Advanced Product Quality Planning

APQP 2nd Edition

Webinar

Presentation

PRODUCT QUALITY PLANNING TIMING CHART
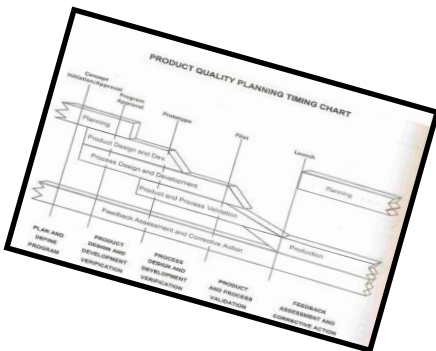
Advanced Product Quality Planning
(APQP)

Course Developer

William R. (Bill) Martin

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Unless otherwise indicated by appropriate notation information shown from any AIAG manual is paraphrased for brevity. The AIAG manual and customer specific requirement must be used for all definition of requirements.

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✓ Participants in this course are in attendance to learn about the basic requirements of Advanced Product Quality Planning (APQP). The participants need to become engaged in this training course, ask questions, challenge the material and your own concepts of the requirements of the standard, customer requirements and your organization's defined quality system.

✓ The material and exercises are designed to bring a clear, overview consideration of APQP.

✓ Engage, Enjoy and Learn!

APQP

❖ Section One

➤ Introduction and Objectives

Notes

✓ **By Choice, Not by Chance?**

✓ Too many organizations take the approach that "we have good people that will do the right thing and quality and everything else will all be OK".

✓ A tragic mistake!

✓ Just like the title of this course and the title of the AIAG manual APQP (Advanced Product Quality Planning). Quality, productivity, cycle time, business success, safety, throughput; do not happen by accident. These business activities only perform at a high level when the organization manages them through the execution of a well thought-out plan. These plans for success must be developed by the appropriate level within the organization, understood by the entire organization, supported by management, and carried out by those responsible for the work. Business procedures, work instructions, set-up instructions, gauge instructions, material handling instructions, safety requirements, all the business activities must be consistently carried out by the organization. This assures the proper result. This is what is meant when we say; "by choice not by chance". By choice is the plan. By chance is the hope everyone will figure out the correct method and apply those methods consistently. The expectations are usually met when the organization manages the business. The expectations are almost never met when the organization is inconsistent in its commitment and involvement in the execution of defined understood plans.

Course Objectives

❖ Understand the APQP – 2nd Edition

❖ Understand the Five Phases of APQP

❖ Understand the Tools of APQP

➢ DFMEA, PFMEA, Process Flow Chart, Process Control Plan, PPAP, etc.

❖ Understand the Planning Requirements

❖ Understand the Team Benefits Applied to APQP

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❖ Section Two

❖ Fundamentals of Product Quality Planning

- ➤ Planning Responsibility Matrix
- ➤ Fundamentals of Product Quality Planning
- ➤ Understanding – Product Quality Planning Timing Chart

Product Quality Planning Responsibility Matrix

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	Design Responsibiltiy	Manufacturing Only	Service Organization i.e. Heat Treat, Warehousing, Transportation, etc.
Define the Scope	X	X	X
Plan and Define Chapter 1.0	X		
Product Design and Development Chapter 2.0	X		
Feasibility Section 2.13	X	X	X
Process Design and Development Chapter 3.0	X	X	X
Product and Process Validatin Chapter 4.0	X	X	X
Feedback, Assessment and Corrective Action Chapter 5.0	X	X	X
Control Plan Methodology Chapter 6.0	X	X	X

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✓ This Matrix does not show all types of business organizations that may be involved in the APQP activity. APQP is a structured process to bring clarity to organizations of the "customer requirements". One of the goals is to facilitate communication between customers, suppliers, design organizations and others. Some of the benefits of APQP are the activity of directing resources to support customer requirements and promoting the early identification of product changes, thus avoiding the higher cost of late changes. This enables the supplying organization to have the ability to provide quality products in a timely manner at a low cost.

Fundamentals of Product Quality Planning

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❖ Definition
  ➢ Structured Approach
  ➢ Goal
    ✓ Facilitate Communication
  ➢ Top Management Commitment
  ➢ Benefits;
    ✓ Direct Resources
    ✓ Promote Identification of Required Changes
    ✓ Avoid Late Changes
    ✓ Provide Quality Product On Time at Low Cost

✓ The management team of the supplying organization should appoint a "project owner" to the APQP process. The organization must follow-up with support for the APQP team and the APQP team leader. Without the proper organizational support the project effectiveness will suffer. The process will not bring the level of success that is expected by the customer or the level of success that is beneficial to the supplier.

