Land & Joint Systems. Thales Australia Mulwala, NSW, Australia

Process Failure Mode and Effects Analysis Workshop

Michael W McLean (FAICD)
michael@mclean-mc.com.au
0419 225 996

Australian Industry Group and © McLean Management Consultants Pty Ltd
MMC Pty Ltd National Entity, Defence, International and Quality Experience

**State Governments and entities:**
- Newcastle City Council, Port Authority & BHP Site development
- NSW Attorney-Generals Dept - Births, Deaths and Marriages
- NSW Fire Services/Rural FB – Planning (“9/11”, 2001 Response)
- NSW Department of IR and T – Long Service Leave Corporation
- NSW DSRD – NSW Manufacturing Council research into status and future of sector
- NSW Mine Subsidence Board and Mines Department
- NSW Police Service - Ministerial Police Emergency Response
- NSW State Rail and City Rail
- QLD Health – Scientific Services
- Sydney Water – Cryptosporidium Outbreak and Supplier QA

**Defence:**
- The Australian Army – ‘AIM’ TQM Strategy
- Australian Defence Industries – Bendigo and Lithgow & Thales Malwala
- Department of Defence – ACT and WA
- Plessey and Exicom Military Telecommunications
- RAAF – ‘RAAFQ’ Air and Logistics Commands for all Bases
- RAN – ‘NQM’ all Establishments, Chief of Navy Strategy
- RAN – DMO – Maritime Systems Division, CQA

**Australian National public & private entities:**
- Aboriginal Hostels Limited
- ACS – VIC, NSW and ACT
- ASIC – Corporate Services Planning
- ATO Legislative Services Group ACT
- AusIndustry – Networking Services
- Australian Police Staff College – UNSW, USA FBI, NZ & Hong Kong
- Enterprise Connect TAS Accredited Consultant for Change Programs

**International:**
- American University Cairo, Egypt – Six Sigma Champions
- Arabian Cement Company – Strategic Objectives and Values to design 4 growth strategies
- ASEAN Secretariat Indonesia, 10 Member Nations and AusAID Supplier Capability Improvement Program
- ASEAN Automotive Federations and Government Representatives, OEMs, Tiered Suppliers and Quality Certification Bodies planning for 2015 ASEAN Integration
- ASEAN SME Working Group, Singapore and 10 Government Member Nation Automotive and other Manufacturing/Value Adding Sector Planning Workshop
- Asian Productivity Organisation business planning process
- Civil Aviation Authority Singapore - Changi Airport and – Visioning and Business Planning process to be #1 Airport
- Fiji Housing Authority – Organisation Review & Structuring
- Qatar Transport Company [www.mowasalat.com](http://www.mowasalat.com), Taxi, Limousine, Buses and Coach Procurement, Asia Olympics and ERP Systems
- Superintending Company of Indonesia – Sucofindo
- Surveyor Indonesia – Consulting, Supplier QA/QE Services
- Thammasat Uni/Thailand Government ‘Creative economy”

**Supplier Quality Assurance and Engineering:**
- Australian Meat Corporation – national TQM and SQA
- BHP Billiton: Steelmaking, Coal Mining, Grooyte Eylandt Mining Coy, Ok Tedi Mining Coy
- GM Holden – Design and implementation of ISO 9001 QMS for Corporate, Vehicle Design, Assembly and Engine Manufacture; Supplier QA/QE
- GM Holden Engine Operations - indirect and lean production improvements; Foundry, Human Resources, L&D HRIS / ERP BPR; Quality and Materials
- QANTAS – Property and Jet Base Risk and Supply Review
Michael W McLean

1. Specialises in strategic and business planning development and deployment through process owners to operations to deliver performance to plan and stakeholder satisfaction
2. Multiple stakeholder facilitation skills at Board, Executive and Management levels
3. His clients seek business improvement strategies and performance management systems that stabilise and improve capabilities for sustainable changes in and business and operational performance.
4. His management background was International Telephone and Telegraph/STC (Australia, USA and Belgium), Clothing Apparel, Aluminium Rolled and Extruded Products, Automotive Parts Manufacturing
5. Country experience: Australia, Belgium, Canada, Egypt, Fiji, Indonesia, Japan, Kingdom of Saudi Arabia, Malaysia, NZ, Philippines, Papua New Guinea, Singapore, Scotland, Thailand, UAE, UK, USA, Vietnam
6. Australian and International author, keynote speaker “RichesfromWaste” Executive Coaching & DVDs
8. AOQ NSW Silver Anniversary Award for Quality 1993 and AOQ Juran Medallist 2008 for contributions to Australian quality
9. Over 25 years consulting experience:
   I. Strategic Planning and Business deployment through the “Plan-on-a-Page”
   II. Deployment Action Planning through Organisation Structuring and Process Job Design
   III. Cross-functional and Self-Managing Productivity and Service Improvement Systems and Teams
   IV. Business Transformation and Structural Cost Reduction
   V. Productivity (Lean), TQM (Six Sigma), TQM and Operational Excellence Program and Projects: American University Cairo; QCMC Kula Lumpur; Etislat Abu Dhabi; Westpac Bank; CBA Bank; BNI Indonesia; Jamieson Mining Consultant, Pasminco Metals Sulphide, Comalco, C & A; Boral; CSR; Shell / Anglo Coal
10. Achievements: Manager STC/ITT 41% indirect productivity gain; Bell Telephone Belgium 35% productivity initiative; GM Holden 35% productivity, 750 to 1500 engines per day. 95% Right First Time Quality; Boral 414% Incremental and 17% ROI improvements; Changi Airport Singapore and CK Tangs #1 Customer Service; Standard Life Scotland and Suncorp (Achieved Cost Reductions)
11. Co-Author of 2 “Continual Improvement Problem Guide and Tools” Books (S. Sadek) & “Q-Skills” (Dr A Burns)
12. Academic qualifications and professional fellowships include:
   • Fellow Australian Institute of Company Directors; Fellow Australian Organisation for Quality; Professional Doctorate candidate QUT 2008 commenced
   • Bachelor of Business (Major Business Administration; sub-major Organisation and Management ) UTS
   • Advanced Diploma of Management (Australian National Competencies reference: BSB60407; Certified Management Consultant (Institute of Management Consultants Australia)
   • Certificates in Production Engineering (Tool Design - Metal and Plastic); Fitter & Turner; Engineering Estimating and Cost Control Sales Engineering (SIT)
   • Certificate IV Training and Assessment
   • Academic Peer Reviewed Papers at and in AUSIMM, QMOT, UJORM, QMOD, IEEE Thailand and Hong Kong Industrial Engineering journals
   • 525 papers, workshops, seminars - Australia (& QLD), Canada, Fiji, Indonesia, KSA, Malaysia, NZ, Philippines, Qatar, Scotland, Singapore, UAE, UK, USA, Vietnam
Objectives and who should attend this PFMEA one-day session

Objectives

The seminar is designed to improve your ability to:

- Analyse your processes and the in-built risks to customers
- Identify likely failures in your key process centric processes
- Better identify potential causes of failures before they happen
- Select controls to minimise risks and likelihood of occurring
- Prioritise cause reduction and risk minimisation actions

Who Should Attend

- Process owners who need to manage and improve their processes
- Those involved in reviewing or designing products and processes
- Quality and/or process managers and engineers, manufacturing, development, project management and safety personnel
One Day Program Outline

1. Establishing Process Objectives
2. Understanding Process Constraints
4. Activity Analysis
5. Cause and Effect Analysis
6. The types of FMEA’s (Design and Process)
7. The components of an FMEA
8. Documenting the FMEA
9. Establishing effective Control
10. Setting the Process Risk reduction actions
11. Developing Action Plans
12. Changes to current practices and system to sustain PFMEA learning’s
### Agenda - overview

- Introductions, Learning Outcomes and Activities
- What is the Output of a PFMEA
- Common errors and pitfalls
- Getting the best out of the cross-functional team
- Defining a 'Function'
- What are 'Failure Modes'
- Defining 'Effects, Causes and Controls'
- A PFMEA Check List within a QMS and Risk Reduction through Poka Yokes
Thales commitment and Three Strategic Pillars

“Our commitment is to leverage the very best of our expertise and our technologies to serve our customers around the world.”

Luc Vigneron,
Chairman & Chief Executive Officer, Thales

Everyone's involvement Presence all along the value chain
• From equipment and systems, to systems integration
• Prime contracting and services

Dual technologies
• Balanced portfolio between defence and civil businesses
• Optimised synergies

Multi-domestic presence
• Long-term customer partnership
• Maximised local commercial opportunities
• Access to local skills and resources
• Meeting national security requirements
**Thales three market driven core processes**

Three market-driven core businesses

- **Aerospace & Space**
  - Aerospace
  - Space

- **Defence**
  - Air Systems
  - Land & Joint Systems
  - Naval

- **Security**
  - Security Solutions & Services

**A coherent organisation**

Bringing customers the benefit of technology expertise and international presence

THALES
A Process Map of critical supplier to hospitals and labs

**Sales and Marketing**
- Strategic Marketing
- Product Development
- Marketing (Tactical)
- Sales Team

**Operations**
- Receipt Customer Order [SAP]
- Process Production Order
- Manufacture Product
- Check Specification (Laboratory)
- Release Product

**Business Support**
- Distribution
- Supplier Management
- Engineering and Facilities
- Finance

**System Support**
- Information Management and SAP
'Product Realisation' Process

- The sequence of processes and sub-processes that you carry out in order to provide your product or service.

