



SLOVENSKI STANDARD

SIST EN 60812:2007

01-januar-2007

Nadomešča:
SIST HD 485 S1:2004

Analizne tehnike za sistemsko zanesljivost – Postopek za analizo vrste okvar in njihovih učinkov (FMEA) (IEC 60812-2006)

Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)

Analysetechniken für die Funktionsfähigkeit von Systemen - Verfahren für die Fehlzustandsart- und -auswirkungsanalyse (FMEA)

Techniques d'analyse de la fiabilité du système - Procédure d'analyse des modes de défaillance et de leurs effets (AMDE)

Ta slovenski standard je istoveten z: EN 60812:2006

ICS:

21.020	Značilnosti in načrtovanje strojev, aparatov, opreme	Characteristics and design of machines, apparatus, equipment
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SIST EN 60812:2007 en

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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN 60812

May 2006

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Supersedes HD 485 S1:1987

English version

**Analysis techniques for system reliability –
Procedure for failure mode and effects analysis (FMEA)
(IEC 60812:2006)**

Techniques d'analyse
de la fiabilité du système –
Procédure d'analyse des modes
de défaillance et de leurs effets (AMDE)
(CEI 60812:2006)

Analysetechniken für
die Funktionsfähigkeit von Systemen –
Verfahren für die Fehlzustandsart-
und -auswirkungsanalyse (FMEA)
(IEC 60812:2006)

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This European Standard was approved by CENELEC on 2006-03-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 56/1072/FDIS, future edition 2 of IEC 60812, prepared by IEC TC 56, Dependability, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60812 on 2006-03-01.

This European Standard supersedes HD 485 S1:1987.

The main changes from HD 485 S1:1987 are as follows:

- introduction of the failure modes effects and criticality concepts;
- inclusion of the methods used widely in the automotive industry;
- added references and relationships to other failure modes analysis methods;
- added examples;
- guidance on advantages and disadvantages of different FMEA methods.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2006-12-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2009-03-01

Annex ZA has been added by CENELEC.

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Endorsement notice

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The text of the International Standard IEC 60812:2006 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 60300-1:2003 (not modified).
IEC 60300-2	NOTE	Harmonized as EN 60300-2:2004 (not modified).
IEC 61160	NOTE	Harmonized as EN 61160:2005 (not modified).
ISO 9000	NOTE	Harmonized as EN ISO 9000:2000 (not modified).

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60300-3-1	2003	Dependability management Part 3-1: Application guide - Analysis techniques for dependability - Guide on methodology	EN 60300-3-1	2004
IEC 61025	- ¹⁾	Fault tree analysis (FTA)	HD 617 S1	1992 ²⁾
IEC 61078	- ¹⁾	Analysis techniques for dependability - Reliability block diagram and Boolean methods	EN 61078	2006 ²⁾

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¹⁾ Undated reference.

²⁾ Valid edition at date of issue.

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INTERNATIONAL STANDARD

IEC 60812

Second edition
2006-01

Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ANALYSIS TECHNIQUES FOR SYSTEM RELIABILITY –
PROCEDURE FOR FAILURE MODE
AND EFFECTS ANALYSIS (FMEA)**

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 second edition cancels and replaces the first edition published in 1985 and constitutes a technical revision.

The main changes from the previous edition are as follows:

- introduction of the failure modes effects and criticality concepts;
- inclusion of the methods used widely in the automotive industry;
- added references and relationships to other failure modes analysis methods;
- added examples;
- provided guidance of advantages and disadvantages of different FMEA methods.

The text of this standard is based on the following documents:

FDIS	Report on voting
56/1072/FDIS	56/1091/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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ANALYSIS TECHNIQUES FOR SYSTEM RELIABILITY – PROCEDURE FOR FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

1 Scope

This International Standard describes Failure Mode and Effects Analysis (FMEA) and Failure Mode, Effects and Criticality Analysis (FMECA), and gives guidance as to how they may be applied to achieve various objectives by

- providing the procedural steps necessary to perform an analysis;
- identifying appropriate terms, assumptions, criticality measures, failure modes;
- defining basic principles;
- providing examples of the necessary worksheets or other tabular forms.

All the general qualitative considerations presented for FMEA will apply to FMECA, since the latter is an extension of the other.

2 Normative references

The following referenced documents are indispensable for the application 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 60300-3-1:2003, *Dependability management – Part 3-1: Application guide – Analysis techniques for dependability – Guide on methodology*

IEC 61025, *Fault tree analysis (FTA)*

IEC 61078, *Analysis techniques for dependability – Reliability block diagram method*

3 Terms and definitions

For the purposes of this document, the following definitions apply.

3.1

item

any part, component, device, subsystem, functional unit, equipment or system that can be individually considered

NOTE 1 An item may consist of hardware, software or both, and may also in particular cases include people.

NOTE 2 A number of items, e.g. a population of items or a sample, may itself be considered as an item.

[IEV 191-01-01]

A process can also be defined as an item which carries out a predetermined function and for which a process FMEA or FMECA is carried out. Normally, a hardware FMEA does not address people and their interactions with hardware/software, while a process FMEA normally includes actions of people.

3.2

failure

termination of the ability of an item to perform a required function

[IEV 191-04-01]

3.3

fault

state of an item characterized by the inability to perform a required function, excluding the inability during preventive maintenance or other planned actions, or due to lack of external resources

NOTE 1 A fault is often the result of a failure of the item itself, but may exist without prior failure.

[IEV 191-05-01]

NOTE 2 In this document “fault” is used interchangeably with the term “failure” for historical reasons.

