Risk Reduction Through Characteristic Management and FMEA

R. Dan Reid
M.B.S., M.A., ASQ Fellow, ASQ CQE
ASQ Automotive, Healthcare and Quality Management Divisions

The Catalyst for Peak Performance

AIAG
Failure Modes Effects Analysis is a tool used to list possible failure modes of a product, service or process and provide a rating so the focus of any improvement effort is placed on the most important.

“Failure Mode” is a manner in which the product or service does not meet the customer requirements.

“Effect Analysis” is the study of the effects of failure on fit for usefulness.
FMEA Benefits

- Quantifies risk to improve risk management as the “right” thing to do is not always “intuitive”
- Drives preventive action to avoid adverse events
- Drives corrective action across similar processes
- Improves quality, safety and profit margin
- Provides documentation for organizational memory
- Can be used to track progress over time
- Improves customer satisfaction
<table>
<thead>
<tr>
<th>Applications</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Analyze products or services before they are released</td>
</tr>
<tr>
<td>Process</td>
<td>Analyze service, manufacturing &amp; assembly processes</td>
</tr>
<tr>
<td>Concept</td>
<td>Analyze systems or subsystems in the early design concept stages</td>
</tr>
<tr>
<td>Equipment</td>
<td>Analyze machinery and equipment design before they are purchased</td>
</tr>
<tr>
<td>Facilities</td>
<td>Analyze facility layout before construction to minimize waste associated with the floor layout</td>
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</tbody>
</table>
• Design FMEA
  – Main focus is on design of the product or service and specifications which enable the product or service to meet the intended use

• Process FMEA
  – Main focus is on the process which will allow the service to be made repeatable to the requirements or design specifications
  – Utilizes process knowledge and historical process data to identify and help eliminate potential process failure modes

The thought pattern for development is identical
All applicable interfaces and interactions should be addressed.
For Each Potential Problem Listed

• (S) - Rate the severity of the problem on a scale from one to 10 (1 being very low and 10 being major)

• (O) - Rate the likelihood of the problem occurring again on a scale from one to 10. (1 being almost never and 10 very likely)

• (D) - If the problem occurs what is the likelihood we would detect it, again one to 10. (1 means we would detect it for sure and 10 means we probably wouldn’t be able to detect it

Each Should Be Rated Independently!
For each problem on the list calculate an RPN or Risk Priority Number.

To do this multiply the Severity number by the Occurrence Number by the Detection Number.

\[ RPN = S \times O \times D \]

This number will be between one and 1000; the higher the number the greater the potential problem.
Failure Modes

There Are 3 Main Types Of Design Failure Modes

• Materials
• Processes
• Costs

There Are 4 Main Types Of Process Failure Modes

• Too Much
• Too Little
• Missing
• Wrong
FMEA Acceptance Criteria:

- A good FMEA should:
  - be completed across to the right side which is the area for re-computing the Risk after initial efforts have been taken to reduce the initial high risk rating, e.g. RPN;
  - list multiple effects for each mode and multiple causes for each effect. Generally there is not a 1:1 relationship as any given failure mode could have many effects;
FMEA Acceptance Criteria:

• A good FMEA should:

  – list actions taken on high severity and high RPN, or other risk ratings, aimed at preventing the occurrence of a potential failure
    • *Responsibility for the actions taken should be assigned and tracked to completion*

  – include efforts to error-proof the design and/or mistake-proof the process

  – ensure that measurement uncertainty is known and adequate for applicable metrics;
FMEA Acceptance Criteria:

• A good FMEA should:

  – identify characteristics which should be designated as “special” or critical on the Control Plan so actions can be planned and implemented to mitigate the effects of the potential failure
    • This should include reference to a contingency plan to protect your customer from receiving non-compliant product

  – carefully consider all the risk, e.g. safety, quality, equipment and resource as well as efficiency of methods used, actions taken and contingency planning;
FMEA Acceptance Criteria:

• A good FMEA should:

  – consider the major types of design failures:
    • materials,
    • processes,
    • costs or

  – consider the major types of process failures:
    • too much,
    • too little,
    • missing or
    • wrong
FMEA Analysis

Severity Rankings

10 9 8 7 6 5 4 3 2 1

Occurrence Ratings

1 2 3 4 5 6 7 8 9 10

Critical Characteristic (Error-Proofing)
Continuous Improvement (RPN Reduction)
Minor issues
Risk Priority Number Reduction

For each business unit or service type:

- List all RPNs
- Pareto's of RPNs
- RPN less than target for each business unit or service type
- Periodic reviews
- Top "5" list
- Action plans
- TRACK progress

* Or any with high severity

Management reviews

Priority action plan by natural owner

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## FMEA Tracking

### Top Five – RPN (can be Top 10 or Top n)

<table>
<thead>
<tr>
<th>No.</th>
<th>OP No.</th>
<th>Function &amp; Failure Mode</th>
<th>RPN Value</th>
<th>Who</th>
<th>Recommended Actions</th>
<th>Completion Date</th>
<th>Revised RPN</th>
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### Master Dot Tracking

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<tr>
<th>ITEM</th>
<th>ACTION ITEM</th>
<th>ACTION LEADER</th>
<th>DATE OPENED</th>
<th>TARGET CLOSE DATE</th>
<th>ACTUAL CLOSE DATE</th>
<th>LAST UPDATE</th>
<th>STATUS HISTORY</th>
<th>COUNTER MEASURES</th>
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**Color Codes**
- Green - Task Completed on Time
- Yellow - Task May Be Late
- Red - Task is Late
- White - Task Re-Timed, No Status
- Blue - Task Status is Incorrect; Not Updated
- On Track (Bold Box/No Color)

Source: General Motors
Remember

• The idea behind a FMEA is to define important product, service or process characteristics so you can focus on these areas to remove, control or improve the product or service, insuring that risk and/or harm is not passed on to your customers!
• What is a Quality Characteristic?
  – *It is the basic building block on which quality is built regardless of the definition*
  – *It is any feature, e.g. property, attribute, of the product / service or process which is needed to achieve quality*
  – *There are several types:*
    - technological (hardness, acidity, wavelengths)
    - psychological (taste, beauty, status, mental state)
    - time-oriented (promptness, reliability, maintainability)
    - contractual (guarantee, provisions)
    - ethical (courtesy, honesty, pride)
  – *Contrasted with “assigned” characteristics, e.g. price*
Interrelation of Quality Parameters

Quality Characteristic

- *higher quality costs more*
- **higher quality costs less**

Quality of Design*

Quality of Conformance**

Availability (time-related)

Field Service

Quality of Market Research

Quality of Concept

Quality of Specification

Technology

Manpower

Management

Reliability

Maintainability

Logistical Support

Promptness

Competence

Integrity

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Design Stage Is The Best Time To Impact Quality & Cost

CHANCES FOR QUALITY & COST IMPROVEMENTS

COST TO IMPLEMENT

START OF PRODUCTION

Cost

Time

Source: General Motors
Characteristics in Design Process

- Planning
- Change control
- System design

- Customer-designated and supplier-designated
- Parameter design (target)
- Tolerance design

Tools include:
- QFD
- APQP
- FMEA
- Statistical Engineering

Customer Requirements → Product Design Requirements → Product Characteristics
Characteristics In Design Process

Tools include:
- QFD
- APQP
- FMEA
- Statistical Engineering

Customer Requirements

- planning
- change control
- system design

Product Design Requirements

- customer-designated and supplier-designated
- parameter design (target)
- tolerance design

Product Characteristics

- manufacturing feasibility
- system design

Process Design Requirements

- customer-designated and supplier-designated
- parameter design (target)

Process Characteristics

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The design record is the part drawing, specifications, and/or electronic (CAD) data used to convey information necessary to produce a product.

