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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.

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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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Europäisches Komitee für Elektrotechnische Normung

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2021-09-14

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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.

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

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Edition 3.0 2018-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Failure modes and effects analysis (FMEA and FMECA)

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

IEC 60812:2018-08(en-fr)

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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.

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)