



SLOVENSKI STANDARD
oSIST prEN IEC 61508-1:2025
01-april-2025

Funkcijska varnost električnih/elektronskih/elektronsko programirljivih varnostnih sistemov - 1. del: Splošne zahteve

Functional safety of electrical/electronic/programmable electronic safety-related systems
- Part 1: General requirements

Funktionale Sicherheit sicherheitsbezogener
elektrischer/elektronischer/programmierbarer elektronischer Systeme - Teil 1:
Allgemeine Anforderungen

Sécurité fonctionnelle des systèmes électriques/électroniques/électroniques
programmables relatifs à la sécurité - Partie 1: Exigences générales

Ta slovenski standard je istoveten z: prEN IEC 61508-1:2025

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TITLE:

Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 1: General requirements

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115 INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**FUNCTIONAL SAFETY OF ELECTRICAL/ELECTRONIC/
PROGRAMMABLE ELECTRONIC SAFETY-RELATED SYSTEMS –****Part 1: General requirements****FOREWORD**

124 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising
125 all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international
126 co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and
127 in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports,
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129 preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with
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150 expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC
151 Publications.

152 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is
153 indispensable for the correct application of this publication.

154 9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a)
155 patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in
156 respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which
157 may be required to implement this document. However, implementers are cautioned that this may not represent
158 the latest information, which may be obtained from the patent database available at <https://patents.iec.ch>. IEC
159 shall not be held responsible for identifying any or all such patent rights.

160 IEC 61508-1 has been prepared by subcommittee 65A: System aspects, of IEC technical
161 committee 65: Industrial-process measurement, control and automation. It is an International
162 Standard.

163 This third edition cancels and replaces the second edition published in 2010. This edition
164 constitutes a technical revision.

165 This edition includes the following significant technical changes with respect to the previous
166 edition (the following list does refer to this document; other parts do mention specific further
167 details):

168 a) Document was upgraded to the 2024 version of the ISO/IEC Directives; this does
169 introduce a significant number of editorial changes, clause renumbering and rewording
170 of the information provided in Notes;

- 171 b) The scope includes clarification on 'artificial Intelligence' (software technology class),
 172 human factors and security. The related requirements are limited to the hazard and risk
 173 analysis (refer to 7.1.2.3 on human factors and 7.4.2.3 for security) and further
 174 references to external guidance;
- 175 c) The interfaces to other parts of IEC 61508 have been clarified and duplication of
 176 requirements in other Parts has been removed;
- 177 d) The differentiation between the required Safety Integrity Level (SIL) and the achieved
 178 Systematic Capability (SC) has been clarified;
- 179 e) Requirements on levels of independence for functional safety assurance activities
 180 (Annex B) have been introduced;
- 181 f) Various minor editorial errors have been corrected, the normative references and the
 182 bibliography has been updated.

183

184 It has the status of a basic safety publication according to IEC Guide 104.

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

Draft	Report on voting
65A/XX/FDIS	65A/XX/RVD

186

187 Full information on the voting for its approval can be found in the report on voting indicated in
 188 the above table.

189 The language used for the development of this document is English.

190 This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in
 191 accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available
 192 at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are
 193 described in greater detail at www.iec.ch/publications.

194 A list of all parts of the IEC 61508 series, published under the general title *Functional safety of*
 195 *electrical / electronic / programmable electronic safety-related systems*, can be found on the
 196 IEC website.

197 The committee has decided that the contents of this document will remain unchanged until the
 198 stability date indicated on the IEC website under webstore.iec.ch in the data related to the
 199 specific document. At this date, the document will be

- 200 • reconfirmed,
- 201 • withdrawn,
- 202 • replaced by a revised edition, or
- 203 • amended.