5.1.1 Process efficiency.

"Top management shall review the product realization processes and the support processes to assure their efficiency and effectiveness."
An OEM Process Structured TS16949/TS2 QMS

Is your QMS by the process-approach?
**TS16949 [2002] TS2**: “Determine processes, sequence and interaction, criteria and methods to ensure operation and control of processes.”

<table>
<thead>
<tr>
<th>A Process Based QMS relationship matrix to show relationship to the TS2 and other Management System requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TS2</strong></td>
</tr>
<tr>
<td>Business Process Description</td>
</tr>
<tr>
<td>2. Design &amp; Engineer Product</td>
</tr>
<tr>
<td>8. Plan, provide &amp; maintain People</td>
</tr>
<tr>
<td>14. Review and improve performance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>A Clausal Based QMS relationship matrix to show relationship to the TS2 and other Management System requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TS2</strong></td>
</tr>
<tr>
<td>TS2 Description</td>
</tr>
<tr>
<td>7.1 Planning of Product Realization</td>
</tr>
<tr>
<td>8.1 Measurement, analysis and improvement</td>
</tr>
<tr>
<td>8.3 Control of non-conforming product</td>
</tr>
</tbody>
</table>

The 3rd Party Bodies certify the Element based systems as it meets the various Standards requirements but NOT the Needs of the Business.
Thales Product/System designed or assembled or serviced process
## Thales Process FMEA Extract

### Design Failure Mode and Effects Analysis

<table>
<thead>
<tr>
<th>Item</th>
<th>Design Function</th>
<th>Verb and Noun from Spec</th>
<th>Potential Failure Mode (Internal or External)</th>
<th>Potential Cause(s) of Failure on Internal or External Customer</th>
<th>Occurrence</th>
<th>Detection</th>
<th>RPN</th>
<th>Recommended Actions to Reduce Risk</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Actions Taken</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>1</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

### Process Failure Mode and Effects Analysis

<table>
<thead>
<tr>
<th>Process Flow</th>
<th>Process Function</th>
<th>Verb and Noun from PCP, SOP</th>
<th>Activity Failure Mode (Internal or External)</th>
<th>Potential Effect(s) of Failure on Internal or External Customer</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>RPN</th>
<th>Recommended Actions to Reduce Risk</th>
<th>Responsibility &amp; Completion Date</th>
<th>Actions Taken</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal</td>
<td>Check for compressor requirements</td>
<td>Absent</td>
<td>Line stoppage</td>
<td>Parts not available</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>25</td>
<td>Reactive Action</td>
<td>Proactive or Reactive or Proactive</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
### Process Control Plan

#### Powder Section

**211B/06 Propellant Colloid - Pressure of Extrusion**

<table>
<thead>
<tr>
<th>Item controlled</th>
<th>Pressures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specification</td>
<td>Operating instruction</td>
</tr>
<tr>
<td>Frequency</td>
<td>Each extrusion</td>
</tr>
<tr>
<td>Records</td>
<td>Form 238</td>
</tr>
<tr>
<td>By</td>
<td>Press operator</td>
</tr>
<tr>
<td>Tested for</td>
<td>Recording of pressures during extrusion</td>
</tr>
<tr>
<td>Test method</td>
<td>Pressure indicators</td>
</tr>
<tr>
<td>Decisions</td>
<td>Report any excessively low or high pressures to higher authority for corrective action.</td>
</tr>
<tr>
<td>Equipment</td>
<td>Pressure gauges 0-3000 psi minimum range with 50 psi graduations or metric equivalent.</td>
</tr>
<tr>
<td>Comment</td>
<td></td>
</tr>
<tr>
<td>Calibration Numbers</td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>E001 applies</td>
</tr>
<tr>
<td>Issue 1</td>
<td>DCA -</td>
</tr>
<tr>
<td>Date</td>
<td>24/10/88</td>
</tr>
</tbody>
</table>
Supplier Quality Assurance (SQA) Plan includes PFMEA

The Quality Assurance Plan is listed on the following pages. Minimum elements of the overall plan that a supplier must always submit are:

- Feasibility Study
- Contract Review Including Quotation
- Process FMEA
- Process Control Plan with Process Flowchart
- Measurement Equipment R&R
- Preliminary Process Capability Study
- Process Capability Study
- Material Handling Plan
- Reliability Test Validation (if applicable)
- Regulatory Approval (if applicable)
- Initial Sample with Approval
- Quality Assurance Plan (Overall)
Preventing problems coming through to Nylex FTS, Edinburgh

Design FMEA

- A Design FMEA mainly applies only when the supplier is the design owner.

- The risk must be quantified and classified and high risk prevented where after the failure risks are updated.

Process FMEA

- A process FMEA is an analysis of potential failure risks in the manufacturing process of the product.

- The whole process shall be analyzed by means of FMEA techniques, to detect potential failure risks and weaknesses in the process.

- The risks must be quantified and classified so that adequate controls and safeguards are in place to prevent failure.
Preventing problems coming through to Thales

Control Plan (Process)

- The necessary inspection and test operations shall be defined, based on the FMEA analysis and process capability indications that show a necessity for process control and monitoring. The plan should include the following:
  - 1. Process identification
  - 2. Control characteristic
  - 3. Gauging data
  - 4. Method of control
  - 5. Frequency of inspection
  - 6. Reaction plan to non-conformances
  - 7. A Flow Chart of these activities is mandatory.
  - 8. Tooling Programme

- A time schedule for the order, delivery and qualification of production tools and other equipment shall be created.

- This schedule shall include the time to make the necessary adjustments and prove process capability prior to producing approved initial samples.

  (NB. Capability of equipment should be to a higher capability index than the parts that it has to produce.)
Preventing problems coming through to Thales

Measurement / Test Equipment

- Activities to ensure the adequacy of proper measurement and gauging will be defined, documented and quantified and must be part of a comprehensive calibration and recall system.

Repeatability and Reproducibility (R&R)

- These determine the extent of the measuring error which the combination of equipment and operator create when working in unison. The following percentages define the targets for R&R:
  - <20% gauge R&R is acceptable
  - >21 - 30% < gauge R&R requires approval
  - >31% gauge R&R is unacceptable

Work Instructions

- If a work instruction is deemed necessary to ensure the product quality, it shall be produced for each such work operation.

- Inspection instructions are a specific form of work instructions.
Preventing problems coming through to Thales

Capability Studies (Ppk and Cpk)

- Potential Process Capability Ppk Studies shall be performed on all critical process characteristics. The target is to achieve a minimum potential process capability of 2.0 Ppk.

- The capability study shall be determined only when all external causes of variation have been removed. (i.e. operators, equipment, materials) and environmental effects are consistent. The study must be performed using normal production and tooling equipment. Equal representation from all cavities or tools must be part of the study and the sample size must be a statistically valid representation of the process output (50 cycles minimum). Adherence to these requirements shall assure long term process capabilities meet the requirements with normal process monitoring.

- Ongoing process capability studies shall be performed on all critical process characteristics, aiming to exceed a minimum process capability performance of 1.67 Cpk. The process capability shall be determined over an extended period of time and under normal operating conditions. (i.e. different - operators, material batches, equipment, environmental conditions and work shifts). Standard data collection and statistical tools (i.e., variable and attribute control charting) should be utilised. Again, 50 results would be expected in the study.
Preventing problems coming through to Thales

Statistical Process Control

- All the critical process parameters should be monitored on an ongoing basis, using Statistical Process Control (SPC) and the process controlled accordingly. Where the process is fully understood, it is better to control specific process parameters, rather than the individual part parameters.

'Preventive' Maintenance

- Systematical preventive maintenance shall be introduced, to ensure a continuous process availability and capability.

- This preventive maintenance shall be based on the follow-up or documented experience of the process or process ongoing capability monitoring, downtime and spares requirement.
Introduction to the improvement process
PDSA – overview of the 7 steps

Step 1 – Selecting a problem
Step 2 – Evaluate the present situation
  (collect and analyze data)
Step 3 – Analyze causes
Step 4 – Develop solution
Step 5 – Implement solutions
Step 6 – Evaluate results
Step 7 – Standardize to make results permanent
Overall PFMEA Process

1. Define project
2. Define functions
3. Define Failure Modes
4. Define effects, causes and controls
5. Organise data
6. Assign SOD
7. Identify Priorities
8. Pass actions to those responsible
9. Follow up actions
10. Feed back into SOD
11. Continue On
PFMEA approach - based upon AIAG FMEA publication ed.4
Potential FMEA - (AIAG publication ed.4 changes)

- Reinforces the need for:
  - management **support**
  - management **interest**
  - management **review** of the FMEA process and results

- Defines and strengthens the understanding of the linkage between DFMEA and PFMEA as well as defining the linkages to other tools;

- Improvements to the ranking tables for:
  - Severity
  - Occurrence (to be more meaningful to real world analysis and usage)
  - Detection

- The suggestion the RPN **not** be used as the primary means for assessing risk;

- Clarification that the use of RPN thresholds is **not** recommended.
Overview of FMEA - Strategy, Planning and Implementation

Ten steps and management involvement

- Identify the Team
- Define the Scope
- Define the Customer
- Identify Functions, Requirements, and Specifications
- Identify Potential Failure Modes
- Identify Potential Effects
- Identify Potential Causes
- Identify Controls
- Identify and Assess Risk
- Recommend Actions and Results
- Management Responsibility

Source: AIAG FMEA publication ed.4
The FMEA cross-functional team and their involvement

In addition to the design / process engineers, cross-functional FMEA team members should have relevant experience and the necessary authority.

