

STN	Analýza druhov a následkov porúch (FMEA a FMECA)	STN EN IEC 60812 01 0675
------------	---	--

Failure modes and effects analysis (FMEA and FMECA)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/19

Obsahuje: EN IEC 60812:2018, IEC 60812:2018

Oznámením tejto normy sa od 14.09.2021 ruší
STN EN 60812 (01 0679) z októbra 2006

EUROPEAN STANDARD

EN IEC 60812

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2018

ICS 03.120.01; 03.120.30; 21.020

Supersedes EN 60812:2006

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)

This European Standard was approved by CENELEC on 2018-09-14. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

EN IEC 60812:2018 (E)**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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

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.

<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	--	-



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)

**THIS PUBLICATION IS COPYRIGHT PROTECTED****Copyright © 2018 IEC, Geneva, Switzerland**

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue

The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing 21 000 terms and definitions in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Catalogue IEC - webstore.iec.ch/catalogue

Application autonome pour consulter tous les renseignements bibliographiques sur les Normes internationales, Spécifications techniques, Rapports techniques et autres documents de l'IEC. Disponible pour PC, Mac OS, tablettes Android et iPad.

Recherche de publications IEC - webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - www.electropedia.org

Le premier dictionnaire en ligne de termes électroniques et électriques. Il contient 21 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary

67 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.



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)

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 03.120.01 03.120.30 21.020

ISBN 978-2-8322-5915-3

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

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.

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>)

koniec náhľadu – text ďalej pokračuje v platenej verzii STN