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INTRODUCTION

207 Systems comprised of electrical and/or electronic elements have been used for many years to
208 perform safety functions in most application sectors. Computer-based systems (generically
209 referred to as programmable electronic systems) are being used in all application sectors to
210 perform non-safety functions and, increasingly, to perform safety functions. If computer system
211 technology is to be effectively and safely exploited, it is essential that those responsible for
212 making decisions have sufficient guidance on the safety aspects on which to make these
213 decisions.

214 This document sets out a generic approach for all safety lifecycle activities for systems
215 comprised of electrical and/or electronic and/or programmable electronic (E/E/PE) elements
216 that are used to perform safety functions. This unified approach has been adopted in order that
217 a rational and consistent technical policy be developed for all electrically-based safety-related
218 systems. A major objective is to facilitate the development of product and application sector
219 international standards based on the IEC 61508 series.

220 NOTE 1 Examples of product and application sector international standards based on the IEC 61508 series are
221 given in the Bibliography (see references [1], [2] and [3]).

222 In most situations, safety is achieved by a number of systems which rely on many technologies
223 (for example mechanical, hydraulic, pneumatic, electrical, electronic, programmable electronic).
224 Any safety strategy shall therefore consider not only all the elements within an individual system
225 (for example sensors, controlling devices and actuators) but also all the safety-related systems
226 making up the total combination of safety-related systems. The safety strategy shall also
227 consider the influence of humans on the achievement of functional safety. Therefore, while this
228 document is concerned with E/E/PE safety-related systems, it may also provide a framework
229 within which safety-related systems based on other technologies may be considered.

230 It is recognized that there is a great variety of applications using E/E/PE safety-related systems
231 in a variety of application sectors and covering a wide range of complexity, hazard and risk
232 potentials. In any particular application, the required safety measures will be dependent on
233 many factors specific to the application. This document, by being generic, will enable such
234 measures to be formulated in future product and application sector international standards and
235 in revisions of those that already exist.

236 This document

- 237 – considers all relevant overall, E/E/PE system and software safety lifecycle phases (for
238 example, from initial concept, through design, implementation, operation and maintenance
239 to decommissioning) when E/E/PE systems are used to perform safety functions;
- 240 – has been conceived with a rapidly developing technology in mind; the framework is
241 sufficiently robust and comprehensive to cater for future developments;
- 242 – enables product and application sector international standards, dealing with E/E/PE safety-
243 related systems, to be developed; the development of product and application sector
244 international standards, within the framework of this document, should lead to a high level
245 of consistency (for example, of underlying principles, terminology etc.) both within
246 application sectors and across application sectors; this will have both safety and economic
247 benefits;
- 248 – provides a method for the development of the safety requirements specification necessary
249 to achieve the required functional safety for E/E/PE safety-related systems;
- 250 – adopts a risk-based approach by which the safety integrity requirements can be determined;
- 251 – introduces safety integrity levels for specifying the target level of safety integrity for the
252 safety functions to be implemented by the E/E/PE safety-related systems;

253 NOTE 2 This document does not specify the safety integrity level requirements for any safety function, nor does it
254 mandate how the safety integrity level is determined. Instead, it provides a risk-based conceptual framework and
255 example techniques.

- 256 – sets target failure measures for safety functions carried out by E/E/PE safety-related
257 systems, which are linked to the safety integrity levels;
- 258 – sets a lower limit on the target failure measures for a safety function carried out by a single
259 E/E/PE safety-related system. For E/E/PE safety-related systems operating in
- 260 • a low demand mode of operation, the lower limit is set at an average probability of a
261 dangerous failure on demand of 10^{-5} ;
 - 262 • a high demand or a continuous mode of operation, the lower limit is set at an average
263 frequency of a dangerous failure of 10^{-9} [h^{-1}];

264 NOTE 3 A single E/E/PE safety-related system does not necessarily mean a single-channel architecture.

265 NOTE 4 It can be possible to achieve designs of safety-related systems with lower values for the target safety
266 integrity for non-complex systems, but these limits are considered to represent what can be achieved for relatively
267 complex systems (for example programmable electronic safety-related systems) at the present time.