<table>
<thead>
<tr>
<th>FMEA Development Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer Program Management Integration responsible individual(s)</td>
</tr>
<tr>
<td>Service Operations Manufacturing and Assembly Logistics Materials Quality Reliability Engineering Analysis Statistical Analysis Equipment Manufacturer Maintenance</td>
</tr>
</tbody>
</table>

### Scope
- X x x

### Functions requirements and expectations
- X x x x x x x x x

### Potential failure mode
- X x x x x x x x x x
  - [the way a process or product might fail]

### Effects and consequences of the failure
- X x x x x x x x x x
  - [to both the organization’s processes or to a downstream customer]

### Causes of the potential failure
- X x x x x x x x x x

### Freq. of occurrence of potential failure
- X x x x x x x x x x x x

### Application of current controls-prevention
- X x x x x x

### Application of current controls-detection
- X x x x

### Recommended actions required
- X x x x x x x x x x x x
What is the Output of a PFMEA

A Well Designed Manufacturing Process
Systematic reduction of risk
Shared understanding between key parties
The PFMEA must have a clear impact on:

- PM schedules
- Operator instructions and competency standards
- Support system performance/assurance, eg coolant system, SQA Process
- Tool/machine design (need to do PFMEA early enough)
- Supervision requirements
- Inspection and testing (via the PCP)
Thales Flow Process Chart (template)
USA Riverside Medical Labs “Lean” see theirs and hospital pressures similar to an Auto Supplier
Last Millennium people called this Housekeeping, clearly it’s “5S” – True?
Figure IV.2 Example Process Flow Diagram

Source: AIAG FMEA publication ed.4
4th Edition Automotive Industry Action Group
FMEA USA & Boeing

• “Determining where key characteristics will be measured
• Identifying potential sources of variation
• Describing how a process works”. Boeing 1999

<table>
<thead>
<tr>
<th>PRINCIPLES, SYSTEMS, TOOLS – Assessment Scale</th>
<th>MODEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organizations which fully match the descriptors would score at 100%</td>
<td></td>
</tr>
<tr>
<td>• clear and ingrained understanding and implementation of the value stream, and the support processes, widespread involvement and empowerment of company key objectives, tenacious strategic focus on high-value-add projects, and a major, fully completed waste prevention and improvement project examples.</td>
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<tr>
<td>80%</td>
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<td>79%</td>
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<td>60%</td>
<td></td>
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<td>40%</td>
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<tr>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>39%</td>
<td></td>
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<tr>
<td>• many good Lean systems, which capitalize on recognition of strategic priorities, tying lean tools and practices to the business processes, frequent use of appropriate human and technical resources, effective implementation of effective systems and processes, and resolution of problems, but occasional problems in getting the right things done.</td>
<td></td>
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<tr>
<td>80%</td>
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<td>79%</td>
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<tr>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>39%</td>
<td></td>
</tr>
<tr>
<td>• existence of some strategic ideas but rarely implemented, a few good applications of appropriate Lean tools, permits for some use of human and technical resources, cooperation and action.</td>
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<td>80%</td>
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<td>20%</td>
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<tr>
<td>39%</td>
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</tr>
<tr>
<td>• no evidence of strategic focus; reactive on minor, incomplete, limited-value applications of Lean tools, and no evidence of use of human and technical resources.</td>
<td></td>
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<td>80%</td>
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<td>39%</td>
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</table>
The APQC has Process Frameworks for many industries (NB: IBM supported)

www.apqc.org
Mr Tooka: Senior MD Toyota Automatic Loom Company and Dr Kusaba JUSE (1968):

“In some US Supplier Companies, top management continues to believe they can improve quality by solving problems – this is truly a critical situation and a terminal illness in some companies – a ‘reactionary approach’. Quality will not improve in companies that follow the defect correction idea. Japanese managers audit the process not the product”.

(‘Company-wide Quality Control for Automotive Suppliers’. LP Sullivan Ford Dearborn. Mi. USA. June 1968)
# Flow Process Chart checklist

<table>
<thead>
<tr>
<th>5. FLOW PROCESS CHARTS (See American Society of Mechanical Engineers)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EVIDENCE / DOCUMENTATION REQUIRED</strong></td>
</tr>
<tr>
<td>5.00 Is a Flow Process Chart available?</td>
</tr>
<tr>
<td>5.01 Does process flow documentation include all process Operations?</td>
</tr>
<tr>
<td>- Does the Flow Process Chart include receiving?</td>
</tr>
<tr>
<td>- Does the Flow Process Chart include rework?</td>
</tr>
<tr>
<td>- Does the Flow Process Chart include scrap?</td>
</tr>
<tr>
<td>- Does the Flow Process Chart include gauging/inspection?</td>
</tr>
<tr>
<td>- Does the Flow Process Chart include shipping?</td>
</tr>
<tr>
<td>- Does the Flow Process Chart include labelling and Part ID at receiving, WHIP, finished good and shipping areas?</td>
</tr>
<tr>
<td>5.02 Are all Operations affecting the customers (AMAs) special characteristics identified?</td>
</tr>
<tr>
<td>5.03 Does it include non-value adding activities of transportation / move, inspection / check; delay / wait; storage / file?</td>
</tr>
<tr>
<td>5.04 Has rework / scrap / returned goods disposition been addressed? Not define on process flow chart, but define on Non-conforming report flow chart.</td>
</tr>
<tr>
<td>5.05 Has the Flow Process Chart show Distances traveled, unit times or cycle times, transport time, inspection or checking time, delay time, storage time</td>
</tr>
<tr>
<td>5.06 Has the Flow Process Chart been used to provide direct inputs for the “Function” to the Process Failure Modes and Effects Analysis</td>
</tr>
</tbody>
</table>
# Types of Failure Modes and Effects Analysis

## FMEA Types

<table>
<thead>
<tr>
<th>SYSTEM FMEA</th>
<th>DESIGN FMEA</th>
<th>PROCESS FMEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>A SYSTEM is a set of parts or subsystems that are interdependent and organized coherently to accomplish one or more functions.</td>
<td>A PART is a unit of physical hardware that is considered a single replaceable piece with respect to repair.</td>
<td>A PROCESS is a sequence of tasks or steps that are organized to produce an individual part or a specific component.</td>
</tr>
<tr>
<td>Systems are made up of subsystems or parts. Parts are basic building blocks of a subsystem. A system is composed of several subsystems that work together for common function.</td>
<td>Parts are made up of various components. Components are produced by manufacturing processes from raw materials and are not individually serviceable. A given part to have only one component.</td>
<td>A manufacturing process transforms inputs such as raw or semi-finished materials into components. A process may also include assembly of components into a part, or parts into a system, or may be part of a service activity.</td>
</tr>
</tbody>
</table>
The focus of Most lean programs

- Takt time planning
- Continuous flow
- Pull system
- Quick changeover
- Integrated logistics

Dr Jeffrey Liker “The Toyota Way”
Dr Jeffrey Liker “The Toyota Way”

“4 P” Model of the Toyota Way

- **Problem Solving** (Continuous Improvement and Learning)
  - Continual organizational learning through Kaizen
  - Go see for yourself to thoroughly understand the situation (Genchi Gembutsu)
  - Make decisions slowly by consensus, thoroughly considering all options, implement rapidly (Nemawashi)

- **People and Partners** (Respect, Challenge and Grow Them)
  - Grow leaders who live the philosophy
  - Respect, develop and challenge your people and teams
  - Respect, challenge, and help your suppliers

- **Process** (Eliminate Waste)
  - Create process “flow” to surface problems
  - Level out the workload (Heijunka)
  - Stop when there is a quality problem (Jidoka)
  - Use pull systems to avoid overproduction
  - Standardize tasks for continuous improvement
  - Use visual control so no problems are hidden
  - Use only reliable, thoroughly tested technology
  - Base management decisions on a long-term philosophy, even at the expense of short-term financial goals

- **Philosophy** (Long-term Thinking)

Toyota’s Terms

Kaizen

Challenge

Respect-Teamwork

Michigan Engineering

OPTIPRIZE

© Copyright Jeffrey Liker
Toyota’s “3P” – Production Preparation Process. Source: Technology Perspectives & ETI Group USA
Boeing’s final Lean Flow – they implemented a range of quality and productivity initiatives in previous years to get to this successful Lean implementation.
Defining FMEAs courtesy of Automotive Standard

- An FMEA can be described as a systematic group of activities intended to:
  
  (a) recognize and evaluate the potential failure of a product/process and the effects of that failure,
  
  (b) identify actions that could eliminate or reduce the chance of the potential failure occurring, and
  
  (c) document the entire process.

- It is complementary to the process of defining what a design or process must do to satisfy the customer.