✓ Additionally the project manager, with the support of management, needs to identify the APQP team made up of the required personnel. In some cases and with some organizations there may be a changing of project leader as the project moves through the five phases of APQP. In all cases the proper identification of well trained, active team members is fundamental to the success of the program.

✓ There will be more about the "team" implementation of APQP in a later section.

Define the Scope

❖ Early Identification of; Customer Needs, Expectations, and Requirements
❖ Define Roles and Responsibilities
❖ ID – Customers, Internal and External
❖ Select the Disciplines, Individuals and/or Suppliers
❖ Understand Customers Expectations
  ➢ Design, Number of Test, etc

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✓ Early definition of the scope that defines the customer's needs expectations and requirements are of the utmost importance to the team and the supplier.

✓ At a minimum the team must meet to:

✓ Select a project team leader responsible for oversight and planning.

✓ Define the roles and responsibilities of team members. These roles and responsibilities should be in writing and reviewed with each team member.

✓ Identify all customers both internal and external that are affected by the APQP project.

✓ Define customer requirements using tools such as QFD as applicable.

✓ Select the disciplines and individuals that may be added to the team, or function in support roles to the team.

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Define the Scope
(Con't)

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❖ **Assess Feasibility**
- ➤ Design
- ➤ Performance
- ➤ Manufacturing

❖ **Identify, Cost, Timing and Constraints**

❖ **Determine Assistance Needs From Customer**

❖ **Identify Documentation Process & Method**

✓ Asses the feasibility of the design
✓ Identify the cost, timing and constraints that must be considered.
✓ Determine the assistance needed from the customer and the methods of documenting the activity.

Five Phases or Chapters of APQP
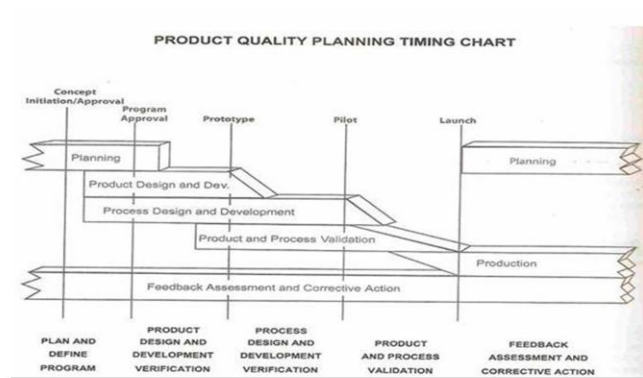
PRODUCT QUALITY PLANNING TIMING CHART

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1. **Plan and Define Program**: This step defines how customer needs and expectations are linked to planning and defining a quality program. The goal is to meet customer needs while providing competitive value. The initial steps are to ensure that customer needs and expectations are clearly understood.

2. **Product Design and Development Verification**: This step defines the planning process during which design features and characteristics are developed into near final form.

3. **Process Design and Development Verification**: This step defines the major features of developing a manufacturing system and its related control plans to achieve quality of products, attain the required volume and support the customer's schedule.

4. **Product and Process Validation**: This step defines the major activities in the validation of the manufacturing process via an evaluation of the significant production run.

5. **Feedback Assessment and Corrective Action**: With all special and common causes of variation present, the organization is now able to make an assessment of the process and product and take the appropriate corrective action.

APQP

❖Section Two - Summary

➢Planning Responsibility Matrix

➢Fundamentals of Product Quality Planning

➢Understanding – Product Quality Planning Timing Chart

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❖ Section Three
  ➤ APQP Chapter one
    ✓ Plan and Define Program

Chapter One

PRODUCT QUALITY PLANNING TIMING CHART

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✓ This section of the APQP process describes how the customer needs and expectations are linked to the planning and defining activity. The goal of a product program is to meet the customer needs and at the same time provide a competitive value for the customer and the supplying organization.

✓ The inputs and outputs applicable to the planning process will vary according to the project at hand and the customer needs, expectations and requirements.

✓ The reader will notice that the input/output activity for each chapter or phase of APQP is a building process. The outputs of each section or chapter become the inputs to the next section or chapter.

✓ It is important that the supplying organization confirm with the customer or procuring division the exact expectations and requirements for each APQP project.