- 268 – sets requirements for the avoidance and control of systematic faults, which are based on
269 experience and judgement from practical experience gained in industry. Even though the
270 probability of occurrence of systematic failures cannot in general be quantified this
271 document does, however, allow a claim to be made, for a specified safety function, that the
272 target failure measure associated with the safety function can be considered to be achieved
273 if all the requirements in this document have been met;
- 274 – adopts a broad range of principles, techniques and measures to achieve functional safety
275 for E/E/PE safety-related systems, but does not explicitly use the concept of fail safe.
276 However, the concept of “fail safe” and “inherently safe” principles may be applicable and
277 adoption of such concepts is acceptable providing the requirements of the relevant clauses
278 in this document are met.

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FUNCTIONAL SAFETY OF ELECTRICAL/ELECTRONIC/ PROGRAMMABLE ELECTRONIC SAFETY-RELATED SYSTEMS –

Part 1: General requirements

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1 Scope

289 **1.1** This document covers those aspects to be considered when
290 electrical/electronic/programmable electronic (E/E/PE) systems are used to carry out safety
291 functions. A major objective of t

292 The goal of this document is to facilitate the development of product and application sector
293 international standards by the technical committees responsible for the product or application
294 sector. This will allow all the relevant factors, associated with the product or application, to be
295 fully taken into account and thereby meet the specific needs of users of the product and the
296 application sector. A second objective of this document is to enable the development of E/E/PE
297 safety-related systems where product or application sector international standards do not exist.

298 The scope of this document is functional safety for E/E/PE safety-related systems but, apart
299 from normative requirements in the hazard and risk analysis phase, does not itself provide
300 normative requirements for malevolent action arising from a
301 cybersecurity risk. However, if a cybersecurity assessment has identified that a reasonably
302 foreseeable cyber security risk will arise, it is essential that measures be taken for all relevant
303 phases of the overall, E/E/PE and software safety lifecycles in order to protect against such
304 threats to ensure that functional safety is achieved.

305 NOTE 1 For requirements and/or guidance on cybersecurity see IEC 62443 series and ISO/IEC 27000 series.

306 NOTE 2 For guidance on the coordination between safety and security refer to IEC TR 63069.

307 **1.2** In particular, this document

308 a) applies to safety-related systems when one or more of such systems incorporates
309 electrical/electronic/programmable electronic elements;

310 NOTE 1 In the context of low complexity E/E/PE safety-related systems, certain requirements specified in this
311 document can be unnecessary, and exemption from compliance with such requirements is possible (see 4.2, and the
312 definition of a low complexity E/E/PE safety-related system in 3.4.3 of IEC 61508-4).

313 NOTE 2 Although a person can form part of a safety-related system (see 3.4.1 of IEC 61508-4), human factor
314 requirements related to those aspects of the design of E/E/PE safety-related systems are not considered in detail in
315 this document.

316 NOTE 3 This document can be applied to custom, low-volume and high volume production safety-related systems,
317 subsystems, elements and compliant items.

318 NOTE 4 This document can be applied to parts of the safety function (e.g., compliant item or tool) but it does not
319 provide a final SIL statement to a part of the safety function.

320 b) is generically based and applicable to all E/E/PE safety-related systems irrespective of the
321 application;

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324 c) covers the achievement of a tolerable risk through the application of E/E/PE safety-related
325 systems, but does not cover hazards arising from the E/E/PE equipment itself (for example
326 electric shock);

327 d) applies to all types of E/E/PE safety-related systems, including protection systems and
328 control systems;

- 329 e) does not cover E/E/PE systems where
330 – a single E/E/PE system is capable on its own of meeting the tolerable risk, and
331 – the required quantitative performance and integrity of the safety functions of the single
332 E/E/PE system is less than that specified for safety integrity level 1 (the lowest safety
333 integrity level in this document).
- 334 f) is mainly concerned with the E/E/PE safety-related systems whose failure could have an
335 impact on the safety of persons and/or the environment; however, it is recognized that the
336 consequences of failure could also have serious economic implications and in such cases
337 this document could be used to specify any E/E/PE system used for the protection of
338 equipment or product;

