

Australian/New Zealand Standard™

Failure modes and effects analysis (FMEA and FMECA)



AS/NZS IEC 60812:2020

This Joint Australian/New Zealand Standard™ was prepared by Joint Technical Committee QR-005, Dependability. It was approved on behalf of the Council of Standards Australia on 23 March 2020 and by the New Zealand Standards Approval Board on 5 February 2020.

This Standard was published on 3 April 2020.

The following are represented on Committee QR-005:

- Asset Management Council (Australia)
- Australian Industry Group
- Department of Defence (Australian Government)
- Engineering New Zealand
- Engineers Australia
- Human Factors and Ergonomics Society of New Zealand
- Institution of Occupational Safety and Health
- National Rail Safety Regulator (Australia)
- National Road Carriers Association (New Zealand)
- New Zealand Institute of Safety Management
- Professionals Australia
- Risk Engineering Society (Australia)
- Risk Management Institute of Australasia
- RiskNZ
- University of New South Wales
- University of Western Australia
- University of Wollongong

This Standard was issued in draft form for comment as DR AS/NZS IEC 60812:2019.

Keeping Standards up-to-date

Ensure you have the latest versions of our publications and keep up-to-date about Amendments, Rulings, Withdrawals, and new projects by visiting:

www.standards.org.au

www.standards.govt.nz

ISBN 978 1 76072 792 5

This is a preview. [Click here to purchase the full publication.](#)

Australian/New Zealand Standard™

Failure modes and effects analysis (FMEA and FMECA)

Originated as AS IEC 60812—2008.
Revised and redesignated as AS/NZS IEC 60812:2020.

COPYRIGHT

© IEC 2020 — All rights reserved
© Standards Australia Limited/the Crown in right of New Zealand, administered by the New Zealand Standards Executive 2020

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968 (Cth) or the Copyright Act 1994 (New Zealand).

Preface

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee QR-005, Dependability, to supersede AS IEC 60812—2008, *Analysis techniques for system reliability — Procedure for failure mode and effects analysis (FMEA)*.

The objective of this Standard is to explain 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 application.

This Standard is identical with, and has been reproduced from, IEC 60812:2018, *Failure modes and effects analysis (FMEA and FMECA)*.

As this document has been reproduced from an International Standard, a full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a Standard, whereas an “informative” appendix or annex is only for information and guidance.

NOTES

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.