AIAG | Automotive Industry Action Group

VDA | Verband der Automobilindustrie

Failure Mode and Effect Analysis

FMEA

Design FMEA and Process FMEA - Handbook

1st Edition 2019

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FOREWORD

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TABLE OF CONTENTS

FOREWORD **3**

ACKNOWLEDGEMENTS **4**

TABLE OF CONTENTS **7**

1 INTRODUCTION **17**

1.1 PURPOSE AND DESCRIPTION 17
1.2 OBJECTIVES AND LIMITS OF FMEA 18
1.3 INTEGRATION OF FMEA IN THE COMPANY 19
1.3.1 Potential Considerations of the FMEA *19*
1.3.2 Senior Management commitment *20*
1.3.3 Know-How Protection of the Design FMEA/Process FMEA *20*
1.3.4 Agreements between Customers and Suppliers *20*
1.3.5 Transition Strategy *21*
1.3.6 Foundation and Family FMEAs *21*
1.4 FMEA FOR PRODUCTS AND PROCESSES 22
1.4.1 Design FMEA *23*
1.4.2 Process FMEA *23*
1.4.3 Collaboration between FMEAs *24*
1.5 PROJECT PLANNING 25
1.5.1 FMEA InTent *25*
1.5.2 FMEA Timing *25*
1.5.3 FMEA Team *27*
1.5.4 FMEA Tasks *30*
1.5.5 FMEA Tools *30*
1.6 FMEA METHODOLOGY 30

2 EXECUTION OF THE DESIGN FMEA **33**

2.1 DESIGN FMEA 1ST STEP: PLANNING AND PREPARATION 33
2.1.1 Purpose *33*
2.1.2 DFMEA Project Identification and Boundaries *33*
2.1.3 DFMEA Project Plan *34*
2.1.4 Identification of the Baseline DFMEA *34*
2.1.5 DFMEA Header *35*
2.1.6 Basis for Structure Analysis *35*
2.2 DESIGN FMEA 2ND STEP: STRUCTURE ANALYSIS 36
2.2.1 Purpose *36*
2.2.2 System Structure *36*
2.2.3 Define the Customer *36*
2.2.4 Visualize System Structure *37*
2.2.5 Collaboration between Customer and Supplier *42*
2.2.6 Basis for Function Analysis *42*
2.3 DESIGN FMEA 3RD STEP: FUNCTION ANALYSIS 42
2.3.1 Purpose *42*
2.3.2 Function *43*
2.3.3 Requirements *43*
2.3.4 Parameter Diagram (P-Diagram) *44*
2.3.5 Function Analysis *47*
2.3.6 Collaboration between Engineering Teams (Systems, Safety, and Components) *49*

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2.3.7 Basis for Failure Analysis *50*
2.4 DESIGN FMEA 4TH STEP: FAILURE ANALYSIS 50
2.4.1 Purpose *50*
2.4.2 Failures *50*
2.4.3 The Failure Chain *52*
2.4.4 Failure Effects *53*
2.4.5 Failure Mode *53*
2.4.6 Failure Cause *54*
2.4.7 Failure Analysis *55*
2.4.8 Failure Analysis Documentation *58*
2.4.9 Collaboration between Customer and Supplier (Failure Effects) *59*
2.4.10 Basis for Risk Analysis *59*
2.5 DESIGN FMEA 5TH STEP: RISK ANALYSIS 59
2.5.1 Purpose *59*
2.5.2 Design Controls *59*
2.5.3 Current Prevention Controls (PC) *60*
2.5.4 Current Detection Controls (DC) *61*
2.5.5 Confirmation of Current Prevention and Detection Controls *62*
2.5.6 Evaluations *63*
2.5.7 Severity (S) *63*
2.5.8 Occurrence (O) *64*
2.5.9 Detection (D) *69*
2.5.10 Action Priority (AP) *70*
2.5.11 Collaboration between Customer and Supplier (Severity) *75*
2.5.12 Basis for Optimization *76*
2.6 DESIGN FMEA 6TH STEP: OPTIMIZATION 76
2.6.1 Purpose *76*
2.6.2 Assignment of Responsibilities *77*
2.6.3 Status of the Actions *77*
2.6.4 Assessment of Action Effectiveness *78*
2.6.5 Continual Improvement *78*
2.6.6 Collaboration between the FMEA team, Management, Customers, and Suppliers regarding Potential Failures *79*
2.7 DESIGN FMEA 7TH STEP: RESULTS DOCUMENTATION 79

3 EXECUTION OF THE PROCESS FMEA (PFMEA) 81

3.1 PROCESS FMEA 1ST STEP: PLANNING AND PREPARATION 81
3.1.1 Purpose *81*
3.1.2 PFMEA Project Identification and Boundaries *81*
3.1.3 PFMEA Project Plan *84*
3.1.4 Identification of the Baseline PFMEA *84*
3.1.5 Process FMEA Header *84*
3.2 PROCESS FMEA 2ND STEP: STRUCTURE ANALYSIS 85
3.2.1 Purpose *85*
3.2.2 Process Flow Diagram *86*
3.2.3 Structure Tree *86*
3.2.4 Collaboration between Customer and Supplier engineering teams (interface responsibilities) *89*
3.2.5 Basis for Function Analysis *89*
3.3 PROCESS FMEA 3RD STEP: FUNCTION ANALYSIS 90
3.3.1 Purpose *90*
3.3.2 Function *90*
3.3.3 Requirement(s) (Characteristics) *91*

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3.3.4 Visualization of functional relationships *93*
3.3.5 Collaboration between Engineering Teams (Systems, Safety, and Components) *95*
3.3.6 Basis for Failure Analysis *95*
3.4 PROCESS FMEA 4TH STEP: FAILURE ANALYSIS 95
3.4.1 Purpose *95*
3.4.2 Failures *95*
3.4.3 The Failure Chain *96*
3.4.4 Failure Effects *96*
3.4.5 Failure Mode *99*
3.4.6 Failure Cause: *100*
3.4.7 Failure Analysis *101*
3.4.8 Relationship between PFMEA and DFMEA *103*
3.4.9 Failure Analysis Documentation *104*
3.4.10 Collaboration between Customer and Supplier (Failure Effects) *105*
3.4.11 Basis for Risk Analysis *105*
3.5 PROCESS FMEA 5TH STEP: RISK ANALYSIS 105
3.5.1 Purpose *105*
3.5.2 Current Prevention Controls (PC) *106*
3.5.3 Current Detection Controls (DC) *107*
3.5.4 Current Prevention and Detection Controls *108*
3.5.5 Evaluations *108*
3.5.6 Severity (S) *109*
3.5.7 Occurrence (O) *111*
3.5.8 Detection (D) *113*
3.5.9 Action Priority (AP) *115*
3.5.10 Collaboration between Customer and Supplier (Severity) *119*
3.5.11 Basis for Optimization *120*
3.6 PROCESS FMEA 6TH STEP: OPTIMIZATION 120
3.6.1 Purpose *120*
3.6.2 Assignment of Responsibilities *121*
3.6.3 Status of the Actions *121*
3.6.4 Assessment of Action Effectiveness *122*
3.6.5 Continual Improvement *122*
3.6.6 Collaboration between the FMEA team, Management, Customers, and Suppliers regarding Potential Failures *123*
3.7 PROCESS FMEA 7TH STEP: RESULTS DOCUMENTATION 123

4 SUPPLEMENTAL FMEA FOR MONITORING AND SYSTEM RESPONSE (FMEA-MSR) 125

4.1 FMEA-MSR 1ST STEP: PLANNING AND PREPARATION 126
4.1.1 Purpose *126*
4.1.2 FMEA-MSR Project Identification and Boundaries *127*
4.1.3 FMEA-MSR Project Plan *128*
4.2 FMEA-MSR 2ND STEP: STRUCTURE ANALYSIS 129
4.2.1 Purpose *129*
4.2.2 Structure Trees *129*
4.3 FMEA-MSR 3RD STEP: FUNCTION ANALYSIS 131
4.3.1 Purpose *131*
4.4 FMEA-MSR 4TH STEP: FAILURE ANALYSIS 132
4.4.1 Purpose *132*
4.4.2 Failure Scenario *132*
4.4.3 Failure Cause *134*
4.4.4 Failure Mode *135*

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4.4.5 Failure Effect *136*
4.5 FMEA-MSR 5TH STEP: RISK ANALYSIS 137
4.5.1 Purpose *137*
4.5.2 Evaluations *137*
4.5.3 Severity (S) *137*
4.5.4 Rationale for Frequency Rating *138*
4.5.5 Frequency (F) *139*
4.5.6 Current Monitoring Controls *141*
4.5.7 Monitoring (M) *141*
4.5.8 Action Priority (AP) for FMEA-MSR *145*
4.6 FMEA-MSR 6TH STEP: OPTIMIZATION 150
4.6.1 Purpose *150*
4.6.2 Assignment of Responsibilities *151*
4.6.3 Status of the Actions *152*
4.6.4 Assessment of Action Effectiveness *152*
4.6.5 Continuous Improvement *153*
4.7 FMEA-MSR 7TH STEP: RESULTS DOCUMENTATION 154

APPENDICES 157

A DEVELOPMENT HISTORY OF THE FMEA 159
B CHANGE POINT SUMMARIES 161
B1 AIAG 4TH EDITION FMEA REFERENCE MANUAL TO AIAG-VDA FMEA HANDBOOK 161
B1.1 AIAG 4th Edition DFMEA to AIAG-VDA FMEA Handbook DFMEA *161*
B1.2 AIAG 4th Edition PFMEA to AIAG-VDA FMEA Handbook PFMEA *165*
B2 VDA VOLUME 4, CHAPTER PRODUCT AND PROCESS FMEA TO AIAG-VDA FMEA HANDBOOK 170
B2.1 VDA Volume 4, Chapter Product DFMEA to AIAG-VDA FMEA Handbook *170*
B2.2 VDA Volume 4, Chapter Product PFMEA to AIAG-VDA FMEA Handbook *174*
B2.3 VDA Volume 4, Chapter Product FMEA-MSR to AIAG-VDA FMEA Handbook *178*
C ADDITIONS 181
C1 Special Characteristics *181*
C2 FMEA and Functional Safety *181*
D FORM SHEETS 184
D1 DFMEA Form Sheet *184*
D1.1 DFMEA Form Sheet Step 1 ..... *184*
D1.2 DFMEA Form Sheet Step 2 ..... *185*
D1.3 DFMEA Form Sheet Step 3 ..... *186*
D1.4 DFMEA Form Sheet Step 4 ..... *187*
D1.5 DFMEA Form Sheet Step 5 ..... *189*
D1.6 DFMEA Form Sheet Step 6 ..... *191*
D1.7 DFMEA Form Sheet Step 7 ..... *192*
D1.8 DFMEA Software Examples *193*
D2 PFMEA Form Sheet *195*
D2.1 PFMEA Form Sheet Step 1 ..... *195*
D2.2 PFMEA Form Sheet Step 2 ..... *196*
D2.3 PFMEA Form Sheet Step 3 ..... *197*
D2.4 PFMEA Form Sheet Step 4 ..... *198*
D2.5 PFMEA Form Sheet Step 5 ..... *199*
D2.6 PFMEA Form Sheet Step 6 ..... *201*
D2.7 PFMEA Form Sheet Step 7 ..... *202*
D2.8 PFMEA Software Examples *203*
D3 FMEA-MSR Form Sheet Template *208*
D3.1 FMEA-MSR Form Sheet Step 1 ..... *208*

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D3.2 FMEA-MSR Form Sheet Step 2 ..... *209*
D3.3 FMEA-MSR Form Sheet Step 3 ..... *210*
D3.4 FMEA-MSR Form Sheet Step 4 ..... *211*
D3.5 FMEA-MSR Form Sheet Step 5 ..... *212*
D3.6 FMEA-MSR Form Sheet Step 6 ..... *214*
D3.7 FMEA-MSR Form Sheet Step 7 ..... *215*
D3.8 FMEA-MSR Software Examples *216*
D4.0 Customer Specific Requirements Form Sheets *218*
D4.1 GM and FCA DFMEA Form Sheet *218*
D4.2 Ford DFMEA Form Sheet *218*
D4.3 GM and FCA PFMEA Form Sheet *218*
D4.4 Ford PFMEA Form Sheet *218*
E Further Application Fields 219
E1 FMEA for Software Scopes *219*
E2 Objective of the Software Scopes Inspection *219*
E3 FMEA in the Software Development Process *219*
E4 FMEA for Machine and Facility Manufacturers *219*
F: Severity, Occurrence, Detection and Action Priority Tables 221
F1 DFMEA SOD Tables *221*
F1.1 DFMEA SEVERITY (S) *221*
F1.2 DFMEA OCCURRENCE (O) *222*
F1.3 DFMEA DETECTION (D) *228*
F1.4 ACTION PRIORITY TABLE FOR DFMEA *229*
F2 PFMEA SOD Tables *231*
F2.1 PFMEA SEVERITY (S) *231*
F2.2 PFMEA OCCURRENCE (O) *234*
F2.3 PFMEA DETECTION (D) *237*
F2.4 ACTION PRIORITY TABLE FOR PFMEA *239*
F3 FMEA-MSR Tables *241*
F3.1 Supplemental FMEA-MSR SEVERITY (S) *241*
F3.2 Supplemental FMEA-MSR FREQUENCY (F) *242*
F3.3 Supplemental FMEA-MSR MONITORING (M) *244*
F3.4 ACTION PRIORITY FOR FMEA-MSR *246*
G References and Suggested Readings 249
H Glossary 250

Table of Figures

Figure 1.1-1 Aspects of Risks 18
Figure 1.4-1 FMEA Collaboration 24
Figure 1.5-1 FMEA Timing Aligned with APQP Phases 26
Figure 1.5-2 FMEA Timing Aligned to MLA Phases 26
FIGURE 1.6-1 FMEA SEVEN STEP APPROACH 29
Figure 2.1-1 Example of Completed DFMEA Header Planning and Preparation Step 1 35
Figure 2.2-1 Example of Block/Boundary Diagram 39
Figure 2.2-2 Example of Structure Analysis Structure Tree 41
Figure 2.2-3 Example of Structure Analysis Form 41
Figure 2.3-1 Input/Interface/Output Flow 43
Figure 2.3-2 Example of system behavior 45
Figure 2.3-3 Example of Parameter Diagram with Electrical Motor 47

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FIGURE 2.3-4 EXAMPLE OF FUNCTION ANALYSIS STRUCTURE TREE....48
FIGURE 2.3-5 EXAMPLE OF FUNCTION ANALYSIS FORM....49
FIGURE 2.4-1 TYPES OF FAILURE MODES....51
FIGURE 2.4-2 DEFINITION OF A FAILURE....52
FIGURE 2.4-3 THEORETICAL FAILURE CHAIN MODEL....52
FIGURE 2.4-4 FAILURE STRUCTURE AT DIFFERENT LEVELS....56
FIGURE 2.4-5 EXAMPLE OF FAILURE ANALYSIS STRUCTURE TREE....57
FIGURE 2.4-6 EXAMPLE OF FAILURE ANALYSIS FORM....57
FIGURE 2.4-7 VIEW OF PRODUCT END ITEM-FUNCTION-FAILURE FORM....58
FIGURE 2.4-8 VIEW OF FOCUS ITEM/ELEMENT-FUNCTION-FAILURE FORM....58
FIGURE 2.4-9 VIEW OF LOWER LEVEL ITEM-FUNCTION-FAILURE FORM....58
FIGURE 2.5-1 PREVENTION AND DETECTION IN THE DESIGN FMEA....62
FIGURE 2.5-2 ROADMAP OF DESIGN UNDERSTANDING....62
FIGURE 2.5-3 EXAMPLE OF DFMEA RISK ANALYSIS FORM....75
FIGURE 2.6-1 EXAMPLE OF DFMEA OPTIMIZATION WITH NEW RISK EVALUATION FORM....79
FIGURE 3.1-1 DEMONSTRATION OF THE PROCESS FOR NARROWING THE PREPARATION....83
FIGURE 3.1-2 EXAMPLE OF COMPLETED PFMEA HEADER PREPARATION (STEP 1)....85
FIGURE 3.2-1 PROCESS FLOW DIAGRAM....86
FIGURE 3.2-2 EXAMPLE OF STRUCTURE ANALYSIS STRUCTURE TREE (ELECTRICAL MOTOR ASSEMBLY LINE)....87
FIGURE 3.2-3 PROCESS ITEM....87
FIGURE 3.2-4 PROCESS STEPS....88
FIGURE 3.2-5 EXAMPLE OF STRUCTURE ANALYSIS FORM....89
FIGURE 3.3-1 EXAMPLE OF PARAMETER DIAGRAM OF PRESS IN SINTERED BEARING....93
FIGURE 3.3-2 EXAMPLE OF FUNCTION ANALYSIS STRUCTURE TREE....94
FIGURE 3.3-3 EXAMPLE OF FUNCTION ANALYSIS FORM....94
FIGURE 3.4-1 THEORETICAL FAILURE CHAIN MODEL....96
FIGURE 3.4-2 EXAMPLE OF FAILURE ANALYSIS STRUCTURE TREE....102
FIGURE 3.4-3 EXAMPLE OF FAILURE ANALYSIS FORM....102
FIGURE 3.4-4 RELATIONSHIP BETWEEN PFMEA AND DFMEA....104
FIGURE 3.4-5 VIEW OF PROCESS ITEM-FUNCTION-FAILURE FORM....104
FIGURE 3.4-6 VIEW OF PROCESS STEP-FUNCTION-FAILURE FORM....105
FIGURE 3.4-7 VIEW OF PROCESS WORK ELEMENT-FUNCTION-FAILURE FORM....105
FIGURE 3.5-1 PREVENTION AND DETECTION IN THE PROCESS FMEA....107
FIGURE 3.5-2 ROADMAP OF PROCESS UNDERSTANDING....108
FIGURE 3.5-3 EXAMPLE OF PFMEA WITH RISK ANALYSIS FORM....119
FIGURE 3.6-1 EXAMPLE OF PFMEA OPTIMIZATION WITH NEW RISK EVALUATION FORM....123
FIGURE 4.1-1 GENERIC BLOCK DIAGRAM OF AN ELECTRICAL / ELECTRONIC / PROGRAMMABLE ELECTRONIC SYSTEM....128
FIGURE 4.2-1 EXAMPLE OF A STRUCTURE TREE OF A WINDOW LIFT SYSTEM FOR INVESTIGATING ERRONEOUS SIGNALS, MONITORING, AND SYSTEM RESPONSE....129
FIGURE 4.2-2 EXAMPLE OF A STRUCTURE TREE OF A SMART SENSOR WITH AN INTERNAL SENSING ELEMENT AND OUTPUT TO AN INTERFACE 130
FIGURE 4.2-3 EXAMPLE OF STRUCTURE ANALYSIS IN THE FMEA-MSR FORM....130
FIGURE 4.3-1 EXAMPLE OF A STRUCTURE TREE WITH FUNCTIONS STRUCTURE TREE....132
FIGURE 4.3-2 EXAMPLE OF FUNCTION ANALYSIS IN FMEA-MSR FORM....132
FIGURE 4.4-1 THEORETICAL FAILURE CHAIN MODEL DFMEA AND FMEA-MSR....133
FIGURE 4.4-2 FAILURE SCENARIO (1) - NON-HAZARDOUS....133
FIGURE 4.4-3 FAILURE SCENARIO (2) - HAZARDOUS....134
FIGURE 4.4-4 FAILURE SCENARIO (3) - MITIGATED (EFFECT)....134
FIGURE 4.4-5 EXAMPLE OF A STRUCTURE WITH FAILURE CHAIN WITHOUT A MONITORING OR WITH A MONITORING WHICH IS ONLY PARTIALLY EFFECTIVE (SCENARIO (1) AND (2)).....136
FIGURE 4.4-6 EXAMPLE OF A STRUCTURE WITH HYBRID FAILURE CHAIN INCLUDING A MONITORING WHICH ALWAYS IS EFFECTIVE AND SWITCHES THE SYSTEM TO A MITIGATED FAILURE EFFECT (SCENARIO (3)).....136

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FIGURE 4.4-7 EXAMPLE OF A FAILURE NETWORK 136
FIGURE 4.4-8 EXAMPLE OF FAILURE ANALYSIS IN FMEA-MSR FORM 136
FIGURE 4.5-1 FMEA-MSR MONITORING NOT IMPLEMENTED OR NOT CONSIDERED 142
FIGURE 4.5-2 FMEA-MSR RELIABLE DIAGNOSTIC MONITORING 142
FIGURE 4.5-3 FMEA-MSR DIAGNOSTIC MONITORING PARTIALLY EFFECTIVE 143
FIGURE 4.5-4 EXAMPLE OF FMEA-MSR RISK ANALYSIS - EVALUATION OF CURRENT RISK FORM 150
FIGURE 4.6-1 EXAMPLE OF FMEA-MSR OPTIMIZATION WITH NEW RISK EVALUATION FORM 153
FIGURE C2-1 LINKAGE BETWEEN FAILURE CAUSES IN FMEA-MSR TO FAULTS IN ISO 26262 183
FIGURE D1.1-1 BLANK DFMEA FORM: STEP 1 184
FIGURE D1.1-2 DFMEA FORM WITH HINTS: STEP 1 184
FIGURE D1.1-3 COMPLETED DFMEA FORM: STEP 1 184
FIGURE D1.2-1 BLANK DFMEA FORM: STEP 2 185
FIGURE D1.2-2 DFMEA FORM WITH HINTS: STEP 2 185
FIGURE D1.2-3 COMPLETED DFMEA FORM: STEP 2 185
FIGURE D1.3-1 BLANK DFMEA FORM: STEP 3 186
FIGURE D1.3-2 DFMEA FORM WITH HINTS: STEP 3 186
FIGURE D1.3-3 COMPLETED DFMEA FORM: STEP 3 186
FIGURE D1.4-1 BLANK DFMEA FORM: STEP 4 187
FIGURE D1.4-2 DFMEA FORM WITH HINTS: STEP 4 187
FIGURE D1.4-3 COMPLETED DFMEA FORM: STEP 4 188
FIGURE D1.5-1 BLANK DFMEA FORM: STEP 5 189
FIGURE D1.5-2 DFMEA FORM WITH HINTS: STEP 5 189
FIGURE D1.5-3 COMPLETED DFMEA FORM: STEP 5 190
FIGURE D1.6-1 BLANK DFMEA FORM: STEP 6 191
FIGURE D1.6-2 DFMEA FORM WITH HINTS: STEP 6 191
FIGURE D1.6-3 COMPLETED DFMEA FORM: STEP 6 191
FIGURE D1.8-1 DFMEA FAILURE STRUCTURE (SOFTWARE VIEW) 193
FIGURE D1.8-2 DFMEA RISK ANALYSIS (SOFTWARE VIEW) 193
FIGURE D1.8-3 DFMEA OPTIMIZATION WITH NEW RISK EVALUATION (SOFTWARE VIEW) 194
FIGURE D2.1-1 BLANK PFMEA FORM: STEP 1 195
FIGURE D2.1-2 PFMEA FORM WITH HINTS: STEP 1 195
FIGURE D2.1-3 COMPLETED PFMEA FORM: STEP 1 195
FIGURE D2.2-1 BLANK PFMEA FORM: STEP 2 196
FIGURE D2.2-2 PFMEA FORM WITH HINTS: STEP 2 196
FIGURE D2.2-3 COMPLETED PFMEA FORM: STEP 2 196
FIGURE D2.3-1 BLANK PFMEA FORM: STEP 3 197
FIGURE D2.3-2 PFMEA FORM WITH HINTS: STEP 3 197
FIGURE D2.3-3 COMPLETED PFMEA FORM: STEP 3 197
FIGURE D2.4-1 BLANK PFMEA FORM: STEP 4 198
FIGURE D2.4-2 PFMEA FORM WITH HINTS: STEP 4 198
FIGURE D2.4-3 COMPLETED PFMEA FORM: STEP 4 198
FIGURE D2.5-1 BLANK PFMEA FORM: STEP 5 199
FIGURE D2.5-2 PFMEA FORM WITH HINTS: STEP 5 199
FIGURE D2.5-3 COMPLETED PFMEA FORM: STEP 5 200
FIGURE D2.6-1 BLANK PFMEA FORM: STEP 6 201
FIGURE D2.6-2 PFMEA FORM WITH HINTS: STEP 6 201
FIGURE D2.6-3 COMPLETED PFMEA FORM: STEP 6 201
FIGURE D2.8-1 PFMEA FAILURE STRUCTURE (SOFTWARE VIEW) 203
FIGURE D2.8-2 PFMEA WITH RISK ANALYSIS (SOFTWARE VIEW) 203
FIGURE D2.8-3 PFMEA OPTIMIZATION WITH NEW RISK EVALUATION (SOFTWARE VIEW) 204
FIGURE D3-7 PFMEA FAILURE STRUCTURE (SPREADSHEET VIEW) OPTIONAL 205
FIGURE D3-8 PFMEA FAILURE STRUCTURE (SPREADSHEET) OPTIONAL: 206

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FIGURE D3-9 PFMEA FAILURE STRUCTURE (SPREADSHEET) OPTIONAL:....206
FIGURE D3-10 PFMEA FAILURE STRUCTURE (SOFTWARE) OPTIONAL:....207
FIGURE D4-7 PROCESS FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA) HINTS OPTIONAL: SPLIT OF FUNCTION AND CHARACTERISTICS – STEP 3....207
FIGURE D3.1-1 BLANK FMEA-MSR FORM: STEP 1....208
FIGURE D3.1-2 FMEA-MSR FORM WITH HINTS: STEP 1....208
FIGURE D3.1-3 COMPLETED FMEA-MSR FORM: STEP 1....208
FIGURE D3.2-1 BLANK FMEA-MSR FORM: STEP 2....209
FIGURE D3.2-2 FMEA-MSR FORM WITH HINTS: STEP 2....209
FIGURE D3.2-3 COMPLETED FMEA-MSR FORM: STEP 2....209
FIGURE D3.3-1 BLANK FMEA-MSR FORM: STEP 3....210
FIGURE D3.3-2 FMEA-MSR FORM WITH HINTS: STEP 3....210
FIGURE D3.3-3 COMPLETED FMEA-MSR FORM: STEP 3....210
FIGURE D3.4-1 BLANK FMEA-MSR FORM: STEP 4....211
FIGURE D3.4-2 FMEA-MSR FORM WITH HINTS: STEP 4....211
FIGURE D3.4-3 COMPLETED FMEA-MSR FORM: STEP 4....211
FIGURE D3.5-1 BLANK FMEA-MSR FORM: STEP 5....212
FIGURE D3.5-2 FMEA-MSR FORM WITH HINTS: STEP 5....212
FIGURE D3.5-3 COMPLETED FMEA-MSR FORM: STEP 5....213
FIGURE D3.6-1 BLANK FMEA-MSR FORM: STEP 6....214
FIGURE D3.6-2 FMEA-MSR FORM WITH HINTS: STEP 6....214
FIGURE D3.6-3 COMPLETED FMEA-MSR FORM: STEP 6....214
FIGURE D3.8-1 FMEA-MSR FAILURE STRUCTURE (SOFTWARE VIEW)....216
FIGURE D3.8-2 FMEA-MSR RISK ANALYSIS (SOFTWARE VIEW)....216
FIGURE D3.8-3 FMEA-MSR OPTIMIZATION WITH NEW RISK EVALUATION (SOFTWARE VIEW)....217

Table of Tables

FIGURE 1.6-1 FMEA 7 STEP APPROACH....31
TABLE D1 - DFMEA SEVERITY (S)....64
TABLE D2 - DFMEA OCCURRENCE (O)....68
TABLE D3 - DFMEA DETECTION (D)....70
TABLE AP – ACTION PRIORITY FOR DFMEA AND PFMEA....74
TABLE P1 - PFMEA SEVERITY (S)....111
TABLE P2 - PFMEA OCCURRENCE (O)....113
TABLE P3 - PFMEA DETECTION (D)....115
TABLE AP – ACTION PRIORITY FOR DFMEA AND PFMEA....118
TABLE MSR2 - SUPPLEMENTAL FMEA-MSR FREQUENCY (F)....140
TABLE MSR2.1 - SUPPLEMENTAL FMEA-MSR FREQUENCY ADAPTION FOR INFREQUENT OPERATING CONDITIONS....140
TABLE MSR3 - SUPPLEMENTAL FMEA-MSR MONITORING (M)....145
TABLE AP – ACTION PRIORITY FOR FMEA-MSR....149
TABLE G1-1 - DFMEA SEVERITY (S)....221
TABLE G1-2 - DFMEA OCCURRENCE (O)....223
TABLE G1-3 - DFMEA DETECTION (D)....229
TABLE G2-1 - PFMEA SEVERITY (S)....233
TABLE G2-2 - PFMEA OCCURRENCE (O)....234
TABLE G2-3 - PFMEA DETECTION (D)....238
TABLE AP – ACTION PRIORITY FOR DFMEA AND PFMEA....240
TABLE G4-1 - SUPPLEMENTAL FMEA-MSR SEVERITY (S)....241
TABLE G4-2 - SUPPLEMENTAL FMEA-MSR FREQUENCY (F)....242
TABLE MSR2.1 - SUPPLEMENTAL FMEA-MSR FREQUENCY ADAPTION FOR INFREQUENT OPERATING CONDITIONS....243

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TABLE G4-3 - SUPPLEMENTAL FMEA-MSR MONITORING (M) 245
TABLE AP – ACTION PRIORITY FOR FMEA-MSR 248

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1 INTRODUCTION

This joint publication is the culmination of more than three years of collaboration between OEM and Tier 1 supplier members of the Automotive Industry Action Group (AIAG), and the Verband der Automobilindustrie (VDA). The text has been completely rewritten, and the FMEA method has been revised in a few key areas. The intent is to provide a common foundation for FMEA across the sectors of the automotive industry which are represented by these organizations. While every effort was made to achieve consensus, it may be necessary to refer to individual corporate publications or Customer-Specific Requirements (CSR).

A new method: Supplemental FMEA for Monitoring and System Response (FMEA-MSR) has been added. It provides a means for the analysis of diagnostic detection and fault mitigation during customer operation for the purpose of maintaining a safe state or state of regulatory compliance.

This handbook supersedes AIAG 4th Edition FMEA and VDA Volume 4, chapter 3 Product and Process FMEA.

1.1 Purpose and Description

The industry is challenged by increasing quality demands of the customer, the necessary cost optimization of the products and processes, and higher complexity, as well as the product liability of the designer and manufacturer required by legislation. Therefore, the FMEA method is used to address the technical aspects of risk reduction.

Failure Mode and Effects Analysis (FMEA) is a team-oriented, systematic, qualitative, analytical method intended to:

- evaluate the potential technical risks of failure of a product or process
- analyze the causes and effects of those failures
- document preventive and detection actions
- recommend actions to reduce risk

Manufacturers consider different types of risk including technical risks, financial risks, time risks, and strategy risks. The FMEA is used for analyzing the technical risks to reduce failures and improve safety in the products and processes. Figure 1.1-1 shows the scope of FMEA and this handbook.

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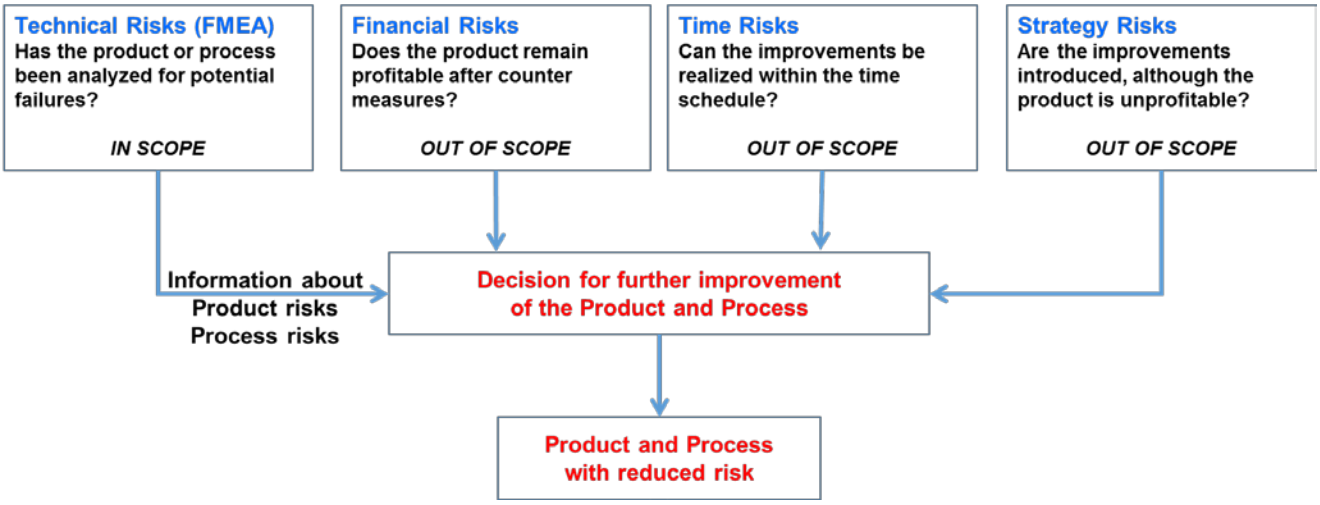


Figure 1.1-1 Aspects of Risks

1.2 Objectives and limits of FMEA

The objective of FMEA is to identify the functions of a product or steps of a process and the associated potential failure modes, effects, and causes. Furthermore, it is used to evaluate whether prevention and detection controls already planned are enough, and to recommend additional actions. The FMEA documents and tracks actions that are taken to reduce risk. The FMEA methodology helps engineers prioritize and focus on preventing product and/or process problems from occurring.

Business objectives exist that are supported by the FMEA and other activities, such as:

- Increase the quality, reliability, manufacturability, serviceability, and safety of automotive products
- Ensure the hierarchy, linkage, interface, and cascading and alignment of requirements between components, systems and vehicles are captured
- Reduce warranty and goodwill costs
- Increased customer satisfaction in a highly competitive market
- Prove product and process risk analysis in the case of product liability
- Reduce late changes in development
- Maintain defect-free product launches
- Target communication in internal and external customer and supplier relationships
- Build up a knowledge base in the company, i.e. document lessons-learned

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- Comply with regulations in the registration approval of the components, systems, and vehicles

Limitations of the FMEA include the following:

- It is qualitative (subjective), not quantitative (measurable)
- It is a single-point failure analysis, not a multi-point failure analysis
- It relies on the team's level of knowledge which may, or may not predict future performance
- It is a summary of the team's discussions and decisions therefore, the quality of the FMEA report is subject to the recording skills of the team which may reflect the discussion points in whole, or in part (it is not a transcript of a meeting)

For quantitative analysis and multi-point failure analysis, other methods such as FTA (Fault Tree Analysis) and FMEDA (Failure Modes, Effects, and Diagnostic Analysis) are used. These are the methods which can calculate and analyze the relevant metrics (single-point failure analysis, multi-point faults, latent faults) to reach a quantified analysis result.

1.3 Integration of FMEA in the Company

FMEA is a multi-disciplined activity affecting the entire product realization process. The implementation of FMEA needs to be well planned to be fully effective. The FMEA method is an integral element of Product Development and Process Development activities. The FMEA can reduce product redevelopment timing and cost. It supports the development of comprehensive specifications, test plans, and Control Plans.

1.3.1 Potential Considerations of the FMEA

The competent performance of the FMEA and the implementation of its results are among the responsibilities of companies that design, manufacture, and/or assemble products for the automotive industry. When the FMEA is performed, the following norms are observed:

- **Clear**, i.e. potential failure modes are described in technically precise, specific terms, enabling a specialist to assess failure causes and possible effects. Descriptions are free from possible misunderstanding. Emotion-laden terms (dangerous, intolerable, irresponsible, etc.) are not appropriate.
- **True**, i.e. the consequences of potential failures are described accurately (potential for odor, smoke, fire, etc.).
- **Realistic**, i.e. failure causes are reasonable. Extreme events are not considered (falling rock on road, no power to manufacturing plant, etc.). Failures resulting from misuse relative to perception, judgement, or action are considered

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foreseeable when documented by systematic methods (including brainstorming, expert judgement, field reports, use case analysis, etc.). Failures resulting from intentional misuse are not considered (e.g. deliberate manipulation and sabotage).

- **Complete**, i.e. foreseeable potential failures are not concealed. Concern about revealing too much know-how by creating a correct and competent FMEA is not a valid reason for an incomplete FMEA. Completeness refers to the entirety of the product/process under analysis (system elements and functions). However, the depth of detail depends on the risks involved.

Technical risks of failure identified in the FMEA are either assessed as acceptable, or actions are assigned to further reduce risk. The closure status of actions to reduce the risk is documented.

The competent performance of the FMEA and the proper implementation of its results are among the duties of every manufacturer of products for the automotive industry. It is critical that the analysis take into consideration the product's operating conditions during its useful life, particularly with regard to safety risks and foreseeable (but unintentional) misuse.

1.3.2 Senior Management commitment

The FMEA process can take considerable time to complete. A commitment of the required resources is vital. Active participation of the product and process owners and commitment from senior management are important to successful FMEA development.

Senior Management carries the responsibility for the application of FMEA. Ultimately, senior management is responsible for acceptance of the risks and risk minimization actions identified in the FMEA.

1.3.3 Know-How Protection of the Design FMEA/Process FMEA

The sharing of intellectual property found in the Design FMEA and/or Process FMEA between suppliers and customers is governed by contractual agreements between suppliers and customers and is beyond the scope of this handbook.

1.3.4 Agreements between Customers and Suppliers

The customer specific requirements regarding FMEA should be coordinated with the parties involved and/or the suppliers. An agreement made about the execution of FMEAs may include but is not limited to items such as; system boundaries, necessary work documents, analysis methods, and evaluation tables.

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1.3.5 Transition Strategy

Existing FMEAs developed using the previous AIAG 4th Edition FMEA or VDA Volume 4, Chapter 3 Product and Process FMEA Edition, may remain in their original form for subsequent revisions.

The organization should thoughtfully plan the transition from their current FMEA process(es) and methods to the new AIAG VDA FMEA process and tools. When practical, existing FMEAs used as a starting point for new programs should be converted to reflect the new rating scales, analytical methods, and format. However, if the team determines that the new program is considered a minor change to the existing product, they may decide to leave the FMEA in the existing format.

New projects should follow the FMEA method presented in this Handbook unless company leadership and Customer Specific Requirements (CSRs) mandate a different approach. The transition date and project milestone after which new projects follow this method should be defined by the company taking into consideration customer specific requirements.

1.3.6 Foundation and Family FMEAs

Foundation and family FMEAs are recommended to be created and used as a basis for new analyses. These optional practices provide the greatest opportunity to leverage past experience and knowledge and ensure that knowledge is accumulated over product lifecycles and that prior performance issues are not repeated (lessons learned). Furthermore, such reuse also reduces effort and expenditures.

Foundation FMEAs (also known as generic, baseline, template, core, master, or best practice FMEAs, etc.) are FMEAs that contain knowledge of the organization from prior developments which make them useful as a starting point for new FMEAs. The foundation FMEA is not program specific, therefore the generalization of requirements, functions, and measures is allowed.

Family FMEAs are specialized foundation FMEAs. It is common to develop products that generally contain common or consistent product boundaries and related functions (a Product Family) or processes which contain a series of operations that produce multiple products or part numbers. In these cases, it is appropriate to develop Family FMEAs which cover the commonalities for these Families.

When using the family or foundation FMEA approach, for the new product or process under development the team should identify and focus the analysis on the differences between the existing and the new product, process or application. The information and ratings carried over from the family or foundation are to be

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critically examined with regard to the respective use case and experiences from the known application.

1.4 FMEA for Products and Processes

There are three basic cases for which the FMEA is to be applied, each with a different scope or focus.

Case 1: New designs, new technology, or new process.

The scope of the FMEA is the complete design, technology, or process.

Case 2: New application of existing design or process

The scope of the FMEA is an existing design or process in a new environment, location, application, or usage profile (including duty cycle, regulatory requirements, etc.). The scope of the FMEA should focus on the impact of the new environment, location, or application usage on the existing design or process.

Case 3: Engineering changes to an existing design or process.

New technical developments, new requirements, product recalls, and reports of failures in the field may drive the need for design and/or process changes. In these cases, a review or revision of the FMEA may be necessary.

The FMEA contains a collection of knowledge about a design or process and may be revised after start of production if at least one of the following points applies:

- Changes to designs or processes
- Changes to the operating conditions
- Changed requirements (law, norms, customer, state of the art)
- Quality Issues, i.e. Plant experience, zero mileage, or field issues, internal / external complaints
- Changes to the Hazard Analysis and Risk Assessment (HARA)
- Changes to the Threat Analysis and Risk Assessment (TARA)
- Findings due to product monitoring
- Lessons learned

There are two main approaches to FMEA: the analysis according to product functions (Design FMEA) or according to process steps (Process FMEA).

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1.4.1 Design FMEA

A Design FMEA (DFMEA) is an analytical technique utilized primarily by a design responsible engineer/team as a means to assure that, to the extent possible, potential Failure Modes and their associated Causes or mechanisms of failure have been considered and addressed prior to releasing the part to production.

The Design FMEA analyzes the functions of a system, subsystem, or component of interest as defined by the boundary shown on the Block/Boundary Diagram, the relationship between its underlying elements, and to external elements outside the system boundary. This enables the identification of possible design weaknesses to minimize potential risks of failure.

A System DFMEA is comprised of various subsystems and components which are represented as system elements (items).

System and subsystem analyses are dependent on the viewpoint or responsibility. Systems provide functions at the vehicle level. These functions cascade through subsystems and components. For purpose of analysis, a sub-system is considered the same way as a system.

Interfaces and interactions among systems, subsystems, the environment and the customers (i.e. Tier N, OEM, and end user) may be analyzed in System FMEAs.

Within a system there may be software, electronic, and mechanical elements. Examples of systems include: Vehicle, Transmission System, Steering System, Brake System or Electronic Stability Control System, etc.

A component DFMEA is a subset of a system or subsystem DFMEA. For example, an Electrical Motor is a component of the Window Lifter, which is a subsystem of Window Lifter System. A Housing for the Electrical Motor may also be a component or part. For this reason, the terms “system element” or “item” are used regardless of the level of analysis.

Design FMEA may also be used to assess the risks of failure of non-automotive products such as machines, and tooling. The actions resulting from the analysis may be used to recommend design changes, additional testing, and other actions which reduce the risk of failure or increase the ability of a test to detect failures prior to delivery of the design for production.

1.4.2 Process FMEA

In contrast to the Design FMEA (DFMEA), which analyzes the failure possibilities that may be created during the design phase of the product, the Process FMEA (PFMEA) analyzes the potential failures of manufacturing, assembly and logistical processes to

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produce products which conform to design intent. Process-related failures are different than the failures analyzed in the Design FMEA.

The Process FMEA analyzes processes by considering the potential failure modes which may result from process variation, to establish priority of actions for prevention, and as needed; improve controls. The overall purpose is to analyze processes and take action prior to production start, to avoid unwanted defects related to manufacturing and assembly and the consequences of those defects.

1.4.3 Collaboration between FMEAs

There are opportunities for collaboration between both Design and Process FMEAs in the same company and outside of the company. To help communicate effects and severities, a joined and agreed to severity evaluation can be reviewed between Tiers (different companies in the supply chain starting with Tier 1, Tier two, Tier 3, etc.) as shown in Figure 1.4-1 FMEA Collaboration.

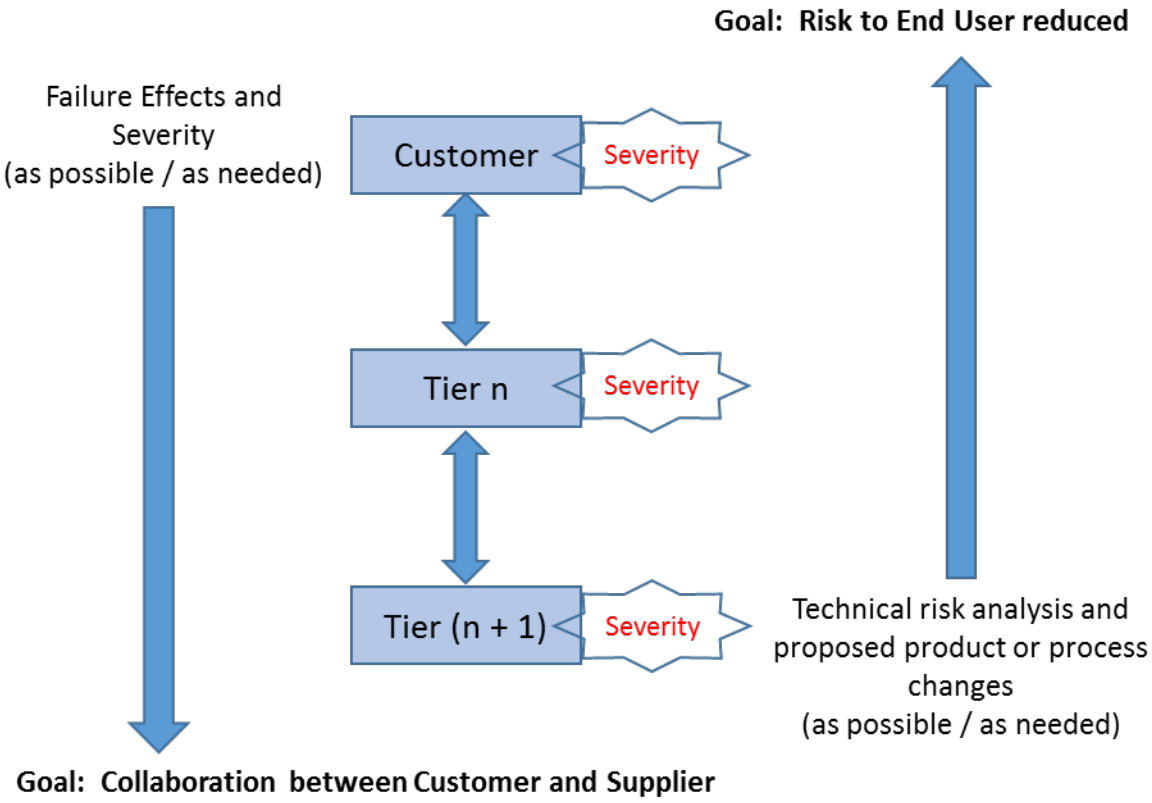


Figure 1.4-1 FMEA Collaboration

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A good starting point for a manufacturer is to make sure the severity in the DFMEA and PFMEA are the same when the failure effects are the same. If the “product” failure effects to the end user (vehicle-level) are not included in the PFMEA then the correlation between the DFMEA and PFMEA is not possible. A correlation needs to be made so that a failure of a feature in design that leads to a certain failure effect is also captured in the PFMEA for the same feature (product characteristic). Please see the note in Section 3.4.8 for non-traditional development flows.