- All FMEAs focus on the design, whether it be of the product, or process.
Engineers responsibility in FMEAs

- The responsible engineer has several means of assuring that recommended actions are implemented.
- They include, but are not limited to the following:
  - a. Reviewing designs, processes, and drawings, to ensure that recommended actions have been implemented,
  - b. Confirming the incorporation of changes to design/assembly/manufacturing documentation, and,
  - c. Reviewing Design/Process FMEAs, special FMEA applications, and Control Plans.
Design FMEA purpose

- A Design Potential FMEA is an analytical technique used primarily by a Design-Responsible Engineer/Team as a means to ensure that, to the extent possible, potential failure modes and their associated causes/mechanisms have been considered and addressed.
- End items, along with every related system, subsystem, and component, should be evaluated. In its most rigorous form, an FMEA is a summary of the team’s thoughts (including an analysis of items that could go wrong based on experience) as a component, subsystem, or system is designed.
- This systematic approach parallels, formalizes, and documents the mental disciplines that an engineer normally goes through in any design process.
Design FMEA supports identifying risks in Design

The Design Potential FMEA supports the design process in reducing the risk of failures (including unintended outcomes) by:

– Aiding in the objective evaluation of the design, including functional requirements and design alternatives,
– Evaluating the initial design for manufacturing, assembly, service, and recycling requirements,
– Increasing the probability that potential failure modes and their effects on system and vehicle operation have been considered in the design/development process,
– Providing additional information to aid in the planning of thorough and efficient design, development, and validation programs,
Design FMEA supports identifying risks in Design

- Developing a ranked list of potential failure modes according to their effect on the “customer,” thus establishing a priority system for design improvements, development, and validation testing/analysis,
- Providing an open issue format for recommending and tracking risk-reducing actions, and,
- Providing future reference, (e.g. lessons learned), to aid in analyzing field concerns, evaluating design changes, and developing advanced designs.
Design FMEA supports identifying risks in Design

- Unless the responsible engineer is experienced with FMEA and team facilitation, it is helpful to have an experienced FMEA facilitator assist the team in its activities.

- The Design FMEA is a living document and should:
  - Be initiated before or at design concept finalization,
  - Be continually updated as changes occur or additional information is obtained throughout the phases of product development, and
  - Be fundamentally completed before the engineering drawings are released for tooling.
Design FMEA supports identifying risks in Design

- Considering that manufacturing/assembly needs have been incorporated, the Design FMEA addresses the design intent and assumes the design will be manufactured/assembled to this intent.

- Potential failure modes and/or causes/mechanisms that can occur during the manufacturing or assembly process need not but may be included in a Design FMEA.

- When not included, their identification, effect, and control are covered by the Process FMEA.

- The Design FMEA does not rely on process controls to overcome potential design weaknesses, but it does take the technical/physical limits of a manufacturing/assembly process into consideration,
The APQP Process (Advanced Production Quality Planning)

**PROGRAM APPROVAL**

- **PLANNING & DEFINITION**
- **PRODUCT DESIGN & DEVELOPMENT**
- **PROCESS DESIGN & DEVELOPMENT**
- **PRODUCT & PROCESS VALIDATION**

**PROTO TYPES**

**PILOT**

**LAUNCH**

**PRODUCTION**

**FEEDBACK / ANALYSIS & CORRECTIVE ACTION**

**NEXT CYCLE PLANNING**

---

**APQP: SECTION 1**
The Quality Lever (LTS USA)
"Quality cannot be inspected-in, quality has to be built-in."

Customer Takes Possession--
Loss of Control For Manufacturer

Customer Service

$1 of Net Improvement

100:1
10:1
1:1
½:1

Product Engineering
Mfg. Process Engineering
Mfg. Assembly Operations
Product Engineering
Key Events in APQP and Control Plan from AIAG USA
Getting the best out of the cross-functional team

Reserve team time for when the team is really needed
- Confirmation of process flow, functions and FMs
- Identification of effects, causes and controls
- Clarification of the flow of the process
- Action Planning

Maximise opportunities to pass on (and create) knowledge of the process

Use technology to:
- speed up meetings
- Improve information exchange
- Increase depth of learning

Have other tasks performed by small core group of 2 or 3
- SOD scores
- Function and FM identification
Understanding "Function"

1. Identify Project Scope
2. Identify Process Functions
3. Deduce Failure Modes
4. Brainstorm Effects & Rate Severity
5. Brainstorm Causes & Rate Occurrence
6. Develop Controls & Rate Detection
7. RPN & Action Planning
8. Measure, Track & Drive Action
9. Reduce Risk Improve Customer Satisfaction

Main Worksheet

Function List
Characteristics Matrix
F/Mode Worksheet

Project Assignment
Team
FMEA Knowledge

SC/CC/KC List

Main Worksheet

Main Worksheet

Main Worksheet

Main Worksheet

Main Worksheet

Main Worksheet

Main Worksheet

Main Worksheet
Defining a "Function"

What Is FUNCTION?

“The natural, proper, or characteristic action of any thing…”

- Webster’s New Collegiate Dictionary

The actions that a system, part, or manufacturing process performs to satisfy a customer.

- The FMEA Definition
Defining a "Function"

To talk FUNCTION, you must use special language.

Function must be described using:

- **AN ACTIVE VERB**
- **A MEASURABLE NOUN**

If you use this rule, you can get to the point quickly and reach consensus sooner--and better organize continual improvement activities.

**VERB Should Be Active and Direct**

- **TEST**: Can you subject the action described by the verb to reasonable verification?
- **Avoid verbs like provide, be, supply, facilitate, allow, and other “nerd verbs”**

**NOUN Should Be Determinate and Not the Name of a Part, Operation or Activity**

- **TEST**: Can you measure the noun?
### PFMEA (example)

- Lets us review this Process – first check: Does the Recommended [Corrective Action] address the Potential Failure Mode [s] of the Function?

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode(s)</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Potential Cause(s)/Mechanism(s) of Failure</th>
<th>RPN</th>
<th>Current Design Controls</th>
<th>Recommended Action(s)</th>
<th>Responsibility &amp; Target Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seals Coolant containment</td>
<td></td>
<td></td>
<td>2</td>
<td>FITTING NOT HELD IN PLACE</td>
<td>16</td>
<td>1</td>
<td>Obtain GMB vibration road tape.</td>
<td>J.P. Aguire 11/1/96</td>
</tr>
<tr>
<td>Sensor mount.</td>
<td></td>
<td></td>
<td>2</td>
<td>FITTING NOT HELD IN PLACE</td>
<td>16</td>
<td>1</td>
<td>Obtain GMB vibration road tape.</td>
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<td>Obtain GMB vibration road tape.</td>
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</tr>
</tbody>
</table>

These need to describe the 'Manufacturing Process' not 'Product Characteristics'. One has to assume that the design of the product is perfect; i.e. you are not there to consider issues of design.

We are here to do 'Process' not 'Design', otherwise it is different participants in this room.

Do these "Functions" described by "Verb – Noun – Extent"?

If not, then subsequent PFMEA attributes are sub-optimal.
"Function" in processes

- PFMEA functions require a manufacturing process viewpoint
  - Start with a Process Flow Diagram
  - Look for Functions in each Flow Chart Activity
    - How is the product assembled?
      - fabrication processed can also be analyzed.

- How can this be done deductively?
  - Use a "Characteristics Matrix"
  - Relate each Process Step to each Characteristic in the product
Robust Process Control

- The 'Characteristic Matrix' is the key to in-depth analysis of manufacturing processes:
  - Detailed "Break Down" of Flow Diagram steps
  - Interaction of Design Requirements and Process Flow

- Relates process steps to Product Characteristics:
  - Requires understanding of "Dominance Factors"
  - Reveals Critical Process Functions
  - Creates a comprehensive list of Functions
Process Dominance Factors

- Set-Up
- Machine
- Operator
- Component or Material
- Tooling
- Preventive Maintenance
- Fixture / Pallet / Work Holding
- Environment
Summary: Function Analysis

1. Determine Customers & Needs

2. Product or Process?

3. Brainstorm Functions

3. Develop Process Flow Diagram

4. Create Function Hierarchy

4. Determine Process Purposes/Functions

5. Product Function Listing Worksheet

Item, Functions and Failure - bicycle example

**System Level**

**Bicycle**

*Function:*
- Ease of use

*Potential Failure Modes:*
- Difficult to steer
- Difficult to pedal

**Design Objectives:**
1. Minimum 3,000 hours of riding without the need for maintenance and 10,000 hours of riding for the design life.
2. Accommodate males comfortably to the 99.5th percentile
3. Etc.

**Subsystem Level**

**Frame**

*Function:*
- Provide pleasing appearance

*Potential Failure Modes:*
- Finish (shine) deteriorates
- Paint chips

*Function:*
- Provide stable support for seat post

*Potential Failure Modes:*
- Structural failure of seat support
- Excessive deflection of seat support

**Handle Bar Assembly**

**Front Fork**

**Front Wheel Assembly**

**Rear Wheel Assembly**

**Chain Ring**

**Chain**

**Seat Assembly**

**Component Level**

**Top Tube**

*Function:*
- Provide structural support

*Potential Failure Modes:*
- Structural failure
- Excessive deflection

*Function:*
- Provides dimensional control for correct finished frame geometry

*Potential Failure Modes:*
- Length of tube too long
- Length of tube too short

**Headset Tube**

**Seat Tube**

**Lower Tube**

**Bottom Bracket**

**Rear Wheel Support Tube**

**Rear Brakes Support Tube**
Summary: Process Function Analysis

1. Verified Product Design Information
2. The Language of Function
3. Develop Process Flow Diagram
4. Develop Characteristics Matrix
5. Determine Process Functions & Specifications
6. Process Function Listing Worksheet
Thales QMS - Problem Follow-Up Worksheet
Function and Failure Mode

Failures Can Arise When Function Is Not Fulfilled In Four Different Ways:

FUNCTION

FAILURE MODE Categories

- Absence of Function
- Incomplete, Partial, Excess or Decayed Function
- Function Occurs Too Soon or Too Late
- Additional Unwanted Function
**Failure Mode - summary**

- A Failure Mode is:
  - A disruption of Function
  - An interruption of Function
  - A cessation of Function

- Modes occur at an instant in time:
  - Once a Mode occurs, you can only sense a Failure Effect!
    - If you Sense it, it's no longer a Mode

- Potential failure modes that could occur only:
  - under certain conditions (i.e. hot cold dry dusty, etc.) and
  - under certain usage conditions (i.e. above-average mileage, rough terrain, city driving only, etc.) should be considered. (*ed.4 change*)
Brainstorming, Selecting and defining an 8D Problem - "FOE"

- Charles Kettering, R&D Manager General Motors USA, said, "A problem well stated is half solved." and an FPC, "helps make that statement".
  Allan H Mogensen 1901 – 1989

- Ensure the problem describes what is unsatisfactory about a situation - not an objective, goal or solution.