PPAP’s purpose is to provide the evidence that all customer engineering design record and specification requirements are properly understood by the organization and that the manufacturing process has the potential to produce product consistently meeting these requirements during an actual production run at the quoted production rate.

The organization shall have the design record for the saleable product/part, including design records for components or details...

The organization shall record the actual results: all dimensions, characteristics, and specifications as noted on the design record and Control Plan.

Over-specifying increases the cost and may restrict competition.

Under-specifying may compromise the quality level you need.

* A poor specification adversely affects quality and cost!
Quality Characteristics
...a common thread

Design Record

Design Failure Mode and Effects Analysis (FMEA)

Process FMEA

Includes Initial Critical Characteristic Identification

Quantifies Risk of Potential Failures Due To Design to Identify Other Critical Characteristics

Quantifies Risk of Potential Failures Due To Process to Identify Other Critical Characteristics
Quality Characteristics
...a common thread

Design Record

Design Failure Mode and Effects Analysis (FMEA)

Process FMEA

Control Plan

Standard operating procedures

Work instructions

Includes Initial Critical Characteristic Identification

Quantifies Risk of Potential Failures Due To Design to Identify Other Critical Characteristics

Quantifies Risk of Potential Failures Due To Process to Identify Other Critical Characteristics

Lists the Controls Needed to Mitigate Potential Failures

Describes Work That Flows Across Functions

Describes Work Done at a Work Station

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<table>
<thead>
<tr>
<th>Process Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Cause(s)/Mechanism(s) of Failure</th>
<th>Current Process Controls</th>
<th>Recommended Action(s)</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual application of wax inside door</td>
<td>Insufficient wax coverage over specified surface</td>
<td>Deterioration of door leading to: unsatisfactory appearance due to rust through paint over time impaired function of interior door hardware</td>
<td></td>
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<tr>
<td>To cover inner door, lower surfaces at minimum wax thickness to retard corrosion</td>
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</tbody>
</table>

**Sample**

**APPENDIX D**

**Process FMEA Example**

Source: APQP, © DCX, Ford, GM
Control Plan

<table>
<thead>
<tr>
<th>Control Plan Number</th>
<th>Part Number/Latest Change Level</th>
<th>Core Team</th>
<th>Cust. Engineering Approval/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part Name/Description</td>
<td>Supplier/Plant Approval/Date</td>
<td>Supplier/Plant Approval/Date</td>
<td>Cust. QA Approval/Date</td>
</tr>
<tr>
<td>Supplier/Plant</td>
<td>Supplier Code</td>
<td>Other Approval/Date (if required)</td>
<td>Other Approval/Date (if required)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part/Process Number</th>
<th>Process Name/Operation Description</th>
<th>Machine, Device, Jig, Tools for Mfg.</th>
<th>Characteristics</th>
<th>Special Char. Class.</th>
<th>Methods</th>
<th>Reaction Plan</th>
</tr>
</thead>
</table>

Form adapted from General Motors
**Control Plan - APQP example**

Set Up Dominant Process

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**EQUIPMENT: SET-UP DOMINANT PROCESS:** The process is highly capable and stable, therefore set-up is major variable impacting product variation.

Automotive grills are produced on plastic injection molding machines. After set-up of the mold, the machine must be adjusted to produce a dimensionally-correct part. Parts must also be free of blemishes, flow lines and sink marks on the surface. The molding machine is highly repeatable because all parameters are computer controlled. A set-up card provides specifications for setting all controls on the machine. After setting the machine to the specifications a sample part is produced. This part is checked for the key control dimensions for mounting holes and perimeter fit, and visually inspected.

- The set-up is the critical variable in this type of process. Capability studies on the product characteristics show that when properly set-up, the operation is highly capable and stable. The set-up specifications become the process characteristics that affect the product characteristic.

- Types of controls for the process characteristic include first piece check procedures, and verification that machine settings are correct to authorized set-up cards.

