PFMEA
Process Failure Mode and Effects Analysis
James Davis, General Dynamics
The purpose of this presentation is to share the benefits of a detailed Process Flow Diagram, conducted during a Process Failure Mode and Effects Analysis, that will ensure product quality in the manufacturing/asemblly process.
Introduction
**Definition of FMEA**

A FMEA is an *analytical* tool that uses a *disciplined technique* to identify and help eliminate product and process potential failure modes.

- By ID of potential failures
- Assessing the risks caused by failure modes and
  - Identify corrective actions
- Prioritizing corrective actions
- Carry out corrective actions
Most **COMMON** Types of FMEA's

**Design** (Potential) Failure Modes and Effects Analysis-DFMEA

- Focus is on potential design-related failures and their causes.

**Process** (Potential) Failures Modes and Effects Analysis-PFMEA

- Focuses is on potential process failures and their causes.
Value of FMEA's

● Aids in improving designs for products and process
  ▪ Increased safety
  ▪ Enhances Customer Satisfaction
    o Better Quality
    o Higher Reliability

● Contributes to cost savings
  ▪ Decreases warranty costs
  ▪ Decreases waste, non-value added operations
PFMEA's

- Focus is on potential process-related failures and their causes.
  - Main drive is to understand the process through the identification of as many potential failures as possible.
    - e.g. Incorrect material used
- PFMEA typically assumes that the design is sound.
- Development of Recommended Actions is targeted at eliminating the Root Cause of the potential failures.
PFMEA

Three Parts:

● **Process Flow Diagram (PFD)**

● **Process Failure Mode and Effects Analysis (PFMEA)**

● **Process Control Plan (PCP)**
Information Flow

Customer Requirements:
- SOR, Vehicle Tech Specs,
- System Technical Specs

Product Definition:
- Key Product Characteristics, DFMEA

Process Definition:
- Process Flow Diagram (PFD),
- Product and Process Characteristics

Failure Mode Analysis:
- PFMEA

Control Strategy:
- Control Plan,
- Error proofing

Manufacturing:
- Work Instructions & Process Monitoring
Process Flow Diagrams

- The Process Flow Diagram provides a logical (visual) depiction of the process that is being analyzed.
Process Function / Requirement

- The SAE/AIAG PFMEA guidelines describe two methods of defining process functions. Either or both may be used.
- Process Functions may be described in terms of:
  - The product features/characteristics that are created
  or
  - The process actions that are performed
- Process functions should be identified in detail as necessary to provide information for the PFMEA to develop effective Process Controls
Consider a simple operation to drill a hole in a metal part.

The product characteristics & requirements are:

- **Hole size**: 4.00 mm +/- 0.13
- **Hole Location**:
  - X = 28.0 mm +/- 0.2
  - Y = 15.0 mm +/- 0.2
- **Perpendicular to surface, no burrs, etc.**

The process operation must create these product characteristics and meet the requirements.
To drill the correct hole size in the specified location, the process must:

- Position and hold the part
- Align the part fixturing with the drill position
- Assure the correct drill bit size is used
- Set and control drill speed
- Anticipate tool wear and schedule preventive maintenance

If the Function/Requirement is defined in the PFMEA as “Drill Hole” could any of these be missed?
Process Flow Diagram (PFD)

- Process Flow Diagram is the **foundation**
  - The process must be defined step by step, including interfaces
  - The PFD provides the structure to document what product characteristics and requirements (OUTPUTS) are affected by a given operation and how these characteristics and sources of variation are controlled (INPUTS)
  - PFD is a graphical representation of every possible path a part can take through the anticipated manufacturing process
  - A well defined PFD establishes the foundation for the PFMEA
- Helps in developing equipment specifications.
  - How will the process control non-conforming material?
  - How and when will inspections be performed, what is required?
  - How and when will parts be re-introduced into the process?
Process Flow Diagram (PFD)

● Hidden Factories:
  ▪ Interfacing Processes
    Quality Audits           Product/tooling Changeovers
    Rework Processes         Part Ident./Labeling
    Alternative Processes    Teardown
    Scrap                    Gauging Stations
    Part Buffers             Reject Handling
    Part Movement
  ▪ Interface process issues affect quality performance
    o Rework and scrap parts bypass process controls
    o Mixed parts in the manufacturing process at changeovers