- "FOE" = Fault + Object + Extent

  - Fault: Describe what is wrong with that object - quantify the fault if possible.
  - Object: Describe the item, service or system that is faulty.
  - Extent: The amount or measure of the fault, defect, waste, variation from standard, interruption, deviation off target, exists.

<table>
<thead>
<tr>
<th>Poor example:</th>
<th>We need a new 'end cap' supplier.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good example:</td>
<td>End cap varies in dimensions with suppliers</td>
</tr>
<tr>
<td>Better example:</td>
<td>Supplier _________ delivers 'end caps' out of Specification across length on side-by-sides</td>
</tr>
</tbody>
</table>
### What are 'Failure Modes'

<table>
<thead>
<tr>
<th>Function</th>
<th>Absence</th>
<th>Partial or incomplete</th>
<th>Too early/late</th>
<th>Unexpected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drill hole to depth of 12mm +/- 0.05mm, at 90° +/- 0.02° to top face at (x,y).</td>
<td>Does not drill hole</td>
<td>Drills hole too short</td>
<td>Drills too early</td>
<td>Create swarf</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Drills hole to long</td>
<td>Drills too late</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Drills hole at angle</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Drills hole in wrong place</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Initially drills correctly but fails/fades over time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clamp part in abc jig to prevent movement in all directions</td>
<td>Does not clamp part</td>
<td>Initially clamps but then allows movement</td>
<td>Clamps too early</td>
<td>Scores or marks product</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Partially clamps part</td>
<td>Clamps too late</td>
<td></td>
</tr>
<tr>
<td>Measure xyz diameter for all parts with error &lt;0.01mm</td>
<td>Does not measure</td>
<td>Measures wrong diameter</td>
<td>Measures too early</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Accuracy &gt; 0.01mm tolerance</td>
<td>Measures too late</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Initially OK, then drifts &gt;0.01mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfer non conforming part to non conforming part bin</td>
<td>Does not transfer part</td>
<td>Transfers part to conforming area</td>
<td>Transfers too early</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Transforms part back up the line</td>
<td>Transfers too late</td>
<td></td>
</tr>
</tbody>
</table>
Reduce 'variation' - the enemy of quality

NB: The Automotive Sector (under ISO/TS 16949:2002) uses PDSA as Dr. Deming changed the Shewhart Cycle from PDCA to better describe the need to Study the Process by Control Charts (Voice of the Process) before determining Process Capability by Histograms (Voice of Customer)
Operational Definition - Failure Effect

FAILURE EFFECT:

- A description of THE CONSEQUENCES of a system, part, or manufacturing process failure. A typical failure mode will have several effects.
**Operational Definition - Failure Cause**

**FAILURE CAUSE**

- A description of the FUNDAMENTAL REASON ("root cause") consistent with the project scope, that gives rise to a manufacturing process failure mode.
- Any particular failure mode may have *more than one* root CAUSE.
Basic Cause and Effect Analysis

- Ask "Why" five times:
  - This is a technique developed by Toyota, to get past the symptom and down to the actual cause. This can be linear or random.
  - Ask "Why" until it becomes a ridiculous question to pose.

- As at August 2007, Toyota Australia and World Corporation just ask "why" until the Cause is identified.
Basic Cause and Effect Analysis

- Vote on all the causes to identify the top 6 to 8 causes and circle them.
- Collect and analyse data to verify whether each is a valid cause.

- If the data does not verify the causes, go back and validate other causes that received fewer votes.
Process Cause and Effect Analysis

- Determine the titles of the major arms or bones, which may vary for each of the steps.

- Use brainstorming to generate causes at each step of the process.

- Be careful not to simply repeat a cause in each step. When that occurs, go back and clarify what the words mean. Often, you will uncover different aspects of the same issue - for example, "staff" may refer to "staff numbers", "staff skills" or "staff rosters".
Process Cause and Effect Diagram

- As PFMEA is based upon 'Process', a Process Cause and Effect Diagram is more powerful than the basic 'Fishbone Diagram (Dr. Ishikawa invented both).
A Problem Solving Storyboard of a Project-based Learning process

**Define the Problem**

The sponge rubber bulb in strip extruded on the microwave line contains lumps. 4% of extruded strip is rejected due to lumps. Each stop cost $310 in material. In May and Jun there was 89 stops, i.e. $14k per month

**Assess Scope and Causes**

Findings, first round:
- No rocks found in master bins
- Housekeeping standard relatively high. Better than 2 months ago
- Majority of lumps are unmixed chemicals
- BUT......some from Rhenogran mixing room move the white rocks

Findings, Second round:
- White rock is a Zinc Sulphide compound.
- Eventually found as impurity within Zn Oxide added in the master compound. A new grade of Zn O will now be trialled in August.

**Collect Data and Analyse Causes**

This pareto shows the causes of extrusion downtime

- Start up – 24%
- Lumps – 17%
- Drill Holes - 9.5%
- Size – 9%
- Shape – 7%

**Implement, Test and Monitor**

Lump types include:
- Outside stones – typically quartz rock. Suspected to come from road surfaces and blown in. Composition is generally silicone, aluminium with other minerals.
- Chemical lumps – these are lumps of chemicals with a white/yellow appearance. Electron microscopy analysis indicate that they consist mainly of zinc with some sulphur.
- Other lumps – composition unable to be determined.

**Standardise and Report**

- Established new housekeeping standards. Conducting regular housekeeping audits and reinforcing correct work practices
- All staff trained in housekeeping practices
- Colour coding now in place in rubber store to drive FIFO
- Staff trained in data entry and use of reject codes and FIFO
- Mixing Unit to be Cleaned, Repaired and then Painted (Prelude TO 5s)
- Zinc Oxide Spec updated and purchasing practices reviewed. No White Rocks have been found since August.
- Re-train in the application of error coding for start up code

Gain = $149 pa (40 stops per month @ $310/stop)
'Data Collection Plan' for identified potential causes

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Cause Description</th>
<th>What</th>
<th>Where</th>
<th>How</th>
<th>By Whom</th>
<th>By When and/or Status</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>
### 'Data Collection Check sheet' for identified potential causes

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Cause Description</th>
<th>Type of Data to Collect</th>
<th>DC / Quality Tool</th>
<th>Period, Time or When</th>
<th>Whom to Collect</th>
<th>By When and/or Status</th>
</tr>
</thead>
</table>
Operational Definition - Prevention vs. Detection

There are two types of controls, that must be listed separately:

- **Prevention controls**
  - These controls prevent a cause from occurring, often involves error proofing et al
  - These are the best controls as they prevent errors from actually occurring.
  - Usually scores a control rating of 1 to 5

- **Detection controls**
  - These controls positively detect the presence of a cause and allow an operator to take action
  - These are less effective as they allow waste to be created and add appraisal costs.
  - Usually scores a control rating of 6 to 10. This level of score will usually force action.
  - People will argue, but inspection on its own is at best 80% effective and you don’t know when it is failing, ie double visual inspection on its own = 7 and single VI = 8. VI must were possible be eliminated from your PCP.
Scoring FMEA "RPN's"

**Work down** the sheet to develop scores (not across).

**Bundle RPN calculations around a failure mode.**
- Identify the highest possible scoring permutation
- Confirm that the permutation could occur
- Record that as the RPN for that function

There is no magic number

Aim to eliminate/reduce the top RPN’s

<table>
<thead>
<tr>
<th>Item Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Potential Cause(s)/Mechanism(s) of Failure</th>
<th>Occurrence</th>
<th>Current Design Controls</th>
<th>Detection</th>
<th>RPN</th>
<th>Recommended Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfer NC Part to non conforming bin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9</td>
<td>3</td>
</tr>
</tbody>
</table>
# PFMEA Checklist (ii)

## 6. PROCESS FMEA

<table>
<thead>
<tr>
<th></th>
<th>EVIDENCE / DOCUMENTATION REQUIRED</th>
<th>N/A</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.00</td>
<td>Is there a PFMEA available?</td>
<td>Current Updated FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.01</td>
<td>Has a Process FMEA been completed on all process functions that affect the Customer elements including receiving, transportation/handling, packaging, and outside services?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.02</td>
<td>Do these process elements coincide with the documented process flow chart?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.03</td>
<td>Is the correct engineering revision level referenced?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.04</td>
<td>Does the PFMEA include known data based Causes issues and corrective actions?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.05</td>
<td>Are failure modes described in physical, technical and measurable terms?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.06</td>
<td>Do Process FMEA severities coincide and &quot;effect or impact of failures&quot; with Design FMEA <strong>Severities (S)</strong>?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.07</td>
<td>Do effects of failures address the impact on each part, next higher assembly, system, vehicle, customer wants, government regulations and operator safety?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.08</td>
<td>Have potential causes been identified for all failure modes and have they been described in terms of something that can be corrected or controlled?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.09</td>
<td>Are the special characteristics noted with appropriate symbols on the PFMEA?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.10</td>
<td>Are detection rates consistent with controls and agree with the Control Plan?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.11</td>
<td>Do occurrence rates coincide with process data and / or defect rates (Note Parts Per Million = PPM) and consistent with Electrolux Manufacturing System?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.12</td>
<td>Are <strong>Occurrence (O) and Detection's (D) rates consistent with AIAG Manual?</strong></td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.14</td>
<td>Does the PFMEA address all error-proofing</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.15</td>
<td>Have corrective actions been identified for (Severity x Occurrence x Detection) = Risk Priority Number (RPNs) greater than or equal to 125 or other Customer-Specific Requirement?</td>
<td>Process FMEA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.16</td>
<td>Is the PFMEA acceptable (RPNs, numbers match Process flow and include KPCs/PQCs/KCCs)?</td>
<td>PFMEA Changed Log, Meeting Minutes or Similar History</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.17</td>
<td>Is there any evidence that it is kept up to date?</td>
<td>PFMEA Changed Log, Meeting Minutes or Similar History</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Process FMEA - definition

- A structured procedure for identifying and eliminating process related failure modes.