Chapter One – Inputs

❖ Inputs
- ➤ 1.1 Voice of the Customer
  - ✓ 1.1.1 Market Research
  - ✓ 1.1.2 Warranty & Quality Information
  - ✓ 1.1.3 Team Experience
- ➤ 1.2 Business Plan/Marketing Strategy
- ➤ 1.3 Product/Process Benchmark Data

- ✓ **INPUTS**:
- ✓ **1.1 Voice of the Customer:** This is an encompassing title that considers many sources. The complaints, recommendations, data and information from all internal and external customers should be considered, as well as market research that includes customer interviews, customer questionnaires and surveys. Further the information from market test and position reports as well as new product quality and reliability studies, competitive product quality studies. This must also consider best practices and lessons learned by the supplying organization and the procuring division. Team experience must also be considered as an input to this phase. From a properly staffed APQP team there will be a great deal of valuable knowledge.
- ✓ **1.2 Business Plan and Marketing Strategy:** The customer business plan as well as the supplying organization business plan may place restrictions on the APQP development project. Consider the strategic impact of timing, cost, investment, R&D, etc.,
- ✓ **1.3 Product/Process Benchmark Data:** The use of benchmark data for world class or best-in-class for both product and process will provide the APQP team with valuable information about these best practices when selecting the appropriate benchmarks understanding your "gap" with the benchmark and developing a plan to close the gap are invaluable steps to become or staying competitive.

Chapter One – Inputs
(Con't)

❖Inputs
- ➢ 1.4 Product/Process Assumptions
- ➢ 1.5 Product Reliability Studies
- ➢ 1.6 Customer Inputs

✓ **1.4 Product/Process Assumptions:** There are always assumptions to be made, many of these are starting points for the team and become valuable guides to the project, these include technical advances, materials, reliability and new technology.

✓ **1.5 Product Reliability Studies:** One of the sources of information may be survey information and/or warranty data.

✓ **1.6 Customer Inputs:** The next users, often internal customers can provide valuable information about their needs and how those needs affect throughput, quality, repair, scrap, etc. These can lead to internal measures of improvement, growth, efficiency etc.

Chapter One – Outems

(Become Inputs for Chapter 2)

❖Outputs

➤1.7 Design Goals

➤1.8 Reliability and Quality Goals

➤1.9 Preliminary Bill of Materials

➤1.10 Preliminary Process Flow Chart

✓ **1.7 Design Goals:** These are a translation of the "voice-of-the-customer" into measurable design objectives. The correct selection of design goals helps to ensure the "voice-of-the-customer" isn't lost in the subsequent APQP project.

✓ **1.8 Reliability and Quality Goals:** These goals are based on customer defined requirements. These are often found as a part of the request-for-quote package. Quality goals are often based on parts-per-million, problem levels, scrap reduction, etc.

✓ **1.9 Preliminary Bill of Materials (BOM):** While the title suggests that this list is tentative and may change; the identification of the preliminary BOM helps to identify supplier and sourcing needs of the organization. If new suppliers must be obtained this may well give the organization the "head-start" they need to bring potential suppliers into the verification, validation process for approval.

✓ **1.10 Preliminary Process Flow Chart:** This is the anticipated manufacturing process and like, the Preliminary BOM, gives the organization a much needed head-start in answering some of the process issues that may be encountered by this particular APQP project. This preliminary-process-flow-chart may be developed from the preliminary BOM and the product assumptions.

❖Outputs

➢1.11 Preliminary List of Special Product and Process Characteristics

➢1.12 Product Assurance Plan

➢1.13 Management Support

✓Management **should** be updated at the completion of each APQP planning phase

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✓ **1.11 Preliminary List of Special Product and Process Characteristics:** Special product and process characteristics are identified by the customer and/or design facility. These are based on the knowledge of the product, regulatory requirements, customer requirements and expectations as well as organizational or team knowledge of the design and the manufacturing process. Special characteristics come from sources such as; product assumptions based on customer needs and/or expectations, the customer defined reliability or quality goals, identification of special process steps as well as Design or Process FMEA for similar parts, subassemblies or assemblies.

✓ **1.12 Product Assurance Plan:** This plan based on customer needs translates design goals into design requirements. The APQP manual does not require a specific method or format. The Product Assurance Plan may be in any format or method needed by the supplying organization, unless the procuring division imposes specific requirements, steps or formats.

✓ **1.13 Management Support:** A KEY to the success of the APQP project is the interest, commitment and support of upper or top management. The updating of top management on a frequent schedule is vital to maintaining their interest, involvement, support and guidance for these vitally important activities. As a primary goal of APQP the continued involvement of top management ensures the success of these vital customer driven activities.