1.5 Project Planning

The Five T's are five topics that should be discussed at the beginning of a DFMEA or PFMEA in order to achieve the best results on time and avoid FMEA rework. These topics can be used as part of a project kick-off.

FMEA InTent – Why are we doing FMEA?

FMEA Timing – When is this due?

FMEA Team – Who needs to be on the team?

FMEA Task – What work needs to be done?

FMEA Tool – How do we conduct the analysis?

1.5.1 FMEA InTent

It is recommended that members of the FMEA team are competent in the method, based on their role on the team. When team members understand the purpose and intent of FMEA, they will be more prepared to contribute to the goals and objectives of the project.

1.5.2 FMEA Timing

FMEA is meant to be a “before-the-event” action, not an “after-the-fact” exercise. To achieve the greatest value, the FMEA is conducted before the implementation of a product or process in which the failure mode potential exists.

One of the most important factors for the successful implementation of an FMEA program is timeliness. Up-front time spent properly completing an FMEA, when product/process changes can be most easily and inexpensively implemented, will minimize late change crises. The FMEA as a method for system analysis and failure prevention is best initiated at an early stage of the product development process. It is used to evaluate the risks, valid at that time, in order to initiate actions to minimize them. In addition, the FMEA can support the compilation of requirements.

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The FMEA should be carried out according to the project plan and evaluated at the project milestones according to the state of the analysis.

It is recommended that a company define desired maturity levels for their FMEAs according to overall company-specific development project milestones.

Advanced Product Quality Planning (APQP) Phases	Plan and Define Program	Product Design and Development Verification	Process Design and Development Verification	Product and Production Validation	Feedback Assessment and Corrective Action
DFMEA	Start FMEA planning in concept phase before product development begins **Information flow from DFMEA to PFMEA** The DFMEA and PFMEA should be executed during the same time period to allow optimization of both the product and process designs	Start DFMEA when the design concept is well understood	Complete DFMEA analysis prior to release of design specifications for quotation	Complete DFMEA actions prior to start of production tooling	**Start again with DFMEA and PFMEA planning if there are changes to an existing design or process**
PFMEA		Start PFMEA when production concept is well understood	Complete PFMEA analysis prior to final process decisions	Complete PFMEA actions prior to PPAP/PPA	

Figure 1.5-1 FMEA Timing Aligned with APQP Phases

VDA Maturity Level Assurance for New Parts	RG0	RG1	RG2	RG3	RG4	RG5	RG6	RG7
	Innovation Approval for serial Development	**Requirement Management for Procurement Extensive**	**Definition of the Supply Chain and Placing of Extensive**	**Approval of Technical Specification**	**Production Planning Done**	**Serial tools, Spare Parts and Serial Machines Available**	**Product and Process Approval**	**Project End, Responsibility Transfer to Serial Production, Start, Requalifikation**
DFMEA		Start FMEA planning in concept phase before product development begins **Information flow from DFMEA to PFMEA** The DFMEA and PFMEA should be executed during the same time period to allow optimization of both the product and process designs	Start DFMEA when the design concept is well understood	Complete DFMEA analysis prior to release of design specifications for quotation			Complete DFMEA actions prior to start of production tooling	**Start again with DFMEA and PFMEA planning if there are changes to an existing design or process**
PFMEA			Start PFMEA when production concept is well understood		Complete PFMEA analysis prior to final process decisions		Complete PFMEA actions prior to PPAP/ PPA	

Figure 1.5-2 FMEA Timing Aligned to MLA Phases

NOTE: Exceptions to this FMEA timing include non-traditional development flows such as where development of a "standard" process precedes the development of products that will be manufactured using the process.

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1.5.3 FMEA Team

The FMEA team consists of multi-disciplinary (cross-functional) members who encompass the necessary subject matter knowledge. This should include facilitation expertise and knowledge of the FMEA process. The success of the FMEA depends on active participation of the cross-functional team as necessary to focus on the topics of discussion.

1.5.3.1 The Design FMEA Team

The Core Team may consist of the following people:

- facilitator
- design engineer
- system engineer
- component engineers
- test engineer
- quality/reliability engineer
- others responsible for the development of the product

The core team members prepare the FMEA System Analysis (Steps 1 – 3) and participate in the FMEA meetings. The extended team may participate on demand (coordinated by the FMEA facilitator or meeting organizer).

The Extended Team may consist of the following people:

- technical experts
- process/manufacturing engineer
- service engineer
- project manager
- functional safety engineer
- purchasing
- supplier
- customer representative
- others that may have specialized knowledge which will help the core team analyze specific aspects of the product

1.5.3.2 The Process FMEA Team

The Core Team may consist of the following people:

- facilitator
- process/manufacturing engineer
- ergonomic engineer
- process validation engineer

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- quality/reliability engineer
- others responsible for the development of the process

The core team members prepare the FMEA System Analysis (Steps 1 – 3) and participate in the FMEA meetings. The extended team may participate on demand (coordinated by the FMEA facilitator or meeting organizer).

The Extended Team may consist of the following people:

- design engineer
- technical experts
- service engineer
- project manager
- maintenance staff
- line worker
- purchasing
- supplier
- others (as necessary)

1.5.3.3 FMEA Team Roles and Responsibilities

Within the organization's product development process, the following roles and responsibilities for FMEA participation should be assigned. Responsibilities of a given role can be shared amongst different persons and/or multiple roles may be assigned to the same person.

1.5.3.3.1 Management, i.e. project manager

- Authority to make decisions about the acceptability of identified risks and the execution of actions
- Defines the persons responsible for pre-work activities, FMEA facilitation, and the design/process engineer responsible for implementation of actions resulting from the analysis
- Responsible for selecting and applying resources and ensuring an effective risk management process is implemented within scheduled project timing
- Responsibility and ownership for development and maintenance of the FMEAs.
- Management responsibility also includes providing direct support to the team(s) through on-going reviews and eliminating roadblocks.
- Responsible for budget.

1.5.3.3.2 Lead Design/Process Engineer (Technical Lead)

- Technical responsibility for the FMEA contents

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- Preparation of the Business Case for technical and/or financial decisions
- Definition of elements, functions, requirements, and interfaces
- Focusing on the topics
- Procurement of the necessary documents and information
- Incorporating lessons learned

1.5.3.3.3 FMEA Facilitator

- Coordination and organization of the workflows in the FMEA
- Mitigation of conflicts
- Participation in the team formation
- Participation in the Preparation of the rough schedule
- Participation in the invitation to the 1st team meeting for the analysis phase
- Participation in the Preparation of the decision guidelines/criteria
- Development of Corporate or Product Line Examples for Rating Tables (Optional) with support from Design/Process Engineer
- Method competence (FMEA) and familiarization of participants in the FMEA method
- FMEA Software documentation competence (as necessary)
- Social skills, able to work in a team
- Competent moderator, ability to convince, organization and presentation skills
- Managing execution of the 7 steps of FMEA method
- If necessary, Preparation or wrap-up of FMEA meetings
- Moderation of the FMEA workgroup

> NOTE: Any team member with the relevant competence and training may fulfill the role of facilitator.

1.5.3.3.4 Core Team Members

- Contribute knowledge from relevant product and process experience
- Contribute necessary information about the product or process that is the focus of the FMEA
- Contribution of existing experiences from previous FMEAs already known
- Participation in the execution of the 7 steps of FMEA
- Involvement in the Preparation of the Business Case
- Incorporating lessons learned

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1.5.3.3.5 Extended Team Members / Experts

- Contribution of additional information about special topics
- Contribution of necessary information about the product or process that is the focus of the FMEA
- Involvement in the Preparation of the Business Case

1.5.4 FMEA Tasks

The 7-Step Overview provides the framework for the tasks and deliverables of the FMEA. In addition, the FMEA team should be prepared to review the results of their analysis with management and the customer, upon request.

The FMEA may also be audited by an internal auditor, customer auditor, or third-party registrar to ensure each task has been fulfilled.

1.5.5 FMEA Tools

There are numerous FMEA software packages that can be used to develop a DFMEA and PFMEA as well as follow up on actions. This software ranges from dedicated FMEA software to standard spreadsheets customized to develop the FMEA. Companies may develop their own in-house database solution or purchase commercial software. In any case, the FMEA team needs to have knowledge of how to use the FMEA software selected for their project as required by the company.

There are two views of FMEA examples shown in this manual. The software view depicts what the user sees when developing a FMEA using specialized software that utilized i.e. system element structure, function net, failure net, etc. The Form view depicts what the user sees when developing a FMEA in a spreadsheet.

Figures in this handbook include an example of how to develop an FMEA using either a Structure Tree or Form. In the case of using Structure Trees to develop elements, functions, and failures; a software view is also presented to show how the information may look when placed in documentation. In either case the 7-Step process is the same.

1.6 FMEA METHODOLOGY

The analyses for the Design FMEA, Process FMEA and Supplemental FMEA for Monitoring and System Response (FMEA-MSR) are each described completely in the following sections. Consequently, redundancies are unavoidable. For the user this has the advantage that they can refer directly to the Design FMEA and/or Process FMEA and/or FMEA-MSR chapter without referring to the content of the other chapters.

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The FMEA process is carried out in seven steps.

These seven steps provide a systematic approach to perform a Failure Mode and Effects Analysis and serve as a record of the technical risk analysis.

Seven Step Approach

System Analysis			Failure Analysis and Risk Mitigation			Risk Communication
1st Step	**2nd Step**	**3rd Step**	**4th Step**	**5th Step**	**6th Step**	**7th Step**
Planning & Preparation	**Structure Analysis**	**Function Analysis**	**Failure Analysis**	**Risk Analysis**	**Optimization**	**Results Documentation**
						
Project identification	Visualization of the analysis scope	Visualization of product or process functions	Establishment of the failure chain	Assignment of existing and/or planned controls and rating of failures	Identification of the actions necessary to reduce risks	Communication of actions taken to reduce risks
Project plan: InTent, Timing, Team, Tasks, Tools (5T)	**DFMEA:** Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts **PFMEA:** Structure tree or equivalent: process flow diagram	**DFMEA:** Function tree/net, function matrix parameter diagram (P-diagram) **PFMEA:** Function tree/net or equivalent process flow diagram	**DFMEA:** Potential Failure Effects, Failure Modes, Failure Causes for each product function **PFMEA:** Potential Failure Effects, Failure Modes, Failure Causes for each process function	**DFMEA & PFMEA:** Assignment of Prevention Controls to the Failure Causes **DFMEA & PFMEA:** Assignment of Detection Controls to the Failure Causes and/or Failure Modes **FMEA-MSR:** Analysis of provisions for functional safety and regulatory compliance	Assignment of responsibilities and deadlines for action implementation	The layout of the document may be company specific. The content may include the following: • Executive summary • Scope of the FMEA • A reference to the specific S/O/D Rating Tables used in the analysis • Action Priority • Results and conclusions of the analysis
Analysis boundaries: What is included and excluded from the analysis	**DFMEA:** Identification of design interfaces, interactions, close clearances **PFMEA:** Identification of process steps and sub-steps	**DFMEA:** Cascade of customer (external and internal) functions with associated requirements **DFMEA & PFMEA:** Association of requirements or characteristics to functions	**DFMEA:** Identification of product failure causes using a parameter diagram or failure network **PFMEA:** Identification of process failure causes using a fishbone diagram (4M) or failure network	**DFMEA & PFMEA:** Rating of Severity, Occurrence and Detection for each failure chain **FMEA-MSR:** Rating of Severity, Frequency and Monitoring for each failure chain	Implementation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken	Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
Identification of baseline FMEA with lessons learned	Collaboration between customer and supplier engineer teams (interface responsibilities)	Collaboration between engineering teams (systems, safety, and components)	Collaboration between customer and supplier (Failure Effects)	Collaboration between customer and supplier (Severity)	Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures	The content of the documentation fulfills the requirements of the organization, the intended reader, and relevant stakeholders, and details may be agreed between the relevant parties.
Basis for the Structure Analysis step	Basis for the Function Analysis step	Basis for the Failure Analysis step	Basis for the documentation of failures in the FMEA form and the Risk Analysis step	Basis for the product or process Optimization step	Basis for refinement of the product and/or process requirements and prevention and detection controls	Record of risk analysis and reduction to acceptable levels.

Figure 1.6-1 FMEA 7 Step Approach

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2 EXECUTION OF THE DESIGN FMEA

2.1 Design FMEA 1st Step: Planning and Preparation

2.1.1 Purpose



The purpose of the Design FMEA Planning and Preparation Step is to define which FMEAs will be done for a project, and to define what is included and excluded in each FMEA based on the type of analysis being developed, i.e. system, subsystem or component.

The main objectives of Design FMEA Planning and Preparation are:

- Project identification
- Project plan: InTent, Timing, Team, Tasks, Tools (5T)
- Analysis boundaries: Determine what is included and excluded from the analysis
- Identification of baseline FMEA with lessons learned
- Basis for the Structure Analysis step

2.1.2 DFMEA Project Identification and Boundaries

DFMEA Project identification includes a clear understanding of what needs to be evaluated. This involves a decision-making process to define the DFMEAs that are needed for a customer program. What to exclude can be just as important as what to include in the analysis.

Below are some basic questions that help identify DFMEA projects.

- What is the customer buying from us?
- Are there new requirements?
- Does the customer or company require a DFMEA?
- Do we make the product and have design control?
- Do we buy the product and still have design control?
- Do we buy the product and do not have design control?
- Who is responsible for the interface design?
- Do we need a system, subsystem, component, or other level of analysis?

Answers to these questions and others defined by the company help create the list of DFMEA projects needed. The DFMEA project list assures consistent direction, commitment and focus.

The following may assist the team in defining DFMEA boundaries, as applicable:

- Legal Requirements

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- Technical Requirements
- Customer wants/needs/expectation (external and internal customers)
- Requirements specification
- Diagrams (Block/Boundary) from similar project
- Schematics, Drawings, and/or 3D Models
- Bill of Materials (BOM), Risk Assessment
- Previous FMEA for similar products
- Error proofing requirements, Design for Manufacturability and Assembly (DFM/A)
- QFD Quality Function Deployment

The following may be considered in defining the scope of the DFMEA, as appropriate:

- Novelty of technology/ Degree of innovation
- Quality / Reliability History (In-house, zero mileage, field failures, warranty and policy claims for similar products)
- Complexity of Design
- Safety of people and systems
- Cyber-Physical System (including cyber-security)
- Legal Compliance
- Catalog & standard parts

2.1.3 DFMEA Project Plan

A plan for the execution of the DFMEA should be developed once the DFMEA project is known.

It is recommended that the 5T method (InTent, Timing, Team, Tasks, Tool) be used as described in section 1.5 of this handbook. The plan for the DFMEA helps the company be proactive in starting the DFMEA early. The DFMEA activities (7-step process) should be incorporated into the overall project plan.

2.1.4 Identification of the Baseline DFMEA

Part of the preparation for conducting the DFMEA is knowing what information is already available that can help the cross-functional team. This includes use of a foundation DFMEA (described in Section 1.3), similar product DFMEA, or product family DFMEA. The family DFMEA is a specialized foundation design FMEA for products that generally contain common or consistent product boundaries and related functions. For a new product in the family, the new project specific components and functions to complete the new product's DFMEA would be added to the family FMEA. The additions for the new product may be in the family DFMEA itself, or in a new document with reference to the original family or

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foundation DFMEA. If no baseline is available, then the team will develop a new DFMEA.

2.1.5 DFMEA Header

During the Planning and Preparation Step, the header of the DFMEA document should be filled out. The header may be modified to meet the needs of the organization. The header includes some of the basic DFMEA scope information as follows:

Company Name: Name of Company Responsible for DFMEA

Engineering Location: Geographical Location

Customer Name: Name of Customer(s) or Product

Model Year / Program(s): Customer Application or Company Model /Style

Subject: Name of DFMEA Project (System, Subsystem and/or Component)

DFMEA Start Date: Start Date

DFMEA Revision Date: Latest Revision Date

Cross-Functional Team: Team Roster needed

DFMEA ID Number: Determined by Company

Design Responsibility: Name of DFMEA owner

Confidentiality Level: Business Use, Proprietary, Confidential

Example: Design Failure Mode and Effects Analysis (Design FMEA)					
Scope Analysis (Step 1)					
Company Name:	Acme Automotive	**Subject:**	PX123 Upper Jacket		
Engineering Location:	Munich, Germany	**DFMEA Start Date:**	19-Mar-2018	**DFMEA ID Number:**	123456
Customer Name:	Jackson Industry	**DFMEA Revision Date:**	25-Sep-2018	**Design Responsibility:**	S. Gray
Model Year(s) / Program(s):	2020 PX123	**Cross-Functional Team:**	See Team List	**Confidentiality Level:**	Confidential

Figure 2.1-1 Example of Completed DFMEA Header Planning and Preparation Step 1

2.1.6 Basis for Structure Analysis

The information gathered during Step 1 Planning and Preparation will be used to develop Step 2 Structure Analysis.

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2.2 Design FMEA 2nd Step: Structure Analysis

2.2.1 Purpose



The purpose of Design Structure Analysis is to identify and breakdown the design into system, subsystem, and component, parts for technical risk analysis.

The main objectives of a Design Structure Analysis are:

- Visualization of the analysis scope
- Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts
- Identification of design interfaces, interactions, close clearances
- Collaboration between customer and supplier engineering teams (interface responsibilities)
- Basis for the Function Analysis step

2.2.2 System Structure

A system structure is comprised of System Elements. Depending on the scope of analysis, the system elements of a design structure can consist of a system, subsystems, assemblies, and components. Complex structures may be split into several structures (work packages) or different layers of block diagrams and analyzed separately for organizational reasons or to ensure sufficient clarity. A system has a boundary separating it from other systems and the environment. Its relationship with the environment is defined by inputs and outputs. A system element is a distinct component of a functional item, not a function, a requirement or a feature.

2.2.3 Define the Customer

There are two major customers to be considered in the FMEA analysis:

- END USER The individual who uses a product after it has been fully developed and marketed.
- ASSEMBLY and MANUFACTURING: the locations where manufacturing operations (i.e., powertrain, stamping and fabricating) and vehicle/ product assembly and production material processing takes place. Addressing the interfaces between the product and its assembly process is critical to an effective FMEA analysis. This may be any subsequent or downstream operation or a next Tier manufacturing process.

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Knowledge of these customers can help to define the functions, requirements and specifications more robustly as well as aid in determining the effects of related failure modes.

> NOTE: Reference the NOTE in section 2.4.5 for cases when the end use is not known.

2.2.4 Visualize System Structure

A visualization of the system structure helps the DFMEA team develop the structural analysis. There are various tools which may be used by the team to accomplish this. Two methods commonly used are described in the sections below:

- Block/Boundary Diagrams
- Structure Tree

2.2.4.1 Block/Boundary Diagram

Block/Boundary Diagrams are useful tools that depict the system under consideration; and its interfaces with adjacent systems, the environment and the customer. The diagram is a graphic representation that provides guidelines for structured brainstorming and facilitates the analysis of system interfaces as a foundation for a Design FMEA. The diagram below shows the physical and logical relationships between the components of the product. It indicates the interaction of components and subsystems within the scope of the design as well as those interfaces to the product Customer, Manufacturing, Service, Shipping, etc. The diagram identifies persons and things that the design interacts with during its useful life. The Boundary Diagram can be used to identify the Focus Elements to be assessed in the Structure Analysis and Function Analysis.

The diagram may be in the form of boxes connected by lines, with each box corresponding to a major component of the product. The lines correspond with how the product components are related to, or interface with each other; with arrows at the end point(s) to indicate the direction of flow. Interfaces between elements in the Boundary Diagram can be included as Focus Elements in the Structure and Function Analysis Structure Tree.

There are different approaches and formats to the construction of a Block/Boundary Diagram, which are determined by the organization. In this handbook, the terms “block diagram” and “boundary diagram” are used interchangeably. However, the Boundary Diagram tends to be more comprehensive due to the inclusion of external influences and system interactions.

In the context of the DFMEA, Block/Boundary Diagrams define the analysis scope and responsibility and provides guidelines for structured brainstorming. The scope of analysis is defined by the

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boundaries of the system; however, interfaces with external factors/systems are to be addressed.

- Defines scope of analysis (helps to identify potential team members)
- Identifies internal and external interfaces
- Enables application of system, sub-system, and component hierarchy

When correctly constructed, Block/Boundary Diagrams provide detailed information to the P-Diagram, and the FMEA. Although Block/Boundary diagrams can be constructed to any level of detail, it is important to identify the major elements, understand how they interact with each other, and how they may interact with outside systems.

Block/Boundary Diagrams are steadily refined as the design matures.

The steps involved in completing a Block/Boundary Diagram may be described as follows:

a. Describe components and features

- Naming the parts and features helps alignment within the team, particularly when features have “nicknames’.
- All system components & interfacing components shown.

b. Reorganize blocks to show linkages

- Solid line for direct contact
- Dashed line for indirect interfaces, i.e. clearances or relative motion
- Arrows indicate direction
- All energy flows/ signal or force transfers identified.

c. Describe connections

Consider all types of interfaces, both desired and undesired:

P----Physically touching (welded, bolted, clamped, etc.)

E----Energy transfer (Torque (Nm), heat, etc.)

I-----Information transfer (ECU, sensors, signals, etc.)

M ---Material exchange (Cooling fluid, exhaust gases, etc.)

d. Add interfacing systems and inputs (persons and things)

The following should be included:

- Adjacent systems – including systems that are not physically touching your system but may interact with

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it, require clearance, involve motion, or thermal exposure.

- The customer/end user
- Arrows indicate direction

e. Define the boundary (What parts are within the span of control of the team? What is new or modified?)

Only parts designed or controlled by the team are inside the boundary. The blocks within the boundary diagram are one level lower than the level being analyzed. Blocks within the boundary may be marked to indicate items that are not part of the analysis.

f. Add relevant details to identify the diagram.

- System, program, and team identification
- Key to any colors or line styles used to identify different types of interactions
- Date and revision level

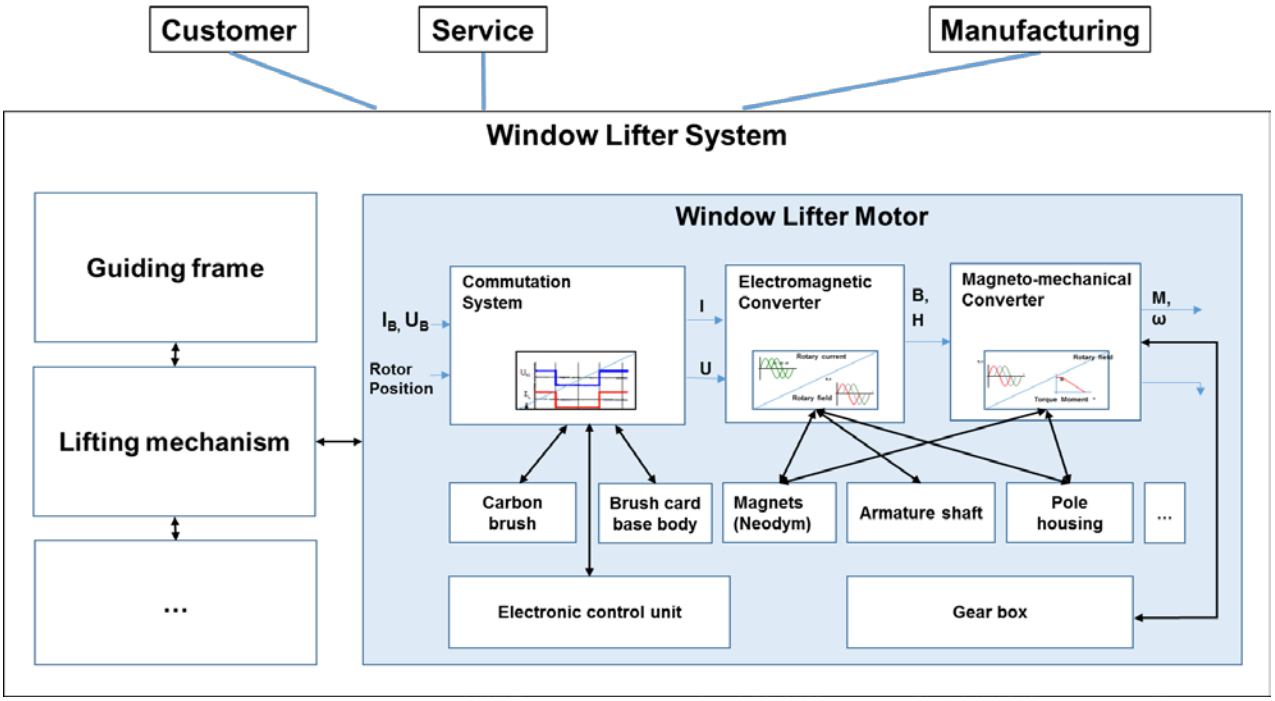


Figure 2.2-1 Example of Block/Boundary Diagram

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2.2.4.2 Interface Analysis

An interface analysis describes the interactions between elements of a system.

There are five primary types of interfaces:

- Physical connection (i.e. brackets, bolts, clamps and various types of connectors)
- Material exchange (i.e. compressed air, hydraulic fluids or any other fluid or material exchange)
- Energy transfer (i.e. heat transfer, friction or motion transfer such as chain links or gears)
- Data exchange (i.e. computer inputs or outputs, wiring harnesses, electrical signals or any other types of information exchange, cyber security items)
- Human-Machine (i.e. controls, switches, mirrors, displays, warnings, seating, entry/exit)

Another type of interface may be described as a physical clearance between parts, where there is no physical connection. Clearances may be static and/ or dynamic.

Consider the interfaces between subsystems and components in addition to the content of the sub-systems and components themselves.

An interface analysis documents the nature (strong/weak/none, beneficial/harmful) and type of relationships (Physical, Energy, Information, or Material Exchange) that occur at all internal and external interfaces graphically displayed in the Block/Boundary Diagram.

Information from an interface analysis provides valuable input to a Design FMEA, such as the primary functions or interface functions to be analyzed with potential causes/mechanisms of failure due to effects from neighboring systems and environments. Interface analysis also provides input to the P-Diagram on ideal functions and noise factors.

2.2.4.3 Structure Trees

The structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections.

The clearly structured illustration of the complete system is thereby guaranteed by the fact that each system element exists only once to prevent redundancy.

The structures arranged under each System Element are independent sub-structures (see figure 2.2-2).

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The interactions between System Elements may be described later as functions and represented by function nets (see Step 3 Function Analysis).

There is always a system element present, even if it is only derived from the function and cannot yet be specified more clearly.

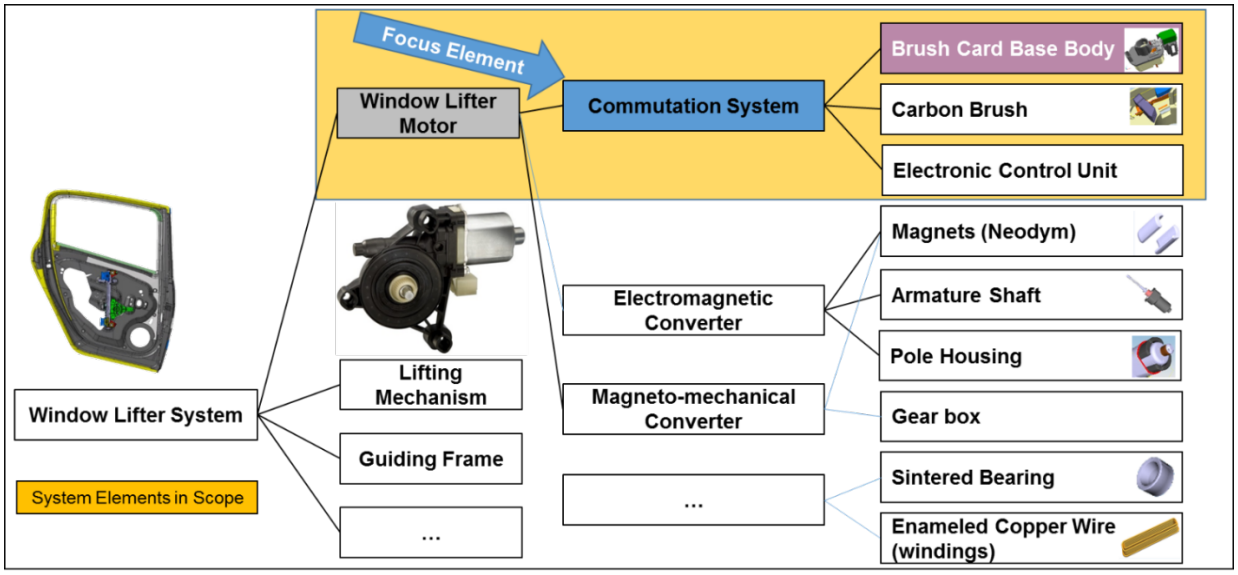


Figure 2.2-2 Example of Structure Analysis Structure Tree

The system structure can be created in the Structure Analysis section:

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lifter Motor	Commutation System	Brush Card Base Body

Figure 2.2-3 Example of Structure Analysis Form

1. Next Higher Level:
   The highest level of integration within the scope of analysis.
2. Focus Element:
   The element in focus. This is the item that is topic of consideration of the failure chain.

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3. Next Lower Level or Characteristic Type:
The element that is the next level down the structure from the focus element.

2.2.5 Collaboration between Customer and Supplier

The output of the Structure Analysis (visualization of the design and its interfaces) provides a tool for collaboration between customers and suppliers during technical reviews of the design and/or DFMEA project.

2.2.6 Basis for Function Analysis

The information defined during Step 2 Structure Analysis will be used to develop Step 3 Function Analysis. If design elements (items) are missing from the Structure Analysis they will also be missing from the Function Analysis.

2.3 Design FMEA 3rd Step: Function Analysis

2.3.1 Purpose



The purpose of the Design Function Analysis is to ensure that the functions specified by requirements/ specifications are appropriately allocated to the system elements. Regardless of the tool used to generate the DFMEA, it is critical that the analysis is written in functional terms.

The main objectives of a Design Function Analysis are:

- Visualization of product or process functions
- Development of function tree/net or function analysis form and parameter diagram (P-diagram)
- Cascade of customer (external and internal) functions with associated requirements
- Association of requirements or characteristics to functions
- Collaboration between engineering teams (systems, safety, and components)
- Basis for the Failure Analysis step

The structure provides the basis so that each System Element may be individually analyzed with regard to its functions and requirements.

For this, comprehensive knowledge of the system and the operating conditions and environmental conditions of the system are necessary, for example heat, cold, dust, splash water, salt, icing, vibrations, electrical failures, etc.

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2.3.2 Function

A function describes what the item/ system element is intended to do.

A function is to be assigned to a system element. Also a structure element can contain multiple functions.

The description of a function needs to be clear.

The recommended phrase format is to use an "action verb" followed by a "noun" to describe a measurable function.

A Function should be in the "PRESENT TENSE"; it uses the verb's base form (deliver, contain, control, assemble, transfer).

Examples: deliver power, contain fluid, control speed, transfer heat, color black.

Functions describe the relationship between the input and output of an item/ system element with the aim of fulfilling a task.

> Note: A component (i.e. a part or item in a part list) may have a purpose/function where there is no input/output. Examples such as a seal, grease, clip, bracket, housing, connector, flux, etc. have functions and requirements including material, shape, thickness, etc.

In addition to the primary functions of an item, other functions that may be evaluated include secondary functions such as interface functions, diagnostic functions, and serviceability functions. (See figure 2.3-1)

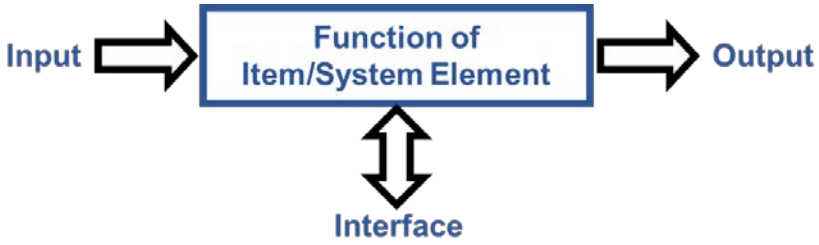


Figure 2.3-1 Input/Interface/Output Flow

2.3.3 Requirements

ISO 9000 defines a requirement as a need or expectation that a particular design, product or process aims to satisfy.

Requirements are divided into two groups: functional requirements and non-functional requirements.

A functional requirement is a criterion by which the intended performance of the function is judged or measured (i.e. material stiffness).

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A non-functional requirement is a limitation on the freedom for design decision (i.e. temperature range).

Requirements may be derived from various sources, external and internal.

Legal requirements:

- Environmentally friendly product design, suitable for recycling, safe in the event of potential misuse by the operator, non-flammable, etc.

Industry Norms and Standards:

- ISO 9001, VDA Volume 6 Part 3, Process audit, SAE J, etc. (i.e. ISO 26262 Functional Safety, SAE J3061 Cyber security)

Customer Requirements:

- Explicit (i.e. in customer specification) and implicit (i.e. freedom from prohibited materials) – under all specified conditions

Internal Requirements:

- Product Specific (i.e. Requirements Specifications, manufacturability, suitability for testing, compatibility with other existing products, reusability, cleanliness, generation, entry and spreading of particles)

Product Characteristics:

- A distinguishing feature (or quantifiable attribute) of a product such as a journal diameter or surface finish.

2.3.4 Parameter Diagram (P-Diagram)

Parameters are considered to be attributes of the behavior of a function. A Parameter (P) Diagram is a graphical representation of the environment in which an item exists. A P-Diagram includes factors which influence the transfer function between inputs and outputs, focusing on design decisions necessary to optimize output.

A P-Diagram is used to characterize the behavior of a system or component in the context of a single function. P-Diagrams are not required for all functions. Teams should focus on a few key functions affected by new conditions and those with history of robustness issues in previous applications. More than one P-Diagram may be needed in order to illustrate the function(s) of the system or component that are of concern to the FMEA Team.

The complete functional description forms the basis for subsequent failure analysis and risk mitigation.

A P-Diagram focuses on achievement of function. It clearly identifies all influences on that function including what can be

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controlled (Control Factors), and what cannot reasonably be controlled (Noise Factors).

The P-Diagram, completed for specific Ideal Functions, assists in the identification of:

- Factors, levels, responses and signals necessary for system optimization
- Functions which are inputs to the DFMEA
- Control and Noise factors which could affect functional performance
- Unintended system outputs (Diverted Outputs)

Information gained through developing a P-Diagram provides input to the test plan.

Referring to Figure 2.3-2 below, the output (grey area) of the Item/ System Element often deviates/varies from the desired behavior (straight line). The control factors act on the design to achieve as close as practical to the desired behavior.

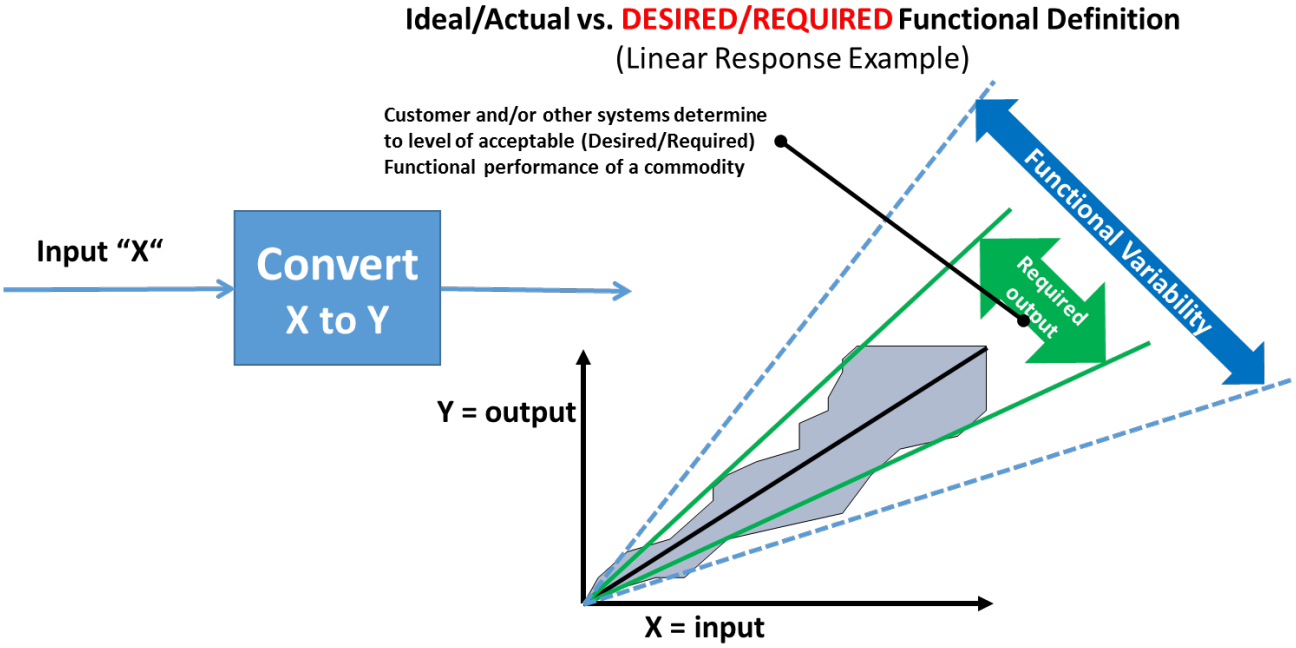


Figure 2.3-2 Example of system behavior

A Parameter Diagram consists of dynamic inputs (including signals), factors that could affect system performance (control and noise), sources of variation, and outputs (intended outputs and unintended/diverted outputs).

The following is an example of a Parameter Diagram which is used to assess the influences on a function of a product includes:

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Input (What you want to put in to get the desired result) is a description of the sources required for fulfilling the system functionality.

Function (What you want to happen) is described in a Parameter Diagram with an active verb followed by a measurable noun in the present tense and associated with requirements.

Functional Requirements (What you need to make the function happen) are related to the performance of a function

Control Factors (What you can do to make it happen) which can be adjusted to make the design more insensitive to noise (more robust) is identified. One type of Control Factor is a Signal Factor. Signal Factors are adjustment factors, set directly or indirectly by a user of a system, that proportionally change the system response (i.e., brake pedal movement changes stopping distance). Only dynamic systems utilize signal factors. Systems without signal factors are called static systems.

Non-Functional Requirements (What you need beside the functional requirements) which limit the design option.

Intended Output (What you want from the system) are ideal, intended functional outputs whose magnitude may (dynamic system) or may not (static system) be linearly proportional to a signal factor (i.e., low beam activation for a headlamp, stopping distance as a function of brake pedal movement).

Unintended Output (What you don't want from the system) are malfunctioning behaviors or unintended system outputs that divert system performance from the ideal intended function. For example, energy associated with a brake system is ideally transformed into friction. Heat, noise and vibration are examples of brake energy diverted outputs. Diverted Outputs may be losses to thermal radiation, vibration, electrical resistance, flow restriction, etc.

Noise Factors (What interferes with achieving the desired output) are parameters which represent potentially significant sources of variation for the system response and cannot be controlled or are not practical to control from the perspective of the engineer. Noises are described in physical units.

Noise factors are categorized as follows:

- Piece to Piece Variation
  (in a component and interference between components)
- Change Over Time
  (aging over life time, i.e. mileage, aging, wear)
- Customer Usage
  (use out of desired spec.)
- External Environment
  (conditions during customer usage, i.e. road type, weather)

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- System Interactions
  (interference between other systems)

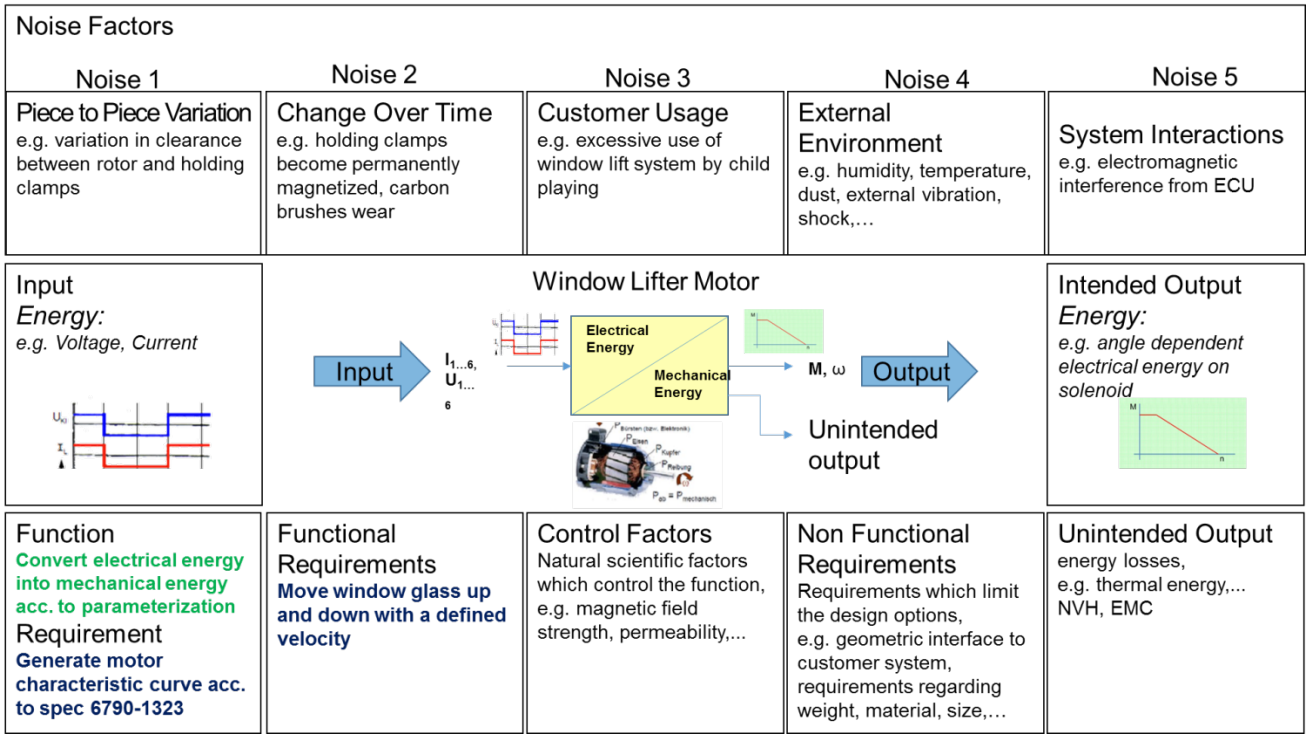


Figure 2.3-3 Example of Parameter Diagram with Electrical Motor

2.3.5 Function Analysis

The interactions of the functions of several System Elements are to be demonstrated, for example as a function tree/network, or using the DFMEA form. The focus of the analysis cascades from OEM to Tier 1 supplier to Tier N supplier.

The purpose of creating a function tree/network or functional matrix is to incorporate the technical dependency between the functions. Therefore, it subsequently supports the visualization of the failure dependencies. When there is a functional relationship between hierarchically linked functions, then there is a potential relationship between the associated failures. Otherwise, if there is no functional relationship between hierarchically linked functions, there will also be no potential relationship between the associated failures.

For the Preparation of the function tree/ network, the functions that are involved need to be examined. Sub-functions enable the

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performance of an overall function. All sub-functions are linked logically with each other in the function structure (Boolean AND-relationships).

A function structure becomes more detailed from top down. The lower level function describes how the higher level function is to be fulfilled. For the logical linking of a function structure, it is helpful to ask:

- "How is the higher level function enabled by lower level functions?" (Top-Down) and
- "Why is the lower level function needed?" (Bottom-Up).