● Need for common systems
  ▪ Part of the overall Quality Strategy must include
    o Common content, common format, common approach
  ▪ Quality strategy must extend to suppliers
    o Considered an extension of the Total Quality processes
## ANNEX H – Process Flow Diagram Example

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<tr>
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<tbody>
<tr>
<td>Manual load, dropped parts</td>
<td>50: Induction Hardening and Heat Treatment</td>
<td>Move from Final Machining</td>
<td>Hardness</td>
<td>Case depth, Microstructure specification</td>
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<td>Missed operation</td>
<td>50: Induction Hardening and Heat Treatment</td>
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<tr>
<td>Machine setup</td>
<td>60: Draw</td>
<td>70</td>
<td>Thread presence, Thread depth</td>
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<td>Calibration of master block</td>
<td>70: Thread Chaser and Inline Check</td>
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<td>Furnace setup</td>
<td>80: Manually Charge and Load as Back-up</td>
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<td>Lack of maintenance</td>
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<td>Manual operation</td>
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<td>Rough handling</td>
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<td>Rough grinder, finish grinder</td>
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<td>Wheel speed, Coolant concentration</td>
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<td>Contamination</td>
<td>110: Wash</td>
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<td>Storage</td>
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</tbody>
</table>

**Symbol Legend:**
- **Oval:** Operation
- **Diamond:** Operation
- **Circle:** Inspect
- **Square:** Measure, Inspection
- **Triangle:** Storage
- **Arrow:** Transport

**Note:** Process flow diagram formats are based on company procedures. Symbol usage and definitions vary.
## Micro Level PFD Example

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
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<tbody>
<tr>
<td>7</td>
<td>Op-Seq</td>
<td>Fab</td>
<td>Move</td>
<td>Store/Get</td>
<td>Inspect</td>
<td>Remwork</td>
<td>Scrap/Contain</td>
<td>Changeover</td>
<td>Operation Description</td>
<td>Class (KPC, QCC)</td>
<td>Significant Product Characteristics (Outputs)</td>
<td>Class (KCC, QCC)</td>
<td>Significant Process Characteristics (Inputs)</td>
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<td>Correct tube</td>
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<td>T Clamp seat tube weld fixture</td>
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<td>T,S Initiate weld sequence / Weld Frame</td>
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<td>Halt and contain if test fails</td>
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<td>Weld penetration</td>
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Process Characteristics

Fishbone Diagram provides thought starters for Process Knowledge

Causes - Process Variation

Material
- Metallurgy
- Chemistry
- Dimensions

Equipment
- Machine
- Material Holding
- Fixture
- Tooling

Manpower

Environment
- Humidity
- Lighting
- Temperature
- Cleanliness

Methods and Systems
- Set-up
- Instructions
- Measurement
- Systems
- Preventive Maintenance
- Ergonomics

Effects on:
- Product
- Next Operation
- Operator
- Assembly Plant
- End User
- Environment
- Gov’t Regs

Causes and Effects of Process Variation
PFD Feeds PFMEA

Identify the Function(s)

• Function is a description of what the Process does to meet the requirements
  ➢ Related to process specification and product characteristics
  ➢ Comes from the PFD operation description column

• Functions can be described as:
  ➢ Do this operation…
  ➢ To this part or material…
  ➢ With this tooling or equipment…
# PFD Feeds PFMEA

## PFMEA Link (Fab)

<table>
<thead>
<tr>
<th>Process Function / Requirements</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Potential Cause(s) / Mechanism(s) of Failure</th>
<th>Current Process Controls</th>
<th>DET</th>
<th>RPN</th>
<th>Recommended Actions</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Actions Taken</th>
<th>S E V</th>
<th>O C C</th>
<th>D E T</th>
<th>R P N</th>
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</thead>
</table>

