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Failure modes and effects analysis (FMEA and FMECA)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 60812:2018 sisaldab Euroopa standardi EN IEC 60812:2018 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 60812:2018 consists of the English text of the European standard EN IEC 60812:2018.
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ICS 03.120.01, 03.120.30, 21.020

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English Version

## Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)

Analyse des modes de défaillance et de leurs effets (AMDE  
et AMDEC)  
(IEC 60812:2018)

Ausfalleffektanalyse (FMEA und FMECA)  
(IEC 60812:2018)

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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

## European foreword

The text of document 56/1775/FDIS, future edition 3 of IEC 60812, prepared by IEC/TC 56 "Dependability" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60812:2018.

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) 2019-06-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2021-09-14

This document supersedes EN 60812:2006.

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The text of the International Standard IEC 60812:2018 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 60300-1	NOTE Harmonized as EN 60300-1
IEC 60300-3-1	NOTE Harmonized as EN 60300-3-1
IEC 60300-3-12	NOTE Harmonized as EN 60300-3-12
IEC 60300-3-11	NOTE Harmonized as EN 60300-3-11
IEC 61025	NOTE Harmonized as EN 61025
IEC 61078	NOTE Harmonized as EN 61078
IEC 61165	NOTE Harmonized as EN 61165
IEC 61508 series	NOTE Harmonized as EN 61508 series
IEC 61709	NOTE Harmonized as EN 61709
IEC 62061	NOTE Harmonized as EN 62061
IEC 62308	NOTE Harmonized as EN 62308
IEC 62502	NOTE Harmonized as EN 62502
IEC 62508	NOTE Harmonized as EN 62508
IEC 62551	NOTE Harmonized as EN 62551
IEC 62740	NOTE Harmonized as EN 62740
IEC 62741	NOTE Harmonized as EN 62741
ISO 9000	NOTE Harmonized as EN ISO 9000
ISO 13849-1	NOTE Harmonized as EN ISO 13849-1

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: [www.cenelec.eu](http://www.cenelec.eu).

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60050-192	-	International electrotechnical vocabulary -- Part 192: Dependability	--	-

## CONTENTS

FOREWORD.....	6
INTRODUCTION.....	8
1 Scope.....	9
2 Normative references .....	9
3 Terms, definitions and abbreviated terms .....	9
3.1 Terms and definitions.....	9
3.2 Abbreviated terms.....	13
4 Overview .....	14
4.1 Purpose and objectives.....	14
4.2 Roles, responsibilities and competences.....	14
4.3 Terminology.....	15
5 Methodology for FMEA .....	15
5.1 General.....	15
5.2 Plan the FMEA.....	17
5.2.1 General .....	17
5.2.2 Define the objectives and scope of analysis.....	17
5.2.3 Identify boundaries and scenarios .....	17
5.2.4 Define decision criteria for treatment of failure modes .....	19
5.2.5 Determine documentation and reporting requirements .....	20
5.2.6 Define resources for analysis.....	21
5.3 Perform the FMEA .....	22
5.3.1 General .....	22
5.3.2 Sub-divide item or process into elements.....	22
5.3.3 Identify functions and performance standards for each element.....	23
5.3.4 Identify failure modes .....	23
5.3.5 Identify detection methods and existing controls.....	23
5.3.6 Identify local and final effects of failure modes .....	24
5.3.7 Identify failure causes.....	25
5.3.8 Evaluate relative importance of failure modes.....	26
5.3.9 Identify actions .....	28
5.4 Document the FMEA .....	29
Annex A (informative) General considerations for tailoring an FMEA.....	30
A.1 General.....	30
A.1.1 Overview .....	30
A.1.2 Start point for FMEA in the hierarchy .....	30
A.1.3 Degree of detail in analysis.....	31
A.1.4 Prioritization of failure modes .....	32
A.2 Factors influencing FMEA tailoring.....	33
A.2.1 Reuse of data/information from analysis of similar item .....	33
A.2.2 Maturity of item design and project progress.....	34
A.2.3 Degree of innovation .....	34
A.3 Examples of FMEA tailoring for items and processes .....	34
A.3.1 General .....	34
A.3.2 Example of tailoring an FMEA for an office equipment product .....	35
A.3.3 Example of tailoring an FMEA for a distributed power system .....	35
A.3.4 Example of tailoring an FMEA for medical processes.....	36