- An analytical technique that for each process step, identifies:
  
  - ways that a process may fail to meet requirements

  - consequences to the internal / external customer (Severity)

  - frequency that the failure will / could happen (Occurrence)

  - effectiveness of current controls (Prevention and Detection)

  - ranking of causes and effects (Risk Priority Number)
## PFMEA

**Process Failure Mode and Effects Analysis (example)**

<table>
<thead>
<tr>
<th>PROCESS NAME/NUMBER</th>
<th>PROCESS FUNCTION</th>
<th>POTENTIAL FAILURE MODE</th>
<th>POTENTIAL EFFECT(S) OF FAILURE</th>
<th>OCC</th>
<th>CURRENT CONTROLS</th>
<th>DET</th>
<th>R PN</th>
<th>RECOMMENDED ACTION(S)</th>
<th>RESPONSIBILITY &amp; TARGET COMPLETION DATE</th>
<th>ACTION RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Correct Part - pilot bearing</td>
<td>Incorrect part installed</td>
<td>Misbuild</td>
<td>7</td>
<td>Manual: incorrectly selected</td>
<td>0</td>
<td>7</td>
<td>No prevention</td>
<td>No detection</td>
<td>10</td>
</tr>
<tr>
<td>20</td>
<td>Correct Assy - piston and rod ass'y</td>
<td>Incorrect Piston or reversed piston</td>
<td>Loss of Engine Power; Engine Failure</td>
<td>7</td>
<td>Machine Vision ID Incorrect</td>
<td>0</td>
<td>3</td>
<td>No prevention</td>
<td>In-line Audits</td>
<td>6</td>
</tr>
</tbody>
</table>

Source: AIAG PFMEA Fourth Edition, Appendix A
PFMEA Worksheet - instructions

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode(s)</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Potential Cause(s)/Mechanism(s) of Failure</th>
<th>Probability</th>
<th>Current Design Controls</th>
<th>D&amp;P</th>
<th>RPN</th>
<th>Recommended Action(s)</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Actions Taken</th>
<th>New Sev</th>
<th>New Occ</th>
<th>New Det</th>
<th>New RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coolant containment. Hose connection Coolant fill. M</td>
<td>Crack/break. Burst. Side wall flex. Bad seal. Poor hose rete</td>
<td>Leak</td>
<td>8</td>
<td>Over pressure</td>
<td>8</td>
<td>Burst, validation pressure cycle.</td>
<td>1</td>
<td>64</td>
<td>Test included in prototype and production validation testing.</td>
<td>J.P. Aguire 11/1/95 E. Eglin 8/1/96</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Write down each Failure Mode and potential consequence(s) of that failure.**

**Severity:** On a scale of 1-10, rate the Severity of each failure (10 = most severe). See Severity sheet.

**Likelihood:** Write down the potential cause(s) and on a scale of 1-10, rate the likelihood of each failure (10 = most likely). See Likelihood sheet.

**Detectability:** Examine the current design, then, on a scale of 1-10, rate the Detectability of each failure (10 = least detectable). See Detectability sheet.

**Risk Priority Number:** The combined weighting of Severity, Likelihood and Detectability. RPN = Sev x Occ x Det

**Response Plans and Tracking**
### PFMEA Worksheet - instructions - Severity

#### PROCESS FMEA

<table>
<thead>
<tr>
<th>Effect</th>
<th>Suggested PFMEA Severity Evaluation Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous without Warning</td>
<td>Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.</td>
</tr>
<tr>
<td>Hazardous with Warning</td>
<td>Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.</td>
</tr>
<tr>
<td>Very High</td>
<td>Vehicle/item imperable (loss of primary function).</td>
</tr>
<tr>
<td>High</td>
<td>Vehicle/item operable but at a reduced level of performance. Customers very dissatisfied.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Vehicle/item operable but common/convenience item imperable. Customers somewhat dissatisfied.</td>
</tr>
<tr>
<td>Low</td>
<td>Vehicle/item operable but common/convenience item operable at a reduced level of performance. Customers somewhat satisfied.</td>
</tr>
<tr>
<td>Very Low</td>
<td>RT &amp; retest/substitute or rework item does not conform. Detect noticed by most customers (greater than 75%).</td>
</tr>
<tr>
<td>Minor</td>
<td>RT &amp; retest/substitute or rework item does not conform. Detect noticed by 50% of customers.</td>
</tr>
<tr>
<td>Very Minor</td>
<td>RT &amp; retest/substitute or rework item does not conform. Detect noticed by discriminating customers (less than 25%).</td>
</tr>
<tr>
<td>None</td>
<td>No discernible effect.</td>
</tr>
</tbody>
</table>

#### Probability of Failure

<table>
<thead>
<tr>
<th>Likely Failure Rates</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High: Persistent failures</td>
<td>≥ 100 per thousand pieces</td>
</tr>
<tr>
<td>High: Frequent failures</td>
<td>50 per thousand pieces</td>
</tr>
<tr>
<td>Moderate/Occasional failures</td>
<td>20 per thousand pieces</td>
</tr>
<tr>
<td>Low</td>
<td>10 per thousand pieces</td>
</tr>
<tr>
<td>Very Low</td>
<td>Controls may detect</td>
</tr>
<tr>
<td>Moderately high</td>
<td>Controls have a good chance to detect</td>
</tr>
<tr>
<td>Low</td>
<td>Controls have good chance to detect</td>
</tr>
<tr>
<td>Very High</td>
<td>Controls almost certain to detect</td>
</tr>
<tr>
<td>Very High</td>
<td>Controls certain to detect</td>
</tr>
<tr>
<td>Remote: Failure is unlikely</td>
<td>&lt; 0.01 per thousand pieces</td>
</tr>
</tbody>
</table>

#### Detection Criteria

<table>
<thead>
<tr>
<th>Detection Criteria</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>Suggested Range of Detection Methods</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost impossible</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Control is achieved with indirect or random checks only.</td>
<td>10</td>
</tr>
<tr>
<td>Very remote</td>
<td>Controls will probably not detect</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>Controls have poor chance of detection</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>Controls may detect</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate controls may detect</td>
<td>X</td>
<td>X</td>
<td>Control is achieved with charting methods, such as SPC (Statistical Process Control)</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Moderately high</td>
<td>Controls have a good chance to detect</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>Controls have good chance to detect</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very high</td>
<td>Controls almost certain to detect</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very high</td>
<td>Controls certain to detect</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>Failure is unlikely</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Inspection Types:
- A = Error Proofed
- B = Gauging
- C = Manual Inspection
Failure Effects and Severity
- Failure Effects are SENSORY

• Effects Are Perceived After Function Is Disrupted…
  – See The Effect
  – Hear The Effect
  – Feel The Effect
  – Smell The Effect
  – Taste The Effect

• Avoid Excessive “What If” Thinking…
## Severity Evaluation Criteria (Rankings)

Source: AIAG PFMEA Fourth Edition

<table>
<thead>
<tr>
<th>Effect</th>
<th>Criteria: Severity of Effect on Product (Customer Effect)</th>
<th>Rank</th>
<th>Effect</th>
<th>Criteria: Severity of Effect on Process (Manufacturing / Assembly Effect)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to Meet Safety and/or Regulatory Requirements</td>
<td>Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.</td>
<td>10</td>
<td>Failure to Meet Safety and/or Regulatory Requirements</td>
<td>May endanger operator (machine or assembly) without warning.</td>
</tr>
<tr>
<td></td>
<td>Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss or Degradation of Primary Function</td>
<td>Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).</td>
<td>8</td>
<td>Major Disruption</td>
<td>100% of product may have to be scrapped. Line shutdown or stop ship.</td>
</tr>
<tr>
<td></td>
<td>Degradation of primary function (vehicle operable, but at reduced level of performance).</td>
<td>7</td>
<td>Significant Disruption</td>
<td>A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.</td>
</tr>
<tr>
<td>Loss or Degradation of Secondary Function</td>
<td>Loss of secondary function (vehicle operable, but comfort / convenience functions inoperable).</td>
<td>6</td>
<td>Moderate Disruption</td>
<td>100% of production run may have to be reworked off line and accepted.</td>
</tr>
<tr>
<td></td>
<td>Degradation of secondary function (vehicle operable, but comfort / convenience functions at reduced level of performance).</td>
<td>5</td>
<td></td>
<td>A portion of the production run may have to be reworked off line and accepted.</td>
</tr>
<tr>
<td>Annoyance</td>
<td>Appearance or Audible Noise, vehicle operable, item does not conform. Defect noticed by most customers (&gt; 75%).</td>
<td>4</td>
<td>Moderate Disruption</td>
<td>100% of production run may have to be reworked in station before it is processed.</td>
</tr>
<tr>
<td></td>
<td>Appearance or Audible Noise, vehicle operable, item does not conform. Defect noticed by many customers (50%).</td>
<td>3</td>
<td></td>
<td>A portion of the production run may have to be reworked in-station before it is processed.</td>
</tr>
<tr>
<td></td>
<td>Appearance or Audible Noise, vehicle operable, item does not conform. Defect noticed by discriminating customers (&lt; 25%).</td>
<td>2</td>
<td>Minor Disruption</td>
<td>Slight inconvenience to process, operation or operator.</td>
</tr>
<tr>
<td>No Effect</td>
<td>No discernible effect.</td>
<td>1</td>
<td>No Effect</td>
<td>No discernible effect.</td>
</tr>
</tbody>
</table>