339 NOTE 7 See 3.1.1 of IEC 61508-4.

- 340 g) considers E/E/PE safety-related systems and other risk reduction measures, in order that
341 the safety requirements specification for the E/E/PE safety-related systems can be
342 determined in a systematic, risk-based manner;
- 343 h) uses an overall safety lifecycle model as the organisational framework for dealing
344 systematically with the processes and activities necessary for ensuring the functional safety
345 of the E/E/PE safety-related systems;

346 NOTE 8 Although the overall safety lifecycle is primarily concerned with E/E/PE safety-related systems, it might
347 also provide a technical framework for considering any safety-related system irrespective of the technology of that
348 system (for example mechanical, hydraulic or pneumatic).

- 349 i) specifies the essential concept of safety integrity levels applicable to any sector application;
- 350 j) does not specify the selection of safety integrity levels required to address risks specific to
351 sector applications (which must be based on detailed information and knowledge of the
352 sector application).
- 353 k) provides general requirements for E/E/PE safety-related systems where no product or
354 application sector international standards exist;
- 355 l) requires malevolent and unauthorised actions to be considered during hazard and risk
356 analysis. The scope of the analysis includes all relevant safety lifecycle phases;

357 NOTE 9 For further details refer to ISO/IEC TR 19791 and IEC 62443 series.

- 358 m) does not cover the precautions that may be necessary to prevent unauthorized persons
359 damaging, and/or otherwise adversely affecting, the functional safety of E/E/PE safety-
360 related systems (see k) above);
- 361 n) does not specify the requirements for the development, implementation, maintenance and/or
362 operation of security policies or security services needed to meet a security policy that may
363 be required by the E/E/PE safety-related system;
- 364 o) does apply to software algorithms of software technology class I;
365 does apply to software algorithms of software technology class II and in combination with
366 the additional requirements provided in ISO/IEC TS 22440.

367 NOTE 1 The software technology classes relate to the generically used term “artificial intelligence” as defined in
368 ISO/IEC 22989; for definitions refer to 61508-4, Clauses 3.2.15, 3.2.16 and 3.2.17.

369 NOTE 2 Refer to ISO/IEC TR 5469:2024 and to ISO/IEC TS 22440-1 for further details.

370 NOTE 3 The concept of safety integrity level as described in this document can be applied to the hardware used
371 to execute or implement software algorithms of software technology class I, II or III

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373 **1.3** This part of the IEC 61508 series of standards includes general requirements that are
374 applicable to all parts. Other parts of the IEC 61508 series concentrate on topics that are more
375 specific:

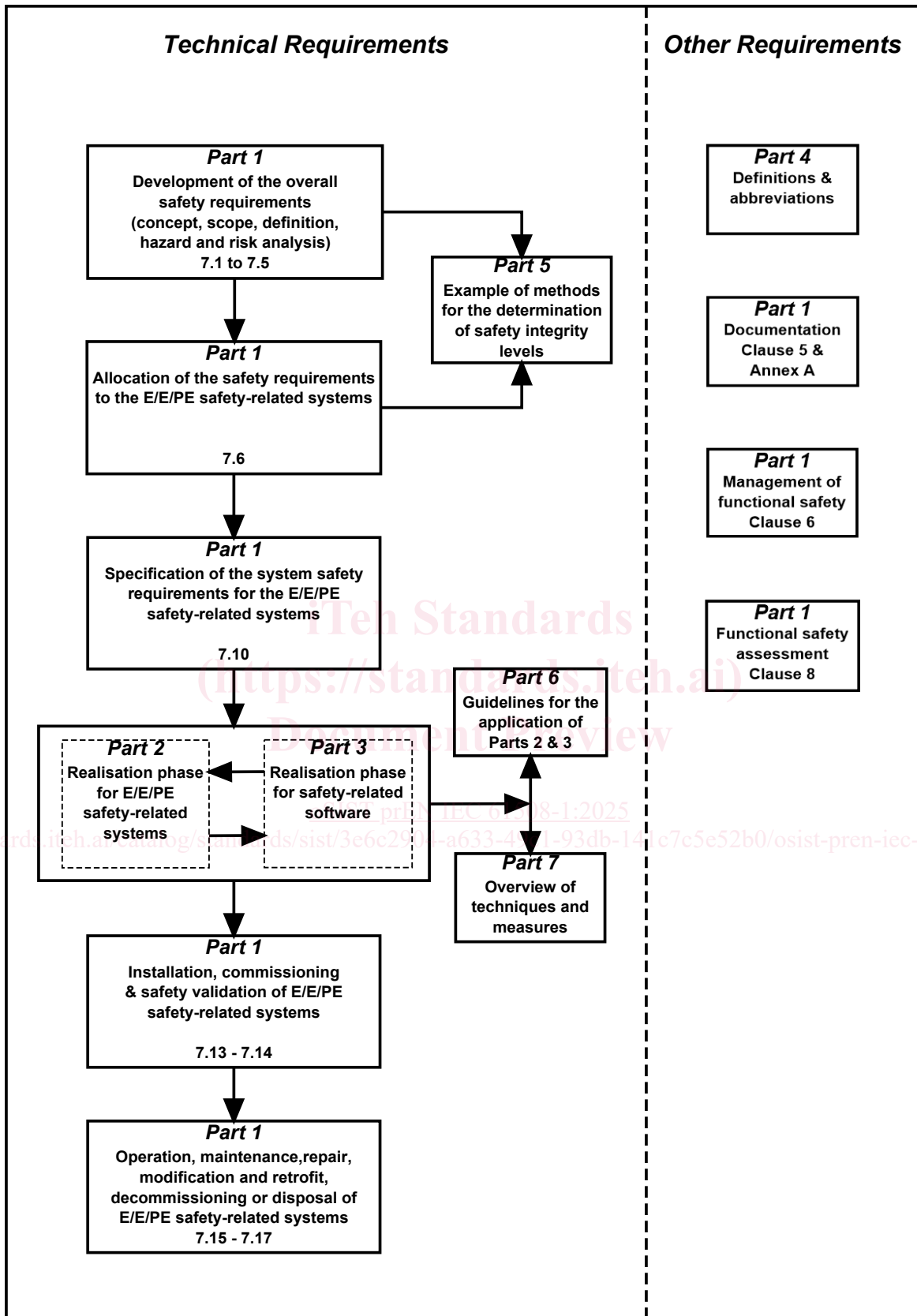
- 376 – parts 2 and 3 provide additional and specific requirements for E/E/PE safety-related systems
377 (part 2 for hardware and part 3 for software);
- 378 – part 4 gives definitions and abbreviations that are used throughout all parts of this document;

- 379 – part 5 provides guidelines on the application of part 1 in determining safety integrity levels,
380 by showing example methods;
- 381 – part 6 provides guidelines on the application of parts 2 and 3;
- 382 – part 7 contains an overview of techniques and measures.
- 383 **1.4** This document is a basic safety publication to be used in conjunction with the other parts
384 of IEC 61508 for use by end users to evaluate functional safety applications, or by technical
385 committees in the preparation of standards in accordance with the principles contained in IEC
386 Guide 104 and ISO/IEC Guide 51. This document does not apply in the context of low complexity
387 E/E/PE safety-related systems (see IEC 61508-4 3.4.3).
- 388 **1.5** Figure 1 shows the overall framework of the IEC 61508 series and indicates the role that
389 IEC 61508-1 plays in the achievement of functional safety for E/E/PE safety-related systems.

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Figure 1 – Overall framework of the IEC 61508 series