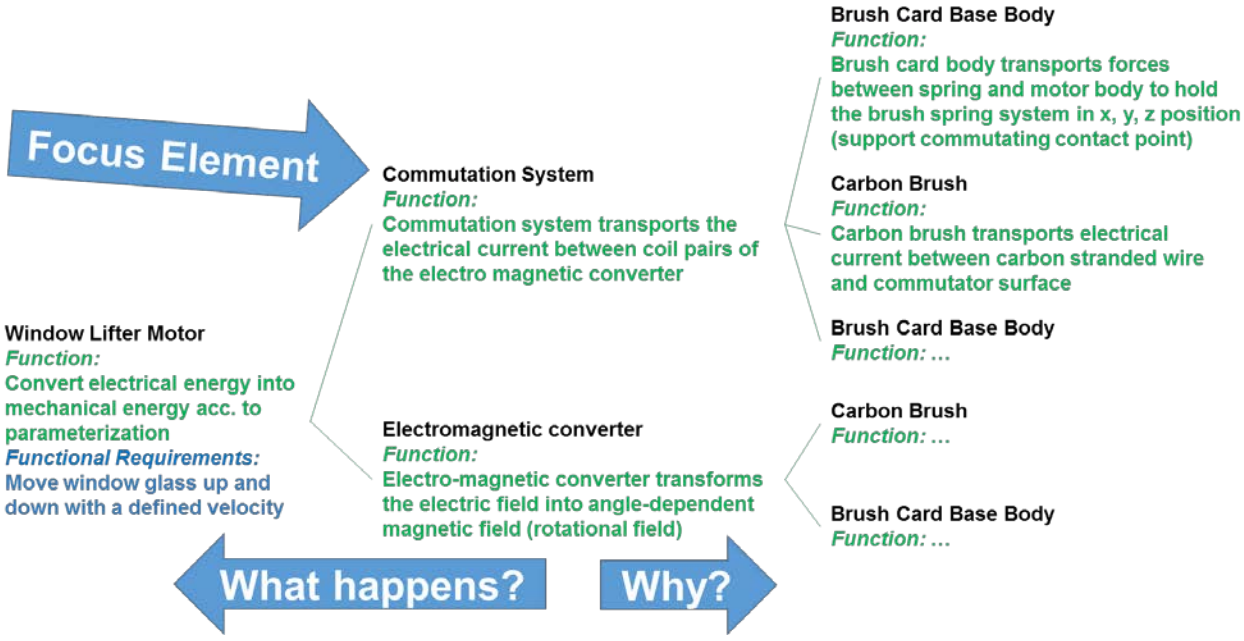


Figure 2.3-4 Example of Function Analysis Structure Tree

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The function structure can be created in the Functional Analysis section:

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Convert electrical energy into mechanical energy according to parameterization	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point)

Figure 2.3-5 Example of Function Analysis Form

The column header numbering (1, 2, 3) and color coding are included to help show alignment between the Structure Analysis and associated content of the Function Analysis (see figure 2.3-5). In this section you work from left to right answering the question: "How is the higher level function enabled by lower level functions?"

1. Next Higher Level Function and Requirement:
   The function in scope of the Analysis.
2. Focus Element Function and Requirement:
   The function of the associated System Element (item in focus) identified in the Structure Analysis.
3. Next Lower Level Function and Requirement or Characteristic:
   The function of the associated Component Element identified in the Structure Analysis.

2.3.6 Collaboration between Engineering Teams (Systems, Safety, and Components)

Engineering teams within the company need to collaborate to make sure information is consistent for a project or customer program especially when multiple DFMEA teams are simultaneously conducting the technical risk analysis. For example, a systems group might be developing the design architecture (structure) and this information would be helpful to the DFMEA to avoid duplication of work. A safety team may be working with the customer to understand the safety goals and hazards. This information would be helpful to the DFMEA to ensure consistent severity ratings for failure effects.

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2.3.7 Basis for Failure Analysis

Complete definition of functions (in positive words) will lead to a comprehensive Step 4 Failure Analysis because the potential failures are ways the functions could fail (in negative words).

2.4 Design FMEA 4th Step: Failure Analysis

2.4.1 Purpose

The purpose of the Design Failure Analysis is to identify failure causes, modes, and effects, and show their relationships to enable risk assessment.



The main objectives of a Design Failure Analysis are:

- Potential Failure Effects, Failure Modes, Failure Causes for each product function (Failure Chain)
- Collaboration between customer and supplier (Failure Effects)
- Basis for the documentation of failures in the FMEA form and the Risk Analysis step

2.4.2 Failures

Failures of a function are deduced from the functions. There are several types of potential failure modes including, but not limited to:

- Loss of function (i.e. inoperable, fails suddenly)
- Degradation of function (i.e. performance loss over time)
- Intermittent function (i.e. operation randomly starts/stops/starts)
- Partial function (i.e. performance loss)
- Unintended function (i.e. operation at the wrong time, unintended direction, unequal performance)
- Exceeding function (i.e. operation above acceptable threshold)
- Delayed function (i.e. operation after unintended time interval)

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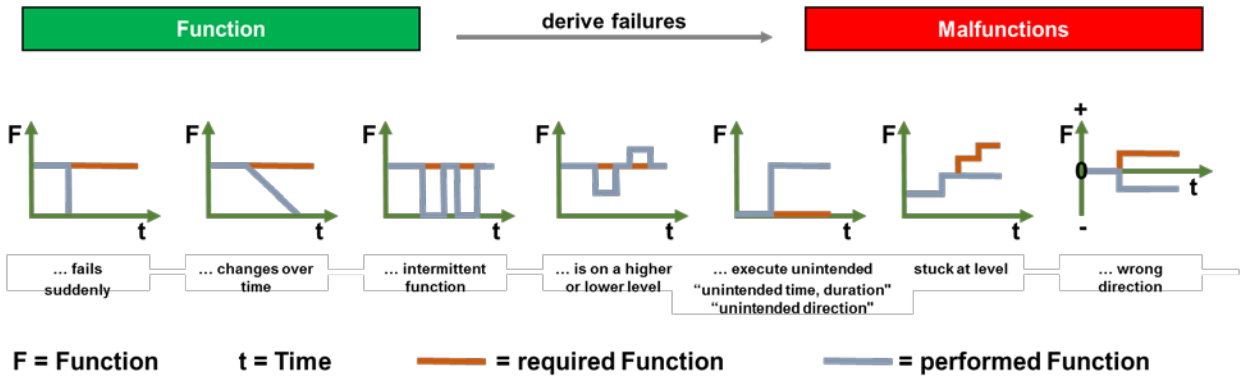


Figure 2.4-1 Types of Failure Modes

The description of a system and subsystem failure mode is described in terms of functional loss or degradation i.e. steering turns right when the hand wheel is moved left, as an example of an unintended function. When necessary the operating condition of the vehicle should be included i.e. loss of steering assist during start up or shut down.

A component/part failure mode is comprised of a noun and a failure description i.e. seal twisted.

It is critical that the description of the failure is clear and understandable for the person who is intended to read it. A statement “not fulfilled”, “not OK”, “defective”, “broken” and so on is not sufficient.

More than one failure may be associated with a function. Therefore, the team should not stop as soon as one failure is identified. They should ask "how else can this fail?"

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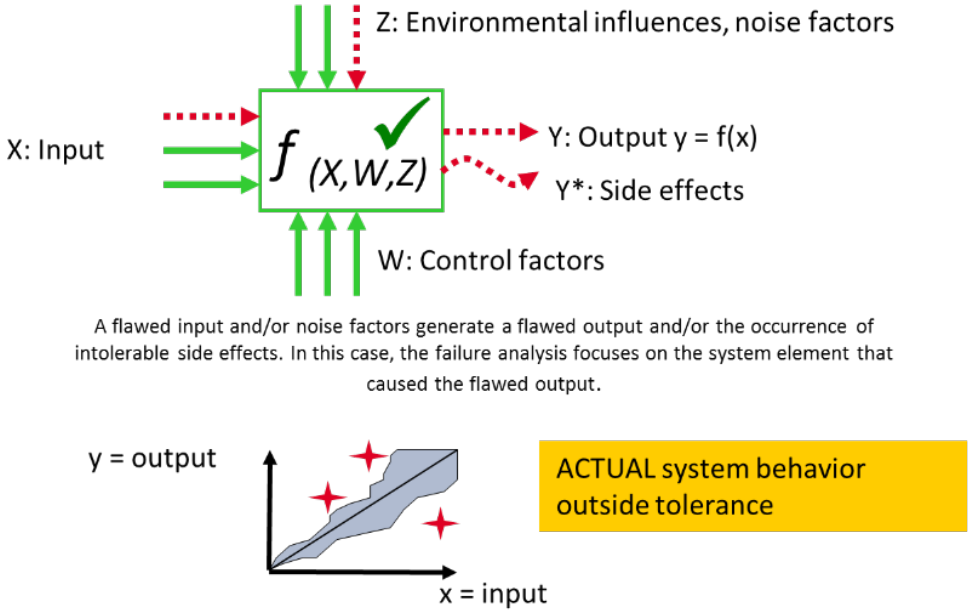


Figure 2.4-2 Definition of a Failure

2.4.3 The Failure Chain

There are three different aspects of failures analyzed in an FMEA:

- Failure Effect (FE)
- Failure Mode (FM)
- Failure Cause (FC)

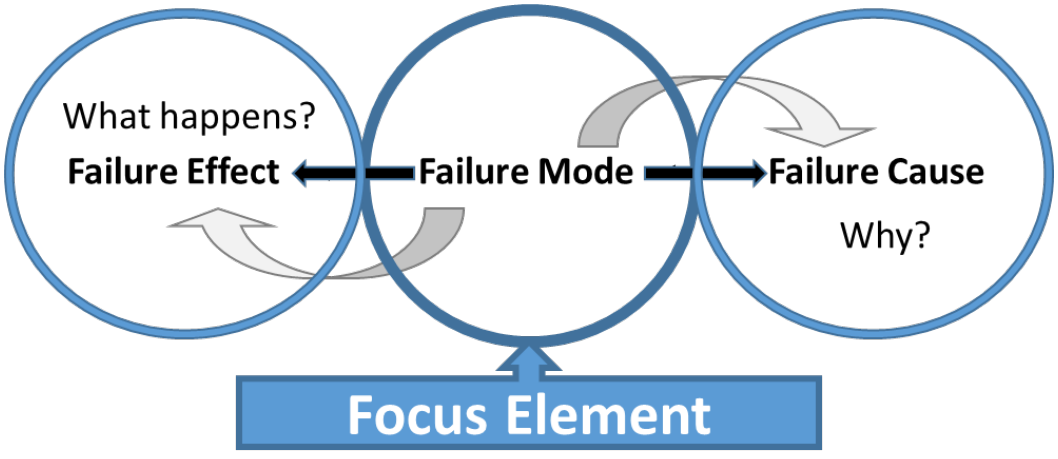


Figure 2.4-3 Theoretical failure chain model

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2.4.4 Failure Effects

A Failure Effect is defined as the consequences of a failure mode.

Describe effects on the next level of product integration (internal or external), the end user who is the vehicle operator (external), and government regulations (regulatory) as applicable

Customer effects should state what the user might notice or experience including those effects that could impact safety. The intent is to forecast the failure effects consistent with the team's level of knowledge. A failure mode can have multiple effects relating to internal and external customers.

Effects may be shared by OEMs with suppliers and suppliers with sub-suppliers as part of design collaboration.

The severity of failure effects is evaluated on a ten-point scale according to Table D1.

Examples of failure effects on the End User:

- No discernible effect
- Poor appearance i.e. unsightly close-out, color fade, cosmetic corrosion
- Noise i.e. misalignment/rub, fluid-borne noise, squeak/rattle, chirp, and squawk
- Unpleasant odor, rough feel, increased efforts
- Operation impaired, intermittent, unable to operate, electro-magnetic in-compatibility (EMC)
- External leak resulting in performance loss, erratic operation, unstable
- Unable to drive vehicle (walk home)
- Noncompliance with government regulations
- Loss of steering or braking

> NOTE: In some cases, the team conducting the analysis may not know the end user effect, i.e. catalogue parts, off-the-shelf products, Tier 3 components. When this information is not known, the effects should be defined in terms of the part function and specification. In these cases the system integrator is responsible for ensuring the correct part for the application is selected, i.e. auto, truck, marine, agriculture.
> An additional column is shown on the Rating Tables for "Corporate or Product Line Examples".

2.4.5 Failure Mode

A Failure Mode is defined as the manner in which an item could fail to meet or deliver the intended function.

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The Failure Modes are derived from the Functions. Failure Modes should be described in technical terms, and not necessarily as symptom noticeable by the customer.

In preparing the DFMEA, assume that the design will be manufactured and assembled to the design intent. Exceptions can be made at the team's discretion where historical data indicates deficiencies exist in the manufacturing process.

Examples of component-level failure modes could be, but are not limited to:

NOT RECOMMENDED	→	RECOMENDED
Cracked	→	Component cracked
Deformed	→	Component deformed
Fractured	→	Component fractured
Loose	→	Part loose
Oxidized	→	Part oxidized
Sticking	→	Component sticking

Examples of system-level failure modes could be, but are not limited to:

- Complete fluid loss
- Disengages too fast
- Does not disengage
- Does not transmit torque
- Does not hold full torque
- Inadequate structural support
- Loss of structural support
- No signal / Intermittent signal
- Provides too much pressure/signal/voltage
- Provides insufficient pressure/signal/voltage
- Unable to withstand load/temperature/vibration

2.4.6 Failure Cause

A Failure Cause is an indication of why the failure mode could occur. The consequence of a cause is the failure mode. Identify, to the extent possible, every potential cause for each failure mode. The consequences of not being robust to noise factors (found on a P-Diagram) may also be Failure Causes. The cause should be listed as concisely and completely as possible so that remedial efforts (controls and actions) can be aimed at appropriate causes.

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The Failure Causes can be derived from the Failure modes of the next lower level function and requirement and the potential noise factors (e.g. from a Parameter Diagram).

Types of potential failure causes could be, but are not limited to:

- Inadequate design for functional performance (incorrect material specified, incorrect geometry, incorrect part selected for application, incorrect surface finish specified, inadequate travel specification, improper friction material specified, insufficient lubrication capability, inadequate design life assumption, incorrect algorithm, improper maintenance instructions, etc.)
- System interactions (mechanical interfaces, fluid flow, heat sources, controller feedback, etc.)
- Changes over time (yield, fatigue, material instability, creep, wear, corrosion, chemical oxidation, electro migration, over-stressing, etc.)
- Design inadequate for external environment (heat, cold, moisture, vibration, road debris, road salt, etc.)
- End user error or behavior (wrong gear used, wrong pedal used, excessive speeds, towing, wrong fuel type, service damage, etc.)
- Lack of robust design for manufacturing (part geometry allows part installation backwards or upside down, part lacks distinguishing design features, shipping container design causes parts to scratch or stick together, part handling causes damage, etc.)
- Software Issues (Undefined state, corrupted code/data)

2.4.7 Failure Analysis

Depending on whether the analysis is being done at the system, sub-system or component level, a failure can be viewed as a failure effect, failure mode, or failure cause. Failure Modes, Failure Causes and Failure Effects should correspond with the respective column in the FMEA Form.

Figure 2.4.-4 shows a cascade of design-related failure modes, causes, and effects from the vehicle level to the characteristic level. The focus element (Failure Mode), Causes, and Effects are different depending on the level of design integration. Consequently, a Failure Cause at the OEM becomes a Failure Mode at a next (Tier1) level. However, Failure Effects at the vehicle level (as perceived by the end user) should be documented when known, but not assumed. Therefore, the communication according to Figure 1.5.-1 should be considered. Failure Networks may be created by the organization that owns multiple levels of the design. When multiple organizations are

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responsible for different levels of the design they are responsible to communicate failure effects to the next higher or next lower level as appropriate.

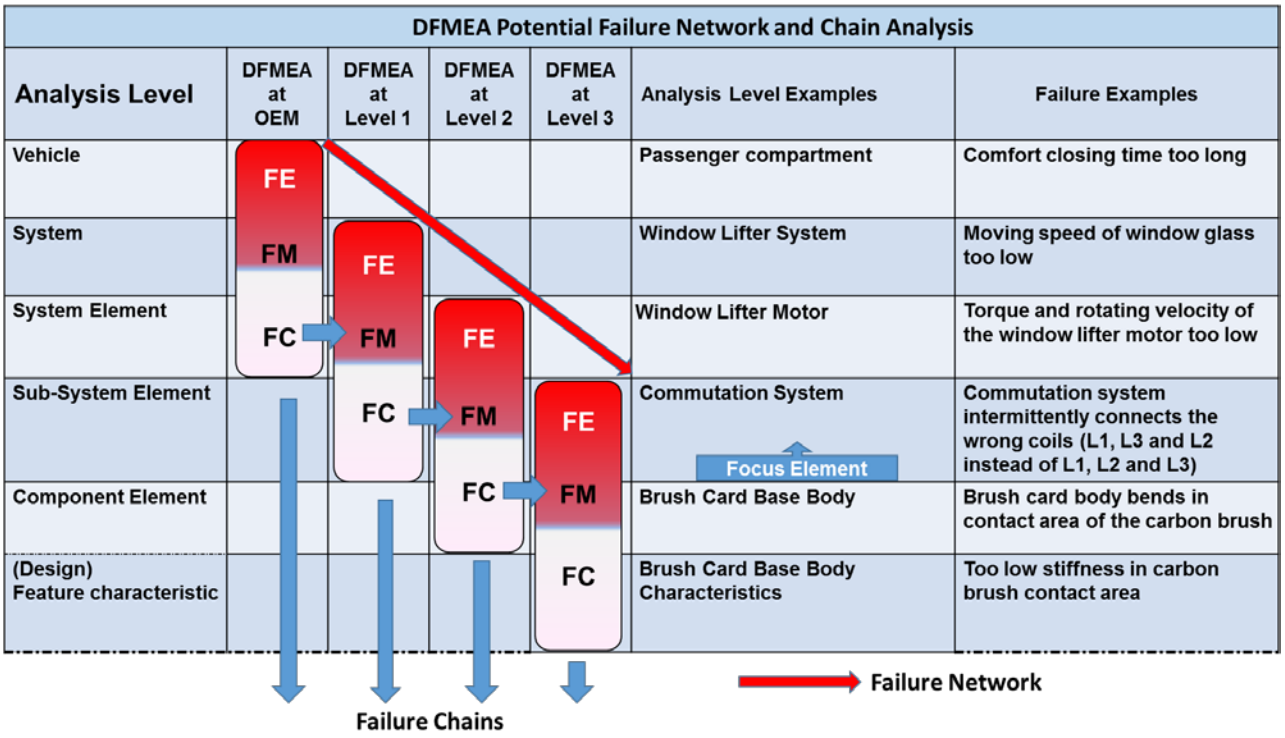


Figure 2.4-4 Failure Structure at different levels

To link Failure Cause(s) to a Failure Mode, the question should be "Why is the Failure Mode happening?"

To link Failure Effects to a Failure Mode, the question should be "What happens in the event of a Failure Mode?"

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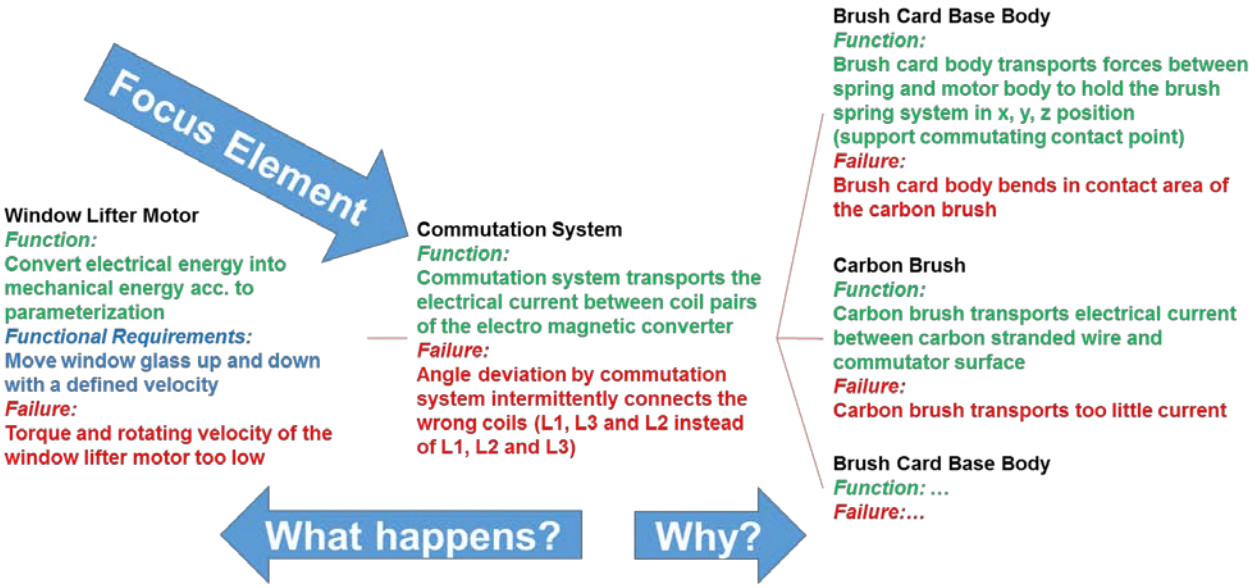


Figure 2.4-5 Example of Failure Analysis Structure Tree

The failure structure can be created in the Failure Analysis section.

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	**2. Failure Mode (FM) of the Focus Element**	**3. Failure Cause (FC) of the Next Lower Element or Characteristic**
Torque and rotating velocity of the window lifter motor too low	Angle deviation by commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush

Figure 2.4-6 Example of Failure Analysis Form

Following once again the header numbering (1, 2, 3) and color coding, by inspecting the items in the Function Analysis, begin building the Failure Chain.

1. Failure Effects (FE):
   The effect of failure associated with the “Next Higher Level Element and/or End User” in the Function Analysis.
2. Failure Mode (FM):
   The mode (or type) of failure associated with the “Focus Element” in the Function Analysis.

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3. Failure Cause (FC):
   The cause of failure associated with the “Next Lower Element or Characteristic” in the Function Analysis.

The Structure Analysis, Function Analysis and Failure Analysis may be documented as in the form below.

2.4.8 Failure Analysis Documentation

The DFMEA Form can have multiple views once the Structure Analysis, Function Analysis and Failure Analysis are complete.

1. Next Higher Level	1. Next Higher Level Function and Requirement	1. Failure Effects (FE) to the Next Higher Level Element and/or End User
Window Lifter Motor	**Convert electrical energy into mechanical energy acc. to parameterization**	Torque and rotating velocity of the window lifter motor too low

Figure 2.4-7 View of Product End Item-Function-Failure Form

2. Focus Element	2. Focus Element Function and Requirement	2. Failure Mode (FM) of the Focus Element
Commutation System	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Angle deviation by commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)

Figure 2.4-8 View of Focus Item/Element-Function-Failure Form

3. Next Lower Level or Characteristic Type	3. Next Lower Level Function and Requirement or Characteristic	3. Failure Cause (FC) of the Next Lower Element or Characteristic
Brush Card Base Body	Brush card body transports forces between spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point)	Brush card body bends in contact area of the carbon brush

Figure 2.4-9 View of Lower Level Item-Function-Failure Form

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2.4.9 Collaboration between Customer and Supplier (Failure Effects)

The output of the Failure Analysis may be reviewed by customers and suppliers prior to the Risk Analysis step or after to the Risk Analysis step based on agreements with the customer and need for sharing with the supplier.

2.4.10 Basis for Risk Analysis

Complete definition of potential failures will lead to a complete Step 5 Risk Analysis because the rating of Severity, Occurrence, and Detection are based on the failure descriptions. The Risk Analysis may be incomplete if potential failures are too vague or missing.

2.5 Design FMEA 5th Step: Risk Analysis

2.5.1 Purpose



The purpose of Design Risk Analysis is to estimate risk by evaluating Severity, Occurrence and Detection, and prioritize the need for actions.

The main objectives of the Design Risk Analysis are:

- Assignment of existing and/or planned controls and rating of failures
- Assignment of Prevention Controls to the Failure Causes
- Assignment of Detection Controls to the Failure Causes and/or Failure Modes
- Rating of Severity, Occurrence and Detection for each failure chain
- Collaboration between customer and supplier (Severity)
- Basis for the product or process Optimization step

2.5.2 Design Controls

Current design controls are proven considerations that have been established for similar, previous designs. Design control documents are a basis for the robustness of the design. Prevention-type controls and detection-type controls are part of the current library of verification and validation methods. Prevention controls provide information or guidance that is used as an input to the design. Detection controls describe established verification and validation procedures that have been previously demonstrated to detect the failure, should it occur. Specific references to design features that act to prevent a failure or line items in published test procedures will establish a credible link

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between the failure and the design control. Those prevention and/or detection methods that are necessary, but not part of a current library of defined procedures should be written as actions in the DFMEA.

2.5.3 Current Prevention Controls (PC)

Current Prevention Controls describe how a potential cause which results in the Failure Mode is mitigated using existing and planned activities. They describe the basis for determining the occurrence rating. Prevention Controls relate back to the performance requirement.

For items which have been designed out-of-context and are purchased as stock or catalog items from a supplier, the prevention control should document a specific reference to how the item fulfills the requirement. This may be a reference to a specification sheet in a catalog.

Current Prevention controls need to be clearly and comprehensively described, with references cited. If necessary, this can be done by reference to an additional document. Listing a control such as “proven material” or “lessons learned” is not a clear enough indication.

The DFMEA team should also consider margin of safety in design as a prevention control.

Examples of Current Prevention Controls:

- EMC directives adhered to, directive 89/336/EEC
- System design according to simulation, tolerance calculation and Procedure - analysis of concepts to establish design requirements
- Published design standard for a thread class
- Heat treat specification on drawing
- Sensor performance specifications.
- Mechanical redundancy (fail-safe)
- Design for testability
- Design and Material standards (internal and external)
- Documentation - records of best practices, lessons learned, etc. from similar designs
- Error-proofing (Poka-Yoke design i.e. part geometry prevents wrong orientation)
- Substantially identical to a design which was validated for a previous application, with documented performance history. (However, if there is a change to the duty cycle or operating conditions, then the carry-over item requires re-validation in order for the detection control to be relevant.)

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- Shielding or guards which mitigate potential mechanical wear, thermal exposure, or EMC
- Conformance to best practices

After completion of the preventive actions the occurrence is verified by the Detection Control(s).

2.5.4 Current Detection Controls (DC)

Current Detection Controls detect the existence of a failure cause or the failure mode before the item is released for production. Current Detection Controls that are listed in the FMEA represent planned activities (or activities already completed), not potential activities which may never actually be conducted.

Current Detection controls need to be clearly and comprehensively described. Listing a control such as “Test” or “Lab Test” is not a clear enough indication of a detection control. References to specific tests, test plans or procedures should be cited as applicable, to indicate that the FMEA team has determined that the test will actually detect the failure mode or cause, if it occurs (i.e. Test No. 1234 Burst Pressure Test, Paragraph 6.1).

Examples of Current Detection controls:

- Function check
- Burst test
- Environmental test
- Driving test
- Endurance test
- Range of motion studies
- Hardware in-the-loop
- Software in-the-loop
- Design of experiments
- Voltage output lab measurements

All controls that lead to a detection of the failure cause, or the failure mode are entered into the “Current Detection Controls” column.

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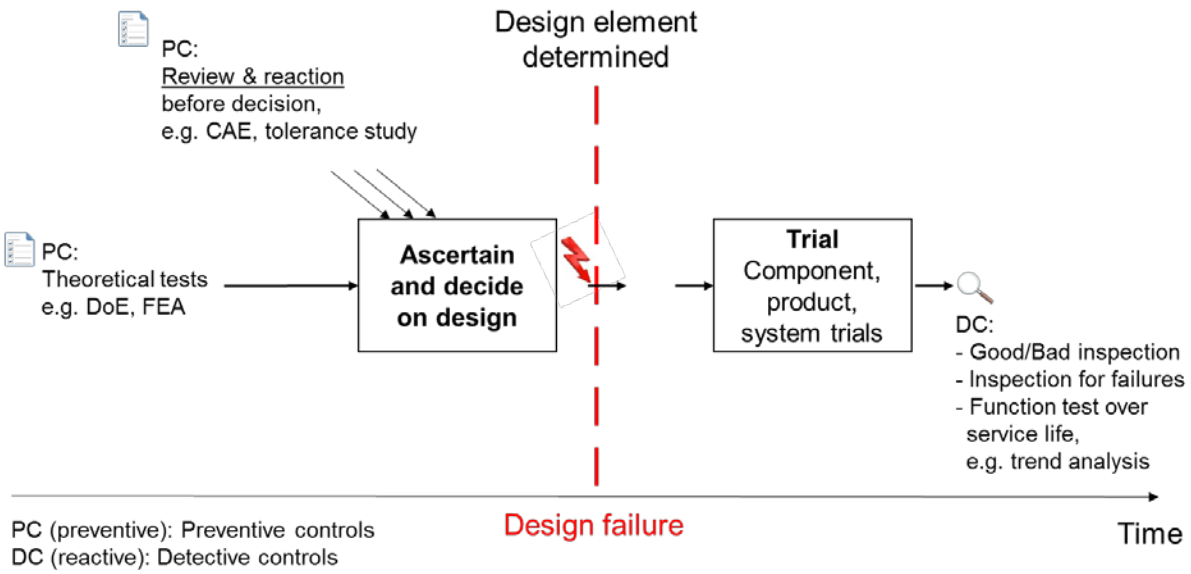


Figure 2.5-1 Prevention and Detection in the Design FMEA

2.5.5 Confirmation of Current Prevention and Detection Controls

The effectiveness of the current prevention and detection controls should be confirmed. This can be done during validation teardown reviews. Such confirmation can be documented within the DFMEA, or within other project documents, as appropriate, according to the team's normal product development procedure. Additional action may be needed if the controls are proven not to be effective.

The occurrence and detection evaluations should be reviewed when using FMEA entries from previous products, due to the possibility of different conditions for the new product.

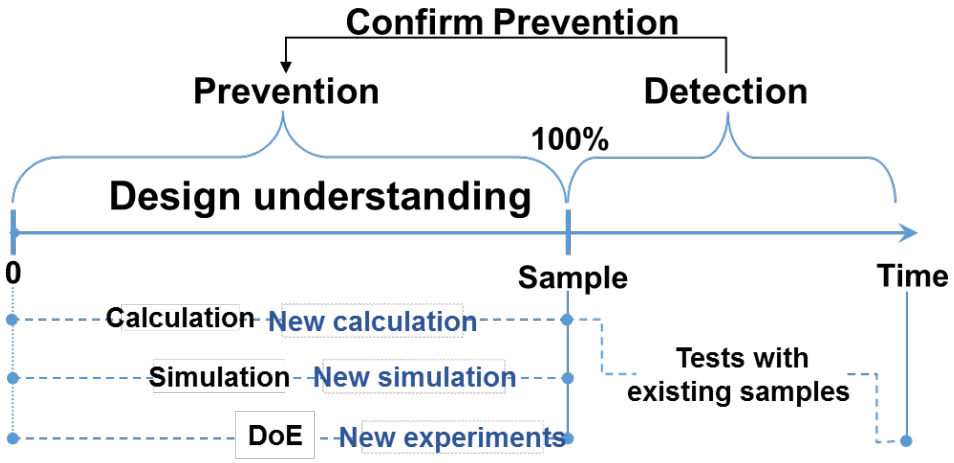


Figure 2.5-2 Roadmap of design understanding

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2.5.6 Evaluations

Each failure mode, cause and effect relationship is assessed to estimate risk. There are rating criteria for the evaluation of risk:

Severity (S): stands for the severity of the failure effect

Occurrence (O): stands for the occurrence of the failure cause

Detection (D): stands for the detection of the occurred failure cause and/or failure mode.

Evaluation numbers from 1 to 10 are used for S, O, and D respectively, where 10 stands for the highest risk contribution.

NOTE: It is not appropriate to compare the ratings of one team's FMEA with the ratings of another team's FMEA, even if the product/ process appear to be identical, since each team's environment is unique and thus their respective individual ratings will be unique (i.e. the ratings are subjective).

2.5.7 Severity (S)

The Severity rating (S) is a measure associated with the most serious failure effect for a given failure mode of the function being evaluated. The rating is used to identify priorities relative to the scope of an individual FMEA and is determined without regard for occurrence or detection.

Severity should be estimated using the criteria in the Severity Table D1. The table may be augmented to include product-specific examples. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent even if modified for individual design analysis.

The Severity evaluations of the failure effects should be transferred by the customer to the supplier, as needed.

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Product General Evaluation Criteria Severity (S)			
Potential Failure Effects rated according to the criteria below.			Blank until filled in by user
S	**Effect**	**Severity criteria**	**Corporate or Product Line Examples**
10	**Very High**	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Noncompliance with regulations.	
8	**High**	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		**Degradation** of primary vehicle function necessary for normal driving during expected service life.	
6	**Moderate**	**Loss** of secondary vehicle function.	
5		**Degradation** of secondary vehicle function.	
4		Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible effect.	

Table D1 - DFMEA SEVERITY (S)

2.5.8 Occurrence (O)

The Occurrence rating (O) is a measure of the effectiveness of the prevention control, taking into account the rating criteria.

Occurrence ratings should be estimated using the criteria in the Occurrence Table D2. The table may be augmented to include product-specific examples. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual de-sign analysis (i.e. passenger car, truck, motorcycle, etc.).

The Occurrence rating number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

The Occurrence rating describes the potential of the failure cause to occur in customer operation, according to the rating table, considering results of already completed detection controls.

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Expertise, data handbooks, warranty databases or other experiences in the field of comparable products, for example, can be consulted for the analysis of the evaluation numbers.

When failure causes are rated for occurrence, it is done taking into account an estimation of the effectiveness of the current prevention control. The accuracy of this rating depends on how well the prevention control has been described.

Questions such as the following may be helpful for a team when trying to determine the appropriate Occurrence rating:

- What is the service history and field experience with similar components, subsystems, or systems?
- Is the item a carryover product or similar to a previous level item?
- How significant are changes from a previous level item?
- Is the item completely new?
- What is the application or what are the environmental changes?
- Has an engineering analysis (i.e. reliability) been used to estimate the expected comparable occurrence rate for the application?
- Have prevention controls been put in place?
- Has the robustness of the product been proven during the product development process?

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Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
10	Extremely high	First application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience. Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.	
9	Very high	First use of design with technical innovations or materials within the company. New application or change in duty cycle / operating conditions. No product verification and/or validation experience. Prevention controls not targeted to identify performance to specific requirements.	
8		First use of design with technical innovations or materials on a new application. New application or change in duty cycle / operating conditions. No product verification and/or validation experience. Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.	

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Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
7	High	New design based on similar technology and materials. New application or change in duty cycle / operating conditions. No product verification and/or validation experience. Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance	
6		Similar to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.	
5	Moderate	Detail changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure. Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.	
4		Almost identical design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience. Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause and indicate likely design conformance.	

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Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
3	Low	Detail changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause and predict conformance of production design.	
2	Very low	Almost identical mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause and indicate confidence in design conformance.	
1	Extremely low	Failure eliminated through preventive control and failure cause is not possible by design	
Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.			
Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins			
Note: O 10, 9, 8, 7 can drop based on product validation activities.			

Table D2 - DFMEA Occurrence (O)

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2.5.9 Detection (D)

The Detection rating (D) is an estimated measure of the effectiveness of the detection control to reliably demonstrate the failure cause or failure mode before the item is released for production. The detection rating is the rating associated with the most effective detection control.

Detection is a relative rating, within the scope of the individual FMEA and is determined without regard for severity or occurrence. Detection should be estimated using the criteria in Table D3. This table may be augmented with examples of common detection methods used by the company. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual product analysis.

The detection rating is initially a prediction of the effectiveness of any yet unproven control. The effectiveness can be verified and re-evaluated after the detection control is completed. However, the completion or cancellation of a detection control (such as a test) may also affect the estimation of occurrence.

In determining this estimate, questions such as the following should be considered:

- Which test is most effective in detecting the Failure Cause or the Failure Mode?
- What is the usage Profile / Duty Cycle required detecting the failure?
- What sample size I s required to detect the failure?
- Is the test procedure proven for detecting this Cause / Failure Mode?

Detection Potential (D) for the Validation of the Product Design				
Detection Controls rated according to Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
10	**Very low**	Test procedure yet to be developed.	Test method not defined	
9		Test method not designed specifically to detect failure mode or cause.	Pass-Fail, Test-to-Fail, Degradation Testing	

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Detection Potential (D) for the Validation of the Product Design				
Detection Controls rated according to Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
8	**Low**	New test method; not proven.	Pass-Fail, Test-to-Fail, Degradation Testing	
7		Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or re-tooling.	Pass-Fail Testing	
6	**Moderate**		Test-to-Failure	
5			Degradation Testing	
4	**High**	Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is sufficient to modify production tools before release for production.	Pass-Fail Testing	
3			Test-to-Failure	
2			Degradation Testing	
1	**Very high**	Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to always detect the failure mode or failure cause.		

Table D3 - DFMEA DETECTION (D)

2.5.10 Action Priority (AP)

Once the team has completed the initial identification of Failure Modes, Failure Effects, Failure Causes and controls, including ratings for severity, occurrence, and detection, they must decide if further efforts are needed to reduce the risk. Due to the inherent limitations on resources, time, technology, and other factors, they must choose how to best prioritize these efforts.

The Action Priority (AP) method is introduced in this handbook. It accounts for all 1000 possible combinations of S, O, and D. It was created to give more emphasis on severity first, then occurrence, then detection. This logic follows the failure-prevention intent of FMEA. The AP table offers a suggested high-medium-low priority for action. Companies can use a single system to evaluate action

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priorities instead of multiple systems required from multiple customers.

Risk Priority Numbers are the product of S x O x D and range from 1 to 1000. The RPN distribution can provide some information about the range of ratings, but RPN alone is not an adequate method to determine the need for more actions since RPN gives equal weight to S, O, and D. For this reason, RPN could result in similar risk numbers for very different combinations of S, O, and D leaving the team uncertain about how to prioritize. When using RPN it is recommended to use an additional method to prioritize like RPN results such as S x O. The use of a Risk Priority Number (RPN) threshold is not a recommended practice for determining the need for actions. The RPN and S x O methods are not included in this publication.

Risk matrices can represent combinations of S and O, S and D, and O and D. These matrices provide a visual representation of the results of the analysis and can be used as an input to prioritization of actions based on company-established criteria not included in this publication.

Since the AP Table was designed to work with the Severity, Occurrence, and Detection tables provided in this handbook, if the organization chooses to modify the S, O, D, tables for specific products, processes, or projects, the AP table should also be carefully reviewed.

> Note: Action Priority rating tables are the same for DFMEA and PFMEA, but different for FMEA-MSR.

Priority High (H): Highest priority for review and action. The team needs to either identify an appropriate action to improve Prevention and / or Detection Controls or justify and document why current controls are adequate.

Priority Medium (M): Medium priority for review and action. The team should identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.

Priority Low (L): Low priority for review and action. The team could identify actions to improve prevention or detection controls.

It is recommended that potential Severity 9-10 Failure Effects with Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

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This is not the prioritization of High, Medium, or Low risk, it is the prioritization of the actions to reduce risk.

> Note: It may be helpful to include a statement such as “No further action is needed” in the Remarks field as appropriate.

Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**ACTION PRIORITY (AP)**	**Comments**
Product or Plant Effect Very high	9-10	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	

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Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**ACTION PRIORITY (AP)**	**Comments**
Product or Plant Effect High	7-8	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect Moderate	4-6	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	M	
				Very high	1	M	
		High	6-7	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	M	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	

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Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**ACTION PRIORITY (AP)**	**Comments**
Product or Plant Effect Low	2-3	Very high	8-10	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		High	6-7	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
No discernible Effect	1	Very low - Very high	1-10				

Table AP – ACTION PRIORITY FOR DFMEA and PFMEA

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FAILURE ANALYSIS (STEP 4)				DFMEA RISK ANALYSIS (STEP 5)					
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)
Torque and rotating velocity of the window lifter motor too low	6	Angle deviation by commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush	Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastics and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L	

Figure 2.5-3 Example of DFMEA Risk Analysis Form

2.5.11 Collaboration between Customer and Supplier (Severity)

The output of the Risk Analysis creates the mutual understanding of technical risk between customers and suppliers. Methods of collaboration range from verbal to formal reports. The amount of information shared is based on the needs of a project, company policy, contractual agreements, and so on. The information shared depends on the placement of the company in the supply chain. Some examples are listed below.

1. The OEM may compare design functions, failure effects, and severity from a vehicle-level DFMEA with the Tier 1 supplier DFMEA.
2. The Tier 1 supplier may compare design functions, failure effects, and severity from a subsystem DFMEA with the Tier 2 supplier who has design responsibility.
3. The Tier 1 supplier communicates necessary information about product characteristics on product drawings and/or specifications, or other means, including designation of standard or special characteristics and severity. This information is used as an input to the Tier 2 supplier PFMEA as well as the Tier 1's internal PFMEA. When the design team communicates the associated risk of making product characteristics out of specification the process

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team can build in the appropriate level of prevention and detection controls in manufacturing. Reference: PFMEA Section 3.4 for more information.

2.5.12 Basis for Optimization

The output of Steps 1, 2, 3, 4, and 5 of the 7-step FMEA process is used to determine if additional design or testing action is needed. The design reviews, customer reviews, management reviews, and cross-functional team meetings lead to Step 6 Optimization.

2.6 Design FMEA 6th Step: Optimization

2.6.1 Purpose



The purpose of the Design Optimization is to determine actions to mitigate risk and assess the effectiveness of those actions.

The main objectives of a Design Optimization are:

- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and deadlines for action implementation
- Implementation and documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
- Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures
- Basis for refinement of the product requirements and prevention and detection controls

The primary objective of Design Optimization is to develop actions that reduce risk and increase customer satisfaction by improving the design. In this step, the team reviews the results of the risk analysis and assigns actions to lower the likelihood of occurrence of the Failure Cause or increase the robustness of the Detection Control to detect the Failure Cause or Failure Mode. Actions may also be assigned which improve the design but do not necessarily lower the risk assessment rating. Actions represent a commitment to take a specific, measurable, and achievable action, not potential actions which may never be implemented. Actions are not intended to be used for activities that are already planned as these are documented in the Prevention or Detection Controls and are already considered in the initial risk analysis.

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If the team decides that no further actions are necessary, “No further action is needed” is written in the Remarks field to show the risk analysis was completed.

The DFMEA should be used to assess technical risks related to continuous improvement of the design.

The optimization is most effective in the following order:

- Design modifications to eliminate or mitigate a Failure Effect (FE).
- Design modifications to reduce the Occurrence (O) of the Failure Cause (FC)
- Increase the Detection (D) ability for the Failure Cause (FC) or Failure Mode (FM).
- In the case of design modifications, all impacted design elements are evaluated again.

In the case of concept modifications, all steps of the FMEA are reviewed for the affected sections. This is necessary because the original analysis is no longer valid since it was based upon a different design concept.

2.6.2 Assignment of Responsibilities

Each action should have a responsible individual and a Target Completion Date (TCD) associated with it.

The responsible person ensures the action status is updated. If the action is confirmed this person is also responsible for the action implementation.

The Actual Completion Date for Preventive and Detection Actions is documented including the date the actions are implemented.

Target Completion Dates should be realistic (i.e. in accordance with the product development plan, prior to process validation, prior to start of production).

2.6.3 Status of the Actions

Suggested levels for Status of Actions:

Open

No action defined.

Decision pending (optional)

The action has been defined but has not yet decided on. A decision paper is being created.

Implementation pending (optional)

The action has been decided on but not yet implemented.

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Completed

Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.

Not Implemented

Not Implemented status is assigned when a decision is made not to implement an action. This may occur when risks related to practical and technical limitations are beyond current capabilities.

The FMEA is not considered “complete” until the team assesses each item’s Action Priority and either accepts the level of risk or documents closure of all actions.

If “No Action Taken”, then Action Priority is not reduced and the risk of failure is carried forward into the product design. Actions are open loops that need to be closed in writing.

2.6.4 Assessment of Action Effectiveness

When an action has been completed, Occurrence, and Detection values are reassessed, and a new Action Priority may be determined.

The new action receives a preliminary Action Priority rating as a prediction of effectiveness.

However, the status of the action remains “implementation pending” until the effectiveness has been tested. After the tests are finalized the preliminary rating has to be confirmed or adapted, when indicated. The status of the action is then changed from “implementation pending” to “completed”.

The reassessment should be based on the effectiveness of the Preventive and Detection Actions taken and the new values are based on the definitions in the Design FMEA Occurrence and Detection rating tables.

2.6.5 Continual Improvement

The DFMEA serves as an historical record for the design. Therefore, the original Severity, Occurrence, and Detection (S, O, D) numbers need to be visible or at a minimum available and accessible as part of version history. The completed analysis becomes a repository to capture the progression of design decisions and design refinements. However, original S, O, D ratings may be modified for foundation, family or generic DFMEAs because the information is used as a starting point for an application-specific analysis.

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DFMEA RISK ANALYSIS (STEP 5)						DFMEA OPTIMIZATION (STEP 6)									
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP
Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastics and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L		None	Final product test: measuring the current under worst case conditions acc. Test spec. MRJ1140	Test Engineer Mr. Max Mueller	dd.mm.yyyy	planned			6	2	1	L

Figure 2.6-1 Example of DFMEA Optimization with new Risk Evaluation Form

2.6.6 Collaboration between the FMEA team, Management, Customers, and Suppliers regarding Potential Failures

Communication between the FMEA team, management, customers and suppliers during the development of the technical risk analysis and/or when the DFMEA is initially complete brings people together to improve their understanding of product functions and failures. In this way, there is a transfer of knowledge that promotes risk reduction.