Product Characteristics (Outputs) Translates into Potential Failure Mode

Process Characteristics (Inputs) Translates into Potential Causes
<table>
<thead>
<tr>
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<td><strong>Opn</strong> 1</td>
<td><strong>Process Function/Requirements</strong></td>
<td><strong>Potential Failure Mode</strong></td>
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<td><strong>Potential Effects of Failure</strong></td>
<td><strong>Potential Cause[s] / Mechanisms of</strong></td>
<td><strong>Occurrence</strong></td>
<td><strong>Current Process</strong></td>
<td><strong>Current Process Controls</strong></td>
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<td><strong>Frame Welding</strong></td>
<td><strong>Position and secure tubes into</strong></td>
<td><strong>assembly fixture</strong></td>
<td><strong>Correct</strong></td>
<td><strong>Dimensions incorrect (8)</strong></td>
<td><strong>Material in supermarket</strong></td>
<td><strong>Material Stocked in cell</strong></td>
<td><strong>Receiving part verification</strong></td>
<td><strong>Second party verification of</strong></td>
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<td><strong>Get seat tube from parts presentation device</strong></td>
<td><strong>Incorrect tubes in presentation device</strong></td>
<td><strong>Frame dimensions incorrect (5)</strong></td>
<td></td>
<td><strong>Parts will not load in fixture (5)</strong></td>
<td><strong>Material Stocked in cell</strong></td>
<td><strong>Receiving part verification</strong></td>
<td><strong>Second party verification of part material stocked in cell</strong></td>
<td><strong>Visual inspection</strong></td>
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<td><strong>Damaged tube</strong></td>
<td><strong>Defective welds from tube damage</strong></td>
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<td><strong>Operator drops parts</strong></td>
<td><strong>Catch net under weld fixture</strong></td>
<td><strong>Visual inspection</strong></td>
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Linkage to PFMEA
PFMEA Example continued..

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<tbody>
<tr>
<td>123</td>
<td>Frame Welding / Initiate Weld Sequence / Correct weld current</td>
<td>Inadequate weld penetration due to current not meeting requirements</td>
<td>Excessive part distortion. (7) Burn-through (8) Scrap. (8)</td>
<td>Current settings incorrect due to inadequate operator instructions</td>
<td>Operator instructions and std cell docs</td>
<td>Operator to set and check current. Visual inspection.</td>
<td>Add closed-loop controls to welder power supply.</td>
</tr>
<tr>
<td>124</td>
<td>Frame Welding / Initiate Weld Sequence / Correct weld current</td>
<td>Inadequate weld penetration due to current too high</td>
<td></td>
<td>Current settings incorrect due to inadequate operator instructions</td>
<td>Operator instructions and std cell docs</td>
<td>Operator to set and check current. Visual inspection.</td>
<td>Add closed-loop controls to welder power supply.</td>
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<td>Frame Welding / Initiate Weld Sequence / Correct weld current</td>
<td>Inadequate weld penetration due to current too high</td>
<td>Excessive part distortion. (7) Burn-through (8) Scrap. (8)</td>
<td>Setting drifts over time.</td>
<td>Operator instructions and std cell docs</td>
<td>Operator to set and check current. Visual inspection.</td>
<td>Add closed-loop controls to welder power supply.</td>
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## Sources and Types of Manufacturing Variation

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>Types of Variation</th>
<th>Typical Process Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator</td>
<td>Operator Skill, Ergonomic Factors</td>
<td>Training, instructions, visual aids, feedback layout, motion analysis, human factors</td>
</tr>
<tr>
<td>Component / Material</td>
<td>Incoming raw material, purchased parts, previous operations</td>
<td>Supplier management, internal controls, error proofing</td>
</tr>
<tr>
<td>Equipment / Machine</td>
<td>Machine capability, adjustment, wear over time</td>
<td>Equipment specifications, closed-loop machine controls, preventive maintenance</td>
</tr>
<tr>
<td>Environment</td>
<td>Temperature, humidity, dust, noise</td>
<td>Climate control, air filtration, clean room, sound insulation</td>
</tr>
<tr>
<td>Methods &amp; Systems</td>
<td>Sequence, procedure, layout</td>
<td>Industrial Engineering techniques, Lean Flow analysis</td>
</tr>
<tr>
<td>Set Up (for stable processes)</td>
<td>Initial set up or adjustment</td>
<td>Process specification, first / last piece check, automated controls</td>
</tr>
<tr>
<td>Tool</td>
<td>Wear over time, breakage, tool-to-tool differences</td>
<td>Predictive maintenance, detection error-proofing, tooling specifications</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Repair, replacement, reassembly, adjustment</td>
<td>Instructions, error-proofing, machine qualification, production trial run</td>
</tr>
<tr>
<td>Fixture / Pallet</td>
<td>Position tolerance, adjustment, wear over time</td>
<td>Predictive maintenance, prevention and detection error-proofing</td>
</tr>
</tbody>
</table>
Process Control Plan

- PCP will be based on the previous activities in PFD and PFMEA.