3.4

failure effect

consequence of a failure mode in terms of the operation, function or status of the item

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3.5

failure mode

manner in which an item fails

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3.6

failure criticality

combination of the severity of an effect and the frequency of its occurrence or other attributes of a failure as a measure of the need for addressing and mitigation

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3.7

system

set of interrelated or interacting elements

NOTE 1 In the context of dependability, a system will have

- a) defined purposes expressed in terms of required functions;
- b) stated conditions of operation use (see 191-01-12);
- c) a defined boundary.

NOTE 2 The structure of a system is hierarchical.

[ISO 9000:2000]

3.8

failure severity

significance or grading of the failure mode's effect on item operation, on the item surrounding, or on the item operator; failure mode effect severity as related to the defined boundaries of the analysed system

4 Overview

4.1 Introduction

Failure Modes and Effect Analysis (FMEA) is a systematic procedure for the analysis of a system to identify the potential failure modes, their causes and effects on system performance (performance of the immediate assembly and the entire system or a process). Here, the term system is used as a representation of hardware, software (with their interaction) or a process. The analysis is successfully performed preferably early in the development cycle so that removal or mitigation of the failure mode is most cost effective. This analysis can be initiated as soon as the system is defined enough to be presented as a functional block diagram where performance of its elements can be defined.

FMEA timing is essential; if done early enough in the development cycle, then incorporating the design changes to overcome deficiencies identified by the FMEA may be cost effective. It is therefore important that the FMEA task and its deliverables be incorporated into the development plan and schedule. Thus, FMEA is an iterative process that takes place coincidentally with design process.

FMEA is applicable at various levels of system decomposition from the highest level of block diagram down to the functions of discrete components or software commands. The FMEA is also an iterative process that is updated as the design develops. Design changes will require that relevant parts of the FMEA be reviewed and updated.

A thorough FMEA is a result of a team composed of individuals qualified to recognize and assess the magnitude and consequences of various types of potential inadequacies in the product design that might lead to failures. Advantage of the team work is that it stimulates thought process, and ensures necessary expertise.

FMEA is considered to be a method to identify the severity of potential failure modes and to provide an input to mitigating measures to reduce risk. In some applications however, FMEA also includes an estimation of the probability of occurrence of the failure modes. This enhances the analysis by providing a measure of the failure mode's likelihood.

Application of FMEA is preceded by a hierarchical decomposition of the system (hardware with software, or a process) into its more basic elements. It is useful to employ simple block diagrams to illustrate this decomposition (IEC 61078). The analysis then starts with lowest level elements. A failure mode effect at a lower level may then become a failure cause of a failure mode of an item in the next higher level. The analysis proceeds in a bottom-up fashion until the end effect on the system is identified. Figure 1 illustrates this relationship.

FMECA (Failure Modes, Effects and Criticality Analysis) is an extension to the FMEA to include a means of ranking the severity of the failure modes to allow prioritization of countermeasures. This is done by combining the severity measure and frequency of occurrence to produce a metric called criticality.

The principles of an FMEA may be applied outside of engineering design. FMEA procedure can be applied to a manufacturing or any other work process such as in hospitals, medical laboratories, school systems, or others. When FMEA is applied to a manufacturing process,

this procedure is known in industry as the Process FMEA, or PFMEA. For an FMEA to be effective, adequate resources for a team work have to be committed. A thorough understanding of the system under analysis may not be essential for a preliminary FMEA. With development of design, a detailed failure mode analysis requires thorough knowledge of the design performance and its specifications. Complex engineering designs usually require the involvement of multiple areas of design expertise (e.g. mechanical engineering, electrical engineering, systems engineering, software engineering, maintenance support, etc).

FMEA generally deals with individual failure modes and the effect of these failure modes on the system. Each failure mode is treated as independent. The procedure is therefore unsuitable for consideration of dependent failures or failures resulting from a sequence of events. To analyse these situations other methods and techniques, such as Markov analysis (see IEC 61165) or fault tree analysis (see IEC 61025), may be required.

In determining the impact of a failure, one must consider higher level induced – resultant failures and possibly the same level of induced failures. The analysis should indicate, wherever possible the combination of failure modes or their sequence that was a cause of a higher level effect. In that case additional modelling is required to estimate the magnitude or probability of occurrence of such an effect.

FMEA is a flexible tool that can be tailored to meet specific industry or product needs. Specialized worksheets requiring specific entries may be adapted for certain applications. If severity levels of failure modes are defined, they may be defined differently for different systems or different system levels.

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4.2 Purpose and objectives of the analysis

The reasons for undertaking Failure Mode Effects Analysis (FMEA) or Failure Mode Effects and Criticality Analysis (FMECA) may include the following:

- a) to identify those failures which have unwanted effects on system operation, e.g. preclude or significantly degrade operation or affect the safety of the user;
- b) to satisfy contractual requirements of a customer, as applicable;
- c) to allow improvements of the system's reliability or safety (e.g. by design modifications or quality assurance actions);
- d) to allow improvement of the system's maintainability (by highlighting areas of risk or nonconformity for maintainability).

In view of the above reasons for undertaking a FMEA effort, the objectives of an FMEA (or FMECA) may include the following:

- a) a comprehensive identification and evaluation of all the unwanted effects within the defined boundaries of the system being analysed, and the sequences of events brought about by each identified item failure mode, from whatever cause, at various levels of the system's functional hierarchy;
- b) the determination of the criticality or priority for addressing/mitigation (see Clause 6) of each failure mode with respect to the system's correct function or performance and the impact on the process concerned;