2.7 Design FMEA 7th Step: Results Documentation



The scope and results of a DFMEA should be summarized in a report. The report may be used for communication purposes within a company, or between companies. The report is not meant to replace reviews of the DFMEA details when requested by management, customers, or suppliers. It is meant to be a summary for the DMFEA team and others to confirm completion of each of the tasks and review the results of the analysis.

It is important that the content of the documentation fulfill the requirements of the organization, the intended reader, and relevant stakeholders. Details may be agreed upon between the

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parties. In this way, it is also ensured that all details of the analysis and the intellectual property remain at the developing company.

The layout of the document may be company specific. However, the report should indicate the technical risk of failure as a part of the development plan and project milestones. The content may include the following:

A. A statement of final status compared to original goals established in 1.5 Project Plan
   a. FMEA Intent – Purpose of this FMEA?
   b. FMEA Timing – FMEA due date?
   c. FMEA Team – List of participants?
   d. FMEA Task - Scope of this FMEA?
   e. FMEA Tool – How do we conduct the analysis Method used?

B. A summary of the scope of the analysis and identify what is new.

C. A summary of how the functions were developed.

D. A summary of at least the high-risk failures as determined by the team and provide a copy of the specific S/O/D rating tables and method of action prioritization (e.g. Action Priority table).

E. A summary of the actions taken and/or planned to address the high-risk failures including status of those actions.

F. A plan and commitment of timing for ongoing FMEA improvement actions.
   a. Commitment and timing to close open actions.
   b. Commitment to review and revise the DFMEA during mass production to ensure the accuracy and completeness of the analysis as compared with the production design (e.g. revisions triggered from design changes, corrective actions, etc., based on company procedures). (Refer to section 1.4 Case 3 FMEA revisions)
   c. Commitment to capture “things gone wrong” in foundation DFMEAs for the benefit of future analysis reuse, when applicable. Refer to section 1.3.6 Foundation and Family FMEAs)

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3 EXECUTION OF THE PROCESS FMEA (PFMEA)

3.1 Process FMEA 1st Step: Planning and Preparation

3.1.1 Purpose

The purpose of the Process Planning and Preparation Step is to describe what product/processes are to be included or excluded for review in the PFMEA project.

The process takes into account that all processes within the facility can be analyzed or reanalyzed using PFMEA. This process allows an organization to review all processes at a high level and to make a final determination for which processes will be analyzed. The overall advantage of Preparation is to focus resources on processes with the highest priority.



The main objectives of the Process Planning and Preparation Step are:

- Project identification
- Project plan: InTent, Timing, Team, Tasks, Tools (5T)
- Analysis boundaries: What is included and excluded from the analysis
- Identification of baseline FMEA with lessons learned
- Basis for the Structure Analysis step

3.1.2 PFMEA Project Identification and Boundaries

PFMEA Project identification includes a clear understanding of what needs to be evaluated. This involves a decision-making process to define the PFMEAs that are needed for a customer program. What to exclude can be just as important as what to include in the analysis.

Below are some basic questions that help identify PFMEA projects.

- What is the customer buying from us?
- Are there new requirements?
- What specific process/elements cause a risk in imparting the requirement/characteristic?
- Does the customer or company require a PFMEA?
- Do we make the product and have design control?
- Do we buy the product and still have design control?
- Do we buy the product and do not have design control?
- Who is responsible for the interface design?
- Do we need a system, subsystem, component, or other level of analysis?

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Answers to these questions and others defined by the company help create the list of DFMEA projects needed. The PFMEA project list assures consistent direction, commitment and focus.

The following may assist the team in defining PFMEA boundaries, as available:

- Legal Requirements
- Technical Requirements
- Customer wants/needs/expectation (external and internal customers)
- Requirements specification
- Diagrams (Block/Boundary/System)
- Schematics, Drawings, and/or 3D Models
- Bill of Materials (BOM), Risk Assessment
- Previous FMEA for similar products
- Error proofing requirements, Design for Manufacturability and Assembly (DFM/A)
- QFD Quality Function Deployment

Preparation needs to be established at the start of the process to assure consistent direction and focus, i.e. an entire process line, process item / process element.

Processes within the plant that can impact the product quality and can be considered for PFMEA analysis: receiving processes, part and material storage, product and material delivery, manufacturing, assembly, packaging, labeling, completed product transportation, storage, maintenance processes, detection processes and rework and repair processes, etc.

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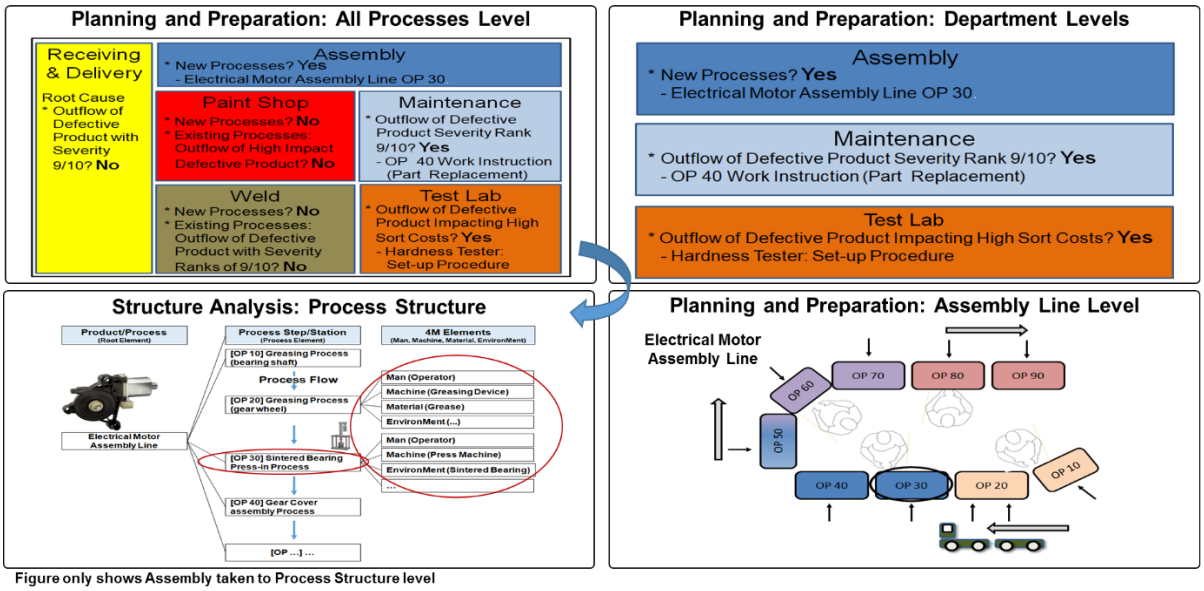


Figure only shows Assembly taken to Process Structure level

Figure 3.1-1 Demonstration of the process for narrowing the Preparation

The following may be considered in defining the scope of the PFMEA, as appropriate:

- Novelty of technology/ Degree of innovation
- Quality/Reliability History (In-house, zero mileage, field failures, warranty and policy claims for similar products)
- Complexity of Design
- Safety of people and systems
- Cyber-Physical System (including cyber-security)
- Legal Compliance
- Catalog & standard parts
- Items that may assist in determining whether an existing PFMEA should be included in the final scope:
- New development of products & processes.
- Changes to products or processes
- Changes to the operating conditions
- Changed requirements (laws/regulations, standards/norms, customers, state of the art)
- Manufacturing experience, 0 km issues, or field issues / Warranty
- Process failures that may result in hazards
- Findings due to internal product monitoring
- Ergonomic issues
- Continuous Improvement

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3.1.3 PFMEA Project Plan

A plan for the execution of the PFMEA should be developed once the DFMEA project is known.

It is recommended that the 5T method (Intent, Timing, Team, Tasks, Tool) be used as described in section 1.5 of this handbook. The organization also needs to factor in development of the applicable Customer Specific Requirement(s) (CSRs) methods and/or deliverables into the project plan. The plan for the PFMEA helps the company be proactive in starting the PFMEA early. The DFMEA activities (7-step process) should be incorporated into the overall project plan.

3.1.4 Identification of the Baseline PFMEA

Part of the preparation for conducting the PFMEA is knowing what information is already available that can help the cross-functional team. This includes use of a foundation PFMEA (described in Section 1.3), similar product PFMEA, or product foundation PFMEA. The foundation PFMEA is a specialized foundation process FMEA for products that generally contain common or consistent product boundaries and related functions. For a new product in the foundation, added to this foundation PFMEA would be the new project specific components and functions to complete the new product's PFMEA. The additions for the new product may be in the foundation PFMEA itself, or in a new document with reference to the original family or foundation PFMEA. If no baseline is available, then the team will develop a new PFMEA.

3.1.5 Process FMEA Header

During Preparation, the header of the PFMEA document should be filled out. The header may be modified to meet the needs of the organization and includes some of the basic PFMEA Preparation information as follows:

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Company Name: Name of Company Responsible of PFMEA
Manufacturing Location: Geographical Location
Customer Name: Name of Customer(s) or Product Family
Model Year / Program(s): Customer Application or Company Model /Style
Subject: Name of PFMEA project
PFMEA Start Date: Start Date
PFMEA Revision Date: Latest Revision Date
Cross-Functional Team: Team: Team Roster needed
PFMEA ID Number: Determined by Company
Process Responsibility: Name of PFMEA owner
Confidentiality Level: Business Use, Proprietary, Confidential

Example: Process Failure Mode and Effects Analysis (Process FMEA)					
Scope Analysis (Step 1)					
Company Name:	Acme Automotive	**Subject:**	PX123 Manual Column Assembly		
Manufacturing Location:	Plant 6, Saginaw, Michigan	**DFMEA Start Date:**	19-Mar-2018	**PFMEA ID Number:**	654321
Customer Name:	Jackson Industry	**DFMEA Revision Date:**	25-Sep-2018	**Process Responsibility:**	B. Black
Model Year(s) / Program(s):	2020 PX123	**Cross Functional Team:**	See Team List	**Confidentiality Level:**	Confidential

Figure 3.1-2 Example of Completed PFMEA Header Preparation (Step 1)

3.2 Process FMEA 2nd Step: Structure Analysis

3.2.1 Purpose

The purpose of Process Structure Analysis is to identify and breakdown the manufacturing system into Process items, Process steps, and Process Work Elements.



The main objectives of a Process Structure Analysis are:

- Visualization of the analysis scope
- Structure tree or equivalent: process flow diagram
- Identification of process steps and sub-steps
- Collaboration between customer and supplier engineering teams (interface responsibilities)
- Basis for the Function Analysis step

A Process Flow Diagram or a Structure Tree helps define the process and provide the basis for Structure Analysis. Formats may vary by company including the use of symbols, symbol type and their meaning. A Process FMEA is intended to represent the process flow as it physically exists when “walking the process”, describing the flow of the product through the process. Function Analysis (Step 3) should not begin until Structure Analysis (Step 2) is complete.

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3.2.2 Process Flow Diagram

A Process Flow Diagram is a tool that can be used as an input to the Structure Analysis.

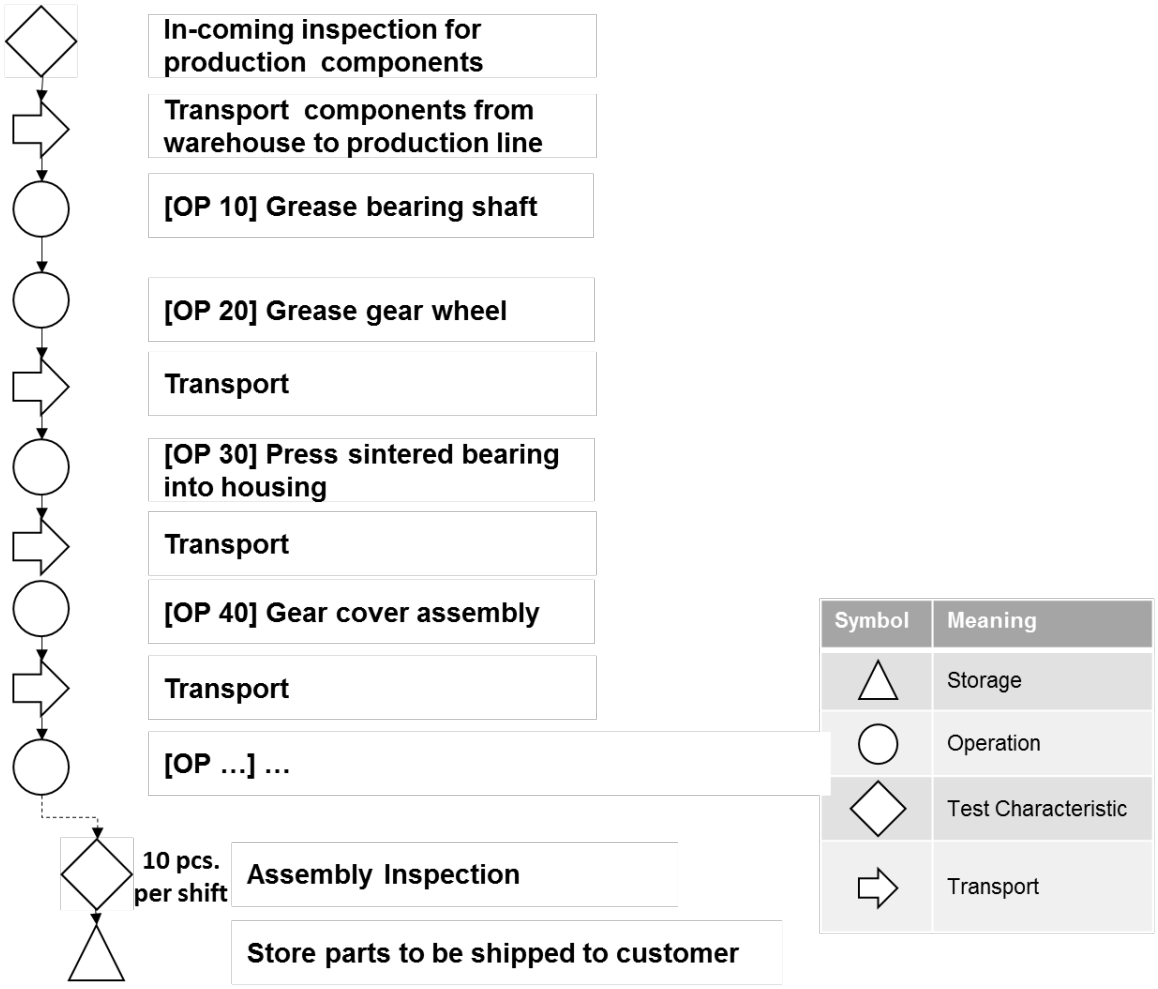


Figure 3.2-1 Process Flow Diagram

3.2.3 Structure Tree

The structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections. This pictorial structure allows for an understanding of the relationships between Process Items, Process Steps and Process Work Elements. Each of these is a building block that will later have functions and failures added.

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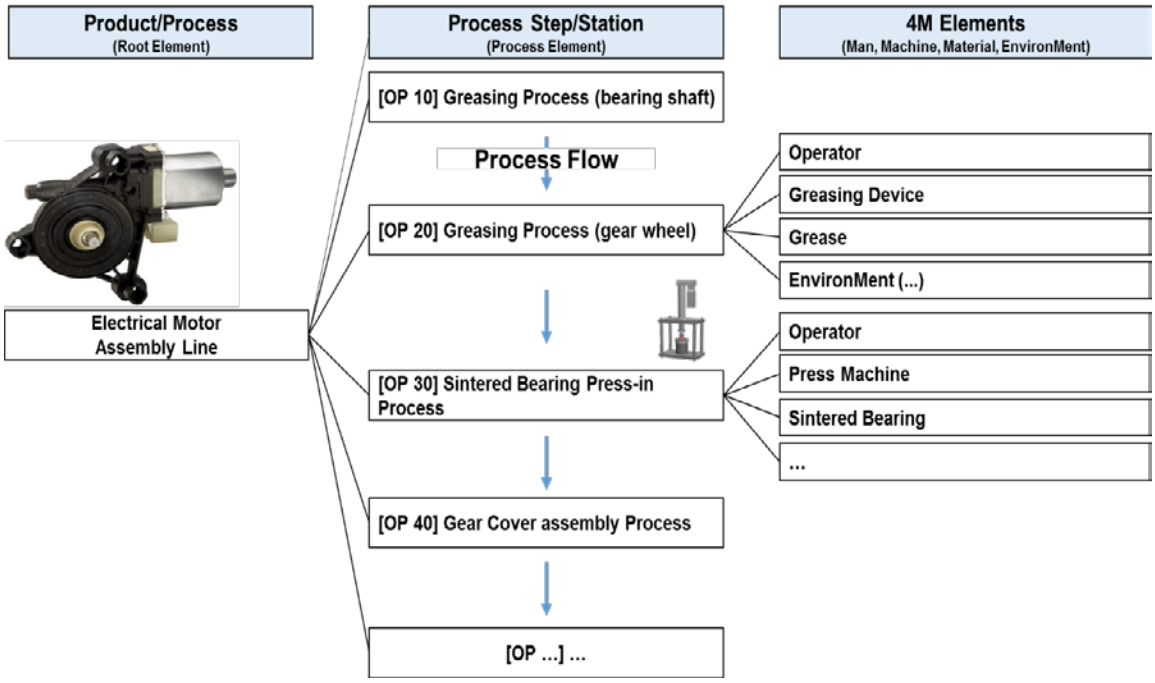


Figure 3.2-2 Example of Structure Analysis Structure Tree (Electrical Motor Assembly Line)

The Process Item of the PFMEA is the highest level of the structure tree or process flow diagram and PFMEA. This can also be considered the end result of all of the successfully completed Process Steps.

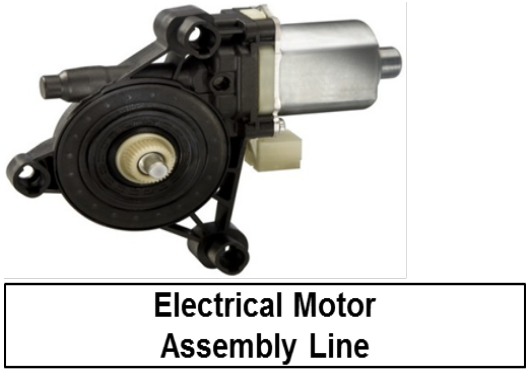


Figure 3.2-3 Process Item

The Process Step is the focus of the analysis. Process Step is a manufacturing operation or station.

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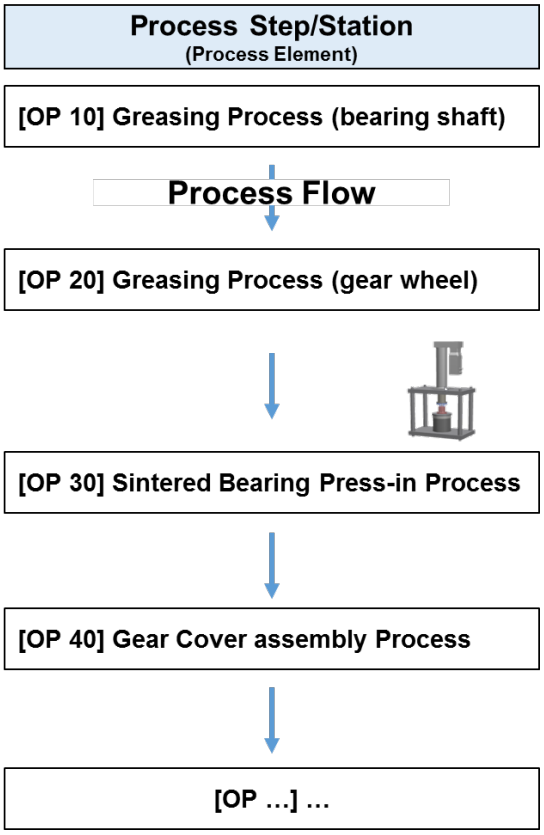


Figure 3.2-4 Process Steps

The Process Work Element is the lowest level of the process flow or structure tree. Each work element is the name of a main category of potential causes that could impact the process step. The number of categories may vary by company, i.e. 4M, 5M, 6M, etc. and is commonly called the Ishikawa Approach. A process step may have one or more categories with each analyzed separately. Refer to Section 3.4-7 Failure Cause for more information about how the 4M approach is used to identify Failure Causes.

4M Categories:

Machine
Man
Material (Indirect)
Milieu (EnvironMent)

Additional categories could be, but are not limited to:

Method
Measurement

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STRUCTURE ANALYSIS (STEP 2)		
1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Operator
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Press Machine

Figure 3.2-5 Example of Structure Analysis Form

1. **Process Item:**

   The highest level of integration within the scope of analysis.

2. **Process Step:**

   The element in focus. This is the item that is topic of consideration of the failure chain.

3. **Process Work Element:**

   The element that is the next level down the structure from the focus element.

3.2.4 Collaboration between Customer and Supplier engineering teams (interface responsibilities)

The output of the Structure Analysis (visualization of the process flow) provides a tool for collaboration between customers and suppliers (including machine suppliers) during technical reviews of the process design and/or PFMEA project.

3.2.5 Basis for Function Analysis

The information defined during Step 2 Structure Analysis will be used to develop Step 3 Function Analysis. If process elements (operations) are missing from the Structure Analysis they will also be missing from the Function Analysis.

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3.3 Process FMEA 3rd Step: Function Analysis

3.3.1 Purpose



The purpose of the Process Function Analysis is to ensure that the intended functions / requirements of the product / process are appropriately allocated.

The main objectives of a Process Function Analysis are:

- Visualization of product or process functions
- Function tree/net or equivalent process flow diagram
- Association of requirements or characteristics to functions
- Collaboration between engineering teams (systems, safety, and components)
- Basis for the Failure Analysis step

3.3.2 Function

A function describes what the process item or process step is intended to do. There may be more than one function for each process item or process step.

Prior to beginning the Function Analysis, information to be gathered could include but is not limited to; product and process functions, product/process requirements, manufacturing environment conditions, cycle time, occupational or operator safety requirements, environmental impact, etc. This information is important in defining the “positive” functions and requirements needed for the Functional Analysis.

The description of a Function needs to be clear.

The recommended phrase format is to use an “action verb” followed by a “noun” to describe the measurable process function (“DO THIS” “TO THIS”).

A Function should be in the "PRESENT TENSE"; it uses the verb's base form (deliver, contain, control, assemble, transfer).

Examples: Drill hole, apply glue, insert pin, weld bracket

The Function of the Process Item begins at a high level, and references the Process Item in the Structure Analysis. As a high-level description, it can take into account functions such as: Internal function, external function, customer related function and/or end user function.

> Note: The negative of these will be the Failure Effects.

Example: Assemble components

The Function of the Process Step describes the resulting product features produced at the station.

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Note: The negative of these will be the Failure Modes.

Example: Press in sintered bearing to pole housing

The Function of the Process Work Element reflects the contribution to the Process Step to create the process / product features.

Note: The negative of these will the Failure Causes.

Example: Get sintered bearing from chute manually

Example: Press force to press sintered bearing into pole housing

For the logical linking of a function and structure, questions are asked as:

“What Happens?”

How to achieve the product / process requirements - from right to left

(Process Item → Process Step → Process Work Element)

“Why?”

Why implement the product / process requirements - from left to right

(Process Work Element → Process Step → Process Item)

3.3.3 Requirement(s) (Characteristics)

A Characteristic is a distinguishing feature (or quantifiable attribute) of a product. For example, a diameter or surface finishes. For PFMEA, Requirements are described in terms of Product Characteristics and Process Characteristics.

Note: The negative of these will be the Failure Mode and the Failure Cause.

A Product Characteristic (Requirement) is related to the performance of a process function and can be judged or measured. A product characteristic is shown on a product drawing or specification document i.e. Geometry, Material, Surface Finish, Coatings, etc. Process functions create product characteristics. The design documents comprehend legal requirements (i.e. lead-free material), industry requirements (i.e. thread class), customer requirements (i.e. quantity), and internal requirements (i.e. part cleanliness). Product characteristics can be measured after the product has been made (i.e. gap). Product Characteristics can

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come from performance requirements, i.e., legal (performance of windshield wipers). In these cases, the measurable Product Characteristic should be listed, followed by the Performance Requirement, i.e., Spline Over-pin Diameter (Government Windshield Wiper Regulation XYZ). The specific quantitative value is optional for the PFMEA form.

Product Characteristics:

- I.e. may be derived from various sources, external and internal

Legal requirements:

- I.e. compliance with designated health & safety and environmental protection regulations

Industry Norms and Standards:

- I.e. ISO 9001, VDA Volume 6 Part 3, Process Audit, SAE J

Customer Requirements:

- According to customer specifications, i.e. adherence to required quality, manufacture and provision of product(s) in time x and quantity y (output z/hour)

Internal Requirements:

- I.e. manufacture of the product, in process cycle, compliance with expected production costs (i.e. facilities availability, limited rejects, no corrective work), production system principles, process quality and cleanliness instructions

Process Characteristics:

- A Process Characteristic is the process control that ensures the Product Characteristic is achieved by the process. It may be shown on manufacturing drawings or specifications (including operator work instructions, set-up instructions, error-proofing verification procedures, etc.). Process characteristics can be measured while the product is being made (i.e. press force). The specific quantitative value is optional for the PFMEA form.

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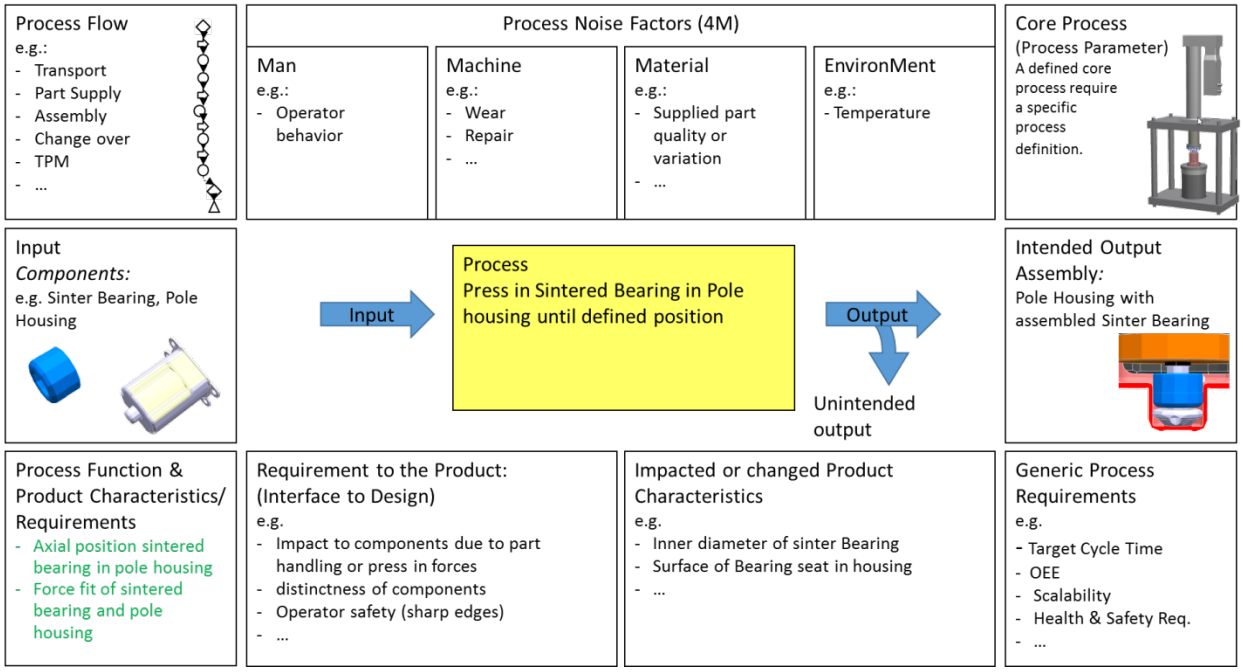


Figure 3.3-1 Example of Parameter Diagram of Press in Sintered Bearing

3.3.4 Visualization of functional relationships

The interaction of process item functions, process step functions and process work element functions may be visualized as: function network, function structure, function tree, function matrix, and/or function analysis depending on the software tool used to perform the PFMEA. For example, Function Analysis is contained in the Form to perform the PFMEA.

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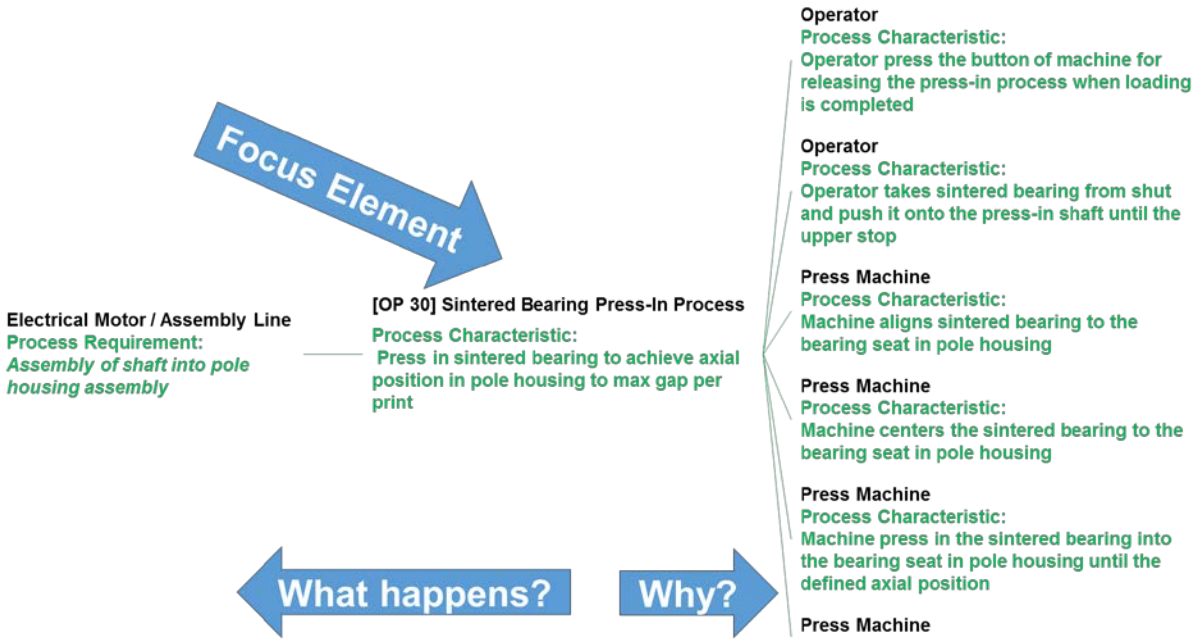


Figure 3.3-2 Example of Function Analysis Structure Tree

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic
Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Machine presses sintered bearing into the pole housing seat until the defined axial position

Figure 3.3-3 Example of Function Analysis Form

The column header numbering (1, 2, 3) and color coding are included to help show alignment between the Structure Analysis and associated content of the Function Analysis. In this section you work from left to right answering the question: “How is the higher level function enabled by lower level functions?”

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3.3.5 Collaboration between Engineering Teams (Systems, Safety, and Components)

Engineering teams within the company need to collaborate to make sure information is consistent for a project or customer program especially when multiple PFMEA teams are simultaneously conducting the technical risk analysis. For example, design information from systems, safety, and/or component groups helps the PFMEA team understand the functions of the product they manufacture. This collaboration may be verbal (program meetings) or written as a summary.

3.3.6 Basis for Failure Analysis

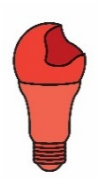
Complete definition of process functions (in positive words) will lead to a comprehensive Step 4 Failure Analysis because the potential failures are ways the functions could fail (in negative words).

3.4 Process FMEA 4th Step: Failure Analysis

3.4.1 Purpose

The purpose of the Process Failure Analysis is to identify failure causes, modes, and effects, and show their relationships to enable risk assessment.

The main objectives of a Process Failure Analysis are:



- Establishment of the failure chain
- Potential Failure Effects, Failure Modes, Failure Causes for each process function
- Identification of process failure causes using a fishbone diagram (4M) or failure network
- Collaboration between customer and supplier (Failure Effects)
- Basis for the documentation of failures in the FMEA form and the Risk Analysis step

A failure analysis is performed for each element/step in the process description (Structure Analysis/Step 2 and Function Analysis/Step 3).

3.4.2 Failures

Failures of a process step are deduced from product and process characteristics. Examples include:

- non-conformities,
- inconsistently or partially executed tasks,
- unintentional activity
- unnecessary activity

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3.4.3 The Failure Chain

For a specific failure, there are three aspects to be considered:

- Failure Effect (FE)
- Failure Mode (FM)
- Failure Cause (FC)

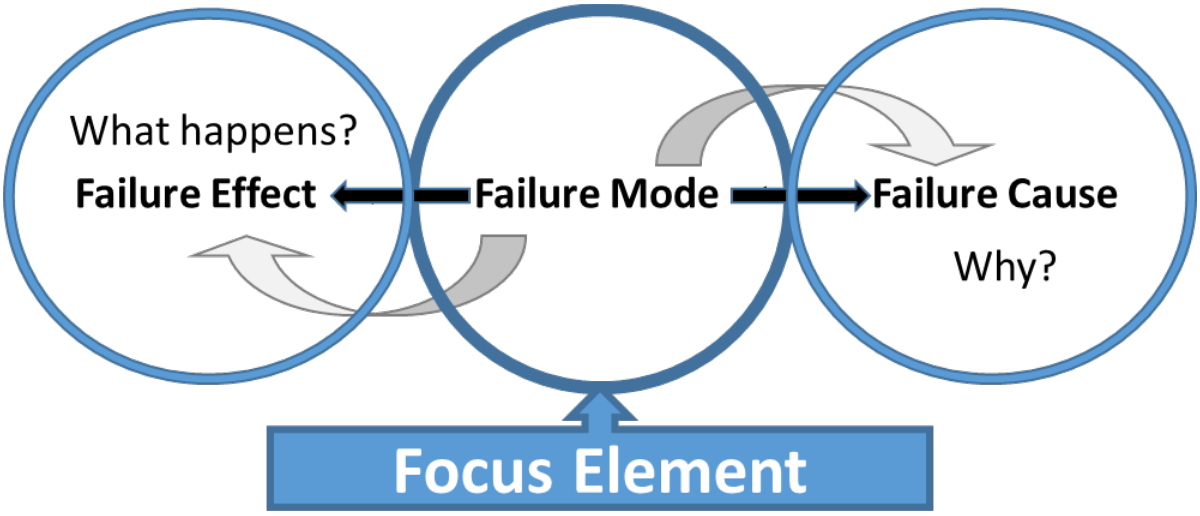


Figure 3.4-1 Theoretical failure chain model

3.4.4 Failure Effects

Failure Effects are related to functions of the process item (System, Subsystem, Part Element or Name of Process). Failure Effects are described in terms of what the customer might notice or experience. Failures that could impact safety or cause noncompliance to regulations should be clearly identified in the PFMEA.

Customers could be:

- Internal customer (next operation/subsequent operation/operation tar-gets)
- External customer (Next Tier Level/OEM/dealer)
- Legislative bodies
- Product or Product end user/operator

Failure Effects that are given a Severity rating:

1. Your Plant: the effect of the failure mode assuming the defect is detected in the plant (what action will the plant take i.e. scrap)

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2. Ship-to plant: the effect of the failure mode assuming the defect is not detected before shipping to the next plant (what action will the next plant take i.e. sort)

3. End user: the effect of the process item effect (what will the end user notice, feel, hear, smell, etc. i.e. window raises too slow)

Failure Effects that are not given a Severity rating:

1. Process item: the effect of the failure mode that leads to the end user effect (what happens if the defect occurs i.e. increased friction in the electrical motor). By making the functions and failure effects more transparent in the PFMEA it improves communication about the impact of manufacturing processes on product functions.

   All, some, or no types of effects may apply depending on the failure mode and its consequences.

The following questions should be asked to help determine which group of failure effects apply:

1. Does the failure mode physically impact downstream processing or cause potential harm to equipment or operators?

   This includes an inability to assemble or join to a mating component at any subsequent customer's facility.

   If so, then identify the manufacturing impact “Your Plant” and/or “ship-to plant” in the PFMEA. If not, then go to question 2.

   Examples could include:

   - Unable to assemble at operation x
   - Unable to attach at customer facility
   - Unable to connect at customer facility
   - Cannot bore at operation x
   - Causes excessive tool wear at operation x
   - Damages equipment at operation x
   - Endangers operator at customer facility

> Note: When parts cannot be assembled there is no impact to the End User and question 2 does not apply.

2. What is the potential impact on the End User?

   Independent of any controls planned or implemented including error or mistake-proofing, consider happens to the process item that leads to what the End User would

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notice or experience. This information may be available within the DFMEA. If an effect is carried from the DFMEA, the description of the product effects in the PFMEA should be consistent with those in the corresponding DFMEA.

NOTE: In some cases, the team conducting the analysis may not know the end user effect (i.e. catalogue parts, off-the-shelf products, Tier 3 components). When this information is not known, the effects should be defined in terms of the part function and/or process specification.

Examples could include:

- Noise
- High effort
- Unpleasant odor
- Intermittent operation
- Water leak
- Rough idle
- Unable to adjust
- Difficult to control
- Poor appearance
- Regulatory System Function reduced or failed
- End user lack of vehicle control
- Safety effect on End user

3. What would happen if a failure effect was detected prior to reaching the End User?

   The failure effect at the current or receiving locations also needs to be considered.

   Identify the manufacturing impact “Your Plant” and/or “ship-to plant” in the PFMEA.

   Examples could include:

   - Line shutdown
   - Stop shipment
   - Yard hold
   - 100% of product scrapped
   - Decreased line speed
   - Added manpower to maintain required line rate
   - Rework and repair

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3.4.5 Failure Mode

A (Process) Failure Mode is defined as the manner in which the process could cause the product not to deliver or provide the intended function.

The team should assume that the basic design of the product is correct; however, if there are design issues which result in process concerns, those issues should be communicated to the design team for resolution.

Assume that the failure mode could occur but may not necessarily occur. Failure modes should be described in technical terms, not as a symptom noticeable by the customer.

Verification of completeness of the failure modes can be made through a review of past things-gone-wrong, reject or scrap reports, and group brainstorming. Sources for this should also include a comparison of similar processes and a review of customer (End User and subsequent operation) claims relating to similar components.

There are several categories of potential failure modes including:

- loss of process function/operation not performed
- Partial function-- Incomplete operation
- Degradation of process function
- Overachieving process function - Too much too high.
- Intermittent process function-operation not consistent
- unstable operation
- Unintended process function-wrong operation
- wrong part installed
- Delayed process function-operation too late

Typical failure modes could be, but are not limited to:

- Hole too shallow, too deep, missing or off location.
- Dirty surface
- Surface finish too smooth
- Misaligned connector pins
- Connector not fully seated
- Pass a bad part, or reject a good part, bypass inspection operation
- Label missing
- Barcode not readable
- ECU flashed with wrong software.

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3.4.6 Failure Cause:

A failure cause is an indication of why a failure mode could occur. The consequence of a cause is the failure mode. Identify, to the extent possible, every potential manufacturing or assembly cause for each failure mode. The cause should be listed as concisely and completely as possible so that efforts (controls and actions) can be aimed at appropriate causes.

Typical failure causes may include the classic Ishikawa's 4M, but are not limited to:

- **Man**: set-up worker, machine operator/ associate, material associate, maintenance technician etc.
- **Machine/Equipment:** robot, hopper reservoir tank, injection molding machine, spiral conveyor, inspection devices, fixtures, etc.
- **Material (Indirect):** machining oil, installation grease, washer concentration, (aid for operation), etc.
- **Milieu/Environment:** ambient conditions such as heat, dust, contamination, lighting, noise, etc.

> Note: In preparing the FMEA, assume that the incoming part(s)/material(s) are correct. Exceptions can be made by the FMEA team where historical data indicate deficiencies in incoming part quality.

One method to help reveal / uncover failure causes is to have a facilitator that leads the team through "Thought Provoking Stimulation Questions". These questions can be broad category questions, enough to stimulate the process experts thought process, while keeping the number of questions to a manageable level. Questions can be process specific and broken down into the 4M categories. Initial list of questions can be formed by reviewing the Failure Causes in previous PFMEA's.

Example - Assembly Process:

3.4.6.1 Man

1. From parts available within the process, can wrong part be applied?
2. Can no part be applied?
3. Can the parts be loaded incorrectly?
4. Can parts be damaged - From pickup to application?
5. Can wrong material be used?

3.4.6.2 Machine

1. Can automated process be interrupted?

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2. Can inputted data be entered incorrectly?
3. Can machine be run in manual mode, bypassing automated controls?
4. Is there a schedule to confirm prevention and detection controls?

3.4.6.3 Material (indirect)

1. Can too much / too little / no material be used?
2. Can material be applied to a wrong location?

3.4.6.4 EnvironMent

1. Is lighting adequate for task?
2. Can parts used within the process, be considered foreign material?

The description of the failure cause needs to be clear. Terms such as defective, broken, operator failure, non-fulfillment or not OK and so on are insufficient to comprehensively assign the failure cause and mode and to determine actions.

3.4.7 Failure Analysis

Based on the process steps, the failures are derived and failure chains (i.e. Failure structure/failure trees/failure network) are created from the function analysis (see figure 3.3-1).

The focus element of the failure structure is the Failure Mode, with its associated Failure Effects and their Failure Causes. Depending on the focus, a failure can be viewed as a Failure Effect, Failure Mode, or Failure Cause.

To link failure cause(s) to a failure mode, the question should be “Why is the failure mode occurring?”

To link failure effects to a failure mode, the question should be “What happens in the event of a failure mode?”

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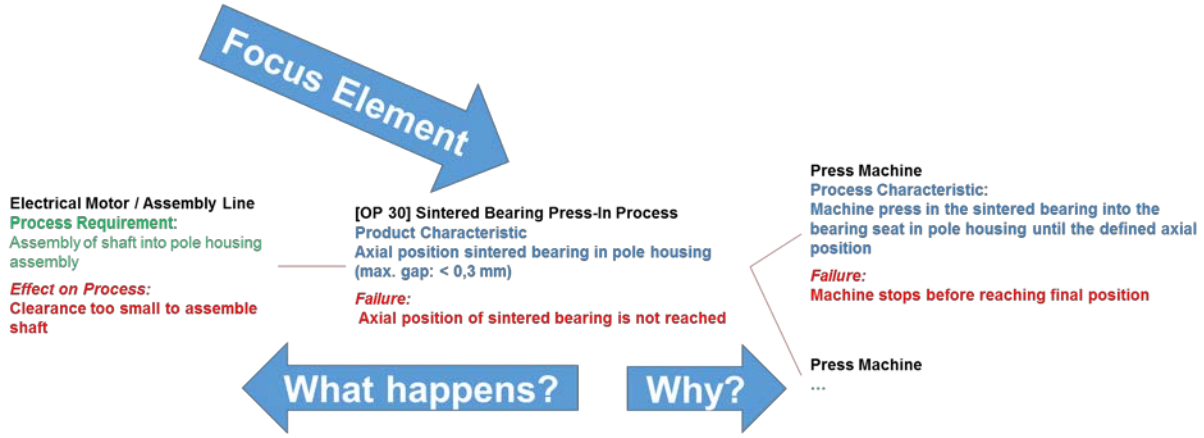


Figure 3.4-2 Example of Failure Analysis Structure Tree

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element
Your Plant: Clearance too small to assemble shaft without potential damage Ship to Plant: Assembly of motor to vehicle door requires additional insertion force with potential damage End User: Comfort closing time too long.	Axial position of sintered bearing is not reached	Machine stops before reaching final position

Figure 3.4-3 Example of Failure Analysis Form

Begin building the failure chain by using the information in the Function Analysis. When using a customer specific form or software, follow the methodology as defined by your customer. This handbook recommends the Function Analysis section of the spreadsheet is filled-out following the header numbering (1, 2, 3) and color coding.

1. Failure Effects (FE):

   The effect of failure associated with “1. Function of Process Item” in the Function Analysis.

> Note for spreadsheet users: A potential failure mode may have more than one failure effect. Failure effects are grouped

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in the spreadsheet in order to avoid excessive duplication of the same failure modes and causes.

2. Failure Mode (FM):

   The mode (or type) of failure associated with “2. Function of Process Step” in the Function Analysis.

Note for spreadsheet users: It is recommended that users start with the failure mode and then identify related failure effects using the information in the #1 Function of the Process Item column of the Function Analysis section because some or all categories may apply.

3. Failure Cause (FC):

   The cause of failure associated with the “3. Function of Process Work Element” in the Function Analysis.

3.4.8 Relationship between PFMEA and DFMEA

A design failure of a feature (product characteristic) can cause a failure for one or more product functions. The corresponding process failure is the inability of the process to manufacture the same feature as designed. The failure to conform to a product characteristic alone leads to the Failure Effect. Only in this case is the Failure Effect in the Design FMEA the same as in the Process FMEA. All Failure Effects which are caused by a failure of the processes and which are not identified in Design FMEA have to be newly defined and assessed in the Process FMEA.

The Failure Effects related to the product, system, and/or end user and their associated severities should be documented when known, but not assumed. The key to the identification of Failure Effects and associated severities is the communication of the involved parties and the understanding of differences and similarities of the analyzed failures in DFMEA and PFMEA see also figure 1.4-1).

Figure 3.4-4 shows a potential interrelation of product-related Failure Effects, Failure Modes and Failure Causes from the “End User” level to the level of production (PFMEA level).

