

## 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