A.3.5	Example of tailoring an FMEA for electronic control systems .....	36
A.3.6	Example of tailoring an FMEA for a pump hydro block .....	37
A.3.7	Example of tailoring an FMEA for a wind turbine for power generation .....	37
Annex B (informative)	Criticality analysis methods .....	38
B.1	General .....	38
B.2	Measurement scales for criticality parameters .....	38
B.2.1	General .....	38
B.2.2	Scale definition .....	38
B.2.3	Assessing likelihood .....	39
B.3	Assigning criticality using a matrix or plot .....	40
B.3.1	General .....	40
B.3.2	Criticality matrix .....	40
B.3.3	Criticality plots .....	41
B.4	Assigning criticality using a risk priority number .....	42
B.4.1	General .....	42
B.4.2	Risk priority number .....	42
B.4.3	Alternative risk priority number method .....	44
Annex C (informative)	Example of FMEA report content .....	46
C.1	General .....	46
C.2	Example of generation of reports from a database information system for an FMEA of a power supply unit .....	46
Annex D (informative)	Relationship between FMEA and other dependability analysis techniques .....	52
Annex E (informative)	Application considerations for FMEA .....	53
E.1	General .....	53
E.2	Software FMEA .....	53
E.3	Process FMEA .....	55
E.4	FMEA for design and development .....	56
E.5	FMEA within reliability centred maintenance .....	56
E.6	FMEA for safety related control systems .....	56
E.6.1	General .....	56
E.6.2	FMEA in planning a safety application .....	57
E.6.3	Criticality analysis including diagnostics .....	57
E.7	FMEA for complex systems with reliability allocation .....	58
E.7.1	General .....	58
E.7.2	Criticality assessment for non-repairable systems with allocated unreliability .....	58
E.7.3	Criticality assessment for repairable systems with allocated availability .....	59
Annex F (informative)	Examples of FMEA from industry applications .....	60
F.1	General .....	60
F.2	Health process application for drug ordering process .....	60
F.3	Manufacturing process application for paint spraying .....	60
F.4	Design application for a water pump .....	61
F.4.1	General .....	61
F.4.2	Item function .....	61
F.4.3	Item failure modes .....	61
F.4.4	Item failure effects .....	61
F.5	Example of an FMEA with criticality analysis for a complex non-repaired system .....	62

F.6	Software application for a blood sugar calculator .....	63
F.7	Automotive electronics device .....	63
F.8	Maintenance and support application for a hi-fi system .....	64
F.9	Safety related control system applications .....	65
F.9.1	Electronic circuit .....	65
F.9.2	Automated train control system.....	65
F.10	FMEA including human factors analysis .....	65
F.11	Marking and encapsulation process for an electronic component .....	66
Bibliography.....		76
Figure 1	– Overview of FMEA methodology before tailoring .....	16
Figure B.1	– Example of a qualitative criticality matrix .....	40
Figure B.2	– Examples of criticality plots.....	41
Figure C.1	– Database information system to support FMEA report generation .....	47
Figure C.2	– Diagram of power supply type XYZ .....	47
Figure C.3	– Criticality matrix for FMECA report in Table C.5 created as a two dimensional image without taking into account detectability .....	51
Figure E.1	– General software failure model for a component software unit (CSU).....	55
Figure E.2	– Allocation of system failure probabilities .....	59
Figure F.1	– Hierarchy of a series electronic system, its subsystems and assemblies with allocated unreliability values, F(t) .....	62
Figure F.2	– Automotive air-bag part.....	64
Table 1	– Example of terms commonly associated with levels of hierarchy.....	15
Table A.1	– Characteristics of top-down and bottom-up approaches to FMEA .....	31
Table A.2	– General application of common approaches to FMEA .....	33
Table C.1	– Example of fields selected for FMEA report of power supply based on database information .....	48
Table C.2	– Example of report of component FMEA .....	49
Table C.3	– Example of report of parts with possible common cause failures .....	50
Table C.4	– Example of report of FMECA using RPN criticality analysis.....	50
Table C.5	– Example of report of FMECA using criticality matrix for global effect.....	51
Table F.1	– Extract from FMEA of the process of ordering a drug from a pharmacy .....	60
Table F.2	– Extract from FMEA of paint spraying step of a manufacturing process.....	61
Table F.3	– Allocation and assessment of unreliability values for different criticality categories of failure modes for the electronic system represented in Figure F.1 .....	63
Table F.4	– Allocation and assessment of unreliability values for different criticality categories of failure modes for subsystem 2 of the system represented in Figure F.1 .....	63
Table F.5	– Hazards and safe/dangerous failures in an automated train control system .....	65
Table F.6	– Extract from FMEA of the process of monitoring blood sugar (1 of 2) .....	67
Table F.7	– Extract of automotive electronic part FMEA .....	69
Table F.8	– Extract from system FMEA for a remote control for a hi-fi system.....	70
Table F.9	– Extract from design FMEA for a remote control for a hi-fi system .....	70
Table F.10	– Extract from process FMEA for a remote control for a hi-fi system.....	71
Table F.11	– Extract from maintenance service FMEA for a remote control for a hi-fi system.....	71