Note: The expectation of the relative time of and the flow of information from the DFMEA to the PFMEA is different in non-standard development flows, such as where development of a "standard" process precedes development of the products that will be manufactured using it. In such cases, the appropriate timing and flow of information between these FMEAs should be defined by the organization.

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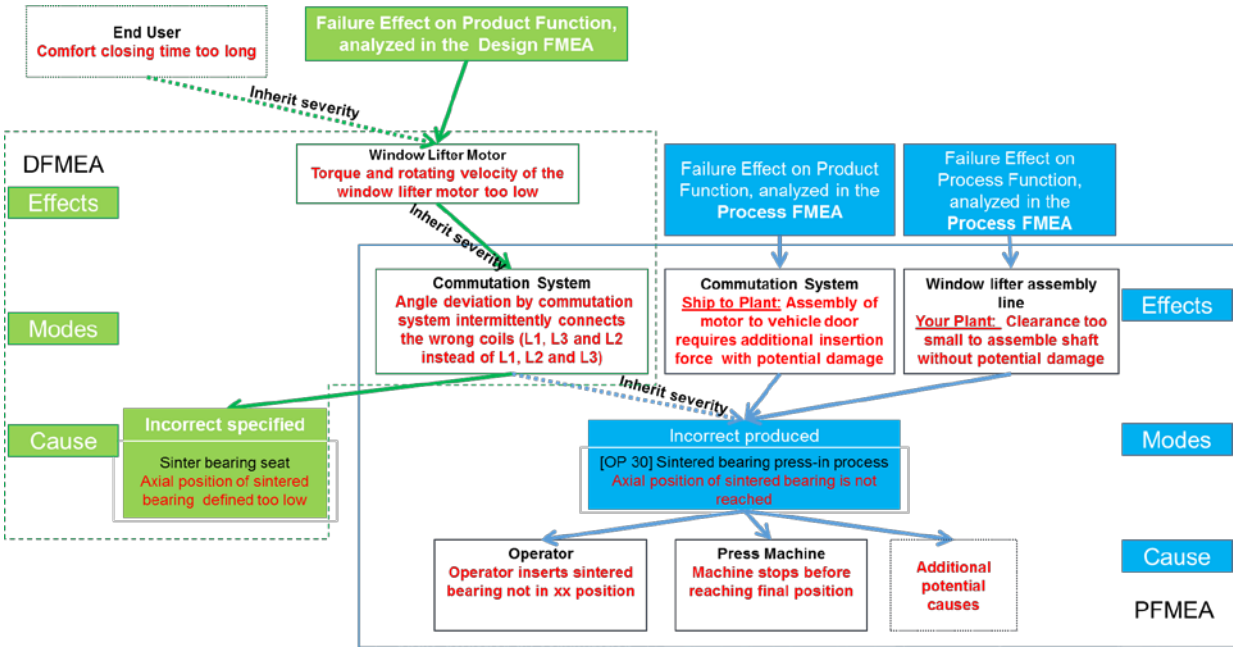


Figure 3.4-4 Relationship between PFMEA and DFMEA

3.4.9 Failure Analysis Documentation

After the Structure Analysis, Function Analysis and Failure Analysis are complete a structure tree or spreadsheet can have multiple views.

1. Process Item System, Subsystem, Part Element or Name of Process	1. Function of the Process Item Function of System, Subsystem, Part Element or Process	1. Failure Effects (FE) to the Next Higher Level Element and/or End User
Electrical Motor Assy Line	Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers	Your Plant: Clearance too small to assemble shaft without potential damage Ship to Plant: Assembly of motor to vehicle door requires additional insertion force with potential damage End User: Comfort closing time too long.

Figure 3.4-5 View of Process Item-Function-Failure Form

2. Process Step Station No. and Name of Focus Element	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	2. Failure Mode (FM) of the Process Step

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[OP 30] Sintered Bearing Press-In Process	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Axial position of sintered bearing is not reached

Figure 3.4-6 View of Process Step-Function-Failure Form

3. Process Work Element 4M Type	3. Function of the Process Work Element and Process Characteristic	3. Failure Cause (FC) of the Work Element
Press Machine	Machine presses sintered bearing into the pole housing seat until the defined axial position	Machine stops before reaching final position

Figure 3.4-7 View of Process Work Element-Function-Failure Form

3.4.10 Collaboration between Customer and Supplier (Failure Effects)

The output of the Failure Analysis may be reviewed by customers and suppliers prior to the Risk Analysis step or after to the Risk Analysis step based on agreements with the customer and need for sharing with the supplier.

3.4.11 Basis for Risk Analysis

Complete definition of potential failures will lead to a complete Step 5 Risk Analysis because the rating of Severity, Occurrence, and Detection are based on the failure descriptions. The Risk Analysis may be incomplete if potential failures are too vague or missing.

3.5 Process FMEA 5th Step: Risk Analysis

3.5.1 Purpose

The purpose of Process Risk Analysis is to estimate risk by evaluating Severity, Occurrence and Detection, in order to prioritize the need for actions.



The main objectives of the Process Risk Analysis are:

- Assignment of existing and/or planned controls and rating of failures
- Assignment of Prevention Controls to the Failure Causes

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- Assignment of Detection Controls to the Failure Causes and/or Failure Modes
- Rating of Severity, Occurrence and Detection for each failure chain
- Collaboration between customer and supplier (Severity)
- Basis for the product or process Optimization step

There are two different Control Groups: Current Prevention Controls, and Current Detection Controls.

3.5.2 Current Prevention Controls (PC)

3.5.2.1 Process planning

Definition: Current Prevention Controls facilitate optimal process planning to minimize the possibility of failure occurrence.

Prevention of possible layout deficiencies of the production facility:

- Test runs according to start-up regulation AV 17/3b

3.5.2.2 Production process

Definition: Eliminate (prevent) the failure cause or reduce its rate of occurrence.

Prevention of defectively produced parts in the production facility:

- Two-handed operation of machines
- Subsequent part cannot be attached (Poka-Yoke)
- Form-dependent position
- Equipment maintenance
- Operator maintenance
- Work instructions / Visual aids
- Machine controls
- First part release

Failure Causes are rated for occurrence, taking into account the effectiveness of the current prevention control (Chapter Risk Evaluation).

Current Prevention Controls describe measures which should be implemented in the design process and verified during prototype, machine qualifications (run-off), and process verification prior to start of regular production. Prevention Controls may also include standard work instructions, set-up procedures, preventive maintenance, calibration procedures, error-proofing verification procedures, etc.

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3.5.3 Current Detection Controls (DC)

Definition: Current Detection controls detect the existence of a failure cause or the failure mode, either by automated or manual methods, before the item leaves the process or is shipped to the customer.

Examples of Current Detection controls:

- Visual inspection
- Visual inspection with sample checklist
- Optical inspection with camera system
- Optical test with limit sample
- Attributive test with mandrel
- Dimensional check with a caliper gauge
- Random inspection
- Torque monitoring
- Press load monitoring
- End of line function check

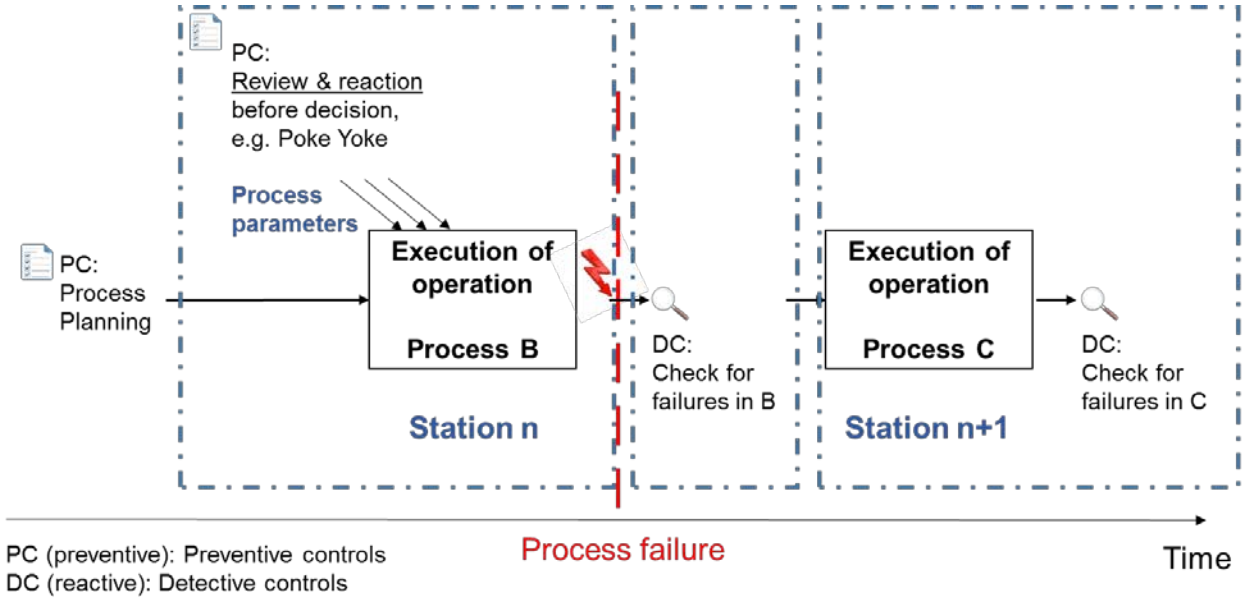


Figure 3.5-1 Prevention and Detection in the Process FMEA

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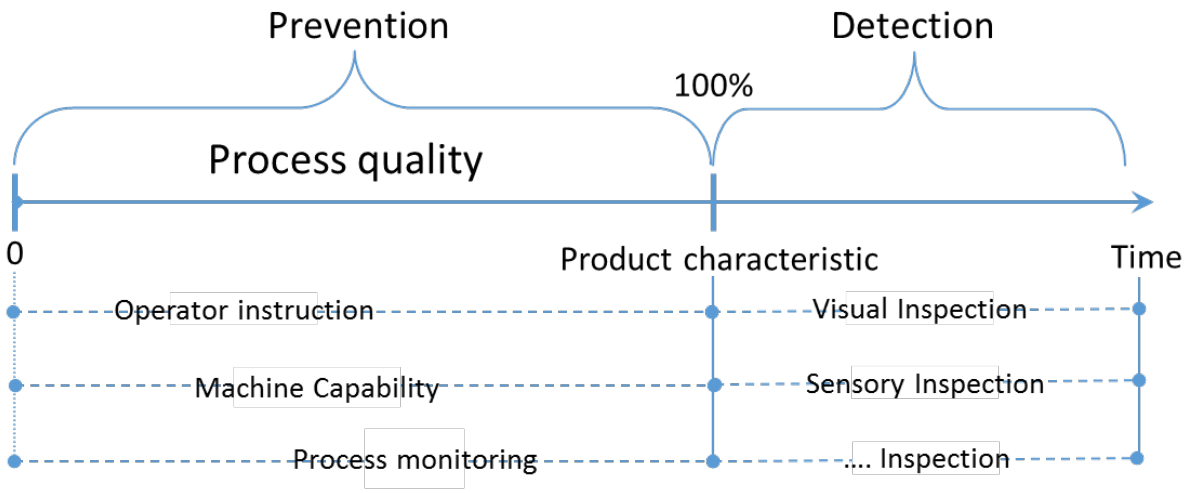


Figure 3.5-2 Roadmap of process understanding

3.5.4 Current Prevention and Detection Controls

Current Prevention and Detection Controls should be confirmed to be implemented and effective. This can be done during an in-station review (i.e. Line Side Review, Line walks and Regular audits). If the control is not effective, additional action may be needed.

The Occurrence and Detection ratings should be reviewed when using data from previous processes, due to the possibility of different conditions for the new process.

3.5.5 Evaluations

Each Failure Mode, Cause and Effect relationship (failure chain or net) is assessed for its independent risk. There are three rating criteria for the evaluation of risk:

Severity (S):	stands for the Severity of the Failure Effect
Occurrence (O):	stands for the Occurrence of the Failure Cause
Detection (D):	stands for the Detection of the occurred Failure Cause and/or Failure Mode

Evaluation numbers from 1 to 10 are used for S, O, and D respectively, in which 10 stands for the highest risk contribution.

> NOTE: It is not appropriate to compare the ratings of one team's FMEA with the ratings of another team's FMEA, even if the product/process appear to be identical, since each team's environment is unique and thus their respective individual ratings will be unique (i.e., the ratings are subjective).

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3.5.6 Severity (S)

Severity is a rating number associated with the most serious effect for a given failure mode for the process step being evaluated. It is a relative rating within the scope of the individual FMEA and is determined without regard for Occurrence or Detection.

For process-specific effects, the Severity rating should be determined using the criteria in evaluation Table P1. The table may be augmented to include corporate or product line specific examples.

The evaluations of the Failure Effects should be mutually agreed to by the customer and the organization.

> NOTE: If the customer impacted by a Failure Mode is the next manufacturing or assembly plant or the product user, assessing the severity may lie outside the immediate process engineer's/team's field of experience or knowledge. In these cases, the Design FMEA, design engineer, and/or subsequent manufacturing or assembly plant process engineer, should be consulted in order to comprehend the propagation of effects.

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Process General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below.					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (when known)**	**Impact to End User (when known)**	**Corporate or Product Line Examples**
10	**High**	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Failure may result in in-plant regulatory noncompliance	Failure may result in in-plant regulatory noncompliance	Noncompliance with regulations.	
8	**Moderately high**	100% of production run affected may have to be scrapped. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker.	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		Product may have to be sorted and a portion (less than 100%) scrapped; deviation from primary process; decreased line speed or added manpower	Line shutdown from 1 hour up to full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance	**Degradation** of primary vehicle function necessary for normal driving during expected service life.	

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Process General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below.					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (when known)**	**Impact to End User (when known)**	**Corporate or Product Line Examples**
6	**Moderately low**	100% of production run may have to be reworked off line and accepted	Line shutdown up to one hour	**Loss** of secondary vehicle function.	
5		A portion of the production run may have to be reworked off line and accepted	Less than 100% of product affected; strong possibility for additional defective product; sort required; no line shutdown	**Degradation** of secondary vehicle function.	
4		100% of production run may have to be reworked in station before it is processed	Defective product triggers significant reaction plan; additional defective products not likely; sort not required	Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	A portion of the production run may have to be reworked in-station before it is processed	Defective product triggers minor reaction plan; additional defective products not likely; sort not required	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slight inconvenience to process, operation, or operator	Defective product triggers no reaction plan; additional defective products not likely; sort not required; requires feedback to supplier	Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible effect	No discernible effect or no effect	No discernible effect.	

Table P1 - PFMEA SEVERITY (S)

3.5.7 Occurrence (O)

The Occurrence rating (O) describes the occurrence of Failure Cause in the process, taking into account the associated current prevention controls.

The occurrence rating number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

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The Occurrence rating describes the potential of the failure cause to occur, according to the rating table, without regard to the detection controls.

Expertise or other experiences with comparable processes, for example, can be considered in the assessment of the rating numbers.

In determining this rating, questions such as the following should be considered:

- What is the equipment history with similar processes and process steps?
- What is the field experience with similar process?
- Is the process a carryover or similar to a previous process?
- How significant are changes from a current production process?
- Is the process completely new?
- What are the environmental changes?
- Are Best Practices already implemented?
- Do standard instructions exist? (i.e. work instructions, set-up and calibration procedures, preventive maintenance, error-proofing verification procedures, and process monitoring verification checklists)
- Are technical error-proofing solutions implemented? (i.e. product or process design, fixture and tool design, established process sequence, production control tracking/traceability, machine capability, and SPC charting)

<table>
<tr><th colspan="5">Occurrence Potential (O) for the Process</th></tr>
<tr><td colspan="4">Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.</td><td>Blank until filled in by user</td></tr>
<tr><th>O</th><th>Prediction of Failure Cause Occurring</th><th>Type of Control</th><th>Prevention Controls</th><th>Corporate or Product Line Examples</th></tr>
<tr><td>10</td><td>Extremely high</td><td>None</td><td>No prevention controls.</td><td></td></tr>
<tr><td>9</td><td rowspan="2">Very high</td><td rowspan="2">Behavioral</td><td rowspan="2">Prevention controls will have little effect in preventing failure cause.</td><td></td></tr>
<tr><td>8</td><td></td></tr>
<tr><td>7</td><td rowspan="2">High</td><td rowspan="4">Behavioral or Technical</td><td rowspan="2">Prevention controls somewhat effective in preventing failure cause.</td><td></td></tr>
<tr><td>6</td><td></td></tr>
<tr><td>5</td><td rowspan="2">Moderate</td><td rowspan="2">Prevention controls are effective in preventing failure cause.</td><td></td></tr>
<tr><td>4</td><td></td></tr>
</table>

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Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
3	**Low**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**Very low**			
1	**Extremely low**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (i.e. part geometry) or process (i.e. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table P2 - PFMEA OCCURRENCE (O)

3.5.8 Detection (D)

Detection is the rating associated with a prediction of the most effective process control from the listed detection-type process controls. Detection is a relative rating, within the scope of the individual FMEA and is determined without regard for Severity or Occurrence. Detection should be estimated using the criteria in Table P3. This table may be augmented with examples of common detection methods used by the company.

The intent of the term “control discrepant product” used in Table P3 Ranks 3 and 4 is to have controls / systems / procedures in place that controls the discrepant product in such a manner, that the probability of the product escaping the facility is very low.

The controls start from when the product is identified as discrepant to the point of final disposition. These controls usually exceed controls that are used for discrepant products with higher Detection Ranks.

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After implementation of any unproven control, the effectiveness can be verified and re-evaluated.

In determining this estimate, questions such as the following should be considered:

- Which test is most effective in detecting the Failure Cause or the Failure Mode?
- What is the usage Profile / Duty Cycle required detecting the failure?
- What sample size is required to detect the failure?
- Is the test procedure proven for detecting this Cause / Failure Mode?

Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	Corporate or Product Line Examples
10	Very low	No testing or inspection method has been established or is known.	The failure mode will not or cannot be detected.	
9		It is unlikely that the testing or inspection method will detect the failure mode.	The failure mode is not easily detected through random or sporadic audits.	
8	Low	Test or inspection method **has not been** proven to be effective and reliable (i.e. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause.	
7			Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause.	
6	Moderate	Test or inspection method **has been** proven to be effective and reliable (i.e. plant has experience with method; gauge R&R results are acceptable on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks).	
5			Machine-based detection (semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that will detect failure mode or failure cause (including product sample checks).	

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Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	Corporate or Product Line Examples
4	High	System has been proven to be effective and reliable (i.e. plant has experience with method on identical process or this application), gauge R&R results are acceptable, etc.	Machine-based automated detection method that will detect the failure mode **downstream**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
3			Machine-based automated detection method that will detect the failure mode **in-station**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
2		Detection method has been proven to be effective and reliable (i.e. plant has experience with method, error-proofing verifications, etc.).	Machine-based detection method that will detect the cause and prevent the failure mode (discrepant part) from being produced.	
1	Very high	Failure mode cannot be physically produced as-designed or processed, or detection methods proven to **always** detect the failure mode or failure cause.		

Table P3 - PFMEA DETECTION (D)

3.5.9 Action Priority (AP)

Once the team has completed the initial identification of failure modes and effects, causes and controls, including ratings for severity, occurrence, and detection, they must decide if further efforts are needed to reduce the risk. Due to the inherent limitations on resources, time, technology, and other factors, they must choose how to best prioritize these efforts.

The Action Priority (AP) method is introduced in this handbook. It accounts for all 1000 possible combinations of S, O, and D. It was created to give more emphasis on severity first, then occurrence, then detection. This logic follows the failure-prevention intent of FMEA. The AP table offers a suggested high-medium-low priority

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for action. Companies can use a single system to evaluate action priorities instead of multiple systems required from multiple customers.

Risk Priority Numbers are the product of S x O x D and range from 1 to 1000. The RPN distribution can provide some information about the range of ratings, but RPN alone is not an adequate method to determine the need for more actions since RPN gives equal weight to S, O, and D. For this reason, RPN could result in similar risk numbers for very different combinations of S, O, and D leaving the team uncertain about how to prioritize. When using RPN it is recommended to use an additional method to prioritize like RPN results such as S x O. The use of a Risk Priority Number (RPN) threshold is not a recommended practice for determining the need for actions. The RPN and S x O methods are not included in this publication.

Risk matrices can represent combinations of S and O, S and D, and O and D. These matrices provide a visual representation of the results of the analysis and can be used as an input to prioritization of actions based on company-established criteria not included in this publication.

Since the AP Table was designed to work with the Severity, Occurrence, and Detection tables provided in this handbook, if the organization chooses to modify the S, O, D, tables for specific products, processes, or projects, the AP table should also be carefully reviewed.

> Note: Because rating tables are different for DFMEA, PFMEA, and FMEA-MSR there are three associated AP tables.

Priority High (H): Highest priority for review and action. The team needs to either identify an appropriate action to improve prevention and / or detection controls or justify and document why current controls are adequate.

Priority Medium (M): Medium priority for review and action. The team should identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.

Priority Low (L): Low priority for review and action. The team could identify actions to improve prevention or detection controls.

It is recommended that potential Severity 9-10 failure effects with Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

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This is not the prioritization of High, Medium, or Low risk, it is the prioritization of the need for actions to reduce risk.

If the team decides that no further actions are necessary, "No further action is needed" is written in the Remarks field to show the risk analysis was completed.

Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							**Blank until filled in by user**
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**ACTION PRIORITY (AP)**	**Comments**
Product or Plant Effect Very high	9-10	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect High	7-8	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	

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Product or Plant Effect Moderate	4-6	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	M	
				Very high	1	M	
		High	6-7	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	M	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect Low	2-3	Very high	8-10	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		High	6-7	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
No discernible Effect	1	Very low - Very high	1-10	Very high - Very low	1-10	L	

Table AP – ACTION PRIORITY FOR DFMEA and PFMEA

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FAILURE ANALYSIS (STEP 4)				PFMEA RISK ANALYSIS (STEP 5)						
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element	Current Prevention Control (PC) o FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)
Your Plant: Assembly of shaft is not possible because clearance too small Ship to Plant: None End User: Comfort closing time too long	8	Axial position of sintered bearing is not reached	Machine stops before reaching final position	Force adjusted acc. data sheet	5	100% check of motor performance curve acc. spec. MRKJ5038	2	M		

Figure 3.5-3 Example of PFMEA with Risk Analysis Form

3.5.10 Collaboration between Customer and Supplier (Severity)

The output of the Risk Analysis creates the mutual understanding of technical risk between customers and suppliers. Methods of collaboration range from verbal to formal reports. The amount of information shared is based on the needs of a project, company policy, contractual agreements, and so on. The information shared depends on the placement of the company in the supply chain. Some examples are listed below.

1. The OEM may compare design functions, failure effects, and severity from a vehicle-level DFMEA with the Tier 1 supplier PFMEA.
2. The Tier 1 supplier communicates necessary information about product characteristics on product drawings and/or specifications, or other means, including designation of standard or special characteristics and severity. This information is used as an input to the Tier 2 supplier PFMEA as well as the Tier 1's internal PFMEA. When the design team communicates the associated risk of making product characteristics out of specification the process team can build in the appropriate level of prevention and detection controls in manufacturing.

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3.5.11 Basis for Optimization

The output of Steps 1, 2, 3, 4, and 5 of the 7-step FMEA process is used to determine if additional design or testing action is needed. The process reviews, customer reviews, management reviews, and cross-functional team meetings lead to Step 6 Optimization.

3.6 Process FMEA 6th Step: Optimization

3.6.1 Purpose



The purpose of the Process Optimization Step is to determine actions to mitigate risk and assess the effectiveness of those actions. The end result is a process which minimizes the risk of producing and delivering products that do not meet the customer and stakeholder expectations.

The main objectives of a Process Optimization are:

- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and deadlines for action implementation
- Implementation and documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
- Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures
- Basis for refinement of the product and/or process requirements and prevention and detection controls

The primary objective of optimization is to develop actions that reduce risk by improving the process. In this step, the team reviews the results of the risk analysis and assigns actions to lower the occurrence of the failure cause or increase the ability to detect the failure cause or failure mode. Actions may also be assigned which improve the process but do not necessarily lower the risk assessment rating. Actions represent a commitment to take a specific, measurable, and achievable action, not potential actions which may never be implemented. Actions are not intended to be used for activities that are already planned as these are documented in the Prevention or Detection Controls, and are already considered in the initial risk analysis. All actions should have a responsible individual and a target completion time associated with the action.

If the team decides that no further actions are necessary, “No further action is needed” is written in the Remarks field to show the risk analysis was completed.

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The PFMEA can be used as the basis for continuous improvement of the process.

The optimization is most effective in the following order:

- Process modifications to eliminate or mitigate a Failure Effect (FE)
- Process modifications to reduce the Occurrence (O) of the Failure Cause (FC).
- Increase the Detection (D) ability for the Failure Cause (FC) or Failure Mode (FM).
- In the case of process modifications, all impacted process steps are evaluated again.

In the case of concept modifications, all steps of the FMEA are reviewed for the affected sections. This is necessary because the original analysis is no longer valid since it was based upon a different manufacturing concept.

The PFMEA can be used as the basis for continuous improvement of the process.

3.6.2 Assignment of Responsibilities

Each action should have a responsible individual and a Target Completion Date (TCD) associated with it.

The responsible person ensures the action status is updated. If the action is confirmed this person is also responsible for the action implementation.

The Actual Completion Date for Preventive and Detection Actions is documented including the date the actions are implemented.

Target Completion Dates should be realistic (i.e. in accordance with the product development plan, prior to process validation, prior to start of production).

3.6.3 Status of the Actions

Suggested levels for Status of Actions:

Open

No action defined.

Decision pending (optional)

The action has been defined but has not yet decided on. A decision paper is being created.

Implementation pending (optional)

The action has been decided on but not yet implemented.

Completed

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Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.

Not Implemented

Not Implemented status is assigned when a decision is made not to implement an action. This may occur when risks related to practical and technical limitations are beyond current capabilities.

The FMEA is not considered “complete” until the team assesses each item’s Action Priority and either accepts the level of risk or documents closure of all actions.

If “No Action Taken”, then Action Priority is not reduced and the risk of failure is carried forward into the product. Actions are open loops that need to be closed in writing.

3.6.4 Assessment of Action Effectiveness

When an action has been completed, Occurrence, and Detection values are reassessed, and a new Action Priority may be determined.

The new action receives a preliminary Action Priority rating as a prediction of effectiveness.

However, the status of the action remains “implementation pending” until the effectiveness has been tested. After the tests are finalized the preliminary rating has to be confirmed or adapted, when indicated. The status of the action is then changed from “implementation pending” to “completed”.

The reassessment should be based on the effectiveness of the Preventive and Detection Actions taken and the new values are based on the definitions in the Process FMEA Occurrence and Detection rating tables.

3.6.5 Continual Improvement

The PFMEA serves as an historical record for the process. Therefore, the original Severity, Occurrence, and Detection (S, O, D) numbers need to be visible or at a minimum available and accessible as part of version history. The completed analysis becomes a repository to capture the progression of process decisions and design refinements. However, original S, O, D ratings may be modified for foundation, family or generic PFMEAs because the information is used as a starting point for an - process specific analysis.

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3.6.6 Collaboration between the FMEA team, Management, Customers, and Suppliers regarding Potential Failures

Communication between the FMEA team, management, customers and suppliers during the development of the technical risk analysis and/or when the PFMEA is initially complete brings people together to improve their understanding of product and process functions and failures. In this way, there is a transfer of knowledge that promotes risk reduction.

PFMEA RISK ANALYSIS (STEP 5)							PFMEA OPTIMIZATION (STEP 6)												
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	Special Characteristics	PFMEA AP	Remarks
Force adjusted acc. data sheet	5	100% check of motor performance curve acc. spec. MRKJ5038..	2	M			Selected press with position control sensor	Selected press with force monitoring	Process Engineer Mr. Paul Duncan	dd.mm.yyyy	open			8	3	2		L	

Figure 3.6-1 Example of PFMEA Optimization with new Risk Evaluation Form

3.7 Process FMEA 7th Step: Results Documentation



The scope and results of an FMEA should be summarized in a report. The report can be used for communication purposes within a company, or between companies. The report is not meant to replace reviews of the PFMEA details when requested by management, customers, or suppliers. It is meant to be a summary for the PFMEA team and others to confirm completion of each of the tasks and review the results of the analysis.

It is important that the content of the documentation fulfill the requirements of the organization, the intended reader, and relevant stakeholders. Details may be agreed upon between the parties. In this way, it is also ensured that all details of the analysis and the intellectual property remain at the developing company.

The layout of the document may be company specific. However, the report should indicate the technical risk of failure as a part of

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the development plan and project milestones. The content may include the following:

A. A statement of final status compared to original goals established in 1.5 Project Plan
    a. FMEA Intent – Purpose of this FMEA?
    b. FMEA Timing – FMEA due date?
    c. FMEA Team – List of participants?
    d. FMEA Task - Scope of this FMEA?
    e. FMEA Tool – How do we conduct the analysis Method used?

B. A summary of the scope of the analysis and identify what is new.

C. A summary of how the functions were developed.

D. A summary of at least the high-risk failures as determined by the team and provide a copy of the specific S/O/D rating tables and method of action prioritization (e.g. Action Priority table).

E. A summary of the actions taken and/or planned to address the high-risk failures including status of those actions.

F. A plan and commitment of timing for ongoing FMEA improvement actions.
    a. Commitment and timing to close open actions.
    b. Commitment to review and revise the PFMEA during mass production to ensure the accuracy and completeness of the analysis as compared with the production design (e.g. revisions triggered from design changes, corrective actions, etc., based on company procedures). (Refer to section 1.4 Case 3 FMEA revisions)
    c. Commitment to capture “things gone wrong” in foundation PFMEAs for the benefit of future analysis reuse, when applicable. (Refer to section 1.3.6 Foundation and Family FMEAs)

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4 SUPPLEMENTAL FMEA FOR MONITORING AND SYSTEM RESPONSE (FMEA-MSR)

In a Supplemental FMEA for Monitoring and System Response, potential Failure Causes which might occur under customer operating conditions are analyzed with respect to their technical effects on the system, vehicle, people, and regulatory compliance. The method considers whether or not Failure Causes or Failure Modes are detected by the system, or Failure Effects are detected by the driver. Customer operation is to be understood as end-user operation or in-service operation and maintenance operations.

FMEA-MSR includes the following elements of risk:

a) Severity of harm, regulatory noncompliance, loss or degraded functionality, and unacceptable quality; represented by (S)

b) Estimated frequency of a Failure Cause in the context of an operational situation; represented by (F)

c) Technical possibilities to avoid or limit the Failure Effect via diagnostic detection and automated response, combined with human possibilities to avoid or limit the Failure Effect via sensory perception and physical reaction; represented by (M)

The combination of F and M is an estimate of the probability of occurrence of the Failure Effect due to the Fault (Failure Cause) and resulting malfunctioning behavior (Failure Mode).

> NOTE: The overall probability of a Failure Effect to occur may be higher, because different Failure Causes may lead to the same Failure Effect.

FMEA-MSR adds value by assessing risk reduction as a result of monitoring and response. FMEA-MSR evaluates the current state of risk of failure and derives the necessity for additional monitoring by comparison with the conditions for acceptable residual risk. The analysis can be part of a Design FMEA in which the aspects of Development are supplemented by aspects of Customer Operation. However, it is usually only applied when diagnostic detection is necessary to maintain safety or compliance.

Detection in DFMEA is not the same as Monitoring in Supplemental FMEA-MSR. In DFMEA, Detection controls document the ability of testing to demonstrate the fulfillment of requirements in development and validation. For monitoring that is already part of the system design, validation is intended to demonstrate that diagnostic monitoring and system response works as intended. Conversely, Monitoring in FMEA-MSR assesses the effectiveness of fault detection performance in customer operation, assuming that specifications are fulfilled. The

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Monitoring rating also comprehends the safe performance and reliability of system reactions to monitored faults. It contributes to the assessment of the fulfillment of Safety Goals and may be used for deriving the Safety Concept.

Supplemental FMEA-MSR addresses risks that in DFMEA would otherwise be assessed as High, by considering more factors which accurately reflect lower assessed risk according to the diagnostic functions of the vehicle operating system. These additional factors contribute to an improved depiction of risk of failure (including risk of harm, risk of noncompliance, and risk of not fulfilling specifications).

FMEA-MSR contributes to the provision of evidence of the ability of the diagnostic, logical, and actuation mechanisms to achieve and maintain a safe or compliant state (in particular, appropriate failure mitigation ability within the maximum fault handling time interval and within the fault tolerant time interval).

FMEA-MSR evaluates the current state of risk of failure under end-user conditions (not just risk of harm to persons). The detection of faults/failures during customer operation can be used to avoid the original failure effect by switching to a degraded operational state (including disabling the vehicle), informing the driver and/or writing a diagnostic trouble code (DTC) into the control unit for service purposes. In terms of FMEA, the result of RELIABLE diagnostic detection and response is to eliminate (prevent) the original effect, and replace it with a new, less severe effect.

FMEA-MSR is useful in deciding whether the system design fulfills the performance requirements with respect to safety and compliance. The result may be i.e.

- additional sensor(s) may be needed for monitoring purposes
- redundancy in processing may be needed
- plausibility checks may reveal sensor malfunctions

4.1 FMEA-MSR 1st Step: Planning and Preparation

4.1.1 Purpose



The main objectives of Planning and Preparation in FMEA-MSR are:

- Project identification
- Project plan (InTent, Timing, Team, Tasks, Tools (5T))
- Analysis boundaries: What is included and excluded from the analysis
- Identification of baseline DFMEA
- Basis for the Structure Analysis step

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4.1.2 FMEA-MSR Project Identification and Boundaries

FMEA-MSR Project identification includes a clear understanding of what needs to be evaluated. This involves a decision-making process to define the FMEA-MSRs that are needed for a customer program. What to exclude can be just as important as what to include in the analysis.

The following may assist the team in defining FMEA-MSR projects, as applicable:

- Hazard Analysis and Risk Assessment
- Legal Requirements
- Technical Requirements
- Customer wants/needs/expectation (external and internal customers)
- Requirements specification
- Diagrams (Block/Boundary/System)
- Schematics, Drawings, and/or 3D Models
- Bill of Materials (BOM), Risk Assessment
- Previous FMEA for similar products

Answers to these questions and others defined by the company help create the list of FMEA-MSR projects needed. The FMEA-MSR project list assures consistent direction, commitment and focus.

Below are some basic questions that help identify FMEA-MSR boundaries:

(1) After completing a DFMEA on an Electrical / Electronic / Programmable Electronic System, are there effects that may be harmful to persons or involve regulatory noncompliance?

(2) Did the DFMEA indicate that all of the causes which lead to harm or noncompliance can be detected by direct sensing, and/or plausibility algorithms?

(3) Did the DFMEA indicate that the intended system response to any and all of the detected causes is to switch to a degraded operational state (including disabling the vehicle), inform the driver and/or write a Diagnostic Trouble Code (DTC) into the control unit for service purposes?

FMEA for Monitoring and System Response may be used to examine systems which have integrated fault monitoring and response mechanisms during operation. Typically, these are more complex systems composed of sensors, actuators and logical processing units. The diagnosis and monitoring in such systems may be achieved through hardware and/or software.

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Systems that may be considered in a Supplemental FMEA for Monitoring and System Response consist in general of at least a sensor, a control unit, and an actuator or a subset of them and are called mechatronic systems. Systems in-scope may also consist of mechanical hardware components (i.e. pneumatics and hydraulics).

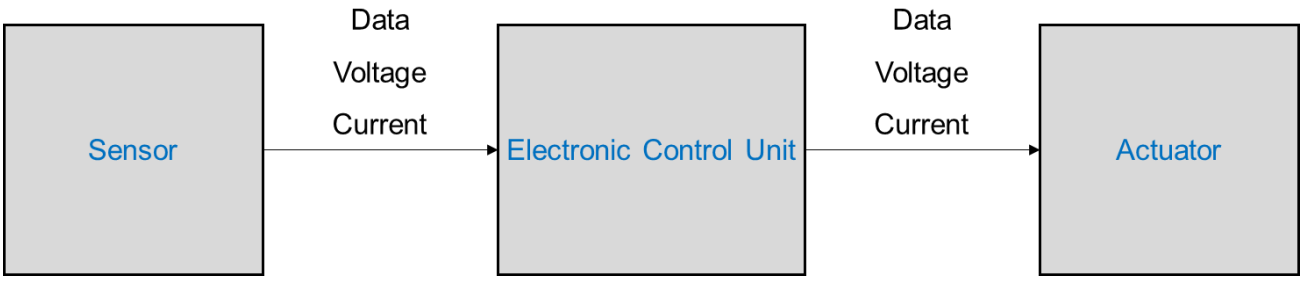


Figure 4.1-1 Generic block diagram of an Electrical / Electronic / Programmable Electronic System

The scope of a Supplemental FMEA for Monitoring and System Response may be established in consultation between customer and supplier. Applicable scoping criteria may include, but are not limited to:

1. System Safety relevance
2. ISO Standards, i.e. Safety Goals according to ISO 26262
3. Documentation requirements from legislative bodies, i.e. UN/ECE Regulations, FMVSS/CMVSS, NHTSA, and On Board Diagnostic Requirements (OBD) Compliance.

4.1.3 FMEA-MSR Project Plan

A plan for the execution of the FMEA-MSR should be developed once the FMEA-MSR project is known.

It is recommended that the 5T method (Intent, Timing, Team, Tasks, Tool) be used as described in section 1.5 of this handbook. The plan for the FMEA-MSR helps the company be proactive in starting the FMEA-MSR early. The FMEA-MSR activities (7-step process) should be incorporated into the overall design project plan.

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4.2 FMEA-MSR 2nd Step: Structure Analysis



4.2.1 Purpose

The main objectives of Structure Analysis in FMEA-MSR are:

- Visualization of the analysis scope
- Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts
- Identification of design interfaces, interactions
- Collaboration between customer and supplier engineering teams (interface responsibilities)
- Basis for the Function Analysis step

Depending on the scope of analysis, the structure may consist of hardware elements and software elements. Complex structures may be split into several structures (work packages) or different layers of block diagrams and analyzed separately for organizational reasons or to ensure sufficient clarity.

The scope of the FMEA-MSR is limited to the elements of the system for which the baseline DFMEA showed that there are causes of failure which can result in hazardous or noncompliant effects.

In order to visualize a system structure, two methods are commonly used:

- Block (Boundary) Diagrams
- Structure Trees

For more details, refer to Section 2.2 Design FMEA

4.2.2 Structure Trees

In a Supplemental FMEA for Monitoring and System Response, the root element of a structure tree can be at vehicle level, i.e. for OEMs which analyze the overall system (see Figure 4.2-1) or at the system level, i.e. for suppliers which analyze a subsystem or component (see Figure 4.2-2).



Figure 4.2-1 Example of a structure tree of a window lift system for investigating erroneous signals, monitoring, and system response

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The sensor element and the control unit may also be part of one component (smart sensor). Diagnostics and monitoring in such systems may be realized by hardware and/or software elements.

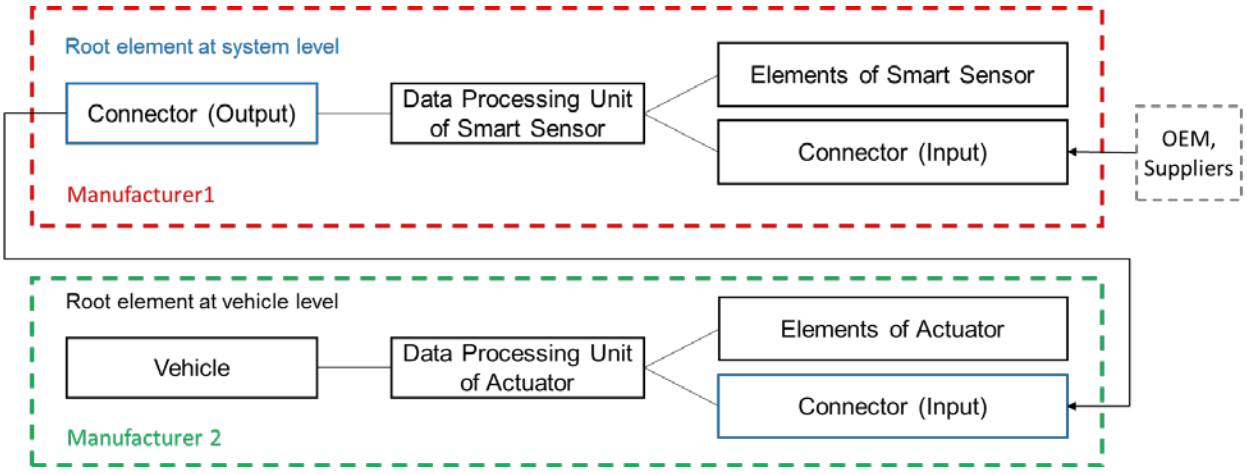


Figure 4.2-2 Example of a structure tree of a smart sensor with an internal sensing element and output to an interface

In case there is no sensor within the scope of analysis, an Interface Element is used to describe the data/current/voltage received by the ECU. One function of any ECU is to receive signals, i.e. via a connector. These signals can be missing or erroneous. With no monitoring, you get erroneous output.

In case there is no actuator within the scope of analysis, an Interface Element is used to describe the data/current/voltage sent by the ECU. Another function of any ECU is to send signals, i.e. via a connector. These signals can also be missing or erroneous. It can also be “no output” or “failure information.

The causes of erroneous signals may be within a component which is outside the scope of responsibility of the engineer or organization. These erroneous signals may have an effect on the performance of a component which is within the scope of responsibility of the engineer or organization. It is therefore necessary to include such causes in the FMEA-MSR analysis.

NOTE: Ensure that the structure is consistent with the Safety Concept (as applicable).

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lift System	ECU Window Lifter	Connector ECU Window Lifter

Figure 4.2-3 Example of Structure Analysis in the FMEA-MSR Form

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4.3 FMEA-MSR 3rd Step: Function Analysis

4.3.1 Purpose



The main objectives of Function Analysis in FMEA-MSR are:

- Visualization of functions and relationships between functions
- Function tree/net, or equivalent function matrix parameter diagram (P-diagram)
- Cascade of customer (external and internal) functions with associated requirements
- Association of requirements or characteristics to functions
- Collaboration between engineering teams (systems, safety, and components)
- Basis for the Failure Analysis step

In a Supplemental FMEA for Monitoring and System Response, monitoring for failure detection and failure responses are considered as functions. Hardware and software functions may include monitoring of system states.

Functions for monitoring and detection of faults/failures may consist of, for example: out of range detections, cyclic redundancy checks, plausibility checks and sequence counter checks.

Functions for failure reactions may consist of, for example, provision of default values, switching to a limp home mode, switching off the corresponding function and/or display of a warning.

Such functions are modeled for those structural elements that are carriers of these functions, i.e. control units or components with computational abilities like smart sensors.

Additionally, sensor signals can be considered which are received by control units. Therefore, functions of signals may be described as well.

Finally, functions of actuators can be added, which describe the way the actuator or vehicle reacts on demand.

Performance requirements are assumed to be the maintenance of a safe or compliant state. Fulfillment of requirements is assessed through the risk assessment.

In case sensors and/or actuators are not within the scope of analysis, functions are assigned to the corresponding interface elements (consistent with the Safety Concept-as applicable).

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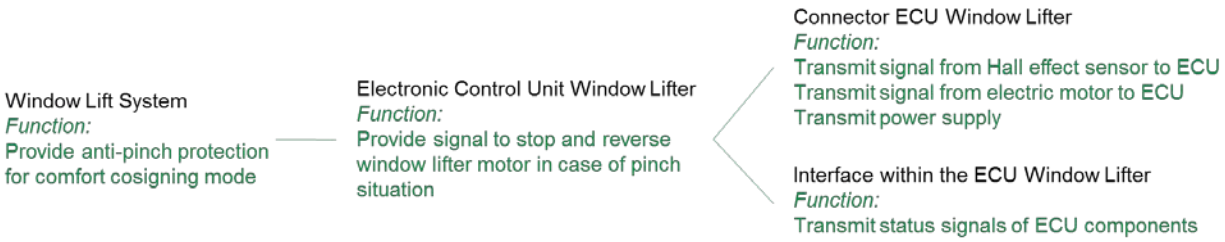


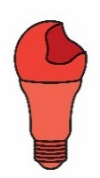
Figure 4.3-1 Example of a structure tree with functions Structure Tree

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Provide anti-pinch protection for comfort closing mode	Provide signal to stop and reverse window lifter motor in case of pinch situation	Transmit signal from Hall effect sensor to ECU

Figure 4.3-2 Example of Function Analysis in FMEA-MSR Form

4.4 FMEA-MSR 4th Step: Failure Analysis

4.4.1 Purpose



The purpose of Failure Analysis in FMEA-MSR is to describe the chain of events which lead up to the end effect, in the context of a relevant scenario.

