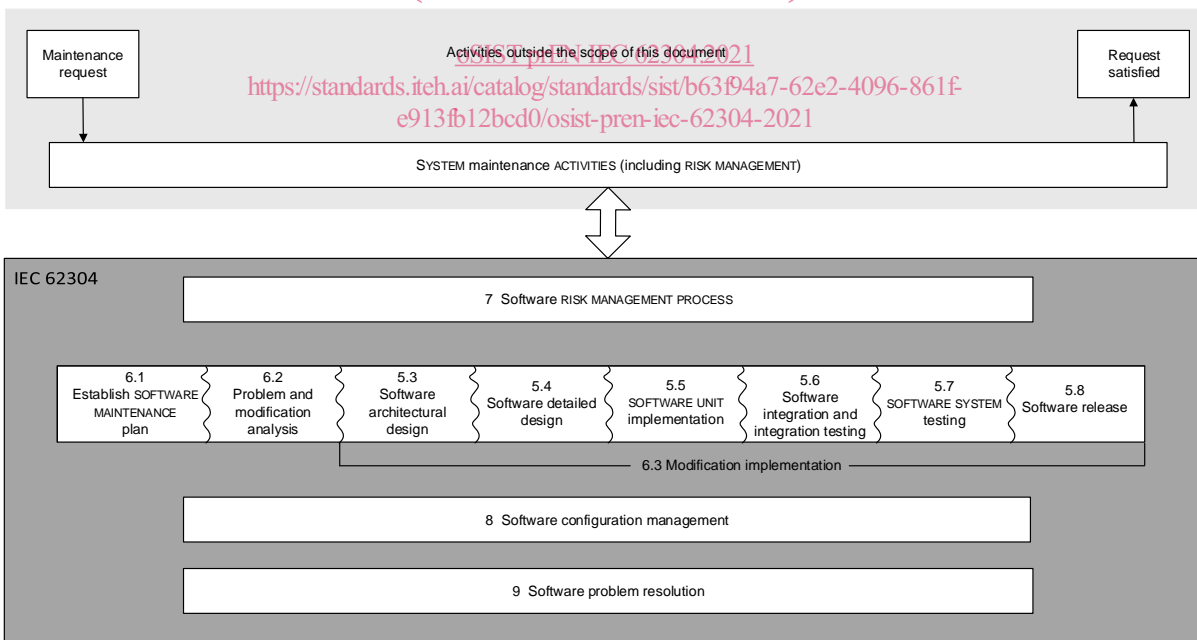
232 inappropriate software updates and upgrades. The SOFTWARE MAINTENANCE PROCESS is  
 233 therefore as important as the software development PROCESS. It is shown in Figure 2 and  
 234 described in Clause 6.



235

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**Figure 1 – Overview of software development PROCESSES and ACTIVITIES**  
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238

**Figure 2 – Overview of SOFTWARE MAINTENANCE PROCESSES and ACTIVITIES**

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

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

246 This document does not prescribe the name, format, or explicit content of the documentation to  
247 be produced. This document calls for adequate evidence of required ACTIVITIES and TASKS by  
248 documentation. Regardless how content is structured and packaged, it is expected that a  
249 controlled documentation PROCESS is in place. This document does not prescribe a specific life  
250 cycle model. The users of this document are responsible for selecting a life cycle model for the  
251 software project and for mapping the PROCESSES, ACTIVITIES, and TASKS in this document onto  
252 that model.

253 Annex A provides rationale for the clauses of this document. Annex B provides guidance on the  
254 provisions of this document.

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## HEALTH SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES

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### 261 1 Scope

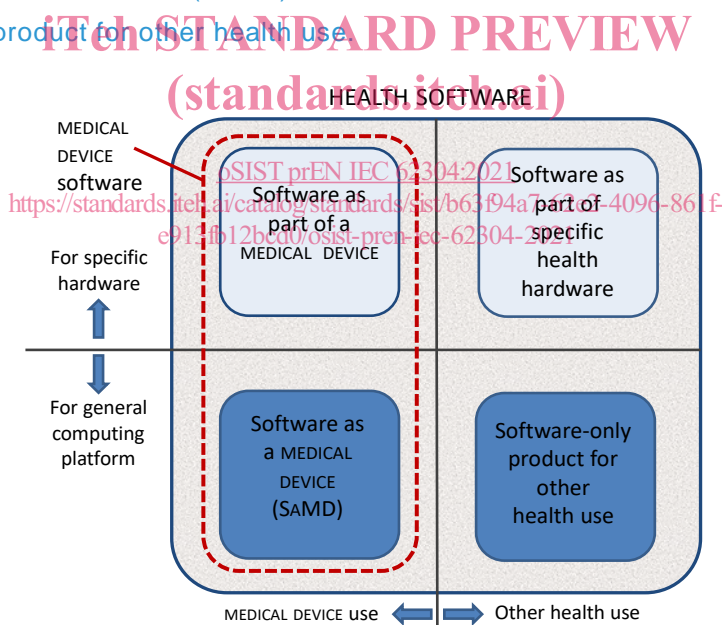
#### 262 1.1 \* Purpose

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

#### 266 1.2 \* Field of application

267 This document applies to the development and maintenance of HEALTH SOFTWARE by a  
268 MANUFACTURER. MEDICAL DEVICE SOFTWARE is a subset of HEALTH SOFTWARE (see Figure 3).  
269 Therefore, this document applies to:

- 270 – software as part of a MEDICAL DEVICE;  
271 – software as part of specific health hardware;  
272 – software as a medical device (SaMD);  
273 – software-only product for other health use



274  
275

**Figure 3 – HEALTH SOFTWARE field of application**

276 NOTE 1 Examples of HEALTH SOFTWARE include the following:

- 277 1) HEALTH SOFTWARE not part of a MEDICAL DEVICE: mobile applications running on devices without physiologic  
278 sensors or detectors, hospital information systems;
- 279 2) MEDICAL DEVICE SOFTWARE: software that is an integral part of a device such as a infusion pump or dialysis  
280 machine;
- 281 3) software as a MEDICAL DEVICE (SaMD): Software that is itself a MEDICAL DEVICE, such as a software application  
282 that reviews images generated by an MRI. For definition of software as a MEDICAL DEVICE see  
283 IMDRF/SaMD/WG/N10Final:2013<sup>[33]</sup>.
- 284 4) software as a service, i.e., software executed in an external environment, providing calculation-results that fulfil  
285 the definition of a MEDICAL DEVICE.

286 NOTE 2 This document can be used in the development and maintenance of health software. Before any type of  
287 software can be placed into service, activities are necessary at the SYSTEM level. These SYSTEM activities are not  
288 covered by this document (see Figure 1), but can be found in related product standards (e.g., IEC 60601-1<sup>[1]</sup> or

289 IEC 82304-1<sup>[15]</sup>. For software as a medical device (SaMD) additional guidance on activities at a system level (e.g.  
290 clinical EVALUATION) can be found in regulatory authority guidance documents.

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

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

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

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

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

### 307 1.3 Relationship to other standards

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

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### 311 1.4 Conformance

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

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

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

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

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

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

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

## 325 2 \* Normative references

326 The following documents are referred to in the text in such a way that some or all of their content  
327 constitutes requirements of this document. For dated references, only the edition cited applies.  
328 For undated references, the latest edition of the referenced document (including any  
329 amendments) applies.

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

### 331 **3 \* Terms and definitions**

332 For the purposes of this document, the following terms and definitions apply.

333 ISO and IEC maintain terminological databases for use in standardisation at the following  
334 addresses:

- 335 • IEC Electropedia: available at <http://www.electropedia.org/>
- 336 • ISO Online browsing platform: available at <http://www.iso.org/obp>

#### 337 **3.1**

##### 338 **ACTIVITY**

339 set of one or more interrelated or interacting TASKS

#### 340 **3.2**

##### 341 **ANOMALY**

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

344 [SOURCE: ISO/IEC 25051:2014]

#### 345 **3.3**

##### 346 **ARCHITECTURE**

347 organizational structure of a SYSTEM or component

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

#### 349 **3.4**

350 **CHANGE REQUEST** [https://standards.iteh.ai/catalog/standards/sist/b63f94a7-62e2-4096-861f-](https://standards.iteh.ai/catalog/standards/sist/b63f94a7-62e2-4096-861f-62304-2021)  
351 documented specification of a change to be made to HEALTH SOFTWARE

#### 352 **3.5**

##### 353 **CONFIGURATION ITEM**

354 entity that can be uniquely identified at a given reference point

#### 355 **3.6**

##### 356 **DELIVERABLE**

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

#### 358 **3.7**

##### 359 **EVALUATION**

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

#### 361 **3.8**

##### 362 **HARM**

363 injury or damage to the health of people, or damage to property or the environment

364 [SOURCE: ISO 81001-1:—1, 3.15]

#### 365 **3.9**

##### 366 **HAZARD**

367 potential source of HARM

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

<sup>1</sup> Under preparation. Stage at the time of this CDV: ISO/DIS 81001-1:2019.