



NSAI
Standards

Irish Standard
I.S. EN IEC 60812:2018

Failure modes and effects analysis (FMEA and FMECA)

I.S. EN IEC 60812:2018

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

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EN IEC 60812

NORME EUROPÉENNE

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October 2018

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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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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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EN IEC 60812:2018 (E)

European foreword

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2021-09-14

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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
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IEC 61508 series	NOTE Harmonized as EN 61508 series
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ISO 9000	NOTE Harmonized as EN ISO 9000
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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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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.

<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	--	-

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IEC 60812

Edition 3.0 2018-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Failure modes and effects analysis (FMEA and FMECA)

Analyse des modes de défaillance et de leurs effets (AMDE et AMDEC)



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IEC 60812

Edition 3.0 2018-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Failure modes and effects analysis (FMEA and FMECA)

Analyse des modes de défaillance et de leurs effets (AMDE et AMDEC)

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COMMISSION

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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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

FAILURE MODES AND EFFECTS ANALYSIS (FMEA and FMECA)

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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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

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- replaced by a revised edition, or
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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.

FAILURE MODES AND EFFECTS ANALYSIS (FMEA and FMECA)

1 Scope

This document explains how failure modes and effects analysis (FMEA), including the failure modes, effects and criticality analysis (FMECA) variant, is planned, performed, documented and maintained.

The purpose of failure modes and effects analysis (FMEA) is to establish how items or processes might fail to perform their function so that any required treatments could be identified. An FMEA provides a systematic method for identifying modes of failure together with their effects on the item or process, both locally and globally. It may also include identifying the causes of failure modes. Failure modes can be prioritized to support decisions about treatment. Where the ranking of criticality involves at least the severity of consequences, and often other measures of importance, the analysis is known as failure modes, effects and criticality analysis (FMECA).

This document is applicable to hardware, software, processes including human action, and their interfaces, in any combination.

An FMEA can be used in a safety analysis, for regulatory and other purposes, but this being a generic standard, does not give specific guidance for safety applications.

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.

IEC 60050-192, *International electrotechnical vocabulary – Part 192: Dependability* (available at <http://www.electropedia.org>)

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purpose of this document, the terms and definitions given in IEC 60050-192 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
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3.1.1

failure mode

DEPRECATED: fault mode
manner in which failure occurs

Note 1 to entry: A failure mode may be determined by the function lost or other state transition that occurred.

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