The main objectives of Failure Analysis in FMEA-MSR are:

- Establishment of the failure chain
- Failure Cause, Monitoring, System Response, Reduced Failure Effect
- Identification of product Failure Causes using a parameter diagram or failure network
- Collaboration between customer and supplier (Failure Effects)
- Basis for the documentation of failures in the FMEA form and the Risk Analysis step

4.4.2 Failure Scenario

A Failure Scenario is comprised of a description of relevant operating conditions in which a fault results in malfunctioning behavior and possible sequences of events (system states) that lead to an end system state (Failure Effect). It starts from defined

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Failure Causes and leads to the Failure Effects. (See Figure 4.4-1)

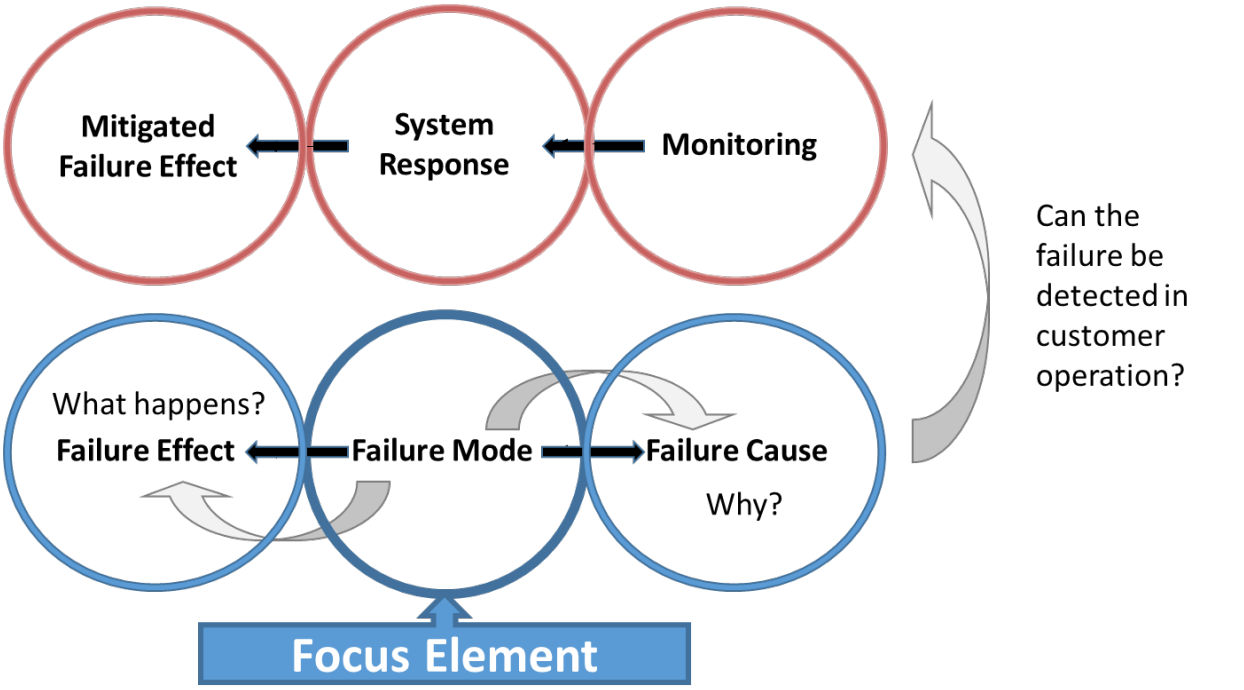


Figure 4.4-1 Theoretical failure chain model DFMEA and FMEA-MSR

The focus of the analysis is a component with diagnostic capabilities, i.e. an ECU.

If the component is not capable of detecting the fault/failure, the Failure Mode will occur which leads to the end effect with a corresponding degree of Severity.

However, if the component can detect the failure, this leads to a system response with a Failure Effect with a lower Severity compared to the original Failure Effect. Details are described in the following scenarios (1) to (3).

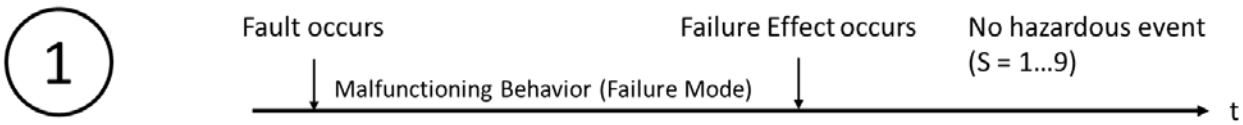


Figure 4.4-2 Failure Scenario (1) - Non-Hazardous

Failure Scenario (1) describes the malfunctioning behavior from the occurrence of the fault to the Failure Effect, which in this

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example is not hazardous but may reach a non-compliant end system state.

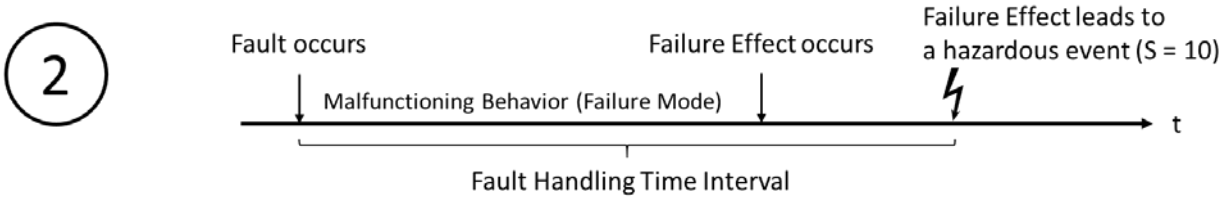


Figure 4.4-3 Failure Scenario (2) - Hazardous

Failure Scenario (2) describes the malfunctioning behavior from the occurrence of the fault to the Failure eEfect, which in this example leads to a hazardous event.

As an aspect of the Failure Scenario, it is necessary to estimate the magnitude of the Fault Handling Time Interval (time between the occurrence of the fault, and the occurrence of the hazard / noncompliant Failure Effect).

The Fault Handling Time Interval is the maximum time span of malfunctioning behavior before a hazardous event occurs, if the safety mechanisms are not activated.

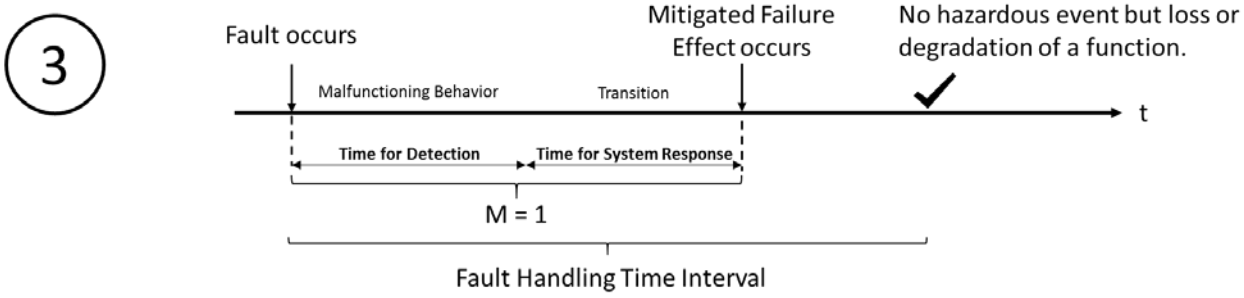


Figure 4.4-4 Failure Scenario (3) - Mitigated (Effect)

Failure Scenario (3) describes the malfunctioning behavior from the occurrence of the fault to the mitigated Failure Effect, which in this example leads to a loss or degradation of a function instead of the hazardous event.

4.4.3 Failure Cause

The description of the Failure Cause is the starting point of the Failure Analysis in a Supplemental FMEA for Monitoring and System Response. The Failure Cause is assumed to have occurred and is not the true Failure Cause (root cause). Typical Failure Causes are electrical/electronic faults (E/E faults) (Refer to Appendix C2). Root causes may be insufficient robustness when exposed to various factors such as the external environment,

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vehicle dynamics, wear, service, stress cycling, data bus overloading, and erroneous signal states, etc. Failure Causes can be derived i.e. from the DFMEA, catalogues for failures of E/E components, and network communication data descriptions.

NOTE: In FMEA-MSR, diagnostic monitoring is assumed to function as intended. (However, it may not be effective.) Therefore, Failure Causes of diagnostics are not part of FMEA-MSR but can be added to the DFMEA section of the form. These include:

- ✓ Failed to detect fault
- ✓ Falsely detected fault (nuisance)
- ✓ Unreliable fault response (variation in response capability)

Teams may decide not to include failures of diagnostic monitoring in DFMEA because Occurrence ratings are most often very low (including “latent failures” Ref. ISO 26262). Therefore, this analysis may be of limited value. However, the correct implementation of diagnostic monitoring should be part of the test protocol.

Prevention Controls of diagnostics in a DFMEA describe how reliable a mechanism is estimated to detect the Failure Cause and reacts on time with respect to the performance requirements.

Detection Controls of diagnostics in a DFMEA would relate back to development tests which verify the correct implementation and the effectiveness of the monitoring mechanism.

4.4.4 Failure Mode

A Failure Mode is the consequence of the fault (Failure Cause). In FMEA-MSR two possibilities are considered:

a. In case of failure scenarios (1) and (2) the fault is not detected or the system reaction is too late. Therefore, the Failure Mode in FMEA-MSR is the same as in DFMEA. (see Figure 4.4-5).

b. Different is failure scenario (3), where the fault is detected and the system response leads to a mitigated Failure Effect. In this case a description for the diagnostic monitoring and system response is added to the analysis. Because the failure chain in this specific possibility consists of a fault/failure and a description of an intended behavior, this is called a hybrid failure chain or hybrid failure network (see Figure 4.4-6).

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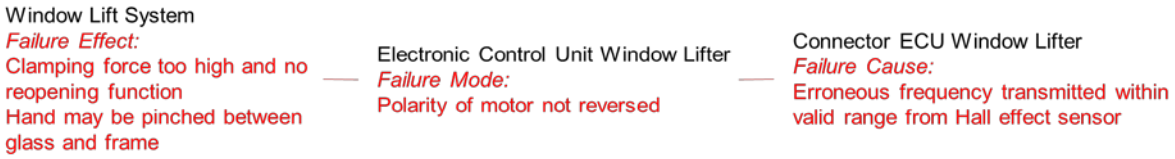


Figure 4.4-5 Example of a structure with failure chain without a monitoring or with a monitoring which is only partially effective (scenario (1) and (2)).

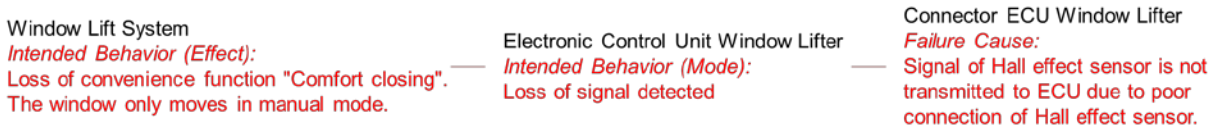


Figure 4.4-6 Example of a structure with hybrid failure chain including a monitoring which always is effective and switches the system to a mitigated Failure Effect (scenario (3)).

4.4.5 Failure Effect

A Failure Effect is defined as the consequence of a Failure Mode. Failure Effects in FMEA-MSR are either a malfunctioning behavior of the system or an intended behavior after detection of a Failure Cause. The end effect may be a “hazard” or “noncompliant state” or, in case of detection and timely system response, a “safe state” or “compliant state” with loss or degradation of a function.

The severity of Failure Effects is evaluated on a ten point scale according to Table MSR1 and Table D1, respectively.

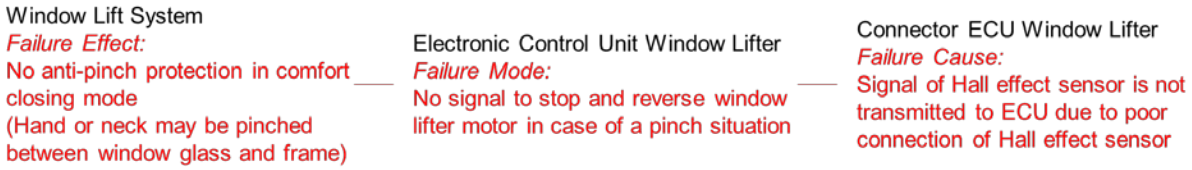


Figure 4.4-7 Example of a failure network

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched between window glass and frame)	No signal to stop and reverse window lifter motor in case of a pinch situation	Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor

Figure 4.4-8 Example of Failure Analysis in FMEA-MSR Form

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4.5 FMEA-MSR 5th Step: Risk Analysis

4.5.1 Purpose

The purpose of Risk Analysis in FMEA-MSR is to estimate risk of failure by evaluating Severity, Frequency, and Monitoring, and prioritize the need for actions to reduce risk.

The main objectives of the FMEA-MSR Risk Analysis are:



- Assignment of existing and/or planned controls and rating of failures
- Assignment of a Rationale for Frequency Rating
- Assignment of Monitoring Controls
- Analysis of provisions for functional safety and regulatory compliance
- Rating of Severity, Frequency and Monitoring for each failure chain.
- Collaboration between customer and supplier (Severity and Frequency)
- Evaluation of Action Priority
- Basis for the product Optimization step

4.5.2 Evaluations

Each Failure Mode, Cause and Effect relationship (failure chain or hybrid network)) is assessed by the following three criteria:

Severity (S): represents the Severity of the Failure Effect

Frequency (F): represents the Frequency of Occurrence of the Cause in a given operational situation, during the intended service life of the vehicle

Monitoring (M): represents the Detection potential of the Diagnostic Monitoring functions (detection of Failure Cause, Failure Mode and/or Failure Effect)

Evaluation numbers from 1 to 10 are used for S, F, and M respectively, where 10 stands for the highest risk contribution.

By examining these ratings individually and in combinations of the three factors the need for risk-reducing actions may be prioritized.

4.5.3 Severity (S)

The Severity rating (S) is a measure associated with the most serious Failure Effect for a given Failure Mode of the function being evaluated and is identical for DFMEA and FMEA-MSR.

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Severity should be estimated using the criteria in the Severity Table MSR1. The table may be augmented to include product-specific examples. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent even if modified for individual design analysis.

The Severity evaluations of the Failure Effects should be transferred by the customer to the supplier, as needed.

Product General Evaluation Criteria Severity (S)			
Potential Failure Effects rated according to the criteria below.			Blank until filled in by user
S	**Effect**	**Severity criteria**	**Corporate or Product Line Examples**
10	**Very High**	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Noncompliance with regulations.	
8	**High**	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		**Degradation** of primary vehicle function necessary for normal driving during expected service life.	
6	**Moderate**	**Loss** of secondary vehicle function.	
5		**Degradation** of secondary vehicle function.	
4		Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible Failure Effect.	

Note: This table is identical to Table D1 - DFMEA SEVERITY (S)

Table MSR1 - Supplemental FMEA-MSR SEVERITY (S)

4.5.4 Rationale for Frequency Rating

In a Supplemental FMEA for Monitoring and System Response, the likelihood of a failure to occur in the field under customer operating conditions during service life is relevant.

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Analysis of end user operation requires assumptions that the manufacturing process is adequately controlled in order to assess the sufficiency of the design.

Examples on which a rationale may be based on:

- Evaluation based on the results of Design FMEAs
- Evaluation based on the results of Process FMEAs
- Field data of returns and rejected parts
- Customer complaints
- Warranty databases
- Data handbooks

The rationale is documented in the column “Rationale for Frequency Rating” of the FMEA-MSR form.

4.5.5 Frequency (F)

The Frequency rating (F) is a measure of the likelihood of occurrence of the cause in relevant operating situations during the intended service life of the vehicle or the system using the criteria in Table MSR2.

If the Failure Cause does not always lead to the associated Failure Effect, the rating may be adapted, taking into account the probability of exposure to the relevant operating condition (according to Table MSR2.1). In such cases the operational situation and the rationale are to be stated in the column “Rationale for Frequency Rating”.



Frequency Potential (F) for the Product			
Frequency criteria (F) for the estimated occurrence of the Failure Cause in relevant operating situations during the intended service life of the vehicle			Blank until filled in by user
F	**Estimated Frequency**	**Frequency criteria - FMEA-MSR**	**Corporate or Product Line Examples**
10	**Extremely high or cannot be determined**	Frequency of occurrence of the Failure Cause is unknown or known to be unacceptably high during the intended service life of the vehicle	
9	**High**	Failure Cause is likely to occur during the intended service life of the vehicle	
8		Failure Cause may occur often in the field during the intended service life of the vehicle	
7	**Medium**	Failure Cause may occur frequently in the field during the intended service life of the vehicle	
6		Failure Cause may occur somewhat frequently in the field during the intended service life of the vehicle	

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5		Failure Cause may occur occasionally in the field during the intended service life of the vehicle.	
4	**Low**	Failure Cause is predicted to occur rarely in the field during the intended service life of the vehicle. At least ten occurrences in the field are predicted.	
3	**Very low**	Failure Cause is predicted not to occur in isolated cases in the field during the intended service life of the vehicle. At least one occurrence in the field is predicted.	
2	**Extremely low**	Failure Cause is predicted not to occur in the field during the intended service life of the vehicle based on prevention and detection controls and field experience with similar parts. Isolated cases cannot be ruled out. No proof it will not happen.	
1	**Cannot Occur**	Failure Cause cannot occur during the intended service life of the vehicle or is virtually eliminated. Evidence that Failure Cause cannot occur. Rationale is documented.	



Example: From field data it is known how often a control unit is defective in ppm/year. This may lead to F=3. The system under investigation is a parking system which is used only a very limited time in comparison to the overall operating time. So harm to persons is only possible when the defect occurs during the parking maneuver. Therefore, Frequency may be lowered to F=2.

NOTE: Probability increases as number of vehicles are increased
Reference value for estimation is one million vehicles in the field

Table MSR2 - Supplemental FMEA-MSR FREQUENCY (F)

Percentage of relevant operating condition in comparison to overall operating time	Value by which F may be lowered
< 10%	1
< 1%	2

Table MSR2.1 - Supplemental FMEA-MSR FREQUENCY adaption for infrequent operating conditions

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4.5.6 Current Monitoring Controls

All controls that are planned or already implemented and lead to a detection of the Failure Cause, the Failure Mode or the Failure Effect by the system or by the driver are entered into the “Current Monitoring Controls” column. In addition, the fault reaction after detection should be described, i.e. provision of default values, (if not already sufficiently described by the Failure Effect).

Monitoring evaluates the potential that the Failure Cause, the Failure Mode or the Failure Effect can be detected early enough so that the initial Failure Effect can be mitigated before a hazard occurs or a noncompliant state is reached. The result is an end state effect with a lower severity.

4.5.7 Monitoring (M)

The Monitoring rating (M) is a measure of the ability of detecting a fault/failure during customer operation and applying the fault reaction in order to maintain a safe or compliant state.

The Monitoring Rating relates to the combined ability of all sensors, logic, and human sensory perception to detect the fault/failure; and react by modifying the vehicle behavior by means of mechanical actuation and physical reaction (controllability). In order to maintain a safe or compliant state of operation, the sequence of fault detection and reaction need to take place before the hazardous or noncompliant effect occurs. The resulting rating describes the ability to maintain a safe or compliant state of operation.

Monitoring is a relative rating within the scope of the individual FMEA and is determined without regard for severity or frequency. Monitoring should be estimated using the criteria in Table MSR3. This table may be augmented with examples of common monitoring. The FMEA project team should agree on an evaluation criteria and rating system which is consistent, even if modified for individual product analysis.

The assumption is that Monitoring is implemented and tested as-designed. The effectiveness of Monitoring depends on the design of the sensor hardware, sensor redundancy, and diagnostic algorithms that are implemented. Plausibility metrics alone are not considered to be effective. Refer to Table MSR3.

Implementation of monitoring and the verification of effectiveness should be part of the development process and therefore may be analyzed in the corresponding DFMEA of the product. (see NOTE for Failure Causes in Section 4.4.1).

The effectiveness of diagnostic monitoring and response, the fault monitoring response time, and the Fault Tolerant Time Interval need to be determined prior to rating. Determination of the

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effectiveness of diagnostic monitoring is addressed in detail in ISO 26262-5:2018 Annex D.

In practice, three different monitoring/response cases may be distinguished:

(1) No fault/failure monitoring

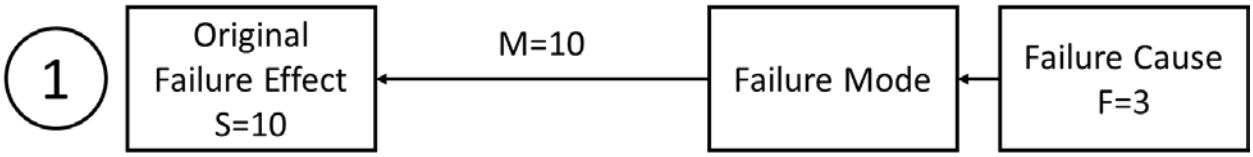


Figure 4.5-1 FMEA-MSR Monitoring not implemented or not considered

If there is no monitoring control, or if monitoring and response do not occur within the Fault Handling Time Interval, then Monitoring should be rated as Not Effective (M=10).

(2) Reliable fault/failure monitoring and system response

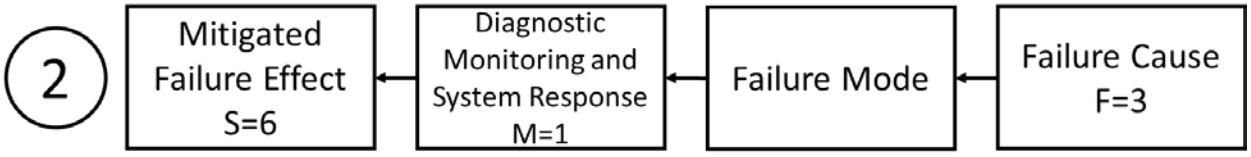


Figure 4.5-2 FMEA-MSR Reliable Diagnostic Monitoring

The original Failure Effect is virtually eliminated. Only the mitigated Failure Effect remains relevant for the risk estimation of the product or system. In this instance only, the mitigated FE is relevant for the Action Priority rating, not the original FE.

The assignment of Monitoring Ratings to Failure Causes and their corresponding Monitoring Controls can vary depending on:

a. Variations in the Failure Cause or Failure Mode
b. Variations in the hardware implemented for diagnostic monitoring
c. The execution timing of the safety mechanism, i.e. failure is detected during “power up” only
d. Variations in system response
e. Variations in human perception and reaction
f. Knowledge of implementation and effectiveness from other projects (newness)

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Depending on these variations or execution timing, Monitoring Controls may not be considered to be RELIABLE in the sense of M=1.

(3) Less-than reliable fault/failure monitoring

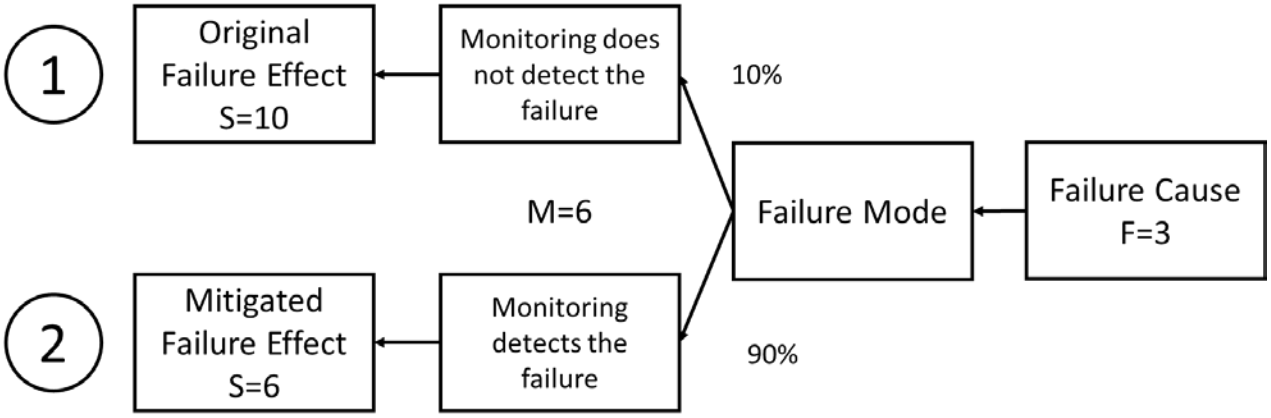


Figure 4.5-3 FMEA-MSR Diagnostic Monitoring partially effective

The original Failure Effect occurs less often. Most of the failures are detected and the system response leads to a mitigated Failure Effect. The reduced risk is represented by the Monitoring rating. The most serious Failure Effect remains S=10.

Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
10	**Not effective**	The fault/failure cannot be detected at all or not during the Fault Handling Time Interval; by the system, the driver, a passenger, or service technician.	No response during the Fault Handling Time Interval.	
9	**Very Low**	The fault/failure can almost never be detected in relevant operating conditions. Monitoring control with low effectiveness, high variance, or high uncertainty. Minimal diagnostic coverage.	The reaction to the fault/failure by the system or the driver may not reliably occur during the Fault Handling Time Interval.	

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Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
8	**Low**	The fault/failure can be detected in very few relevant operating conditions. Monitoring control with low effectiveness, high variance, or high uncertainty. Diagnostic coverage estimated <60%.	The reaction to the fault/failure by the system or the driver may not always occur during the Fault Handling Time Interval.	
7	**Moderately Low**	Low probability of detecting the fault/failure during the Fault Handling Time Interval by the system or the driver. Monitoring control with low effectiveness, high variance, or high uncertainty. Diagnostic coverage estimated >60%.	Low probability of reacting to the detected fault/failure during the Fault Handling Time Interval by the system or the driver.	
6	**Moderate**	The fault/failure will be automatically detected by the system or the driver only during power-up, with medium variance in detection time. Diagnostic coverage estimated >90%.	The automated system or the driver will be able to react to the detected fault/failure in many operating conditions.	
5		The fault/failure will be automatically detected by the system during the Fault Handling Time Interval, with medium variance in detection time, or detected by the driver in very many operating conditions. Diagnostic coverage estimated between 90% - 97%.	The automated system or the driver will be able to react to the detected fault/failure during the Fault Handling Time Interval in very many operating conditions.	
4	**Moderately High**	The fault/failure will be automatically detected by the system during the Fault Handling Time Interval, with medium variance in detection time, or detected by the driver in most operating conditions. Diagnostic coverage estimated >97%.	The automated system or the driver will be able to react to the detected fault/failure during the Fault Handling Time interval, in most operating conditions.	
3	**High**	The fault/failure will be automatically detected by the system during the Fault Handling Time Interval with very low variance in detection time, and with a high probability. Diagnostic coverage estimated >99%.	The system will automatically react to the detected fault/failure during the Fault Handling Time Interval in most operating conditions with very low variance in system response time, and with a high probability.	

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Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
2	**Very High**	The fault/failure will be detected automatically by the system with very low variance in detection time during the Fault Handling Time Interval, and with a very high probability. Diagnostic coverage estimated > 99.9%.	The system will automatically react to the detected fault/failure during the Fault Handling Time Interval with very low variance in system response time, and with a very high probability.	
1	**Reliable** and acceptable for elimination of original Failure Effect.	The fault/failure will always be detected automatically by the system. Diagnostic coverage estimated to be significantly greater than 99.9%.	The system will always automatically react to the detected fault/failure during the Fault Handling Time Interval.	

Table MSR3 - Supplemental FMEA-MSR MONITORING (M)

4.5.8 Action Priority (AP) for FMEA-MSR

The Action Priority is a methodology which allows for the prioritization of the need for action, considering Severity, Frequency, and Monitoring (SFM).

This is done by the assignment of SFM ratings which provide a basis for the estimation of risk.

See previous chapters for discussion of reducing risk first by S, then F, then M.

Priority High (H): Highest priority for review and action. The team needs to either identify an appropriate action to lower frequency and/or to improve monitoring controls or justify and document why current controls are adequate.

Priority Medium (M): Medium priority for review and action. The team should identify appropriate actions to lower frequency and/or to improve monitoring controls, or, at the discretion of the company, justify and document why controls are adequate.

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Priority Low (L): Low priority for review and action.
The team could identify actions to lower frequency and/or to improve monitoring controls.

It is recommended that potential Severity 9-10 failure effects with Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

This is not the prioritization of High, Medium, or Low risk. It is the prioritization of the need for actions to reduce risk.

If the team decides that no further actions are necessary, “No further action is needed” is written in the Remarks field to show the risk analysis was completed.

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Action Priority (AP) for FMEA-MSR

Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.

Effect	S	Prediction of Failure Cause Occurring During Service Life of Vehicle	F	Effectiveness of Monitoring	M	ACTION PRIORITY (AP)
Product Effect High	**10**	Medium - Extremely high	5-10	Reliable - Not effective	1-10	H
		Low	4	Moderately high - Not effective	4-10	H
				Very high - High	2-3	H
				Reliable	1	M
		Very low	3	Moderately high - Not effective	4-10	H
				Very high - High	2-3	M
				Reliable	1	L
		Extremely low	2	Moderately high - Not effective	4-10	M
				Reliable - High	1-3	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect High	**9**	Low - Extremely high	4-10	Reliable - Not effective	1-10	H
		Extremely low - Very low	2-3	Very high - Not effective	2-10	H
				Reliable - High	1	L
		Cannot occur	1	Reliable - Not effective	1-10	L

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Action Priority (AP) for FMEA-MSR

Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.

Effect	S	Prediction of Failure Cause Occurring During Service Life of Vehicle	F	Effectiveness of Monitoring	M	ACTION PRIORITY (AP)
Product Effect Moderately high	**7-8**	Medium - Extremely high	6-10	Reliable - Not effective	1-10	H
		Medium	5	Moderately high - Not effective	5-10	H
				Reliable - Moderately high	1-4	M
		Low	4	Moderately low - Not effective	7-10	H
				Moderately high - Moderate	4-6	M
				Reliable - High	1-3	L
		Very low	3	Very low - Not effective	9-10	H
				Moderately low - Low	7-8	M
				Reliable - Moderate	1-6	L
		Extremely low	2	Moderately low - Not effective	7-10	M
				Reliable - Moderate	1-6	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect Moderately low	**4-6**	High - Extremely high	7-10	Reliable - Not effective	1-10	H
		Medium	5-6	Moderate - Not effective	6-10	H
				Reliable - Moderately high	1-5	M
		Extremely low - Low	2-4	Very low - Not effective	9-10	M
				Moderately high - Moderate	7-8	M
				Reliable - Moderate	1-6	L
		Cannot occur	1	Reliable - Not effective	1-10	L

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Action Priority (AP) for FMEA-MSR

Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.

Effect	S	Prediction of Failure Cause Occurring During Service Life of Vehicle	F	Effectiveness of Monitoring	M	ACTION PRIORITY (AP)
Product Effect Low	**2-3**	High - Extremely high	7-10	Reliable - Not effective	1-10	H
		Medium	5-6	Moderately low - Not effective	7-10	M
				Reliable - Moderate	1-6	L
		Extremely low - Low	2-4	Reliable - Not effective	1-10	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect Very Low	**1**	Cannot occur - Extremely high	1-10	Reliable - Not effective	1-10	L

NOTE 1: If M=1, the Severity rating of the Failure Effect after Monitoring and System Response is to be used for determining MSR Action Priority. If M is not equal to 1, then the Severity Rating of the original Failure Effect is to be used for determining MSR Action Priority.

NOTE 2: When FMEA-MSR is used, and M=1, then DFMEA Action Prioritization replaces the severity rating of the original Failure Effect with the Severity rating of the mitigated Failure Effect.

Table AP – ACTION PRIORITY FOR FMEA-MSR

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SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5)									
Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)
The connection principle of the Hall effect sensor and ECU is according to standard xyz.	2	None	Window will close with full clamping force.	10	Hand or neck may be pinched between glass and frame	10	10	M	

Figure 4.5-4 Example of FMEA-MSR Risk Analysis - Evaluation of Current Risk Form

4.6 FMEA-MSR 6th Step: Optimization

4.6.1 Purpose

The primary objective of Optimization in FMEA-MSR is to develop actions that reduce risk and improve safety. In this step, the team reviews the results of the risk analysis and evaluates action priorities.

The main objectives of FMEA-MSR Optimization are:



- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and target completion dates for action implementation
- Implementation and documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and deadlines for action implementation
- Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures

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- Basis for refinement of the product requirements and prevention/detection controls

High and medium action priorities may indicate a need for technical improvement.

Improvements may be achieved by introducing more reliable components which reduce the occurrence potential of the Failure Cause in the field or introduce additional monitoring which improve the detection capabilities of the system. Introduction of monitoring is similar to design change. Frequency of the Failure Cause is not changed. It may also be possible to eliminate the Failure Effect by introducing redundancy.

If the team decides that no further actions are necessary, “No further action is needed” is written in the Remarks field to show the risk analysis was completed.

The optimization is most effective in the following order:

- Component design modifications in order to reduce the Occurrence (O) of the Failure Cause (FC)
- Component design modifications in order to reduce the occurrence of the Failure Cause (FC).
- Increase the Detection (D) ability for the Failure Cause (FC) or Failure Mode (FM).

In the case of design modifications, all impacted design elements are evaluated again.

In the case of concept modifications, all steps of the FMEA are reviewed for the affected sections. This is necessary because the original analysis is no longer valid since it was based upon a different design concept.

4.6.2 Assignment of Responsibilities

Each action should have a responsible individual and a Target Completion Date (TCD) associated with it.

The responsible person ensures the action status is updated. If the action is confirmed this person is also responsible for the action implementation.

The Actual Completion Date is documented including the date the actions are implemented.

Target Completion Dates should be realistic (i.e. in accordance with the product development plan, prior to process validation, prior to start of production).

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4.6.3 Status of the Actions

Suggested levels for Status of Actions:

Open

No Action defined.

Decision pending (optional)

The action has been defined but has not yet decided on. A decision paper is being created.

Implementation pending (optional)

The action has been decided on but not yet implemented.

Completed

Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.

Not Implemented

Not Implemented status is assigned when a decision is made not to implement an action. This may occur when risks related to practical and technical limitations are beyond current capabilities.

The FMEA is not considered “complete” until the team assesses each item’s Action Priority and either accepts the level of risk or documents closure of all actions. Closure of all actions should be documented before the FMEA is released at Start of Production (SOP).

Describe the actual preventive and detection actions regarding design change, test procedure, test plan, process change, control plan, or other documents.

If “No Action Taken”, then Action Priority is not reduced and the risk of failure is carried forward into the product design.

4.6.4 Assessment of Action Effectiveness

When an action has been completed, Frequency, and Monitoring values are reassessed, and a new Action Priority may be determined.

The new action receives a preliminary Action Priority rating as a prediction of effectiveness.

However, the status of the action remains “implementation pending” until the effectiveness has been tested. After the tests are finalized the preliminary rating has to be confirmed or adapted, when indicated. The status of the action is then changed from “implementation pending” to “completed”.

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The reassessment should be based on the effectiveness of the MSR Preventive and Diagnostic Monitoring Actions taken and the new values are based on the definitions in the FMEA-MSR Frequency and Monitoring rating tables.

4.6.5 Continuous Improvement

FMEA-MSR serves as an historical record for the design. Therefore, the original Severity, Frequency, and Monitoring (S, F, M) numbers are not modified once actions have been taken.

The completed analysis becomes a repository to capture the progression of design decisions and design refinements. However, original S, F, M ratings may be modified for basis, family or generic DFMEAs because the information is used as a starting point for an application-specific analysis.

SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 6)

MSR Preventive Action	Diagnostic Monitoring Action	System Response	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Frequency (F)	Monitoring (M)	MSR AP	Remarks
None	Introduc-tion of plausibility check between motor current and loss of signal from Hall effect sensor.	Comfort closing mode disabled	Loss of conven-ience function "Comfort closing". The window only moves in manual mode.	6	Test engineer Mr. Warren Watchful	dd.mm.yyyy	Implement-tation pending			2	1	L	

Figure 4.6-1 Example of FMEA-MSR Optimization with new Risk Evaluation Form

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4.7 FMEA-MSR 7th Step: Results Documentation



The scope and results of an FMEA should be summarized in a report. The report can be used for communication purposes within a company, or between companies. The report is not meant to replace reviews of the FMEA-MSR details when requested by management, customers, or suppliers. It is meant to be a summary for the FMEA-MSR team and others to confirm completion of each of the tasks and review the results of the analysis.

It is important that the content of the documentation fulfill the requirements of the organization, the intended reader, and relevant stakeholders. Details may be agreed upon between the parties. In this way, it is also ensured that all details of the analysis and the intellectual property remain at the developing company.

The layout of the document may be company specific. However, the report should indicate the technical risk of failure as a part of the development plan and project milestones. The content may include the following:

A. A statement of final status compared to original goals established in 1.5 Project Plan
   a. FMEA Intent – Purpose of this FMEA?
   b. FMEA Timing – FMEA due date?
   c. FMEA Team – List of participants?
   d. FMEA Task - Scope of this FMEA?
   e. FMEA Tool – How do we conduct the analysis Method used?

B. A summary of the scope of the analysis and identify what is new.

C. A summary of how the functions were developed.

D. A summary of at least the high-risk failures as determined by the team and provide a copy of the specific S/F/M rating tables and method of action prioritization (e.g. Action Priority table).

E. A summary of the actions taken and/or planned to address the high-risk failures including status of those actions.

F. A plan and commitment of timing for ongoing FMEA improvement actions.
   a. Commitment and timing to close open actions.
   b. Commitment to review and revise the FMEA-MSR during mass production to ensure the accuracy and completeness

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of the analysis as compared with the original production design (e.g. revisions triggered from design changes, corrective actions, etc., based on company procedures). (Refer to section 1.4 Case 3 FMEA revisions)

c. Commitment to capture “things gone wrong” in foundation FMEA-MSRs for the benefit of future analysis reuse, when applicable. (Refer to section 1.3.6 Foundation and Family FMEAs)

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APPENDIX

A Development History of the FMEA 159
B Change Point Summaries 161
B1 AIAG 4th Edition FMEA Reference Manual to AIAG-VDA FMEA Handbook 161
B1.1 AIAG 4th Edition DFMEA to AIAG-VDA FMEA Handbook DFMEA 161
B1.2 AIAG 4th Edition PFMEA to AIAG-VDA FMEA Handbook PFMEA 165
B2 VDA Volume 4, Chapter Product and Process FMEA to AIAG-VDA FMEA Handbook 170
B2.1 VDA Volume 4, Chapter Product DFMEA to AIAG-VDA FMEA Handbook 170
B2.2 VDA Volume 4, Chapter Product PFMEA to AIAG-VDA FMEA Handbook 174
B2.3 VDA Volume 4, Chapter Product FMEA-MSR to AIAG-VDA FMEA Handbook 178
C Additions 181
C1 Special Characteristics 181
C2 FMEA and Functional Safety 181
D Form Sheets 184
D1 DFMEA Form Sheet 184
D1.1 DFMEA Form Sheet Step 1 184
D1.2 DFMEA Form Sheet Step 2 185
D1.3 DFMEA Form Sheet Step 3 186
D1.4 DFMEA Form Sheet Step 4 187
D1.5 DFMEA Form Sheet Step 5 189
D1.6 DFMEA Form Sheet Step 6 191
D1.7 DFMEA Form Sheet Step 7 192
D1.8 DFMEA Software Examples 193
D2 PFMEA Form Sheet 195
D2.1 PFMEA Form Sheet Step 1 195
D2.2 PFMEA Form Sheet Step 2 196
D2.3 PFMEA Form Sheet Step 3 197
D2.4 PFMEA Form Sheet Step 4 198
D2.5 PFMEA Form Sheet Step 5 199
D2.6 PFMEA Form Sheet Step 6 201
D2.7 PFMEA Form Sheet Step 7 202
D2.8 PFMEA Software Examples 203
D3 FMEA-MSR Form Sheet Template 208
D3.1 FMEA-MSR Form Sheet Step 1 208
D3.2 FMEA-MSR Form Sheet Step 2 209
D3.3 FMEA-MSR Form Sheet Step 3 210
D3.4 FMEA-MSR Form Sheet Step 4 211
D3.5 FMEA-MSR Form Sheet Step 5 212
D3.6 FMEA-MSR Form Sheet Step 6 214
D3.7 FMEA-MSR Form Sheet Step 7 215
D3.8 FMEA-MSR Software Examples 216
D4.0 Customer Specific Requirements Form Sheets 218
D4.1 GM and FCA DFMEA Form Sheet 218
D4.2 Ford DFMEA Form Sheet 218
D4.3 GM and FCA PFMEA Form Sheet 218
D4.4 Ford PFMEA Form Sheet 218
E Further Application Fields 219
E1 FMEA for Software Scopes 219
E2 Objective of the Software Scopes Inspection 219

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E3 FMEA in the Software Development Process *219*
E4 FMEA for Machine and Facility Manufacturers *219*
F: SEVERITY, OCCURRENCE, DETECTION AND ACTION PRIORITY TABLES 221
F1 DFMEA SOD Tables *221*
F2 PFMEA SOD Tables *231*
F2.4 ACTION PRIORITY TABLE FOR PFMEA *239*
F3 FMEA-MSR Tables *241*
G REFERENCES AND SUGGESTED READINGS 249
H GLOSSARY 250

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A Development History of the FMEA

The history of the development of the FMEA goes back over 60 years. The following milestones are important for the method:

1949: The FMEA method was developed by the US military as Military Specification MIL-P-1629. It was used as an evaluation technique for reliability, in order to depict the effects of system and equipment failures. The failures were classified according to the influence on the success, the people, and the equipment safety.

1955: Widespread use of the “Analysis of Potential Problems (APP)” by Kepner/Tregoe

1963: US National Aeronautics and Space Administration (NASA) developed the “Failure Mode, Effects, and Criticality Analysis” (FMECA) for the Apollo project.

1965: Widespread use in aviation and aerospace applications, the food industry, and nuclear technology applications.

1975: This method was deployed in nuclear power engineering and other industries.

1977: Beginning of the use of the FMEA Method in the automotive industry by Ford Motor Co.

1980: In Germany, Failure Mode and Effects Analysis with the subtitle FMEA (DIN 25448) was standardized. In the German Association of Automotive Industry (Verband der Automobilindustrie -VDA) this method was developed further specifically for automobiles.

1986: The first method description was published as VDA volume 4, Quality Assurance Prior to Serial Application. This method has been increasingly used in the automotive industry.

1990: The method for System FMEA Design and System FMEA Process for the Automotive Industry was developed further by the VDA. The application of the FMEA method in the areas of medicine and telecommunications engineering took place in the 90s.

1993: The AIAG FMEA Reference Manual was developed by the FMEA teams at Chrysler, Ford and General Motors working under the auspices of the Automotive Division of the American Society for Quality Control (ASQC) and was published to improve upon the situation where differences between guidelines and formats resulted in additional demands on supplier resources.

1994: The SAE J1739 FMEA Standard was jointly developed by Chrysler, Ford and GM under the sponsorship of the

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United States Council for Automotive Research LLC (USCAR).

1995: SAE J1739 2nd Edition.

1996: VDA Volume 4, Part 2, Quality Assurance Prior to Serial Application was published with the subtitle System FMEA.

1999: The German Registered Association for Quality (Deutsche Gesellschaft für Qualität e.V. - DGQ) founded a workgroup in order to describe the application of the FMEA for additional fields, for example, Service Industry and Project Management.

2000: SAE J1739 was revised as a Recommended Practice

2001: The DGQ volume 13-11 was published.

2001: International standardization (IEC 60812). SAE J1739 3rd Edition of the manual served as a reference for ISO QS-9000. The 3rd edition of the AIAG FMEA Manual was published.

2002: The DGQ volume 13-11 was also revised

2006: In 2006, the VDA Volume 4, Chapter Product and Process FMEA handbook was revised.

2008: SAE J1739 4th Edition is the technical basis for the AIAG Reference Manual, with members of the J1739 work group contributing to the technical changes and improvements in the AIAG FMEA Reference Manuals. The AIAG FMEA Manual 4th Edition was also published.

2015: The need was recognized to harmonize FMEA Manuals for the benefit of multi-national OEM’s and suppliers. This presented an opportunity to develop improved text, standardize rating scales, and improve the risk rating methodology, and incorporate risk assessments in support of functional safety.

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B Change Point Summaries

B1 AIAG 4th Edition FMEA Reference Manual to AIAG-VDA FMEA Handbook

B1.1 AIAG 4th Edition DFMEA to AIAG-VDA FMEA Handbook DFMEA

The AIAG-VDA FMEA method is described by a 7-Step process. The steps are the synthesis of AIAG and VDA DFMEA process steps. For example, Block/Boundary Diagrams are shown as Step 2 of the 7-Step process and the same deliverable is shown as a prerequisite in the 4th Edition.

Special Characteristics are removed from DFMEA but stay in PFMEA, see Annex D1 Special Characteristics.

For continuous Improvement a History / Change Authorization column is added (For use as applicable)

The linkage between DFMEA and PFMEA is explained and FMEA Collaboration (Customer – Tier n – Tier n+1).

1st Step: Preparation and Planning

Preparation is partly considered in the 4th Edition General FMEA Guidelines, Chapter II Overview of FMEA, and Chapter III DFMEA. Step 1 includes definition of the “5T’s”: InTent, Timing, Team, Task, and Tool to be used to document the analysis as well as identification of the analysis subject and baseline DFMEA as appropriate.

FMEA Form header is defined within Step 1 and the following changes apply:

i. **Company Name** added
ii. Marking of **System, Subsystem or Component** removed
iii. **Engineering Location** added
iv. **Customer Name** added
v. **Model Year(s)/Program(s)** changed to **Model Year/Platform**
vi. **Subject** added
vii. **Key Date** removed
viii. **Revision Date** added
ix. **FMEA Number** changed to **DFMEA ID Number**
x. **Page Number** of **Page Number** removed
xi. **Prepared By** changed to **Design Responsibility**
xii. **FMEA Date (orig.)** changed to **Start Date**
xiii. **Core Team** changed to **Cross-Functional Team**
xiv. **Confidentiality Level** added

Reason for change: To use common terms and include necessary information for record management

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2nd Step: Structure Analysis

For DFMEA, ITEM is expanded to SYSTEM, SYSTEM ELEMENT, and COMPONENT ELEMENT with SYSTEM as Next Higher Level, SYSTEM ELEMENT as Focus Element, and COMPONENT ELEMENT as Next Lower Level or Characteristic Type.