- Review the PFMEA information developed & supplied and use to identify:
  - Specific controls that may be needed due to the information added
  - Identify which controls are Product or Process
    - Note any Special Characteristics
    - Identify evaluation methods, frequency and Control Methods
    - Note Reaction Plans (particularly related to NC parts)
### Process Control Plan Example

#### Welding Process Control Plan Example

<table>
<thead>
<tr>
<th>Part/Process Number</th>
<th>Process Name / Operation Description</th>
<th>Characteristics</th>
<th>Special Characterization</th>
<th>Product / Process Specification / Tolerance</th>
<th>Evaluation Measurement Technique</th>
<th>Sample</th>
<th>Frequency</th>
<th>Control Method</th>
<th>Reaction Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>Initiate weld sequence / Perform TIG weld of frame parts.</td>
<td>Weld beads per design specification.</td>
<td>Tube welds meet pull test with failure in parent material.</td>
<td>Pull test using test fixture 20-1.</td>
<td>1 pc.</td>
<td>Per shift.</td>
<td>Hydraulic pull test instruction T121-01 Process monitoring form PMF-20-01</td>
<td>Quarantine material since last good pull test.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Weld voltage</td>
<td>24 Volts AC +/- 2.0 volts</td>
<td>Machine Control</td>
<td>100%</td>
<td>Each weld cycle.</td>
<td>Closed-loop machine control.</td>
<td>Scrap part &amp; Re-start welder.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inert gas flow rate</td>
<td>5 cubic feet / min. +/- 0.5 cfm</td>
<td>Visual</td>
<td>twice</td>
<td>Per shift.</td>
<td>Operator cleans gas cup twice per shift PM-WI-20, Process monitoring form PMF-20-01</td>
<td>Scrap current part. Shut down. Notify maintenance.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inert gas flow rate</td>
<td>5 cubic feet / min. +/- 0.5 cfm</td>
<td>Visual of verification of Flow Meter</td>
<td>Once each</td>
<td>Shift start or change-over or maint. event</td>
<td>Set-up OWI #20-02 &amp; Form PMF-20-02 Periodic maintenance per PM-WI #20.</td>
<td>Notify maintenance.</td>
<td></td>
</tr>
</tbody>
</table>

---

**Form 818-1 (Rev 12Apr02)**

- **Prototype**
- **Pre-Launch**
- **Production**

**CONTROL PLAN**

<table>
<thead>
<tr>
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<tr>
<td></td>
<td></td>
<td>Inert gas flow rate</td>
<td>5 cubic feet / min. +/- 0.5 cfm</td>
<td>Visual</td>
<td>twice</td>
<td>Per shift.</td>
<td>Operator cleans gas cup twice per shift PM-WI-20, Process monitoring form PMF-20-01</td>
<td>Scrap current part. Shut down. Notify maintenance.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inert gas flow rate</td>
<td>5 cubic feet / min. +/- 0.5 cfm</td>
<td>Visual of verification of Flow Meter</td>
<td>Once each</td>
<td>Shift start or change-over or maint. event</td>
<td>Set-up OWI #20-02 &amp; Form PMF-20-02 Equipment Calibration Procedure #368</td>
<td>Quarantine material since last good pull test. Notify maintenance.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Process Control Plan Example

