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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)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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- withdrawn,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.

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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/
- ISO Online browsing platform: available at http://www.iso.org/obp

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.

Note 2 to entry: Examples of hardware failure modes might be for a valve, "does not open", or for an engine, "does not start".

Note 3 to entry: A human failure mode is determined by the function lost as a result of human action, whether committed or omitted.

[SOURCE: IEC 60050-192:2015, 192-03-17, modified — Note 1 has been modified, Note 2 and Note 3 have been added.]

3.1.2
failure effect
consequence of a failure, within or beyond the boundary of the failed item

Note 1 to entry: For some analyses, it may be necessary to consider individual failure modes and their effects.

Note 2 to entry: Failure effect also covers the consequence of a failure, within or beyond the boundary of the failed process.

[SOURCE: IEC 60050-192:2015, 192-03-08, modified — Note 2 has been added.]

3.1.3
system
combination of interacting elements organized to achieve one or more stated purposes

Note 1 to entry: A system is sometimes considered as a product or as the services it provides.

Note 2 to entry: In practice, the interpretation of its meaning is frequently clarified by the use of an associative noun, e.g., aircraft system. Alternatively, the word "system" is substituted simply by a context-dependent synonym, e.g., aircraft, though this potentially obscures a system principles perspective.

[SOURCE: ISO/IEC/IEEE 15288:2015, 4.1.46, modified — Note 3 has been deleted.]

3.1.4
item
subject being considered

Note 1 to entry: The item may be an individual part, component, device, functional unit, equipment, subsystem, or system.

Note 2 to entry: The item may consist of hardware, software, people or any combination thereof.

Note 3 to entry: The item is often comprised of elements that may each be individually considered.

Note 4 to entry: IEC 60050-191:1990 (now withdrawn; replaced by IEC 60050-192:2015) identified the term "entity" as an English synonym, which is not true for all applications.

Note 5 to entry: The definition for item in IEC 60050-191:1990 (now withdrawn; replaced by IEC 60050-192:2015) is a description rather than a definition. This new definition provides meaningful substitution throughout this document. The words of the former definition form new note 1.

[SOURCE: IEC 60050-192:2015, 192-01-01]

3.1.5
process
set of interrelated or interacting activities that transforms inputs into outputs

[SOURCE: IEC 60050-192:2015, 192-01-08]

3.1.6
hierarchy level
level of sub-division within a system, item or process hierarchy

Note 1 to entry: Hierarchy level may also be known as the indenture level [see IEC 60050-192:2015, 192-01-05].

Note 2 to entry: Top-level and low-level corresponds to the highest and lowest levels of the hierarchy, respectively. Mid-level corresponds to levels between the highest and lowest levels.

3.1.7
element
level of sub-division of a system, item or process hierarchy at which failure modes are to be identified

3.1.8
scenario
possible sequence of specified conditions under which the system, item or process functions are performed

Note 1 to entry: Conditions may include activities or factors outside the defined item or process boundaries under study which may affect the performance of the item or process.

Note 2 to entry: Physical conditions include all environmental factors such as temperature, humidity, light levels, shock, contamination, radiation levels.

Note 3 to entry: Organizational conditions include factors such as staffing levels, physical/psychological stresses.

3.1.9
failure cause
set of circumstances that leads to failure

Note 1 to entry: A failure cause may originate during specification, design, manufacture, installation, operation or maintenance of an item.

Note 2 to entry: Examples of a failure cause may be contamination or inadequate lubrication which leads to the failure mode of bearing seizure.

Note 3 to entry: Failure causes for a process might include human error mechanisms such as stimulus overload, memory failure, misunderstanding, false assumption.

[SOURCE: IEC 60050-192:2015, 192-03-11, modified — Note 2 and Note 3 have been added.]

3.1.10
failure mechanism
process that leads to failure

Note 1 to entry: The process may be physical, chemical, logical, psychological or a combination thereof.

[SOURCE: IEC 60050-192:2015, 192-03-12, modified — Note 1 has been reworded.]

3.1.11
likelihood
chance of something happening

Note 1 to entry: In this document, the term “likelihood” is used to refer to the chance of something happening, whether defined, measured or determined objectively or subjectively, qualitatively or quantitatively, and described using general terms or mathematically [such as probability or a frequency over a given time period].