Collaboration between customer and supplier is defined and added.

Reason for change: To correctly identify the system, subsystem, component and/or characteristic in relation to the item (focus element) being analyzed. This information is needed for Step 3, Function Analysis.

1. Next Higher Level SYSTEM	2. Focus Element SYSTEM ELEMENT	3. Next Lower Level or Characteristic Type COMPONENT ELEMENT

3rd Step: Function Analysis

AIAG 4TH Edition Form A and C: Item/Function and Requirement are split so that Item is part of Step 1 and Function and Requirement space is available for each of the levels defined in Step 2.

The description is more detailed how to formulate functions.

Detailed definition of requirements / characteristics and usage of P-Diagram explained.

Collaboration between engineering teams is described.

Reason for change: To establish the functions for each Item/System Element to demonstrate an understanding of how each level contributes to the functionality of the next higher level. Considering and listing the positive Functions and Requirements of the Product leads to listing the negatives, the Effect of Failure, and the Causes of Failure.

> Important note: AIAG Form A and C: Item/Function needed correction due to instances where customers have received DFMEAs showing an Item description and Failure Mode with no Function or Requirement identified. The expectation is that a Function and Requirement are necessary for an understanding of how the Function could fail.

1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic

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4th Step: Failure Analysis

Concept of FOCUS ELEMENT establishes the focus of the analysis.

i. **Potential Failure Mode** changed to: **Failure Mode (FM) of the Focus Element**
ii. **Potential Failure Effect** changed to: **Failure Effects (FE) to the Next Higher level Element and/or End User**
iii. **Potential Failure Cause** changed to: **Failure Cause (FC) of the Next Lower Element or Characteristic**
iv. Order of columns changed from **FM, FE, FC** to **FE, FM, FC**

> Important note: Although the order of columns changed, the order of creating the analysis using a spreadsheet remains the same. It is necessary to identify first the (FM), then either the (FE) or (FC) depending on the team. When using FMEA-dedicated software the team may perform the DFMEA in a different way e.g. identifying failures and then linking them in a proper failure chain of (FE), (FM), (FC).

Identify failures by systematic description of question approach.

More detailed description how to formulate failure effects, failure mode and failure cause with examples.

Relationship is shown between PFMEA and DFMEA.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

Reason for change: To promote the cause and effect analysis in terms of a chain of potential events. The structure, function, and failure sections of the form are designed using a pattern that leads to three levels of a failure chain (FE), (FM), (FC).

5th Step: Risk Analysis

The term “ranking” replaced by “rating” because each failure is rated according to the criteria defined in the rating charts. Each rating chart has a new column to add company-specific examples

i. **Severity** rating – Ten-point scale with similar definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA, PFMEA, and FMEA-MSR when rating the (FE) to the end user level.
ii. **Occurrence** rating – Ten-point scale with added emphasis on Prevention Controls as input to the Occurrence rating.

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iii. **Detection** rating – Ten-point scale that considers Ability to Detect, Detection Method Maturity, and Opportunity for Detection.

iv. **Action Priority (AP)** is offered as a replacement for Risk Priority Number (RPN) – Reference AP table for High-Medium-Low assignments. There is a common AP table for DFMEA and PFMEA.

v. **Classification** replaced with **Filter Code (Optional)** – The Filter Code column may be used to flag potential special characteristics or other information designated by the company.

Reason for change: Rating charts revised for global use by automotive OEMs and suppliers to encourage more effective and efficient DFMEAs by using common rating criteria. The AP table considers the importance of Severity, then Occurrence, then Detection when prioritizing actions for risk reduction as described in the AIAG 4th Edition FMEA Manual. The AP (H-M-L) considers the ratings of S, O, and D at the same time and applies logic to determine the priority of action. The table also makes recommendations on how work through the three AP levels.

Classification of failures as shown on product drawings and/or specifications (standard or special type) is not a requirement of DFMEA, therefore the column was removed and replaced with a Filter Code column.

Current Controls, even if the implementation is in the future, are part of Risk Analysis.

More detailed evaluation tables for occurrence and detection with examples.

Collaboration between customer and supplier explained.

1. Failure Effects (FE) to the Next Higher- Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)

6th Step: Optimization

The definition of optimization is detailed in the AIAG-VDA FMEA Handbook.

i. Recommended Action split into two columns: **Preventive Action and Detection Action**

ii. New: **Status** (Suggested status levels: Open, Completed, Discarded)

iii. Changed: **Action Taken with Pointer to Evidence**

iv. New: **Remarks** (for DFMEA team or internal use)

New assessment of action effectiveness defined.

Continual improvement described.

Collaboration between FMEA team, management, customer and supplier explained.

Reason for change: The information helps the user with visual management to be sure each piece of information is included and correct. Important is the “Pointer to Evidence” for follow-up reasons.

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DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Remarks

7th Step: Result Documentation

Step 7 summarizes the scope and results of the DFMEA in a report for review by internal management and/or the customer. The AIAG 4th Edition FMEA manual indicates that management owns the FMEA process and has the ultimate responsibility of selecting and applying resources and ensuring an effective risk management process including timing. These statements are found in Chapter 2, Strategy, Planning, Implementation. However, the 4th Edition does not provide additional guidance on how to engage management in the DFMEA team. Step 7 provides recommendations for what to include in results documentation. This report should indicate the technical risk of failure as a component of the development plan and project milestones.

B1.2 AIAG 4th Edition PFMEA to AIAG-VDA FMEA Handbook PFMEA

The AIAG-VDA FMEA method is described by a 7-Step process. The descriptions below compare these 7-Steps to the current AIAG. The comparisons include all forms used in both manuals. As appropriate, it will be pointed out why (Reason for change or Reason for use) the change can help lead to a more complete PFMEA.

1st Step: Planning & Preparation –

i. **Define the Scope** changed to **1st Step: Planning & Preparation**

2nd Step: Structure Analysis -

i. **Item** changed to **Process Item System, Subsystem, Part Element or Name of Process**
   Note: Different form formats, allow this to be listed a single place or on each line.
ii. **Process Step** changed to **Process Step Station No.** and **Name of Focus Element**
iii. Process Work Element 4M Type has been added.

Reason for use: This added step (4M) requires the users to consider the 4M's while reviewing the activity taking place within the process.

1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type

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Or alternate form

1. Process Item System, Subsystem, Part Element or Name of Process	
2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type

3rd Step: Function Analysis -

i. **Function of the Process Item Function of System, Subsystem, Part Element or Process has been added**.
Reason for use - Listing the positive functions of the process helps to identify the negatives, which are the Failure Effects.

ii. **Function** (one column) and its **Requirement / Product** (one column) changed to **Function of the Process Step** and **Product Characteristic** (single column) or **Function of the Process Step** (one column) and **Product Characteristic** (one column), depending on form used.

iii. **Function** (one column) and its **Requirements / Process** (one column) changed to **Function of the Process Work Element** and **Process Characteristic** (single column) or **Function of the Process Work Element** (one column) and **Process Characteristic** (one column), depending on form used.

> Note: AIAG Forms G and H, added an additional column to list the Requirements / Process. While the forms include this additional column, it did not include an additional column for the Function / Process. The intent, while not stated, was to list Function / Process in the single Function column.

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic

Or alternate form

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	
2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic

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Or alternate form

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2.a Function of the Process Step	2.b Product Characteristic (Quantitative value is optional)	3.a Function of the Process Work Element	3.b Process Characteristic (Quantitative value is optional)

4th Step: Failure Analysis -

i. **Potential Effect(s) of Failure** changed to **Failure Effects (FE)** to the next **Higher Level Element** and/or **Vehicle End User**

ii. **Severity** changed to **Severity (S) of FE**
Note: The AIAG Severity Table was based on **Effect on Customer** and **Effect on Manufacturing**, while AIAG/VDA Severity table is also based on **Effect End User**, it divides **Effect on Manufacturing** into two sections, **Impact to Your Plant** and **Impact to Ship-to Plant (when known)**.

Reason for change: The division of manufacturing requires the user to consider the internal impact and external impact to manufacturing.

iii. **Potential Failure Mode** changed to **Failure Mode (FM) of the Focus Element**.

iv. **Potential Cause(s) of Failure** changed to **Failure Cause (FC) of the Work Element.**

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element

5th Step: Risk Analysis -

i. **Current Process Controls – Prevention** changed to **Current Prevention Control (PC) of FC.**

ii. **Occurrence** changed to **Occurrence (O) of the FC**.

Note: The AIAG Occurrence Table was based on “Likelihood of Failure” and “Incidents items / vehicles” while the AIAG/VDA Table is based on “Prediction of Failure Cause Occurring”, “Type of Control”, and “Prevention Controls”.

Reason for Change: The AIAG/VDA is based on the robustness of the Prevention Controls and can be applied to any production rate.

iii. **Current Detection Process Controls / Cause** and **Current Detection Process Controls / Failure Mode (Form E)** is changed to **Current Detection Controls (DC) of FC or FM**.

iv. **Detection** changed to **Detection (D) of the FC / FM**”.

Note: The AIAG Detection Table was based on “Opportunity for Detection”, “Likelihood of Detection by Process Control” and “Likelihood of Detection, while the AIAG/VDA

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Table is based on “Detection Method Maturity”, “Opportunity for Detection” and “Ability to Detect”. Both tables are based on a 1 to 10 scale.

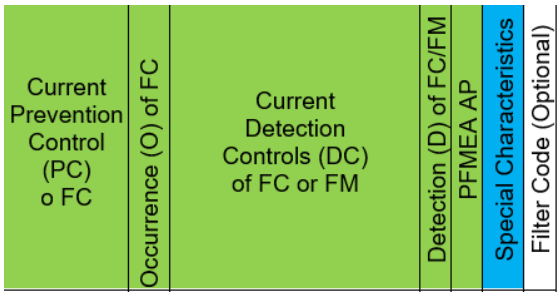
v. **RPN** changed to **PFMEA AP**.

Reason for Change: The RPN scale is 1 to 1,000 based on the simple multiplication of S, O and D and does apply logic. The AP (Action Priority) scale is L (Low), M (Medium) and H (High) and is based on taking into account the rating of S, O, and D at the same time and applies logic to determine the priority of action.

vi. **Classification** changed to **Special Characteristics**.

Note: Special Characteristics and Filter Code are sub-categories of AIAG Classification.

vii. **Filter Code (Optional)** new for AIAG-VDA.



6th Step: Optimization -

i. Recommended Action changed to Prevention Action and Detection Action

Reason for change: The division of information helps the user with visual management of actions related to Prevention and Detection.

ii. **Responsibility & Target Completion Date** changed to **Responsible Persons Name** and **Target Completion Date**.

Reason for change: Requires a name rather than a department.

iii. **Status** new for AIAG-VDA.

Reason for change: Users can track the percentage of completion.

iv. **Action Results - Actions Taken Completion Date and Actions Taken & Effective Date** (Forms A ~ H) is changed to Action Taken with Pointer to Evidence and Completion Date.

Reason for change: In addition to listing actions taken, a direction to evidence is required.

v. **Severity / Occurrence / Detection / RPN** changed to **Severity / Occurrence / Detection / AP**.

vi. **Special Characteristics** new for AIAG-VDA.

vii. **Remarks** new for AIAG-VDA.

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Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	Special Characteristics	PFMEA AP	Remarks

7th Step: Results Documentation –

To be added after this step is finalized

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B2 VDA Volume 4, Chapter Product and Process FMEA to AIAG-VDA FMEA Handbook

B2.1 VDA Volume 4, Chapter Product DFMEA to AIAG-VDA FMEA Handbook

The FMEA Method is described by seven-step approach, similar to the previous five-step approach in VDA Volume 4, Product and Process FMEA.

The section Definition is the new first step Preparation and Project Planning. The result documentation is added as step seven.

1. Preparation and Project Planning
2. Structure Analysis
3. Function Analysis
4. Failure Analysis
5. Risk Analysis
6. Optimization
7. Result Documentation

Special Characteristics are removed from the DFMEA Form Sheet but stay in the PFMEA Form Sheet. See Annex C1 Special Characteristics.

For continuous Improvement history column is added and the authorization column changed.

The linkage between DFMEA and PFMEA is explained and the FMEA Collaboration (Customer – Tier n – Tier n+1).

The comparison below shows the format of FMEA Forms listed in the VDA Volume 4 to the forms listed in the AIAG-VDA Handbook including those listed in the Appendices.

As appropriate, it will be pointed out why (**Reason for change**) the format can help lead to a more complete DFMEA.

1st Step: Preparation and Planning

"Definition - D" is replaced by "**1st Step: Preparation and Planning**". Preparation is partly considered in definition. Both sections define the depth of what will be included in the document.

FMEA Form header is defined within step 1 and new columns are changed or added.

i. Changed: Model Year(s) / Program(s)
ii. Changed: Subject
iii. Changed: Start Date and Revision Date
iv. Changed: Cross Functional Team
v. Changed: DFMEA ID Number
vi. Changed: Design Responsibility
vii. Added: Company Name
viii. Added: Engineering Location
ix. Added: Customer Name
x. Added: Confidentiality Level

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2nd Step: Structure Analysis

For DFMEA, ITEM is expanded to SYSTEM, SYSTEM ELEMENT, and COMPONENT ELEMENT with SYSTEM as Next Higher Level, SYSTEMELEMENT as Focus Element, and COMPONENT ELEMENT as Next Lower Level or Characteristic Type.

1. Next Higher Level SYSTEM	2. Focus Element SYSTEM ELEMENT	3. Next Lower Level or Characteristic Type COMPONENT ELEMENT

Connection descript with process flow diagram and structure tree.

Possible views in form sheet are described.

Collaboration between customer and supplier is defined and added.

Reason for change:

This focus the FMEA team on the Element to analyze. The Next Higher and Lower Level help to identify the Effect of Failure, and the Causes of Failure link in the defined SYSTEM.

3rd Step: Function Analysis

For DFMEA, FUNCTION/REQUIREMENT is expanded to Function and Requirement or Intended Output of System (Next Higher Level), Function and Requirement and Intended Performance Output of System Element (Focus Element), and Function and Requirement or Characteristic or Intended Function or Characteristics of Component Element (Next Lower Level or Characteristic Type).

1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic

The description is more detailed how to formulate functions.

Detailed definition of requirements / characteristics and usage of P-Diagram explained.

Possible view in form sheet is described

Collaboration between engineering teams is described.

Reason for change:

Considering and listing the positive Functions and Requirements of the Product, leads to listing the negatives, the Effect of Failure, and the Causes of Failure.

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4th Step: Failure Analysis

Concept of FOCUS ELEMENT establishes the focus of the analysis.

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

Identify failures by systematic description of question approach.

More detailed description how to formulate failure effects, failure mode and failure cause with examples.

Relationship is shown between PFMEA and DFMEA.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The Failure Effects (FE) to the Next Higher Level Element and/or End User, the Failure Mode (FM) of the Focus Element, and the Failure Cause (FC) of the Next Lower Element or Characteristic are aligned in the SYSTEM.

5th Step: Risk Analysis

Severity (S) rating:

Ten point scale with new definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA, PFMEA, and FMEA-MSR.

Occurrence (O) rating:

Ten point scale with new definitions for each level. Emphasis on Prevention Controls as input to the Occurrence rating added.

Detection (D) rating:

Ten point scale with new definitions for each level. Ability to detect and timing considered.

Action Priority (AP):

Risk Priority Number (RPN) with Action Priority (AP) replaced. The same table is used for DFMEA und PFMEA. The Action Priority is shown by ‘high’, ‘medium’ and ‘low’.

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1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)

More detailed definition of current prevention and current detection controls with examples instead of prevention and detection actions.

Current Controls, even if the implementation is in the future, are part of Risk Analysis.

New and more detailed described evaluation table of severity of “end user”.

More detailed described evaluation tables occurrence and detection with examples.

AP as replacement of RPN introduced with Action Priority high, medium, and low.

New column “Filter Code (Optional)” introduced.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The AP (Action Priority) scale is L (Low), M (Medium), and H (High) is based on taking into account the rating of S, O, and D at the same time and applying logic to determine the priority of action. The table also makes recommendations on how work through the three AP levels.

6th Step: Optimization

Definition of optimization detailed.

DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Remarks

Status of different action defined.

New assessment of action effectiveness defined;

Continual improvement described

Remarks column added to document internal comments, notes, and filter column for manipulation of data.

Possible views in form sheet are described.

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Collaboration between FMEA team, management, customer and supplier explained.

Reason for change:

The information helps the user with visual management; each piece of information is included and correct. Important is the “Pointer to Evidence” for follow-up reasons.

7th Step: Result Documentation

The added step seven summarizes the scope and results of an FMEA in a report.

This report should indicate the technical risk of failure as a component of the development plan and project milestones.

B2.2 VDA Volume 4, Chapter Product PFMEA to AIAG-VDA FMEA Handbook

The FMEA Method is described by seven-step approach, similar to the previous five-step approach in VDA Volume 4, Product and Process FMEA.

The section Definition is the new first step Preparation and Project Planning. The result documentation is added as step seven.

1. Preparation and Project Planning
2. Structure Analysis
3. Function Analysis
4. Failure Analysis
5. Risk Analysis
6. Optimization
7. Result Documentation

Special Characteristics stay in the PFMEA Form Sheet but are removed from the DFMEA Form Sheet. See Annex C1 Special Characteristics.

For continuous Improvement history column is added and the authorization column changed.

The linkage between DFMEA and PFMEA is explained and the FMEA Collaboration (Customer – Tier n – Tier n+1).

The comparison below shows the format of FMEA Forms listed in the VDA Volume 4 to the forms listed in the AIAG-VDA Handbook including those listed in the Appendices.

As appropriate, it will be pointed out why (**Reason for change**) the format can help lead to a more complete PFMEA.

1st Step: Preparation and Planning

“**Definition - D**” is replaced by “**1st Step: Preparation and Planning**”. Preparation is partly considered in definition. Both sections define the depth of what will be included in the document.

FMEA Form header is defined within step 1 and new columns are changed or added.

i. Changed: Model Year(s) / Program(s)
ii. Changed: Subject
iii. Changed: Start Date and Revision Date
iv. Changed: Cross Functional Team

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v. Changed: PFMEA ID Number
vi. Changed: Process Responsibility
vii. Added: Company Name
viii. Added: Customer Name
ix. Added: Manufacturing Location
x. Added: Confidentiality Level

2nd Step: Structure Analysis

For PFMEA, ITEM is expanded to PROCESS ITEM with System, Subsystem, Part Element or Name of Process, PROCESS STEP with Station No. and Name of Focus Element, and PROCESS WORK ELEMENT with 4M Type. PROCESS WORK ELEMENT labels added: Machine, Man, Material (Indirect), Milieu (EnvironMent), etc.

1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type

Connection descript with process flow diagram and structure tree.

4M especially Material (indirect) is more clarified and detailed explained;

Possible views in form sheet are described.

Collaboration between customer and supplier is defined and added.

Reason for change:

This focus the FMEA team on the Element to analyze. The Process Item and Process Work Element help to identify the Effect of Failure, and the Causes of Failure link in the defined PROCESS.

3rd Step: Function Analysis

For PFMEA, FUNCTION of Process Item is expanded to Function of System, Subsystem, Part Element or Process, FUNCTION OF PROCESS STEP is expanded to Function of System, Subsystem, Part Element or Process, and FUNCTION OF WORK ELEMENT to Function of the Process Work Element and Process Characteristic.

1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic

The description is more detailed how to formulate functions.

Detailed definition of functions / characteristics and usage of P-Diagram explained.

Possible view in form sheet is described

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Collaboration between engineering teams is described.

Reason for change:

Considering and listing the positive Functions / characteristics of the Process, leads to listing the negatives, the Effect of Failure, and the Causes of Failure.

4th Step: Failure Analysis

Concept of FOCUS ELEMENT establishes the focus of the analysis.

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

Identify failures by systematic description of question approach.

More detailed description how to formulate failure effects, failure mode and failure cause with examples.

Effects between “your plant”, “ship-to-plant” and “end user” defined.

Relationship is shown between PFMEA and DFMEA.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The Failure Effects (FE) to the Next Higher Level Element and/or End User, the Failure Mode (FM) of the Focus Element, and the Failure Cause (FC) of the Next Lower Element or Characteristic are aligned in the SYSTEM.

5th Step: Risk Analysis

Severity (S) rating:

Ten point scale with new definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA, PFMEA, and FMEA-MSR.

Occurrence (O) rating:

Ten point scale with new definitions for each level. Emphasis on Prevention Controls as input to the Occurrence rating added.

Detection (D) rating:

Ten point scale with new definitions for each level. Ability to detect and timing considered.

Action Priority (AP):

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Risk Priority Number (RPN) with Action Priority (AP) replaced. The same table is used for DFMEA und PFMEA. The Action Priority is shown by ‘high’, ‘medium’ and ‘low’.

1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)

More detailed definition of current prevention and current detection controls with examples instead of prevention and detection actions.

Current Controls, even if the implementation is in the future, are part of Risk Analysis.

New and more detailed described evaluation table of severity with differentiation of “your plant”, “ship-to-plant” and “end user”.

More detailed described evaluation tables occurrence and detection with examples.

AP as replacement of RPN introduced with Action Priority high, medium, and low.

New column “Filter Code (Optional)” introduced.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The AP (Action Priority) scale is L (Low), M (Medium), and H (High) is based on taking into account the rating of S, O, and D at the same time and applying logic to determine the priority of action. The table also makes recommendations on how work through the three AP levels.

6th Step: Optimization

Definition of optimization detailed.

PFMEA Preventive Action	PFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	PFMEA AP	Remarks

Status of different action defined.

New assessment of action effectiveness defined;

Continual improvement described

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Remarks column added to document internal comments, notes, and filter column for manipulation of data.

Possible views in form sheet are described.

Collaboration between FMEA team, management, customer and supplier explained.

Reason for change:

The information helps the user with visual management; each piece of information is included and correct. Important is the “Pointer to Evidence” for follow-up reasons.

7th Step: Result Documentation

The added step seven summarizes the scope and results of an FMEA in a report.

This report should indicate the technical risk of failure as a component of the development plan and project milestones.

B2.3 VDA Volume 4, Chapter Product FMEA-MSR to AIAG-VDA FMEA Handbook

The VDA Volume 4, Chapter: Product and Process FMEA, section “A2.1 FMEA for Mechatronic Systems” is replaced by “Supplemental FMEA for Monitoring and System Response (FMEA-MSR)”.

The FMEA-MSR supplements the Design FMEA. It shows the linkage between Functional Safety and Supplemental FMEA for Monitoring and System Response (FMEA-MSR).

This methodology evaluate the effects of monitoring and system response in a system or product.

Changes to DFMEA are in step five and six.

5th Step: Risk Analysis

Severity (S) rating:

> Ten point scale with new definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA, PFMEA, and FMEA-MSR.

Frequency rating:

> Ten point scale with new definitions for each level. FMEA-MSR replaces the Occurrence rating scale of a Design FMEA with a Frequency rating scale. Frequency of a failure cause to occur is estimated under customer operating conditions.

Monitoring:

> Ten point scale with new definitions for each level. FMEA-MSR replaces the Detection rating scale of a Design FMEA with a Monitoring rating scale. Consider capability to monitor and system response.

Action Priority (AP):

> Risk Priority Number (RPN) with Action Priority (AP) replaced. The Action Priority is shown by ‘high’, ‘medium’ and ‘low’.

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Supplement of FMEA-MSR Risk Analysis:

Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)

The Supplement shows detailed definition of Rationale for Frequency, Current Diagnostic Monitoring and System Response, Most Severe Failure Effect after System Response, Severity (S) of FE after MSR, Severity (S) of Original FE from Failure Analysis (Step 4), and MSR AP.

MSR AP introduced with Action Priority high, medium, and low.

Possible views in form sheet are described.

Collaboration between customer and supplier explained.

Reason for change:

The FMEA-MSR is a supplement to DFMEA and takes aspects of road vehicle safety in account.

6th Step: Optimization

Definition of optimization detailed.

MSR Preventive Action	Diagnostic Monitoring Action	System Response	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Frequency (F)	Monitoring (M)	MSR AP	Remarks

Status of different action defined.

New assessment of action effectiveness defined;

Continual improvement described

Remarks column added to document internal comments, notes, and filter column for manipulation of data.

Possible views in form sheet are described.

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Collaboration between FMEA team, management, customer and supplier explained.

Reason for change:

The information helps the user with visual management; each piece of information is included and correct. Important is the “Pointer to Evidence” for follow-up reasons.

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C Additions

C1 Special Characteristics

Special Characteristics are intended to provide information regarding design characteristics which require particular attention to process controls. Characteristics which lead directly to a failure of a product function in regard to safety, fit, form, performance, further processing of the product, or compliance to government regulations and industry standards may be identified as Special Characteristics.

Special Characteristics are identified to reduce the instances of scrap, rework, non-conforming parts, and assembly errors. The likelihood of customer complaints, product warranty claims, and government recalls is thereby mitigated by specifying Special Characteristics to ensure effective process controls. Special Characteristics are marked with abbreviations or symbols* in documents such as Product documents (as required), Process FMEA (Special Characteristics column) and Control Plans. Evidence for the implementation of process controls for Special Characteristics should be monitored, documented, and accessible.

In the Design FMEA, the Filter Code column replaces the Classification column because Special Characteristics are not required to be shown in the DFMEA.

The Design FMEA is one of several inputs to the selection of Special Characteristics. The team may use the Design FMEA to highlight when process controls may be needed to ensure conformance to specifications. The Design FMEA Form column named “Filter Code (Optional)” may be used to document that information.

To properly identify Special Characteristics, the Process FMEA team considers how variation in the manufacturing process can affect the functionality of the product. In other words, characteristics may be sensitive to manufacturing/assembly variation (Special Characteristic) or not sensitive to manufacturing/assembly variation (Standard Characteristic).

The Process FMEA contains the column titled “Classification”. This column may be used to specify Special Characteristics (i.e., critical, key, major, significant) that require additional process controls.

*NOTE: Special Characteristics may be company-specific or customer-specific designations. Customer specified Special Characteristics symbols can be translated into the organization`s symbols for Special Characteristics (i.e. in a correlation table).

C2 FMEA and Functional Safety

A Linkage between Functional Safety and Supplemental FMEA for Monitoring and System Response (FMEA-MSR)

The Hazard Analysis and Risk Assessment (HARA) (see ISO26262- 3:2018 Clause 6.4) provides Safety Goals relative to safety-related functions. It also assigns Automotive Safety Integrity Levels (ASILs) which are used to identify the mitigation which and are applied to ensure a socially acceptable residual risk of malfunctioning behavior. The Functional Safety Concept (FSC) further defines requirements to ensure the Safety Goals are met by the design. It defines the Warning and Degradation Concept, and the Test Cases which are necessary to demonstrate that the design fulfills the Safety Goals and Safety Requirements. However, ISO 26262 refers to FMEA (along with Systems Theoretic Process Analysis (STPA) and Fault Tree

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Analysis (FTA) as methods to identify potential causes of malfunctioning behavior. FMEA-MSR may be used to supplement the DFMEA by analyzing the effectiveness of diagnostic monitoring and system response in maintaining functional safety. In addition to safety considerations, the method can also be used for analysis of regulatory compliance topics.

B Linkage between Frequency (F) and Exposure in ISO 26262

Exposure in ISO 26262 refers to the duration or frequency of an operational situation. However, Frequency in FMEA-MSR refers to the occurrence of a fault during an operational situation. Therefore, the two metrics are related, but not equivalent.

C Linkage between Frequency (F) and FIT Rates in ISO 26262

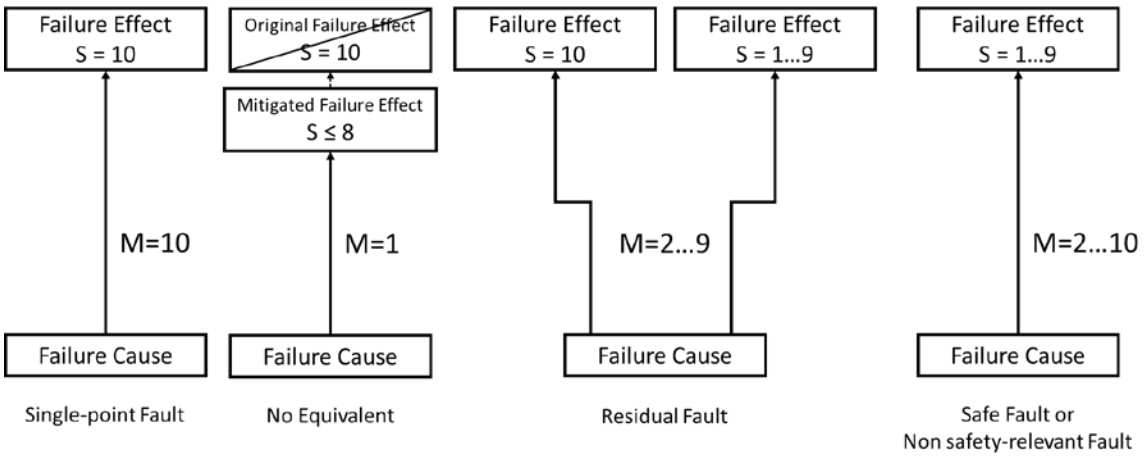
Frequency is a qualitative estimation of how often the considered failure cause may occur during an operational situation. FIT Rates are a quantitative assessment of the measured reliability of an E/E component, based on exposure of the component to specific test conditions. Therefore, the two metrics are related, but not equivalent.

D Linkage between Monitoring (M) and Diagnostic Coverage in ISO 26262

Monitoring (M) considers the ability of persons and/or the system to detect a specific cause (fault or failure), and react to that detected fault or failure within the Fault Tolerant Time Interval (FTTI). Diagnostic Coverage in ISO 26262 refers to the ability of the system to detect a percentage of all possible faults, and react to a fault within the Fault Tolerant Time Interval (FTTI). Therefore, the Monitoring rating in FMEA-MSR has a wider scope of detection, but relates only to a specific cause.

E Linkage between Failures in FMEA-MSR to Faults/Errors/Failures in ISO 26262

A Failure Cause in FMEA-MSR is equivalent to a Fault in ISO 26262. However, it is not necessarily a root cause, depending on whether the scope of analysis is a component or a system. A Failure Mode in FMEA-MSR is equivalent to an “Error” in ISO 26262. A Failure Effect in FMEA-MSR is equivalent to a “Failure” in ISO 26262 (Ref. Part 10, Clause 4.3.1).



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NOTE: Multiple-point Faults are not in scope of FMEA-MSR

Figure C2-1 Linkage between Failure Causes in FMEA-MSR to Faults in ISO 26262

F Applicability of FMEA-MSR to manufacturers of microcontrollers

FMEDA is the recommended method for quantitative analysis of microcontrollers. FMEA-MSR may be used for qualitative analysis, but may not provide any additional value.

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D Form Sheets

D1 DFMEA Form Sheet

D1.1 DFMEA Form Sheet Step 1

PLANNING and PREPARATION (STEP 1)					
Company Name:		Subject:		DFMEA ID Number:	
Engineering Location:		DFMEA Start Date:		Design Responsibility:	
Customer Name:		DFMEA Revision Date:		Confidentiality Level:	
Model Year / Platform:		Cross-Functional Team:			

Figure D1.1-1 Blank DFMEA Form: Step 1

Design Failure Mode and Effects Analysis (Design FMEA)					
Planning and Preparation (Step 1)					
Company Name:	Name of Company Responsible for DFMEA	**Subject:**	Name of DFMEA Project (System, Subsystem and/or Component)	**DFMEA ID Number:**	Determined by Company
Engineering Location:	Geographical Location	**DFMEA Start Date:**	Start Date	**Design Responsibility:**	Name of DFMEA owner
Customer Name:	Name of Customer(s) or Product Family	**DFMEA Revision Date:**	Latest Revision Date	**Confidentiality Level:**	Business Use, Proprietary, Confidential
Model Year(s) / Program(s):	Customer Application or Company Model/ Style	**Cross-Functional Team:**	Team Roster needed		

Figure D1.1-2 DFMEA Form with Hints: Step 1

Example: Design Failure Mode and Effects Analysis (Design FMEA)					
Preparation (Step 1)					
Company Name:	Acme Automotive	**Subject:**	PX123 Upper Jacket		
Engineering Location:	Munich, Germany	**DFMEA Start Date:**	19-Mar-2018	**DFMEA ID Number:**	123456
Customer Name:	Jackson Industry	**DFMEA Revision Date:**	25-Sep-2018	**Design Responsibility:**	S. Gray
Model Year(s) / Program(s):	2020 PX123	**Cross-Functional Team:**	See Team List	**Confidentiality Level:**	Confidential

Figure D1.1-3 Completed DFMEA Form: Step 1

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D1.2 DFMEA Form Sheet Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type

Figure D1.2-1 Blank DFMEA Form: Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Subsystem, System, Array of Systems, Vehicle	Subsystem, Component or Interface Name	Component or Interface Name or Characteristic Characteristic Type: Geometry, Material, Surface Finish, Coatings, etc.

Figure D1.2-2 DFMEA Form with Hints: Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lifter	Commutation System	Brush Card Base Body

Figure D1.2-3 Completed DFMEA Form: Step 2

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D1.3 DFMEA Form Sheet Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic

Figure D1.3-1 Blank DFMEA Form: Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Function of Vehicle, System or Subsystem and a description of the Requirement or Intended Output it must fulfill (Quantitative value is optional, one Requirement per row)	Function of Subsystem, Component or Interface and a description of the Requirement or Intended Output it must fulfill (Quantitative value is optional, one Requirement per row)	Function of Component or Interface or Characteristic Description (Quantitative value is optional, one Characteristic per row)

Figure D1.3-2 DFMEA Form with Hints: Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Raise and Lower window according to parameterization	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Brush card body transports forces between spring

Figure D1.3-3 Completed DFMEA Form: Step 3

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D1.4 DFMEA Form Sheet Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

Figure D1.4-1 Blank DFMEA Form: Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
How the Vehicle, System or Subsystem could fail to perform the Function described at the Next Higher level. Include potential effects to the vehicle (End User) level and regulations, as applicable	1-10	How the Subsystem, Component or Interface could fail to perform the Function described as the Focus Element and lead to the Failure Effects Failure Analysis can begin with the FM, FE or FC as long as there is an accurate Failure Chain	How the Subsystem, Component or Interface could fail to perform the Function described as the Next Lower level and lead to the Failure Mode

Figure D1.4-2 DFMEA Form with Hints: Step 4

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FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
Window does not lower	6	Commutation system intermittently connects wrong coils (L1, L3 and L2 instead of L1, L2, and L3)	Brush card body bends in contact area of the carbon brush

Figure D1.4-3 Completed DFMEA Form: Step 4

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D1.5 DFMEA Form Sheet Step 5

DFMEA RISK ANALYSIS (STEP 5)					
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)

Figure D1.5-1 Blank DFMEA Form: Step 5

DFMEA RISK ANALYSIS (STEP 5)					
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)
Initial State - Past controls proven and/or controls committed to	1-10	Initial State - Past controls proven and/or controls committed to	1-10	H, M, L, NA	LL

Figure D1.5-2 DFMEA Form with Hints: Step 5

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DFMEA RISK ANALYSIS (STEP 5)					
Current Prevention Control (PC) of FC	**Occurrence (O) of FC**	**Current Detection Controls (DC) of FC or FM**	**Detection (D) of FC/FM**	**DFMEA AP**	**Filter Code (Optional)**
Simulation of dynamic forces on brush card body acc. FEM 6370	**2**	**Sample test: measuring the elastic and plastic deformation effect of brush card body acc. Test spec. MRJ82/60**	**2**	**L**	

Figure D1.5-3 Completed DFMEA Form: Step 5

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D1.6 DFMEA Form Sheet Step 6

DFMEA OPTIMIZATION (STEP 6)											
DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrance (O)	Detection (D)	DFMEA AP	Filter Code (Optional)

Figure D1.6-1 Blank DFMEA Form: Step 6

DFMEA OPTIMIZATION (STEP 6)												
DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Filter Code (Optional)	Remarks
Additional Actions needed to reduce Occurrence	Additional Actions needed to improve Detection	Name, not title or department	mmyy or ddmmyy	Open, Decision pending (optional), Implementation pending (optional), Completed, Discarded	Description of action taken and document number, report name and date, etc.	mmyy or ddmmyy	1-10	1-10	1-10	H, M, L, NA	LL	For DFMEA team use

Figure D1.6-2 DFMEA Form with Hints: Step 6

DFMEA OPTIMIZATION (STEP 6)											
DFMEA Preventive Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Filter Code (Optional)
None	Final product test: measuring the current under worst case conditions acc. Test spec. MRJ1140	Mr. Max Mueller	dd.mm.yyyy	Planned							

Figure D1.6-3 Completed DFMEA Form: Step 6

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D1.7 DFMEA Form Sheet Step 7

DFMEA Step 7 is independently handled by each organization and is not recorded on the DFMEA form.

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D1.8 DFMEA Software Examples

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lifter	Commutation System	Brush Card Base Body
FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Convert electrical energy into mechanical energy acc. to Parameterization	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point)
FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
Torque and rotating velocity of the window lifter motor too low	Angle deviation by commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush

Figure D1.8-1 DFMEA Failure Structure (Software View)

STRUCTURE ANALYSIS (STEP 2)										
1. Next Higher Level		2. Focus Element		3. Next Lower Level or Characteristic Type						
Window Lifter		Commutation System		Brush Card Base Body						
FUNCTION ANALYSIS (STEP 3)										
1. Next Higher Level Function and Requirement		2. Focus Element Function and Requirement		3. Next Lower Level Function and Requirement or Characteristic						
Convert electrical energy into mechanical energy acc. to Parameterization		Commutation system transports the electrical current between coil pairs of the electromagnetic converter		Brush card body transports forces between spring						
FAILURE ANALYSIS (STEP 4)					**DFMEA RISK ANALYSIS (STEP 5)**					
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic		Prevention Control (PC) of FC	Occurrence (O) of FC	Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)
					DFMEA CURRENT CONTROLS					
Torque and rotating velocity of the window lifter motor too low	6	Angle deviation by commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush		Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastics and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L	

Figure D1.8-2 DFMEA Risk Analysis (Software View)

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FAILURE ANALYSIS (STEP 4)				DFMEA RISK ANALYSIS (STEP 5) and DFMEA OPTIMIZATION (STEP 6)											
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Prevention Control (PC) of FC	Occurrence (O) of FC	Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks
				DFMEA CURRENT CONTROLS											
Window does not lower	6	Commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3)	Brush card body bends in contact area of the carbon brush	Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastics and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L							
				DFMEA OPTIMIZATION											
				None		final product test: measuring the current under worst case conditions acc. Test spec. MRJ1140	1	L		Test Engineer Mr. Max Mueller	dd.mm.yyyy	planned			

Figure D1.8-3 DFMEA Optimization with new Risk Evaluation (Software View)

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D2 PFMEA Form Sheet

D2.1 PFMEA Form Sheet Step 1

PLANNING and PREPARATION (STEP 1)

Company Name:		Subject:		PFMEA ID Number:	
Manufacturing Location:		PFMEA Start Date:		Process Responsibility:	
Customer Name:		PFMEA Revision Date:		Confidentiality Level:	
Model Year / Platform:		Cross-Functional Team:			

Figure D2.1-1 Blank PFMEA Form: Step 1

Process Failure Mode and Effects Analysis (Process FMEA)					
Planning and Preparation (Step 1)					
Company Name:	Name of Company Responsible for PFMEA	**Subject:**	Name of PFMEA Project	**PFMEA ID Number:**	Determined by Company
Manufacturing Location:	Geographical Location	**PFMEA Start Date:**	Start Date	**Process Responsibility:**	Name of PFMEA Owner
Customer Name:	Name of Customer(s) or Product Family	**PFMEA Revision Date:**	Latest Revision Date	**Confidentiality Level:**	Business Use, Proprietary, Confidential
Model Year(s) / Program(s):	Customer Application or Company Model/ Style	**Cross Functional Team:**	Team Roster needed		

Figure D2.1-2 PFMEA Form with Hints: Step 1

Example: Process Failure Mode and Effects Analysis (Process FMEA)					
Preparation (Step 1)					
Company Name:	Acme Automotive	**Subject:**	PX123 Manual Column Assembly		
Manufacturing Location:	Plant 6, Saginaw, Michigan	**PFMEA Start Date:**	19-Mar-2018	**PFMEA ID Number:**	654321
Customer Name:	Jackson Industry	**PFMEA Revision Date:**	25-Sep-2018	**Process Responsibility:**	B. Black
Model Year(s) / Program(s):	2020 PX123	**Cross Functional Team:**	See Team List	**Confidentiality Level:**	Confidential

Figure D2.1-3 Completed PFMEA Form: Step 1

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D2.2 PFMEA Form Sheet Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item **System, Subsystem, Part Element or Name of Process**	**2. Process Step** **Station No. and Name of Focus Element**	**3. Process Work Element** **4M Type**

Figure D2.2-1 Blank PFMEA Form: Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item **System, Subsystem, Part Element or Name of Process**	**2. Process Step** **Station No. and Name of Focus Element**	**3. Process Work Element** **4M Type**
The name of the process being analyzed e.g. electrical motor assembly line which is the end result of all successfully completed process steps May also be a non-direct manufacturing process e.g. shipping	The operation or station to be analyzed that produces the Process Item e.g. OP 30 Sintered bearing press-in process	Use the 4M's to identify types of variation that have an influence on the operation or station being analyzed. 4M Types: Man, Machine, Material (Indirect), Milieu (Environment) List a single "M" for each line. Types may vary by company

Figure D2.2-2 PFMEA Form with Hints: Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item **System, Subsystem, Part Element or Name of Process**	**2. Process Step** **Station No. and Name of Focus Element**	**3. Process Work Element** **4M Type**
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-in Process	Operator

Figure D2.2-3 Completed PFMEA Form: Step 2

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D2.3 PFMEA Form Sheet Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item **Function of System, Subsystem, Part Element or Process**	**2. Function of the Process Step and Product Characteristic** **(Quantitative value is optional)**	**3. Function of the Process Work Element and Process Characteristic**

Figure D2.3-1 Blank PFMEA Form: Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic
A description of what the Process Item is expected to achieve broken down into several categories. Some categories may be unknown and listed as Not Applicable (NA). These expectations can be referred to when completing Failure Effects (FE). These expected results may apply for the entire Process Item e.g. electrical motor assembly line.	A description of what the operation or station must achieve e.g. Axial position sintered bearing in pole housing. This is the positive Product Characteristic and must be detectable/measurable in the product after the product has been produced. The Failure Mode or Failure Modes will be the negative or negatives of the positive Product Characteristic.	A positive description of how the work is completed including the positive process characteristic related to each 4M. The negative of these positives will be used for the Failure Cause column. The more detail used here, more positives, will produce more Failure Causes. Quantitative value/specification optional, refer to process documents. Examples: Press force, machine temperature, wash concentration, speed, etc. Process characteristics are measured when the process is running.

Figure D2.3-2 PFMEA Form with Hints: Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item **Function of System, Subsystem, Part Element or Process**	**2. Function of the Process Step and Product Characteristic** **(Quantitative value is optional)**	**3. Function of the Process Work Element and Process Characteristic**
Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Operator press the button of machine for releasing the press-in process when loading is completed

Figure D2.3-3 Completed PFMEA Form: Step 3

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D2.4 PFMEA Form Sheet Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element

Figure D2.4-1 Blank PFMEA Form: Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
How the Vehicle, System or Subsystem could fail to perform the Function described at the Next Higher level. When considering Effects, consider items listed in "Function of the Process Item" and the "Failure Mode" and how they can Effect the 3 areas being considered (Your Plant, Ship-to plant, Process Item, End User) It is recommended to list the Severity Rating next to each of the 3 areas (Your Plant, Ship to plant, Process Item, End User) being considered and use the highest Rating for the Severity. Rank. One area, such as End User, may not always have the highest Severity Rating.	1-10	Failure mode must be detectable/measureable in the product (defect) The Failure Mode will be the negative or negatives of the positive Product Characteristic.	The Failure Cause is the negative of the positive listed in "Function of the Process Work Element and Process Characteristic" Cause must be detectable in the process (error) and lead to the Failure Mode.