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>Initiate weld sequence / Close and latch curtain</td>
<td>Robotic Arm TIG welders</td>
<td>Weld beads per design specification.</td>
<td>yes</td>
<td>Weld appearance meets visual standard.</td>
<td>Pull test using test fixture 20-1.</td>
<td>1 pc.</td>
<td>Per shift.</td>
</tr>
<tr>
<td></td>
<td>Initiate weld sequence / Confirm Weld voltage</td>
<td>Robotic Arm TIG welders and controllers.</td>
<td>Weld voltage</td>
<td>yes</td>
<td>24 Volts AC +/- 2.0 volts</td>
<td>Machine Control</td>
<td>100%</td>
<td>Each weld cycle.</td>
</tr>
<tr>
<td></td>
<td>Initiate weld sequence / Confirm Inert Gas flow rate</td>
<td>Robotic Arm TIG welders and controllers.</td>
<td>Inert gas flow rate</td>
<td>yes</td>
<td>5 cubic feet / min. +/- 0.5 cfm</td>
<td>Visual</td>
<td>twice</td>
<td>Per shift.</td>
</tr>
<tr>
<td></td>
<td>Initiate weld sequence / Confirm Wire feed rate</td>
<td>Robotic Arm TIG welders and controllers.</td>
<td>Weld wire feed rate</td>
<td>yes</td>
<td>300 mm / minute +/- 10 mm / min.</td>
<td>Machine Control</td>
<td>100%</td>
<td>Each weld cycle.</td>
</tr>
</tbody>
</table>

### Frequency
- Each piece
- Once each shift
- Each weld cycle
- Once each
- Per shift
- Per shift
- Per shift
- Per shift
- Per shift
- Per shift
- Per shift

### Special Characteristics
- Class
- Specification
- Tolerance
- Product
- Process
- Operation Description
- Part
Case Studies – Supplier A

- Not ISO Certified, Primarily Defense business base
- Sole Source - Unique Technology
- No Process Flow
  - Operator work instruction for 100 piece component
    - 20 process steps on a single piece of paper (included machining)
    - Building the component relied on Tribal Knowledge
- Diagramming the Process Flow
  - 20 steps turned into 951 steps to produce the component
  - 22 manufacturing related issues (from DFMEA) were incorporated in the PFD/PFMEA
- Supplier A used PFD - FMEA to
  - Develop work instructions
  - Determine the requirement to developed training programs for assemblers / machinists, QC personnel
  - Develop safety program / training
Case Studies – Supplier B

- ISO Certified, Primarily Defense business base
- Sole Source - Unique Design
- “Fair” Documented Process Flow
  - Relied on a combination of operator knowing what should be done next with operator work instructions.
    - However it did allow for repeatable assembly of component with skilled employee
- Diagramming the Process Flow
  - 270 step PFD became 1,170 steps
    - FMEA analysis determined: work instructions that needed improvement and new work instructions were required
- Supplier B used PFD- FMEA to
  - Update work instructions to error proof build process
Case Studies – Supplier C

- ISO Certified, Defense/Civil business base
- Well Documented Process Flow
  - Operator work instructions allowed for repeatable assembly
  - Error Proofing allows for assembly with “average” employees
- Diagramming the Process Flow
  - 263 step PFD became 268 steps
  - 32 manufacturing related issues (from DFMEA) were incorporated in the PFD/PFMEA
    - FMEA analysis determined: work instructions that needed improvement and new work instructions were required
- Supplier C used PFD- FMEA to
  - Update work instructions
Case Studies – Supplier D

- ISO Certified, Aerospace business base
- Very Small Company
  - 2 Master Assemblers (1 of which was the Assembly & Test Manager)
- Unique Technology
- “Fair” Documented Process Flow
  - Relied on a combination of operator knowing what should be done next with broad operator work instructions.
    - However it did allow for repeatable assembly of component with highly skilled employee
- Diagramming the Process Flow
  - 5 page PFD became 22 pages
  - FMEA analysis determined: work instructions needed improvement to allow for production of more than 1 component at a time
- Supplier D used PFD - FMEA to
  - Develop work instructions with boundary photos
  - Recall non-compliant parts
  - Determine the requirement to developed training programs for assemblers, QC personnel
  - Develop detailed ATP
Recapping

Process Flow Diagram
“*What does the process do?*

PFMEA
“*What could go wrong?*”
“*Could we prevent or detect?*”

Control Plan
“*What needs to be controlled/monitored?*”
“*How do we react to problems?*”

Operator Instructions & Monitoring
“*What am I supposed to do?*”
“*How am I supposed to do it?*”
“*Where am I supposed to record it?*”
References

- AIAG FMEA Fourth Edition June 2008
- SAE J1739 March 2009
Vocabulary

- AIAG FMEA Fourth Edition Published June 2008
- SAE FMEA J1739 Published March 2009
- PFD, Process Flow Diagram
- PFMEA, Process Failure Modes and Effects Analysis
- PCP, Process Control Plan