Note 2 to entry: The English term “likelihood” does not have a direct equivalent in some languages; instead, the equivalent of the term “probability” is often used. However, in English, “probability” is often narrowly interpreted as a mathematical term. Therefore, in terminology used in this document, the term “likelihood” is used with the intent that it should have the same broad interpretation as the term “probability” has in many languages other than English.

[SOURCE: ISO Guide 73:2009, 3.6.1.1, modified — Note 1 and Note 2 have been reworded.]

3.1.12
severity
relative ranking of potential or actual consequences of a failure or a fault

Note 1 to entry: The severity may be related to any consequence.

[SOURCE: EN 13306:2010, 5.13, modified — “relative ranking” has been added.]

3.1.13
detection method
means by which a failure mode or incipient failure become evident

3.1.14
control
design features, or other existing provisions, that have the ability to prevent or reduce the likelihood of the failure mode or modify its effect

Note 1 to entry: Controls can also be referred to as compensating provisions.

3.1.15
criticality
<of a failure mode> importance ranking determined using a specified evaluation criteria

Note 1 to entry: The criticality evaluation criteria normally refer to the effects of the failure mode on the top-level in the system, item or process hierarchy.

Note 2 to entry: Criticality measures normally combine severity of effect with at least one other characteristic of a failure mode.

Note 3 to entry: The specific meaning of criticality is dependent upon the evaluation method defined within an analysis and is discussed in detail within this document.

Note 4 to entry: Criticality relates to the failure mode and not to the failure causes (if the latter are identified at all).

3.1.16
treatment
action to modify the likelihood and/or effects of a failure mode

Note 1 to entry: Treatment is sometimes referred to as mitigation.

Note 2 to entry: Treatment may involve actions to eliminate the failure cause, change the likelihood of the failure mode occurring, and/or change the consequences.

3.1.17
human error
discrepancy between the human action taken or omitted, and that intended or required

EXAMPLE Performing an incorrect action; omitting a required action; miscalculation; misreading a value.

[SOURCE: IEC 60050-192:2015, 192-03-14]

3.1.18
redundancy
<in a system> provision of more than one means for performing a function

Note 1 to entry: The additional means of performing the function can be intentionally different (diverse) to reduce the potential for common mode failures.

[SOURCE: IEC 60050-192:2015, 192-10-02]

3.1.19
common cause failures
failures of multiple items, which would otherwise be considered independent of one another resulting from a single cause

Note 1 to entry: Common cause failures can also be "common mode failures".

Note 2 to entry: The potential for common cause failures reduces the effectiveness of system redundancy.

[SOURCE: IEC 60050-192:2015, 192-03-18]

3.1.20
common mode failures
<within a system> failures of different items characterized by the same failure mode

Note 1 to entry: Common mode failures can have different causes.

Note 2 to entry: Common mode failures can also be “common cause failures”.

Note 3 to entry: The potential for common mode failures reduces the effectiveness of system redundancy.

[SOURCE: IEC 60050-192:2015, 192-03-19]

3.1.21
testability
<of an item> degree to which an item can be tested, during and after operation to detect and isolate failures/faults

[SOURCE: IEC 60050-192:2015, 192-09-20, modified — "during and after operation to detect and isolate failures/faults" has been added.]

3.2 Abbreviated terms

ARPN	alternative risk priority number
CCF	common cause failure
COTS	commercial off the shelf
CSU	component software unit
DC	diagnostic coverage
EMI	electromagnetic interference
EMP	electromagnetic pulse
ESD	emergency shutdown
ETA	event tree analysis
FIT	failure in time
FTA	fault tree analysis
FMEA	failure modes and effects analysis
FMECA	failure modes, effects and criticality analysis
FMEDA	failure modes, effects and diagnostic analysis
MTBF	mean operating time between failures
MTTR	mean time to restoration
OEM	original equipment manufacturer
RBD	reliability block diagram
RCM	reliability centred maintenance
RPN	risk priority number
SFF	safe failure fraction
SIL	safety integrity level
SOD	severity, occurrence and detectability