- Product characteristics are measured to insure the set-up is correct and that no unusual special cause has occurred. In some cases lot control may be appropriate between checks.

---

### CONTROL PLAN

<table>
<thead>
<tr>
<th>PART/PROCESS NUMBER</th>
<th>PROCESS NAME/OPERATION DESCRIPTION</th>
<th>MACHINE, DEVICE, JIG, TOOLS FOR MFG.</th>
<th>CHARACTERISTICS</th>
<th>SPECIAL CHAR. CLASS</th>
<th>PRODUCT/PROCESS SPECIFICATION/TOLERANCE</th>
<th>EVALUATION/MEASUREMENT TECHNIQUE</th>
<th>SAMPLE SIZE</th>
<th>FREQ.</th>
<th>CONTROL METHOD</th>
<th>REACTION PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Plastic Injection Molding Machine No. 1-5</td>
<td>18 Appearance</td>
<td>* Free of blemishes</td>
<td>Visual Inspection</td>
<td>100% Continuous</td>
<td>100% inspection</td>
<td>Notify Inspector</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>No blemishes</td>
<td>Flow lines</td>
<td>1st piece buy-off</td>
<td>Check Sheet</td>
<td>Adjust/re-check</td>
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<td></td>
<td>Sink marks</td>
<td>1st piece buy-off</td>
<td>Check Sheet</td>
<td>Adjust/re-check</td>
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<tr>
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<td>Machine No. 1-5</td>
<td>19 Mounting hole loc.</td>
<td>* Hole &quot;X&quot; location</td>
<td>Fixture #10</td>
<td>1st piece buy-off per run</td>
<td>Check Sheet</td>
<td>Adjust/re-check</td>
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</tbody>
</table>

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**Be sure to use a Control Plan based on the critical process variable**
Adjust Temperature

1. Press and hold to view set point

2. While holding, press ▲ or ▼ to adjust set point:
   - Heating – Raise to 105°F
   - Cooling – Lower until display shows “OFF”

CAUTION: Monitor and adjust temperature to patient’s tolerance.

© 2003 The Bishop Company. (www.explainers.com) Used with permission
• Standard Characteristics
  – require “due care”

• Key, Critical, Significant
  – ISO 9001:1994 used the term “crucial”
  – QS-9000 & ISO TS 16949 uses “special”
  – TS16949 definition: a “product characteristic or manufacturing process parameter which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product” (clause 3.1.12)
  – require extra care to mitigate the effects of a potential problem
  – types of controls necessary are customer-specific
Characteristic Identification

- **Sources:**
  - QFD
  - APQP
  - Warranty
  - FMEA Analysis
  - recall data
  - customer complaints
  - Simulation
  - Modeling studies
  - Group consensus
  - Designed experiments
  - SPC data
  - Loss Function
Characteristic Identification

• Requires input from multiple functions:
  • ISO TS 16949, clause 7.3.1.1
    – *The organization shall use a multi-disciplinary approach to prepare for product realization, including*
      ❑ Development / finalization and monitoring of special characteristics
      ❑ Development and review of FMEAs, including actions to reduce potential risks, and
      ❑ Development and review of Control Plans
• Suppliers are also required to identify and
  – “include all special characteristics in the control plan
  – comply with customer-specified definitions and symbols, and
  – identify process control documents including drawings, FMEAs, control plans and operator instructions with the customer’s special characteristic symbol or the organization’s equivalent symbol or notation to include those process steps that affect special characteristics”
  (ISO TS 16949, clause 7.3.2.3)
Characteristic Identification

• ISO 9001:2008, Clause 7.3.3.d)
  – Design and development outputs shall specify the characteristics of the product that are essential for its safe and proper use

• ISO/TS 16949:2009, Clause 7.3.3.1
  – “...The product design output shall include
    ☐ design FMEA, reliability results
    ☐ product special characteristics and specifications
    ☐ product error-proofing, as appropriate...”
• Should consider BOTH variable and attribute characteristics!
• The **Description/Rationale** column includes all special process and product **characteristics** agreed upon by the cross functional team.