*It is not recommended to modify criteria ranking values of 9 and 10. Failure modes with a severity rank of 1 should not be analysed further.*

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## PFMEA Worksheet - instructions - Occurrence

### PROCESS FMEA

#### Suggested PFMEA Severity Evaluation Criteria

<table>
<thead>
<tr>
<th>Effect</th>
<th>Critical Severity of Effect: This ranking refers to potential failures mode results in a fatal customer and/or manufacturing assembly point defect. The final customer should always be considered first, if both occur, use the higher of the two severities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous without Warning</td>
<td>Very high severity ranking when a potential failure mode affects safety vehicle operation and/or involves noncompliance with government regulation without warning.</td>
</tr>
<tr>
<td>Hazardous with Warning</td>
<td>Very high severity ranking when a potential failure mode affects safety vehicle operation and/or involves noncompliance with government regulation with warning.</td>
</tr>
<tr>
<td>Very High</td>
<td>Vehicle/item is operable but at a rapid degradation level of performance. Customer may be very dissatisfied.</td>
</tr>
<tr>
<td>High</td>
<td>Vehicle/item is operable but at a rapid degradation level of performance. Customer or very dissatisfied.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Vehicle/item is operable but at a reduced level of performance. Customer is somewhat dissatisfied.</td>
</tr>
<tr>
<td>Low</td>
<td>Vehicle/item is operable but at a reduced level of performance. Customer is somewhat dissatisfied.</td>
</tr>
<tr>
<td>Very Low</td>
<td>RT &amp; rt/wt/spec: rattle item does not conform. Detected by large majority of customers (greater than 70%).</td>
</tr>
<tr>
<td>Minor</td>
<td>RT &amp; rt/wt/spec: rattle item does not conform. Detected by 50% of customers.</td>
</tr>
<tr>
<td>Very Minor</td>
<td>RT &amp; rt/wt/spec: rattle item does not conform. Detected by 25% of customers.</td>
</tr>
<tr>
<td>None</td>
<td>No discernible affect.</td>
</tr>
</tbody>
</table>

### Suggested PFMEA Occurrence Evaluation Criteria

#### Probability of Failure

- Very High: Persistent failures
  - ≥ 100 per thousand pieces
  - 10

- High: Frequent failures
  - 50 per thousand pieces
  - 9

- Moderate: Occasional failures
  - 20 per thousand pieces
  - 8

- Low: Relatively few failures
  - 10 per thousand pieces
  - 7

- Moderately High: Controls have a good chance to detect.
  - 5 per thousand pieces
  - 6

- High: Controls have a good chance to detect.
  - 2 per thousand pieces
  - 5

#### Likely Failure Rates

<table>
<thead>
<tr>
<th>Detection</th>
<th>Criteria</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>Suggested Range of Detection Methods</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Impossible</td>
<td>Absolute certainty of non-detection.</td>
<td>X</td>
<td>Cannot detect or is not checked.</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very Remote</td>
<td>Controls will probably not detect.</td>
<td>X</td>
<td>Control is achieved with indirect or random checks only.</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>Controls have poor chance of detection.</td>
<td>X</td>
<td>Control is achieved with visual inspection only.</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very Low</td>
<td>Controls have poor chance of detection.</td>
<td>X</td>
<td>Control is achieved with double visual inspection only.</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>Controls may detect.</td>
<td>X</td>
<td>Control is achieved with charting methods, such as SPC (Statistical Process Control).</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Controls may detect.</td>
<td>X</td>
<td>Control is based on variable gauging after parts have left the station, OR Go/No Go gauging performed on 100% of the parts after parts have left the station.</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderately High</td>
<td>Controls have a good chance to detect.</td>
<td>X</td>
<td>Error detection in subsequent operations, OR gauging performed on setup and first-piece check (for setup causes only).</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Controls have a good chance to detect.</td>
<td>X</td>
<td>Error detection in station, OR error detection in subsequent operations by multiple layers of acceptance, supply, install, verify. Can not accept discrepant part.</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very High</td>
<td>Controls almost certain to detect.</td>
<td>X</td>
<td>Error detection in station (automatic gauging with automatic stop feature). Can not pass discrepant part.</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very High</td>
<td>Controls certain to detect.</td>
<td>X</td>
<td>Discrepant parts can not be made because item has been errored proved by process/product design.</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Suggested PFMEA Detection Evaluation Criteria

#### Occurrence

- ≤ 0.01 per thousand pieces
  - 1
Failure Causes and Occurrence
- ‘Columbia’ and Occurrence

- Henry McDonald, former director of NASA's Ames Research Center, in testimony to Congress:
  - Well-intentioned people forget that "if you have a 1 in 100 chance of risk of an event occurring, the event can occur on the first or last opportunity, and there's an equal probability each time."

- NASA’s perception seemed to be "that if I've flown 20 times, the risk is less than if I've just flown once"
  - Unless NASA changed the underlying design, they still have the same issue even after 50 flights or 60 successful flights.

- How Often Are Occurrences Changed As A Result of Testing Outcomes?
## Occurrence Evaluation Criteria (Rankings)

<table>
<thead>
<tr>
<th>Likelihood of Failure</th>
<th>Criteria: Occurrence of Cause - PFMEA (Incidents per items/vehicles)</th>
<th>Rank</th>
</tr>
</thead>
</table>
| Very High             | ≥ 100 per thousand  
|                       | ≥ 1 in 10                                                     | 10   |
| High                  | 50 per thousand  
|                       | 1 in 20                                                     | 9    |
|                       | 20 per thousand  
|                       | 1 in 50                                                     | 8    |
|                       | 10 per thousand  
|                       | 1 in 100                                                   | 7    |
| Moderate              | 2 per thousand  
|                       | 1 in 500                                                   | 6    |
|                       | 0.5 per thousand  
|                       | 1 in 2,000                                                  | 5    |
|                       | 0.1 per thousand  
|                       | 1 in 10,000                                                 | 4    |
| Low                   | 0.01 per thousand  
|                       | 1 in 100,000                                                | 3    |
|                       | ≤0.001 per thousand  
|                       | 1 in 1,000,000                                              | 2    |
| Very Low              | Failure is eliminated through preventive control             | 1    |
## PROCESS FMEA

### Suggested PFMEA Severity Evaluation Criteria

<table>
<thead>
<tr>
<th>Effect</th>
<th>Suggested PFMEA Occurrence Evaluation Criteria</th>
<th>Probability of Failure</th>
<th>Likely Failure Rates</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous Without Warning</td>
<td>Very High: Persistent failures</td>
<td>≥ 100 per thousand pieces</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Hazardous With Warning</td>
<td>High: Frequent failures</td>
<td>50 per thousand pieces</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Very High</td>
<td>Moderate: Occasional failures</td>
<td>20 per thousand pieces</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Low</td>
<td>10 per thousand pieces</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Very Low</td>
<td>5 per thousand pieces</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>Very Low</td>
<td>2 per thousand pieces</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Minor</td>
<td>Very Minor</td>
<td>1 per thousand pieces</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>None</td>
<td>Failure is unlikely</td>
<td>1</td>
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</tr>
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</table>

### Detection Evaluation Criteria

<table>
<thead>
<tr>
<th>Detection</th>
<th>Criteria</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>Suggested Range of Detection Methods</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Impossible</td>
<td>Absolute certainty of non-detection.</td>
<td>X</td>
<td>Cannot detect or is not checked.</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very Remote</td>
<td>Controls will probably not detect.</td>
<td>X</td>
<td>Control is achieved with indirect or random checks only.</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>Controls have poor chance of detection.</td>
<td>X</td>
<td>Control is achieved with visual inspection only.</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very Low</td>
<td>Controls have poor chance of detection.</td>
<td>X</td>
<td>Control is achieved with double visual inspection only.</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>Controls may detect.</td>
<td>X</td>
<td>Control is achieved with charting methods, such as SPC (Statistical Process Control).</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Controls may detect.</td>
<td>X</td>
<td>Control is based on variable gauging after parts have left the station, OR Go/No Go gauging performed on 100% of the parts after parts have left the station.</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderately High</td>
<td>Controls have a good chance to detect.</td>
<td>X</td>
<td>Error detection in subsequent operations, OR gauging performed on setup and first-piece check (for setup-causes only).</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Controls have a good chance to detect.</td>
<td>X</td>
<td>Error detection in station, OR error detection in subsequent operations by multiple layers of acceptance supply, select, inspect, verify, Cannot accept discrepant part.</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very High</td>
<td>Controls almost certain to detect.</td>
<td>X</td>
<td>Error detection in station (automatic gauging with automatic stop feature). Can not pass discrepant part.</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very High</td>
<td>Controls certain to detect.</td>
<td>X</td>
<td>Discrepant parts can not be made because item has been error proofed by process/product design.</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Inspection Types