Figure D2.4-2 PFMEA Form with Hints: Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element
Your Plant: Clearance too small to assemble shaft Ship to Plant: Assembly of motor to vehicle door is not possible End User: Comfort closing time too long	8	Axial position of sintered bearing is not reached	Machine stops before reaching final position

Figure D2.4-3 Completed PFMEA Form: Step 4

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D2.5 PFMEA Form Sheet Step 5

PFMEA RISK ANALYSIS (STEP 5)						
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)

Figure D2.5-1 Blank PFMEA Form: Step 5

3

PFMEA RISK ANALYSIS (STEP 5)						
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Sp Prod Char	Filter Code (Optional)
Initial State - Past controls proven and/or controls committed to	1-10	Initial State - Past controls proven and/or controls committed to	1-10	H, M, L, NA	CC	LL

Figure D2.5-2 PFMEA Form with Hints: Step 5

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PFMEA RISK ANALYSIS (STEP 5)						
Current Prevention Control (PC) of FC	**Occurrence (O) of FC**	**Current Detection Controls (DC) of FC or FM**	**Detection (D) of FC/FM**	**PFMEA AP**	**Special Characteristics**	**Filter Code (Optional)**
None	10	Lot Release Protocol Objective (Effectivity: 100%); Visual Gauge inspection of axial gap of bearing to pole housing seat by Operator; Detection indicator: OK/NOK (RED/GREEN area); 100% check of motor performance curve acc. spec. MRKJ5038	2	H		

Figure D2.5-3 Completed PFMEA Form: Step 5

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D2.6 PFMEA Form Sheet Step 6

OPTIMIZATION (STEP 6)											
Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	SpProd Char	PFMEA AP

Figure D2.6-1 Blank PFMEA Form: Step 6

OPTIMIZATION (STEP 6)												
Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	SpProd Cha	PFMEA AP	Remarks
Additonal Actions needed to reduce Occurrence	Additional Actions needed to improve Detection	Name, not title or department	mmyy or ddmmyy	Open, Decision pending (optional), Implementation pending (optional), Completed, Discarded	Description of action taken and document number, report name and date, etc.	mmyy or ddmmyy	1-10	1-10	1-10	CC SC	H, M, L, NA	For PFMEA team use

Figure D2.6-2 PFMEA Form with Hints: Step 6

OPTIMIZATION (STEP 6)											
Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	SpProd Char	PFMEA AP
Selected press with position control sensor	Selected press with force monitoring	Mr. Paul Duncan	dd.mm.yyyy	Open			8	3	2		L

Figure D2.6-3 Completed PFMEA Form: Step 6

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D2.7 PFMEA Form Sheet Step 7

PFMEA Step 7 is independently handled by each organization and is not recorded on the PFMEA form.

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D2.8 PFMEA Software Examples

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item System, Subsystem, Part Element or Name of Process	**2. Process Step Station No. and Name of Focus Element**	**3. Process Work Element 4M Type**
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Operator
FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item Function of System, Subsystem, Part Element or Process	**2. Function of the Process Step and Product Characteristic (Quantitative value is optional)**	**3. Function of the Process Work Element and Process Characteristic**
Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door without line stoppage, sort or containment End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Operator press the button of machine for releasing the press-in process when loading is completed
FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	**2. Failure Mode (FM) of the Focus Element**	**3. Failure Cause (FC) of the Work Element**
Your Plant: Clearance too small to assemble shaft Ship to Plant: Assembly of motor to vehicle door is not possible End User: Comfort closing time too long	Axial position of sintered bearing is not reached	Machine stops before reaching final position

Figure D2.8-1 PFMEA Failure Structure (Software View)

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item System, Subsystem, Part Element or Name of Process	**2. Process Step Station No. and Name of Focus Element**	**3. Process Work Element 4M Type**
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Operator
FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item Function of System, Subsystem, Part Element or Process	**2. Function of the Process Step and Product Characteristic (Quantitative value is optional)**	**3. Function of the Process Work Element and Process Characteristic**
Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door without line stoppage, sort or containment End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Operator press the button of machine for releasing the press-in process when loading is completed

FAILURE ANALYSIS (STEP 4)				PFMEA RISK ANALYSIS (STEP 5)							
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	**Severity (S) of FE**	**2. Failure Mode (FM) of the Focus Element**	**3. Failure Cause (FC) of the Work Element**	**Prevention Controls (PC) of FC**	**Occurrence (O) of FC**	**Detection Controls (DC) of FC or FM**	**Detection (D) of FC/FM**	**PFMEA AP**	**Special Characteristics**	**Filter Code (Optional)**
				PFMEA CURRENT CONTROLS						
Your Plant: Assembly of shaft is not possible because clearance too small Ship to Plant: None End User: Comfort closing time too long	8	Axial position of sintered bearing is not reached	Machine stops before reaching final position	None	10	Lot Release Protocol Objective (Effectivity: 100%); Visual Gauge inspection of axial gap of bearing to pole housing seat by Operator; Detection indicator: OK/NOK (RED/GREEN area); 100% check of motor performance curve acc. spec. MRKJ5038	2	H		

Figure D2.8-2 PFMEA with Risk Analysis (Software View)

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FAILURE ANALYSIS (STEP 4)				PFMEA RISK ANALYSIS (STEP 5) and PFMEA OPTIMIZATION (STEP 6)												
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element	Prevention Controls (PC) of FC	Occurrence (O) of FC	Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Special Characteristics	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks
				PFMEA CURRENT CONTROLS												
Your Plant: Assembly of shaft is not possible because clearance too small Ship to Plant: None End User: Comfort closing time too long	8	Axial position of sintered bearing is not reached	Machine stops before reaching final position	Force adjusted acc. data sheet	5	100% check of motor performance curve acc. spec. MRKJ5039	3	M								
				PFMEA OPTIMIZATION												
				Selected press with position control sensor	3	Selected press with force monitoring	2	L			Process Engineer Mr. Paul Duncan	dd.mm. yyyy	open			

Figure D2.8-3 PFMEA Optimization with new Risk Evaluation (Software View)

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In PFMEA, one option is to display

“1. Process Item”, and

“1. Function of Process Item”

in a single row and not be prepared in all rows, see below.

STRUCTURE ANALYSIS (STEP 2)		FUNCTION ANALYSIS (STEP 3)		FAILURE ANALYSIS (STEP 4)		
1. Process Item System, Subsystem, Part Element or Name of Process	Electrical Motor Assy Line	1. Function of the Process Item Function of System, Subsystem, Part Element or Process	Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers			
2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic	1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element
[OP 30] Sintered Bearing Press-In Process	Operator	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Operator press the button of machine for releasing the press-in process when loading is completed	Your Plant: Clearance too small to assemble shaft Ship to Plant: Assembly of motor to vehicle door is not possible End User: Comfort closing time too long	Axial position of sintered bearing is not reached	Machine stops before reaching final position

Figure D3-7 PFMEA Failure Structure (Spreadsheet View) Optional

Another option is to split

“2. Function of the Process Step and Product Characteristics”, and

“3. Function of Process Work Element and Process Characteristics”

into multiple columns to make each column a unique category of information, see below.

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STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)					FAILURE ANALYSIS (STEP 4)		
1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type	1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2.a Function of the Process Step	2.b Product Characteristic (Quantitative value is optional)	3.a Function of the Process Work Element	3.b Process Characteristic (Quantitative value is optional)	1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element
Electrical Motor Assy Line	[OP 30] Sintered Bearing Press-In Process	Operator	Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing	Max gap per print	Operator press the button of machine for releasing the press-in process	Loading completed	Your Plant: Clearance too small to assemble shaft Ship to Plant: Assembly of motor to vehicle door is not possible End User: Comfort closing time too long	Axial position of sintered bearing is not reached	Machine stops before reaching final position

Figure D3-8 PFMEA Failure Structure (Spreadsheet) Optional:

Split of Function and Characteristics

Also both options can be combined, see below.

STRUCTURE ANALYSIS (STEP 2)		FUNCTION ANALYSIS (STEP 3)				FAILURE ANALYSIS (STEP 4)		
1. Process Item System, Subsystem, Part Element or Name of Process	Electrical Motor Assy Line	1. Function of the Process Item Function of System, Subsystem, Part Element or Process	Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers					
2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type	2.a Function of the Process Step	2.b Product Characteristic (Quantitative value is optional)	3.a Function of the Process Work Element	3.b Process Characteristic (Quantitative value is optional)	1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element
[OP 30] Sintered Bearing Press-In Process	Operator	Press in sintered bearing to achieve axial position in pole housing	Max gap per print	Operator press the button of machine for releasing the press-in process	Loading completed	Your Plant: Clearance too small to assemble shaft Ship to Plant: Assembly of motor to vehicle door is not possible End User: Comfort closing time too long	Axial position of sintered bearing is not reached	Machine stops before reaching final position

Figure D3-9 PFMEA Failure Structure (Spreadsheet) Optional:

Split of Function and Characteristics

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STRUCTURE ANALYSIS (STEP 2)		FUNCTION ANALYSIS (STEP 3)				FAILURE ANALYSIS (STEP 4)		
1. Process Item System, Subsystem, Part Element or Name of Process	Electrical Motor Assy Line	1. Function of the Process Item Function of System, Subsystem, Part Element or Process	Your Plant: Assembly of shaft into pole housing assembly Ship to Plant: Assembly of motor to vehicle door End User: Window raises and lowers					
2. Process Step Station No. and Name of Focus Element	3. Process Work Element 4M Type	2.a Function of the Process Step	2.b Product Characteristic (Quantitative value is optional)	3.a Function of the Process Work Element	3.b Process Characteristic (Quantitative value is optional)	1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element
[OP 30] Sintered Bearing Press-In Process	Operator	Press in sintered bearing to achieve axial position in pole housing	Max gap per print	Operator press the button of machine for releasing the press-in process	Loading completed	Your Plant: Clearance too small to assemble shaft Ship to Plant: Assembly of motor to vehicle door is not possible End User: Comfort closing time too long	Axial position of sintered bearing is not reached	Machine stops before reaching final position

Figure D3-10 PFMEA Failure Structure (Software) Optional:

Split of Function and Characteristics

FUNCTION ANALYSIS (STEP 3)				
1. Function of the Process Item Function of System, Subsystem, Part Element or Process	2.a Function of the Process Step	2.b Product Characteristic (Quantitative value is optional)	3.a Function of the Process Work Element	3.b Process Characteristic (Quantitative value is optional)
A description of what the Process Item is expected to achieve broken down into several categories. Some categories may be unknown and listed as Not Applicable (NA). These expectations can be referred to when completing Failure Effects (FE). These expected results may apply for the entire Process Item e.g. electrical motor assembly line.	A description of what the operation or station must achieve e.g. Axial position sintered bearing in pole housing.	This is the positive Product Characteristic and must be detectable/measurable in the product after the product has been produced. The Failure Mode or Failure Modes will be the negative or negatives of the positive Product Characteristic.	A positive description of how the work is completed related to each 4M. The negative of these positives will be used for the Failure Cause column. The more detail used here, more positives, will produce more Failure Causes.	A positive description of process characteristic related to each 4M. Quantitative value/specification optional, refer to process documents. Examples: Press force, machine temperature, wash concentration, speed, etc. Process characteristics are measured when the process is running.

Figure D4-7 Process Failure Mode and Effects Analysis (PROCESS FMEA) Hints Optional: Split of Function and Characteristics – Step 3

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D3 FMEA-MSR Form Sheet Template

D3.1 FMEA-MSR Form Sheet Step 1

PLANNING and PREPARATION (STEP 1)					
Company Name:		Subject:		DFMEA ID Number:	
Engineering Location:		DFMEA Start Date:		Design Responsibility:	
Customer Name:		DFMEA Revision Date:		Confidentiality Level:	
Model Year / Platform:		Cross-Functional Team:			

Figure D3.1-1 Blank FMEA-MSR Form: Step 1

Design Failure Mode and Effects Analysis (Design FMEA)					
Planning and Preparation (Step 1)					
Company Name:	Name of Company Responsible for DFMEA	**Subject:**	Name of DFMEA Project (System, Subsystem and/or Component)	**DFMEA ID Number:**	Determined by Company
Engineering Location:	Geographical Location	**DFMEA Start Date:**	Start Date	**Design Responsibility:**	Name of DFMEA owner
Customer Name:	Name of Customer(s) or Product Family	**DFMEA Revision Date:**	Latest Revision Date	**Confidentiality Level:**	Business Use, Proprietary, Confidential
Model Year(s) / Program(s):	Customer Application or Company Model/ Style	**Cross-Functional Team:**	Team Roster needed		

Figure D3.1-2 FMEA-MSR Form with Hints: Step 1

Example: Design Failure Mode and Effects Analysis (Design FMEA)					
Preparation (Step 1)					
Company Name:	Acme Automotive	**Subject:**	PX123 Upper Jacket		
Engineering Location:	Munich, Germany	**DFMEA Start Date:**	19-Mar-2018	**DFMEA ID Number:**	123456
Customer Name:	Jackson Industry	**DFMEA Revision Date:**	25-Sep-2018	**Design Responsibility:**	S. Gray
Model Year(s) / Program(s):	2020 PX123	**Cross-Functional Team:**	See Team List	**Confidentiality Level:**	Confidential

Figure D3.1-3 Completed FMEA-MSR Form: Step 1

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D3.2 FMEA-MSR Form Sheet Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type

Figure D3.2-1 Blank FMEA-MSR Form: Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Subsystem, System, Array of Systems, Vehicle	Subsystem, Component or Interface Name	Component or Interface Name or Characteristic Characteristic Type: Geometry, Material, Surface Finish, Coatings, etc.

Figure D3.2-2 FMEA-MSR Form with Hints: Step 2

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lifter	Commutation System	Brush Card Base Body

Figure D3.2-3 Completed FMEA-MSR Form: Step 2

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D3.3 FMEA-MSR Form Sheet Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic

Figure D3.3-1 Blank FMEA-MSR Form: Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Function of Vehicle, System or Subsystem and a description of the Requirement or Intended Output it must fulfill (Quantitative value is optional, one Requirement per row)	Function of Subsystem, Component or Interface and a description of the Requirement or Intended Output it must fulfill (Quantitative value is optional, one Requirement per row)	Function of Component or Interface or Characteristic Description (Quantitative value is optional, one Characteristic per row)

Figure D3.3-2 FMEA-MSR Form with Hints: Step 3

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Provide anti-pinch protection for comfort closing mode	Provide signal to stop and reverse window lifter motor in case of pinch situation	Transmit signal from Hall effect sensor to ECU

Figure D3.3-3 Completed FMEA-MSR Form: Step 3

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D3.4 FMEA-MSR Form Sheet Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic

Figure D3.4-1 Blank FMEA-MSR Form: Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
How the Vehicle, System or Subsystem could fail to perform the Function described at the Next Higher level. Include potential effects to the vehicle (End User) level and regulations, as applicable	1-10	How the Subsystem, Component or Interface could fail to perform the Function described as the Focus Element and lead to the Failure Effects Failure Analysis can begin with the FM, FE or FC as long as there is an accurate Failure Chain	How the Subsystem, Component or Interface could fail to perform the Function described as the Next Lower level and lead to the Failure Mode

Figure D3.4-2 FMEA-MSR Form with Hints: Step 4

FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched between window glass and frame)	6	No signal to stop and reverse window lifter motor in case of a pinch situation	Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor

Figure D3.4-3 Completed FMEA-MSR Form: Step 4

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D3.5 FMEA-MSR Form Sheet Step 5

SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5)									
Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)

Figure D3.5-1 Blank FMEA-MSR Form: Step 5

SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5)									
Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Most Severe FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)
Internal comments about the reasons for the Frequency rating	1-10	Error detection methods during vehicle use	Error response action during vehicle use	1-10	The new Vehicle, System or Subsystem potential effects to the End User level after monitoring and system response controls are in place	1-10	1-10	H, M, L, NA If M=1 use "Severity after MSR"	LL

Figure D3.5-2 FMEA-MSR Form with Hints: Step 5

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SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5)									
Rationale for Frequency	**Frequency (F) of FC**	**Current Diagnostic Monitoring**	**Current System Response**	**Monitoring (M)**	**Most Severe Failure Effect after System Response**	**Severity (S) of FE after MSR**	**Severity (S) of Original FE from Failure Analysis (Step 4)**	**MSR AP**	**Filter Code (Optional)**
The connection principle of the Hall effect sensor and ECU is according to standard xyz.	2	None	Window will close with full clamping force.	10	Hand or neck may be pinched between glass and frame	10	10	M	

Figure D3.5-3 Completed FMEA-MSR Form: Step 5

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D3.6 FMEA-MSR Form Sheet Step 6

SUPPLEMENTAL FMEA-MSR OPTIMIZATION (STEP 6)														
MSR Preventive Action	Diagnostic Monitoring Action	System Response	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Frequency (F)	Monitoring (M)	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Remarks

Figure D3.6-1 Blank FMEA-MSR Form: Step 6

SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 6)														
MSR Preventive Action	Diagnostic Monitoring Action	System Response	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Frequency (F)	Monitoring (M)	Severity (S) of Most Severe FE from Failure Analysis (Step 4)	MSR AP	Remarks
Additonal Actions needed to reduce Frequency	Additional error detection methods during vehicle use	Additonal Actions needed to reduce Frequency	The Vehicle, System or Subsystem potential effects to the End User level after monitoring and system response are in place	1-10	Name, not title or department	mmyy or ddmmyy	Open, Decision pending (optional), Implementation pending (optional), Completed, Discarded	Description of action taken and document number, report name and date, etc.	mmyy or ddmmyy	1-10	1-10	1-10	H, M, L, NA If M=1 use "Severity after MSR"	For FMEA-MSR team use

Figure D3.6-2 FMEA-MSR Form with Hints: Step 6

SUPPLEMENTAL FMEA-MSR OPTIMIZATION (STEP 6)														
MSR Preventive Action	Diagnostic Monitoring Action	System Response	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Frequency (F)	Monitoring (M)	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Remarks
None	Introduction of plausibility check between motor current and loss of signal from Hall effect sensor	Comfort closing mode disabled	Loss of convenience function "Comfort Closing". The window only moves in manual mode	6	Mr. Max Mueller	dd.mm.yyyy	Implementation pending			2	1	6	L	

Figure D3.6-3 Completed FMEA-MSR Form: Step 6

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D3.7 FMEA-MSR Form Sheet Step 7

FMEA-MSR Step 7 is independently handled by each organization and is not recorded on the FMEA-MSR form.

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D3.8 FMEA-MSR Software Examples

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type
Window Lift System	ECU Window Lifter	Connector ECU Window Lifter
FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Provide anti-pinch protection for comfort closing mode	Provide signal to stop and reverse window lifter motor in case of pinch situation	Transmit signal from Hall effect sensor to ECU
FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched between window glass and frame)	No signal to stop and reverse window lifter motor in case of pinch situation	Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor.

Figure D3.8-1 FMEA-MSR Failure Structure (Software View)

STRUCTURE ANALYSIS (STEP 2)																
1. Next Higher Level		2. Focus Element		3. Next Lower Level or Characteristic Type												
Window Lift System		ECU Window Lifter		Connector ECU Window Lifter												
FUNCTION ANALYSIS (STEP 3)																
1. Next Higher Level Function and Requirement		2. Focus Element Function and Requirement		3. Next Lower Level Function and Requirement or Characteristic												
Provide anti-pinch protection for comfort closing mode		Provide signal to stop and reverse window lifter motor in case of pinch situation		Transmit signal from Hall effect sensor to ECU												
FAILURE ANALYSIS (STEP 4)					**SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5)**											
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic		Rationale for Frequency	Frequency (F) of FC	Current Diagnostic Monitoring	Current System Response	Monitoring (M)	Most Severe Failure Effect after System Response	Severity (S) of FE after MSR	Severity (S) of Original FE from Failure Analysis (Step 4)	MSR AP	Filter Code (Optional)		
					DFMEA CURRENT CONTROLS											
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched between window glass and frame)	10	No signal to stop and reverse window lifter motor in case of pinch situation	Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor.		The connection principle of the Hall effect sensor and ECU is according to standard xyz.	2	None	Window will close with full clamping force.	10	Hand or neck may be pinched between glass and frame	10	10	M			

Figure D3.8-2 FMEA-MSR Risk Analysis (Software View)

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FAILURE ANALYSIS (STEP 4)				SUPPLEMENTAL FMEA-MSR RISK ANALYSIS (STEP 5) and OPTIMIZATION (STEP 6)												
1. Failure Effects (FE) to the Next Higher Level Element and/or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Rationale for Frequency	Frequency (F) of FC	Diagnostic Monitoring and System Response	Monitoring (M)	MSR AP	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Remarks
				FMEA-MSR CURRENT CONTROLS											
No anti-pinch protection in comfort closing mode (Hand or neck may be pinched between window glass and frame)	6	No signal to stop and reverse window lifter motor in case of pinch situation	Signal of Hall effect sensor is not transmitted to ECU due to poor connection of Hall effect sensor.	The connection principle of the Hall effect sensor and ECU is according to standard xyz.	2	None Window will close with full clamping force.	10	M							
				FMEA-MSR OPTIMIZATION											
				None	2	Introduction of plausibility check between motor current and loss of signal from Hall effect sensor. Comfort closing mode disabled	1	L		Test engineer Mr. Warren Watchful	dd.mm.yyyy	implementation pending			

Figure D3.8-3 FMEA-MSR Optimization with new Risk Evaluation (Software View)

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D4.0 Customer Specific Requirements Form Sheets

D4.1 GM and FCA DFMEA Form Sheet

D4.2 Ford DFMEA Form Sheet

D4.3 GM and FCA PFMEA Form Sheet

D4.4 Ford PFMEA Form Sheet

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E Further Application Fields

With the DFMEA and PFMEA described, all application fields can be covered.

The procedure is also transferable to suppliers of the automotive industry of other industrial branches. The special features and specific procedures are to be taken into account.

E1 FMEA for Software Scopes

The functions of a system are realized more and more often by software. A Design FMEA examines the functional capability of a system, and therefore the inspection of software scopes is a part of this. The system and its effect relationships should be inspected as a whole in the analysis of the software scope.

When inspecting software scopes, special problems can occur that are considered in the following sections.

> NOTE: The term “Software FMEA” is misleading, since not the software but the functions that are realized by the software are to be examined in the system context.

E2 Objective of the Software Scopes Inspection

Analysis of the software requirements:

Demand from the complete system

Checking the basis information/boundary conditions/specifications

Systematical actions for risk reduction, i.e. concept change, avoidance, detection.

Analysis of possible faults in software scopes:

Effect on the complete system

Depiction of the interaction of software modules in the complete system

Risk assessment of the of software modules.

E3 FMEA in the Software Development Process

The FMEA is especially suited for the analysis of requirements and for the validation of the implementation. Therefore its field of application is primarily in the upper part of the model shown.

E4 FMEA for Machine and Facility Manufacturers

The DFMEA of a machine is sometimes referred to as a “Machine FMEA” in the literature.

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Starting from a PFMEA in which a machine was identified as a risk, a DFMEA can be prepared for the machine.

In the PFMEA, the requirements on the functions/abilities of the machine are identified in the analysis of the machine.

Separate evaluation tables are to be developed for this Machine FMEA.

At the end the Machinery FMEA follows the rules as Design or Process FMEA.

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F: Severity, Occurrence, Detection and Action Priority Tables

F1 DFMEA SOD Tables

F1.1 DFMEA SEVERITY (S)

Product General Evaluation Criteria Severity (S)			
Potential Failure Effects rated according to the criteria below.			Blank until filled in by user
S	**Effect**	**Severity criteria**	**Corporate or Product Line Examples**
10	**Very High**	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Noncompliance with regulations.	
8	**High**	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		**Degradation** of primary vehicle function necessary for normal driving during expected service life.	
6	**Moderate**	**Loss** of secondary vehicle function.	
5		**Degradation** of secondary vehicle function.	
4		Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible effect.	

Table F1-1 - DFMEA SEVERITY (S)

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F1.2 DFMEA OCCURRENCE (O)

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
10	**Extremely high**	**First** application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience. Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.	
9	**Very high**	**First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Prevention controls not targeted to identify performance to specific requirements.	
8		**First** use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.	
7	**High**	**New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.	
6		**Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.	

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Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
5	**Moderate**	**Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure. Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.	
4		**Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience. Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.	
3	**Low**	**Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause and predict conformance of production design.	
2	**Very low**	**Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.	
1	**Extremely low**	Failure eliminated through preventive control and failure cause is not possible by design	

Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.

Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins

Note: OCC 10, 9, 8, 7 can drop based on product validation activities.

Table F1-2 - DFMEA Occurrence (O)

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F1.2.1 Alternative DFMEA Occurrence (O) Tables

F1.2.1.1 DFMEA OCCURRENCE (O) with Incidents per Thousand Values

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Incidents per 1000 items/vehicles**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
10	**≥ 100 per thousand >/= 1 in 10**	**First** application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience. Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.	
9	**50 per thousand, 1 in 20**	**First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Prevention controls not targeted to identify performance to specific requirements.	
8	**20 per thousand, 1 in 50**	**First** use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.	
7	**10 per thousand 1 in 100**	**New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.	
6	**2 per thousand 1 in 500**	**Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.	

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Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Incidents per 1000 items/vehicles**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
5	**.5 per thousand 1 in 2000**	**Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure. Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.	
4	**.1 per thousand 1 in 10,000**	**Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience. Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.	
3	**.01 per thousand 1 in 100,000**	**Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design.	
2	**≤ .001 per thousand 1 in 1,000,000**	**Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.	
1	**Failure is eliminated through preventive controls**	Failure eliminated through preventive control and failure cause is not possible by design	

Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.

Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and

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Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Incidents per 1000 items/vehicles**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**

effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins

Note: OCC 10, 9, 8, 7 can drop based on product validation activities.

Table F1-2 - DFMEA Occurrence (O)

F1.2.1.2 DFMEA Occurrence (O) with Time Based Failure Prediction Values

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Time Based Failure Cause Prediction**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
10	**Every time**	**First** application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience. Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist.	
9	**Almost every time**	**First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Prevention controls not targeted to identify performance to specific requirements.	
8	**More than once per shift**	**First** use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance.	

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Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Time Based Failure Cause Prediction**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
7	**More than once per day**	**New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience. Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance.	
6	**More than once per week**	**Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause.	
5	**More than once per month**	**Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure. Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance.	
4	**More than once per year**	**Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience. Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance.	
3	**Once per year**	**Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design.	

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Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating).			Blank until filled in by user
O	**Time Based Failure Cause Prediction**	**Occurrence criteria - DFMEA**	**Corporate or Product Line Examples**
2	**Less than once per year**	**Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions. Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.	
1	**Never**	Failure eliminated through preventive control and failure cause is not possible by design	

Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.

Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins

Note: OCC 10, 9, 8, 7 can drop based on product validation activities.

F1.3 DFMEA DETECTION (D)

Detection Potential (D) for the Validation of the Product Design				
Detection Controls rated according to Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
10	**Very low**	Test procedure yet to be developed.	Test method not defined	
9		Test method not designed specifically to detect failure mode or cause.	Pass-Fail, Test-to-Fail, Degradation Testing	

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8	**Low**	New test method; not proven.	Pass-Fail, Test-to-Fail, Degradation Testing	
7		Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or re-tooling.	Pass-Fail Testing	
6	**Moderate**		Test-to-Failure	
5			Degradation Testing	
4	**High**	Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is sufficient to modify production tools before release for production.	Pass-Fail Testing	
3			Test-to-Failure	
2			Degradation Testing	
1	**Very high**	Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to **always** detect the failure mode or failure cause.		

Table F1-3 - DFMEA DETECTION (D)

F1.4 ACTION PRIORITY TABLE FOR DFMEA

Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	ACTION PRIORITY (AP)	Comments
Product or Plant Effect Very high	9-10	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	

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Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	ACTION PRIORITY (AP)	Comments
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect High	7-8	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect Moderate	4-6	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	M	
				Very high	1	M	
		High	6-7	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	M	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	

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		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect Low	2-3	Very high	8-10	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		High	6-7	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
No Discernible Effect	1	Very low - Very high	1-10	Very high - Very low	1-10	L	

Table AP – ACTION PRIORITY FOR DFMEA and PFMEA

F2 PFMEA SOD Tables

F2.1 PFMEA SEVERITY (S)

Process General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below.					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (when known)**	**Impact to End User (when known)**	**Corporate or Product Line Examples**
10	**High**	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Affects safe operation of the vehicle and/or other vehicles, the health of	

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Process General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below.					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (when known)**	**Impact to End User (when known)**	**Corporate or Product Line Examples**
				driver or passenger(s) or road users or pedestrians.	
9		Failure may result in in-plant regulatory noncompliance	Failure may result in in-plant regulatory noncompliance	Noncompliance with regulations.	
8	**Moderately high**	100% of production run affected may have to be scrapped. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker.	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		Product may have to be sorted and a portion (less than 100%) scrapped; deviation from primary process; decreased line speed or added manpower	Line shutdown from 1 hour up to full production shift; stop shipment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance	**Degradation** of primary vehicle function necessary for normal driving during expected service life.	
6	**Moderately low**	100% of production run may have to be reworked off line and accepted	Line shutdown up to one hour	**Loss** of secondary vehicle function.	
5		A portion of the production run may have to be reworked off line and accepted	Less than 100% of product affected; strong possibility for additional defective product; sort required; no line shutdown	**Degradation** of secondary vehicle function.	
4		100% of production run may have to be reworked in station before it is processed	Defective product triggers significant reaction plan; additional defective products not likely; sort not required	Very objectionable appearance, sound, vibration, harshness, or haptics.	

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Process General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below.					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (when known)**	**Impact to End User (when known)**	**Corporate or Product Line Examples**
3	**Low**	A portion of the production run may have to be reworked in-station before it is processed	Defective product triggers minor reaction plan; additional defective products not likely; sort not required	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slight inconvenience to process, operation, or operator	Defective product triggers no reaction plan; additional defective products not likely; sort not required; requires feedback to supplier	Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible effect	No discernible effect or no effect	No discernible effect.	

Table F2-1 - PFMEA SEVERITY (S)

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F2.2 PFMEA OCCURRENCE (O)

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
10	**Extremely high**	None	No prevention controls.	
9	**Very high**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8				
7	**High**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6				
5	**Moderate**		Prevention controls are effective in preventing failure cause.	
4				
3	**Low**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**Very low**			
1	**Extremely low**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (i.e. part geometry) or process (i.e. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table F2-2 - PFMEA OCCURRENCE (O)

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F2.2.1 Alternative PFMEA Occurrence (O) Tables

F2.2.1.1 PFMEA Occurrence (O) with Incidents per Thousand Values

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Incidents per 1000 items/vehicles**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
10	**≥ 100 per thousand >/= 1 in 10**	None	No prevention controls.	
9	**50 per thousand 1 in 20**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8	**20 per thousand 1 in 50**			
7	**10 per thousand 1 in 100**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6	**2 per thousand 1 in 500**			
5	**.5 per thousand 1 in 2000**		Prevention controls are effective in preventing failure cause.	
4	**.1 per thousand 1 in 10,000**			
3	**.01 per thousand 1 in 100,000**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**< .001 per thousand 1 in 1,000,000**			
1	**Failure is eliminated through preventive control**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (i.e. part geometry) or process (i.e. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table F2-2 - PFMEA OCCURRENCE (O)

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F2.2.1.2 PFMEA OCCURRENCE (O) with Time Based Failure Prediction Values

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.				Blank until filled in by user
O	**Time Based Failure Cause Prediction**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
10	**Every time**	None	No prevention controls.	
9	**Almost every time**	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8	**More than once per shift**			
7	**More than once per day**	Behavioral or Technical	Prevention controls somewhat effective in preventing failure cause.	
6	**More than once per week**			
5	**More than once per month**		Prevention controls are effective in preventing failure cause.	
4	**More than once per year**			
3	**Once per year**	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing failure cause.	
2	**Less than once per year**			
1	**Never**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (i.e. part geometry) or process (i.e. fixture or tooling design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

Prevention Control Effectiveness: Consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioral (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention controls will be.

Table F2-2 - PFMEA OCCURRENCE (O)

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F2.3 PFMEA DETECTION (D)

Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
10	Very low	No testing or inspection method has been established or is known.	The failure mode will not or cannot be detected.	
9		It is unlikely that the testing or inspection method will detect the failure mode.	The failure mode is not easily detected through random or sporadic audits.	
8	Low	Test or inspection method **has not been** proven to be effective and reliable (i.e. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause.	
7			Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause.	
6	Moderate	Test or inspection method **has been** proven to be effective and reliable (i.e. plant has experience with method, gauge R&R results are acceptable on comparable process or this application, etc.).	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks).	
5			Machine-based detection (semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that will detect failure mode or failure cause (including product sample checks).	

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Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection.				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
4	High	System has been proven to be effective and reliable (i.e. plant has experience with method on identical process or this application), gauge R&R results are acceptable, etc.	Machine-based automated detection method that will detect the failure mode **downstream**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
3			Machine-based automated detection method that will detect the failure mode **in-station**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
2		Detection method has been proven to be effective and reliable (i.e. plant has experience with method, error-proofing verifications, etc.).	Machine-based detection method that will detect the cause and prevent the failure mode (discrepant part) from being produced.	
1	Very high	Failure mode cannot be physically produced as-designed or processed, or detection methods proven to **always** detect the failure mode or failure cause.		

Table F2-3 - PFMEA DETECTION (D)

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F2.4 ACTION PRIORITY TABLE FOR PFMEA

Action Priority (AP) for DFMEA and PFMEA							
Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction.							Blank until filled in by user
Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	ACTION PRIORITY (AP)	Comments
Product or Plant Effect Very high	9-10	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect High	7-8	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	H	
		High	6-7	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very high	1	M	
		Moderate	4-5	Low - Very low	7-10	H	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	M	
		Low	2-3	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	

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Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	ACTION PRIORITY (AP)	Comments
Product or Plant Effect Moderate	4-6	Very high	8-10	Low - Very low	7-10	H	
				Moderate	5-6	H	
				High	2-4	M	
				Very high	1	M	
		High	6-7	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	M	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	M	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
Product or Plant Effect Low	2-3	Very high	8-10	Low - Very low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very high	1	L	
		High	6-7	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Moderate	4-5	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Low	2-3	Low - Very low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very high	1	L	
		Very low	1	Very high - Very low	1-10	L	
No Discernible Effect	1	Very low - Very high	1-10	Very high - Very low	1-10	L	

Table AP – ACTION PRIORITY FOR DFMEA and PFMEA

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F3 FMEA-MSR Tables

F3.1 Supplemental FMEA-MSR SEVERITY (S)

Product General Evaluation Criteria Severity (S)			
Potential Failure Effects rated according to the criteria below.			Blank until filled in by user
S	**Effect**	**Severity criteria**	**Corporate or Product Line Examples**
10	**Very High**	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Noncompliance with regulations.	
8	**High**	**Loss** of primary vehicle function necessary for normal driving during expected service life.	
7		**Degradation** of primary vehicle function necessary for normal driving during expected service life.	
6	**Moderate**	**Loss** of secondary vehicle function.	
5		**Degradation** of secondary vehicle function.	
4		Very objectionable appearance, sound, vibration, harshness, or haptics.	
3	**Low**	Moderately objectionable appearance, sound, vibration, harshness, or haptics.	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics.	
1	**Very low**	No discernible Failure Effect.	

Note: This table is identical to Table D1 - DFMEA SEVERITY (S)

Table F4-1 - Supplemental FMEA-MSR SEVERITY (S)

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F3.2 Supplemental FMEA-MSR FREQUENCY (F)

Frequency Potential (F) for the Product			
Frequency criteria (F) for the estimated occurrence of the Failure Cause in relevant operating situations during the intended service life of the vehicle			Blank until filled in by user
F	**Estimated Frequency**	**Frequency criteria - FMEA-MSR**	**Corporate or Product Line Examples**
10	**Extremely high or cannot be determined**	Frequency of occurrence of the Failure Cause is unknown or known to be unacceptably high during the intended service life of the vehicle	
9	**High**	Failure Cause is likely to occur during the intended service life of the vehicle	
8		Failure Cause may occur often in the field during the intended service life of the vehicle	
7	**Medium**	Failure Cause may occur frequently in the field during the intended service life of the vehicle	
6		Failure Cause may occur somewhat frequently in the field during the intended service life of the vehicle	
5		Failure Cause may occur occasionally in the field during the intended service life of the vehicle.	
4	**Low**	Failure Cause is predicted to occur rarely in the field during the intended service life of the vehicle. At least ten occurrences in the field are predicted.	
3	**Very low**	Failure Cause is predicted not to occur in isolated cases in the field during the intended service life of the vehicle. At least one occurrence in the field is predicted.	
2	**Extremely low**	Failure Cause is predicted not to occur in the field during the intended service life of the vehicle based on prevention and detection controls and field experience with similar parts. Isolated cases cannot be ruled out. No proof it will not happen.	
1	**Cannot Occur**	Failure Cause cannot occur during the intended service life of the vehicle or is virtually eliminated. Evidence that Failure Cause cannot occur. Rationale is documented.	

NOTE: Probability increases as number of vehicles are increased
Reference value for estimation is one million vehicles in the field

Table F4-2 - Supplemental FMEA-MSR FREQUENCY (F)

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Percentage of relevant operating condition in comparison to overall operating time	Value by which F may be lowered
< 10%	1
< 1%	2

Table MSR2.1 - Supplemental FMEA-MSR FREQUENCY adaption for infrequent operating conditions

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F3.3 Supplemental FMEA-MSR MONITORING (M)

Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
10	**Not effective**	The fault/failure cannot be detected at all or not during the fault tolerant time interval; by the system , the driver, a passenger, or service technician.	No response during the fault tolerant time interval.	
9	**Very Low**	The fault/failure can almost never be detected in relevant operating conditions. Monitoring control with low effectiveness, high variance, or high uncertainty. Minimal diagnostic coverage.	The reaction to the fault/failure by the system or the driver may not reliably occur during the fault tolerant time interval.	
8	**Low**	The fault/failure can be detected in very few relevant operating conditions. Monitoring control with low effectiveness, high variance, or high uncertainty. Diagnostic coverage estimated <60%.	The reaction to the fault/failure by the system or the driver may not always occur during the fault tolerant time interval.	
7	**Moderately Low**	Low probability of detecting the fault/failure during the fault tolerant time interval by the system or the driver. Monitoring control with low effectiveness, high variance, or high uncertainty. Diagnostic coverage estimated >60%.	Low probability of reacting to the detected fault/failure during the fault tolerant time interval by the system or the driver.	
6	**Moderate**	The fault/failure will be automatically detected by the system or the driver only during power-up, with medium variance in detection time. Diagnostic coverage estimated >90%.	The automated system or the driver will be able to react to the detected fault/failure in many operating conditions.	
5		The fault/failure will be automatically detected by the system during the fault tolerant time interval, with medium variance in detection time, or detected by the driver in very many operating conditions. Diagnostic coverage estimated between 90% - 97%.	The automated system or the driver will be able to react to the detected fault/failure in very many operating conditions.	

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Supplemental FMEA for Monitoring and System Response (M)				
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation. Use the rating number that corresponds with the least effective of either criteria for Monitoring or System Response				Blank until filled in by user
M	**Effectiveness of Monitoring Controls and System Response**	**Diagnostic Monitoring / Sensory Perception Criteria**	**System Response / Human Reaction Criteria**	**Corporate or Product Line Examples**
4	**Moderately High**	The fault/failure will be automatically detected by the system during the fault tolerant time interval, with medium variance in detection time, or detected by the driver in most operating conditions. Diagnostic coverage estimated >97%.	The automated system or the driver will be able to react to the detected fault/failure during the fault tolerant time interval, in most operating conditions.	
3	**High**	The fault/failure will be automatically detected by the system during the fault tolerant time interval with very low variance in detection time, and with a high probability. Diagnostic coverage estimated >99%.	The system will automatically react to the detected fault/failure during the fault tolerant time interval in most operating conditions with very low variance in system response time, and with a high probability.	
2	**Very High**	The fault/failure will be detected automatically by the system with very low variance in detection time during the fault tolerant time interval, and with a very high probability. Diagnostic coverage estimated > 99.9%.	The system will automatically react to the detected fault/failure during the fault tolerant time interval with very low variance in system response time, and with a very high probability.	
1	**Reliable** and acceptable for elimination of original failure effect	The fault/failure will always be detected automatically by the system. Diagnostic coverage estimated to be significantly greater than 99.9%.	The system will always automatically react to the detected fault/failure during the fault tolerant time interval.	

Table F4-3 - Supplemental FMEA-MSR MONITORING (M)

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F3.4 ACTION PRIORITY FOR FMEA-MSR

Action Priority (AP) for FMEA-MSR						
Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.						
Effect	**S**	**Prediction of Failure Cause Occurring During Service Life of Vehicle**	**F**	**Effectiveness of Monitoring**	**M**	**ACTION PRIORITY (AP)**
Product Effect High	**10**	Medium - Extremely high	5-10	Reliable - Not effective	1-10	H
		Low	4	Moderately high - Not effective	4-10	H
				Very high - High	2-3	H
				Reliable	1	M
		Very low	3	Moderately high - Not effective	4-10	H
				Very high - High	2-3	M
				Reliable	1	L
		Extremely low	2	Moderately high - Not effective	4-10	M
				Reliable - High	1-3	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect High	**9**	Low - Extremely high	4-10	Reliable - Not effective	1-10	H
		Extremely low - Very low	2-3	Very high - Not effective	2-10	H
				Reliable - High	1	L
		Cannot occur	1	Reliable - Not effective	1-10	L

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Action Priority (AP) for FMEA-MSR						
Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.						
Effect	**S**	**Prediction of Failure Cause Occurring During Service Life of Vehicle**	**F**	**Effectiveness of Monitoring**	**M**	**ACTION PRIORITY (AP)**
Product Effect Moderately high	**7-8**	Medium - Extremely high	6-10	Reliable - Not effective	1-10	H
		Medium	5	Moderately high - Not effective	5-10	H
				Reliable - Moderately high	1-4	M
		Low	4	Moderately low - Not effective	7-10	H
				Moderately high - Moderate	4-6	M
				Reliable - High	1-3	L
		Very low	3	Very low - Not effective	9-10	H
				Moderately low - Low	7-8	M
				Reliable - Moderate	1-6	L
		Extremely low	2	Moderately low - Not effective	7-10	M
				Reliable - Moderate	1-6	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect Moderately Low	**4-6**	High - Extremely high	7-10	Reliable - Not effective	1-10	H
		Medium	5-6	Moderate - Not effective	6-10	H
				Reliable - Moderately high	1-5	M
		Extremely low - Low	2-4	Very low - Not effective	9-10	M
				Moderately high - Moderate	7-8	M
				Reliable - Moderate	1-6	L
		Cannot occur	1	Reliable - Not effective	1-10	L

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Action Priority (AP) for FMEA-MSR						
Action Priority is based on combinations of Severity, Frequency, and Monitoring ratings in order to prioritize actions for risk reduction.						
Effect	**S**	**Prediction of Failure Cause Occurring During Service Life of Vehicle**	**F**	**Effectiveness of Monitoring**	**M**	**ACTION PRIORITY (AP)**
Product Effect Low	**2-3**	High - Extremely high	7-10	Reliable - Not effective	1-10	H
		Medium	5-6	Moderately low - Not effective	7-10	M
				Reliable - Moderate	1-6	L
		Extremely low - Low	2-4	Reliable - Not effective	1-10	L
		Cannot occur	1	Reliable - Not effective	1-10	L
Product Effect Very low	**1**	Cannot occur - Extremely high	1-10	Reliable - Not effective	1-10	L

NOTE: If M=1, the Severity rating of the Failure Effect after Monitoring and System Response is to be used for determining MSR Action Priority. If M is not equal to 1, then the Severity Rating of the original Failure Effect is to be used for determining MSR Action Priority.

Table AP – ACTION PRIORITY FOR FMEA-MSR

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G References and Suggested Readings

- IATF 16949 Quality management systems
  Particular requirements for the application of ISO 9001
  for automotive production and relevant service part
  organizations
- ISO 9001 Quality management systems - Requirements
- ISO 26262 Road vehicles - Functional safety
- SAE°J1739 Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)
- VDA Volume 2 Quality Assurance of Supplies
- VDA Maturity Level Assurance for New Parts
- AIAG APQP Advanced Production and Quality Planning
- AIAG PPAP Production Part Approval Process

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H Glossary

Cyber-Physical Systems: a mechanism that is controlled or monitored by computer-based algorithms, tightly integrated with the Internet and its users

Diagnostic coverage: per ISO 26262-1:2018, the percentage of the failure rate of a hardware element, or percentage of the failure rate of a failure mode of a hardware element that is detected or controlled by the implemented safety mechanism, the diagnostic figures are determined by the hardware functional safety analysis

Failure Chain: A failure chain consists of a Failure Effects, a Failure Mode, and a Failure Cause.

Failure Network: A failure network is the connection of one or more failure chains that can represent failures at multiple levels such that a Failure Cause at one level is a Failure Mode at the next lower level.

Focus Element: the object in the center of the analysis; in a hierarchically described system, a focus element has a super ordinate and a minimum of one subordinate system element.

Hybrid Failure Chain: A hybrid failure chain consists of a Failure Cause or Failure Mode, intended Monitoring Controls, and a mitigated failure effect.

Mechatronics: technology combining electronics and mechanical engineering

Operational situation: per ISO 26262-1:2018, a scenario that can occur during a vehicle's life (e.g. driving at high speed; parking on a slope; maintenance)

Primary Vehicle Function: a function that is essential to fulfil the basic purpose of a vehicle, i.e. steering, braking, propulsion, and visibility

Residual Risk: The risk(s) remaining after the deployment of safety measures. See ISO26262-1:2018.

Secondary Vehicle Function: a function that enhances or enables a primary vehicle function as well as the user experience, i.e. safety, comfort, convenience, interface, diagnostic, and serviceability

Service life: the intended design life of the item (FMEA-MSR: the intended design life of the vehicle)

Structure Tree: A graphical depiction of the hierarchical links between system elements and its dependencies.

System Element: elements of a system that are represented in the structure tree

System response: the system’s reaction to a detected fault, usually in the form of degrading or disabling of a function and/or warning the operator and setting a fault code

Useful life: the operating interval in which a function is correctly provided, and the failure rate is within acceptable tolerance

Zero Mileage / Zero km / Zero Hours: vehicle has not left the assembly plant

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