• Develop a rationale for each special characteristic and add this information to the list for clarification.

• A **sequential number** (No.) is assigned to each characteristics listed to ensure none are overlooked by the supplier when the Control Plan is completed.
Identify Pass-Through Characteristics (PTC)

- PTCs – Part characteristics which are not controlled or functionally tested anywhere downstream in the supply chain and would have a significant impact on customer satisfaction and/or warranty
  - PTCs are ultimately supplied to an OEM customer (i.e. it will “pass through”)
  - A PTC may or may not be a Special Characteristic
  - Develop a potential PTC list from various sources, e.g. engineers, reliability practitioners, customers, historical data and/or market research

- Examples of PTCs
  - Include engine thermostat function, torque converter studs
  - Threaded hole supplied by an external supplier not used by the next downstream organization
  - Incorrect chemistry for bulk material
PTC’s (Contd)

• Determine if each potential PTC is controlled or functionally tested in subsequent operations in the supply chain

• If the potential PTC is not controlled in subsequent operations either in sub-tier supplier operations, determine with your customer if the potential PTC would have significant impact on customer satisfaction or warranty

• Agree with your customer on the appropriate action, e.g. error-proofing or other controls to ensure that no defects reach the customer

• Implement the action and verify that it is effective

• Ensure that applicable procedures, e.g. FMEAs, Control Plans and/or Work Instructions and documents include all PTCs and Special Characteristics

• Design-responsible organizations should identify PTCs on the design records

Source: AIAG CQI-19
• Special Characteristics and PTCs are to be included on the AIAG Potential Failure Mode and Effects Analysis (PFMEA) documents to determine relative risk.

Supplier Name:
Customer Part No:
Part Description:
Drawing No / Revision:
Date:
Supplier Contact: Phone/Email:

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2.2.11 Initial Process Studies

– 2.2.11.1 General

The level of initial process capability or performance shall be determined to be acceptable prior to submission for all Special Characteristics designated by the customer or the organization.

This assumes that special characteristics have been properly identified and designated by the customer and supplier.
2.2.11 Initial Process Studies

– 2.2.11.1 General

NOTE 1: Where no special characteristics have been identified, the customer reserves the right to require demonstration of initial process capability on other characteristics.
If the supplier takes a minimalist approach, the customer stands to lose much of the power of the TS-specified quality tools!
### Part Qualification Process

#### Incomplete FMEAs compromise the system...

...and adversely impact ongoing quality

---

**Efforts should be taken to reduce the RPNs!**

If they remain high, the characteristic should be designated as “special” by the supplier!
“PFMEA In Context” class

- Look what they are saying:

“The class was excellent. It really showed how the PFMEA, Process Flow, and Control Plan are connected and should be utilized to ensure the quality throughout the process, and therefore ensure the part quality. The booklet we received as part of the training has been a great reference in my normal job activities.” Jared Peacock, Toyota

“As a supplier to automobile manufacturers, I found it very valuable to combine the content of the APQP and FMEA manuals into a single training course... the training triggered many ideas which I plan to incorporate into my company’s current practices in order to improve the effectiveness of our FMEA’s by highlighting the linkages between our PFMEA’s and PCP’s.” Clark Johns, Timken

"If you've got defects, your team needs this class." Jim Carter, General Motors

“The workshop ...is the best approach to cover all process risks and their prevention / detection while minimizing the repetitive work. I would encourage our suppliers to take the training if they have not implemented this approach.” Stanley Zhou, Chrysler Group LLC
Questions?
For a complete description of AIAG’s services and product offerings, or to register for an event or place an order, please visit www.aiag.org or contact AIAG Customer Service at 248.358.3003

R. Dan Reid
Program Manager, Quality
o. 248-358-9774
e. dreid@aiag.org