Table F.12 – Extract from an FMEDA for an electronic circuit in a safety control system (1 of 2).....	72
Table F.13 – Extract from an FMEA for a coffee-maker.....	74
Table F.14 – Extract from an FMEA for an electronic component marking and encapsulation process .....	75

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# INTERNATIONAL ELECTROTECHNICAL COMMISSION

## FAILURE MODES AND EFFECTS ANALYSIS (FMEA and FMECA)

### FOREWORD

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International Standard IEC 60812 has been prepared by IEC technical committee 56: Dependability.

This third edition cancels and replaces the second edition published in 2006. This edition constitutes a technical revision.

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

- a) the normative text is generic and covers all applications;
- b) examples of applications for safety, automotive, software and (service) processes have been added as informative annexes;
- c) tailoring the FMEA for different applications is described;
- d) different reporting formats are described, including a database information system;
- e) alternative means of calculating risk priority numbers (RPN) have been added;
- f) a criticality matrix based method has been added;
- g) the relationship to other dependability analysis methods have been described.

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

FDIS	Report on voting
56/1775/FDIS	56/1782/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.

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.

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## INTRODUCTION

Failure modes and effects analysis (FMEA) is a systematic method of evaluating an item or process to identify the ways in which it might potentially fail, and the effects of the mode of failure upon the performance of the item or process and on the surrounding environment and personnel. This document describes how to perform an FMEA.

The purpose of performing an FMEA is to support decisions that reduce the likelihood of failures and their effects, and thus contribute to improved outcomes either directly or through other analyses. Such improved outcomes include, but are not limited to, improved reliability, reduced environmental impact, reduced procurement and operating costs, and enhanced business reputation.

FMEA can be adapted to meet the needs of any industry or organization. FMEA is applicable to hardware, software, processes, human action and their interfaces, in any combination.

FMEA can be carried out several times in the lifetime for the same item or process. A preliminary analysis can be conducted during the early stages of design and planning, followed by a more detailed analysis when more information is available. FMEA can include existing controls, or recommended treatments, to reduce the likelihood or the effects of a failure mode. In the case of a closed loop analysis, FMEA allows for evaluation of the effectiveness of any treatment.

FMEA can be tailored and applied in different ways depending on the objectives.

Failure modes may be prioritized according to their importance. The prioritization can be based on a ranking of the severity alone, or this can be combined with other measures of importance. When failure modes are prioritized, the process is referred to as failure modes, effects and criticality analysis (FMECA). This document uses the term FMEA to include FMECA.

This document gives general guidance on how to plan, perform, document and maintain an FMEA by:

- a) describing the principles;
- b) providing the steps in analysis;
- c) giving examples of the documentation;
- d) providing example applications.

FMEA may be used in a certification or assurance process. For example, FMEA may be used in safety analysis for regulatory purposes but, as this document is a generic standard, it does not specifically address safety.

FMEA should be conducted in a manner that is consistent with any legislation, which is in effect within the scope of FMEA, or the type of risks involved.

Primary users of this document are those who are leading or participating in the analysis.