- A: Error Proofed
- B: Gauging
- C: Manual Inspection
Controls and Detection
- Prevention and Detection

• **PREVENTION CONTROLS** are aimed at INPUTS and the DESIGN DECISIONS—Causes
  • Analytical Engineering

• **DETECTION CONTROLS** are aimed at process OUTPUTS—Effects
  • Physical Testing
**Detection Evaluation Criteria (Rankings)**

Source: AIAG PFMEA Fourth Edition

<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>No detection opportunity</td>
<td>No current process control; Cannot detect or is not analyzed.</td>
<td>10</td>
<td>Almost Impossible</td>
</tr>
<tr>
<td>Not likely to detect at any stage</td>
<td>Failure Mode and/or Error (Cause) is not easily detected (e.g. random audits).</td>
<td>9</td>
<td>Very Remote</td>
</tr>
<tr>
<td>Defect Detection Post Processing</td>
<td>Failure Mode detection post-processing by operator through visual / tactile / audible means.</td>
<td>8</td>
<td>Remote</td>
</tr>
<tr>
<td>Defect Detection at Source</td>
<td>Failure Mode detection in-station by operator through visual / tactile / audible means or post-processing through use of attribute gauging (go / no-go, manual torque check / clicker wrench, etc.).</td>
<td>7</td>
<td>Very Low</td>
</tr>
<tr>
<td>Defect Detection Post Processing</td>
<td>Failure Mode detection post-processing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go / no-go, manual torque check / clicker wrench, etc).</td>
<td>6</td>
<td>Low</td>
</tr>
<tr>
<td>Defect Detection at Source</td>
<td>Failure Mode or Error (Cause) detection in-station by operator through use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for set-up causes only).</td>
<td>5</td>
<td>Moderate</td>
</tr>
<tr>
<td>Defect Detection Post Processing</td>
<td>Failure Mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing.</td>
<td>4</td>
<td>Moderately High</td>
</tr>
<tr>
<td>Defect Detection at Source</td>
<td>Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.</td>
<td>3</td>
<td>High</td>
</tr>
<tr>
<td>Error Detection and/or Problem Prevention</td>
<td>Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made.</td>
<td>2</td>
<td>Very High</td>
</tr>
<tr>
<td>Detection not applicable; Error Prevention</td>
<td>Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because item has been error-proofed by process / product design.</td>
<td>1</td>
<td>Almost Certain</td>
</tr>
</tbody>
</table>
The Quality Lever (LTS USA) "Quality cannot be inspected-in, quality has to be built-in."

Customer Takes Possession--Loss of Control For Manufacturer

$1 of Net Improvement

100:1

10:1

1:1

1/2:1

Product Engineering

Mfg. Process Engineering

Mfg. Assembly Operations

Customer Service
Controls and Detection
- How did the Wright brothers do it?

- They spent most of their time calculating
  - The risks associated with pure experimental approaches—detection controls—were great
  - It can actually be said that they invented analytical design—the basis for prevention controls...
### Risk Priority Number (RPN)

- **Risk Priority Number** (RPN) is the result of Severity, Occurrence and Detection rankings.

**Remember:**
- the RPN should **not** be used as the primary means for assessing risk;
- setting RPN thresholds is **not** recommended.

### Severity x Occurrence x Detection = RPN

(Example)

<table>
<thead>
<tr>
<th>PROCESS NAME/NUMBER</th>
<th>PROCESS FUNCTION</th>
<th>POTENTIAL FAILURE MODE</th>
<th>POTENTIAL EFFECT(S) OF FAILURE</th>
<th>SEV CLASS</th>
<th>POTENTIAL CAUSE(S)/MECHANISM(S) OF FAILURE</th>
<th>OCC CURRENT CONTROLS</th>
<th>DET</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Correct Part - pilot bearing</td>
<td>Incorrect part installed</td>
<td>Misbuild</td>
<td>7</td>
<td>Manual: incorrectly selected</td>
<td>7 No prevention</td>
<td>No detection</td>
<td>10 490</td>
</tr>
</tbody>
</table>
### PFMEA RPN REDUCTION SUMMARY - Part Number: Supplier Name

<table>
<thead>
<tr>
<th>OPERATION NUMBER</th>
<th>COMBINED RPN</th>
<th>TOTAL NUMBER OF CAUSES</th>
<th># OF CAUSES &gt; 40</th>
<th>HIGHEST INDIVIDUAL RPN</th>
<th>OPERATION NUMBER</th>
<th>BASELINE</th>
<th>Month Year RPN</th>
<th>Month Year RPN</th>
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<td>1</td>
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</table>

#### RPN Reduction Plan - Top Ten

<table>
<thead>
<tr>
<th>Item</th>
<th>Oper. / STA. #</th>
<th>RPN Value</th>
<th>Function &amp; Failure Mode</th>
<th>Recommended Action(s)</th>
<th>Compl. Date</th>
<th>Responsibility</th>
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<td>10</td>
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</tbody>
</table>

### Total Number of Causes Range Summary
With Error Proofing device functioning

Failure mode: **Burr**  Cause: **Dull tool**  Control: **Poka Yoke Device**

Severity: Defect caught at GM Assembly Line (scrap): 5
Occurrence: Supplier process PpK ≥ 1.10 4
Detection: Error Proofing in process 3

RPN = 5 x 4 x 3 = 60

With Error Proofing device not-functioning

Failure mode: **Burr**  Cause: **Dull tool**  Control: **Visual Inspection**

Severity: Defect caught at GM Assembly Line (scrap): 5
Occurrence: Supplier process PpK ≥ 1.10 4
Detection: Error Proofing device not functioning 10

RPN = 5 x 4 x 10 = 200
PFMEA information interrelationship flow

- The Process FMEA is not a "stand-alone" document.
  - utilise the information and knowledge gained from the creation of the DFMEA

  DFMEA, Process Flow Diagram, etc.

  PFMEA

  Process Control Plans

- Linkage is not always obvious
  - DFMEA focuses on 'part function'
  - PFMEA focuses on 'manufacturing' process
  - Column information of D/P FMEA not aligned
  - Connection is through 'potential cause of design failure' and 'potential process Failure Mode'

Source: AIAG PFMEA Fourth Edition
# Process Control Plans

## Who, When, Controls Quality in Process

<table>
<thead>
<tr>
<th>Quality Assurance and Control</th>
<th>Core Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Thales Process Control Plan</td>
<td># Issue no.</td>
</tr>
<tr>
<td>Customer</td>
<td>20-Jul-09</td>
</tr>
<tr>
<td>THALES AUSTRALIA, LAND SYSTEMS, MULWALA FACILITY</td>
<td></td>
</tr>
<tr>
<td>Defence Job #:</td>
<td></td>
</tr>
<tr>
<td>Release: #(/<em>/</em>/)</td>
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</tr>
<tr>
<td>Part Description</td>
<td>Prod</td>
</tr>
<tr>
<td>PROPELLANT AR2210</td>
<td></td>
</tr>
<tr>
<td>Core Team</td>
<td></td>
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</table>

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<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Assurance Technique</td>
<td>By Who</td>
<td>Control</td>
<td>By Who</td>
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</tbody>
</table>

### Draft PROCESS CONTROL PLAN  23/06/08

<table>
<thead>
<tr>
<th>Process Step #</th>
<th>Activity description for control</th>
<th>Specification</th>
<th>Critical Control KCC or KPC</th>
<th>Assure</th>
<th>Monitor</th>
<th>Reaction Plan or 8D on Non Conformance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
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</tbody>
</table>
Common errors and pitfalls

Use the Last PFMEA
- No original thinking (status quo accepted)

Poor definition of function and failure mode
- Failure modes are a jumble of causes and effects

Poor use of team time

Reliance on a central individual to do the lot

Seen as an administrative requirement rather than a core engineering discipline

Cause identification is too limited

Team gets bogged down with scoring

SOD Permutations proliferate and create massive documents

Focusing on issues outside your control:
- product design (fixed in the DFMEA)
- Supplier quality (SQA will fix this)
More common errors and pitfalls

Bad Team Composition
- Not Cross-Functional
- Not Multi-Level

Focus on Limited Area
- Shifting Design Concerns To Manufacturing

Lack Of Management Support

Not Enough Time

Too Much Effort By Leader Or Key Participant (Not Really A Team)

Using Symptoms Or Superficial Causes Instead Of Root Cause

Confusion About Ratings As Estimates, Not “Absolutes”

Using “Customer Dissatisfied” As Failure Effect

Improvement Must Be Never Ending

FMEA Reports Stuffed In Binders Have Limited Value

Use FMEA As A Living Guideline To Better Products & Processes

Use FMEA To Get Your Money’s Worth In Quality & Productivity

Confusion About Function

KEEP TO THE FMEA PROCESS OUTLINE TO AVOID THESE PROBLEMS!
A Question: Stability or Capability first? – Source: APQP+CP TS16949 AIAG

(A) Stable and incapable

(B) Unstable and incapable

Centre Process

Reduce Spread

World Class Quality “On-Target Minimum Variation”. Dr DJ Wheeler
A twist on “good, better, best, never let it rest, till you good is better and your better best”
St Jerome. Circa 400AD

Stable process best
Don’t tamper, let it rest
Less causes, less waste
Reduce waste, improve profits
On target is best