APQP

❖Section Three - Summary
  ➤APQP Chapter One
    ✓Plan and Define Program

✓ Notes

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❖Section Four
  ➢APQP Chapter Two
    ✓Product Design and Development

APQP Chapter Two
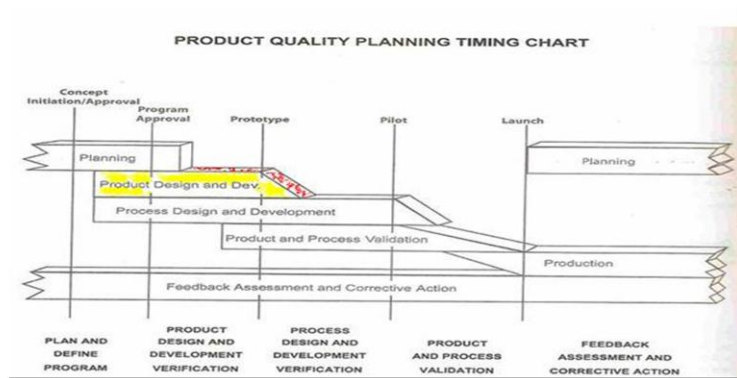
PRODUCT QUALITY PLANNING TIMING CHART

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✓ This chapter or phase of APQP defines the elements of the planning process during which the features of the product are developed into near final form. All design factors should be considered by the organizations APQP team even if the organization is NOT design responsible or only partially design responsible. A feasible design must permit production at the designated volume, cost, schedule, weight and timing.

Chapter Two – Inputs
(From the outputs of Chapter one)

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❖ Inputs
- ➢ Design Goals
- ➢ Reliability and Quality Goals
- ➢ Preliminary Bill of Materials
- ➢ Preliminary Process Flow Chart
- ➢ Preliminary List of Special Product and Process Characteristics
- ➢ Product Assurance Plan
- ➢ Management Support

✓ The inputs to section two of the APQP process are the outputs of chapter or phase one of the APQP process.

Chapter Two – Outputs
(Become Inputs for Chapter 3)

❖ Design Outputs

➢ **2.1 Design Failure Mode Effects Analysis (DFMEA)**

✓ **2.1 Design Failure Mode Effects Analysis (DFMEA):** The DFMEA focuses on the design of the product that will be delivered to the final customer. The DFMEA is developed using a cross functional team. The DFMEA form is used to document the process including any recommended corrective actions. The DFMEA process is laid out on the following pages.

Design FMEA

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❖ AIAG/FMEA – Fourth Edition

  ➢ Design FMEA Benefits

    ✓ Aid in Objective Evaluation of the Design

    ✓ Evaluation of the Initial Design

    ✓ Increases the Probability that Potential Failure Modes and Their Effects are Considered

    ✓ Provides Additional Information to Support Planning

    ✓ Develops a "Ranked" List of Potential Failure Modes

    ✓ Provides an "Open Issues" Format

✓ The DFMEA aids in the objective evaluation of the product, including the functional requirements designated by the customer. The material requirements are examined for potential failures. The dimensional aspects of the design are also analyzed by the FMEA process This objective evaluation prioritizes any recommended corrective actions to the design that may be needed. While the DFMEA may be better defined as "Risk-Analysis" it is a vital input to the APQP process as well as to the supplying organization work in the development of the manufacturing process.

Design FMEA

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❖ AIAG/FMEA – Fourth Edition
  ➢ Design FMEA Benefits – (Con't)
    ✓ Provides Future Reference to Aid in Addressing Field Concerns (Lessons Learned)
  ➢ The DFMEA is a Living Document and Should
    ✓ Be Initiated Before Design Concept Finalization
    ✓ Be Updated as Changes Occur
    ✓ Be Fundamentally Complete Before the Production Design is Released
    ✓ Be a Source of Lessons Learned for Future Designs

✓ The DFMEA also provides a valuable reference for future designs and is a major input to "lessons-learned". The Design FMEA is a living document that is updated as the design evolves, usage changes, regulatory requirements are revised, or new materials or technology are incorporated into the design or manufacturing process. The Design FMEA is completed prior to final release and is update as changes are approved.

Design FMEA

❖ Requirements
- ➤ Team Approach
- ➤ Manufacturing Considerations
  - ✓ Design Effect on Manufacturing
- ➤ Prerequisites
  - ✓ Process and Mating Components
  - ✓ Functions and Features

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✓ The team for the design FMEA should be a multi-disciplined work group made up of the necessary skill sets to ensure a comprehensive DFMEA. Some of the typical members would be; engineering, operations, purchasing, material handling/flow, Human Resources, sales, customer/supplier representatives, quality, and any other persons that would bring value to the process. It is critical that the team be properly sized, and not exceed 8 to 10 members. Typically the team would not be smaller than 5 or 6 members. Again the important thing is to cover the knowledge-base necessary for a thorough evaluation of the components or assemblies being assessed.

✓ The team must take into consideration not only the effect on the end-user but also the manufacturing impacts of the various failure effects. This requires taking into account the mating components, component and functions failures as well as material requirements and their impact on manufacturing.

Design FMEA

❖ **Functional Requirements**

➢ Both Functional and Interface Requirements

✓ General (overall purpose of design)
✓ Safety
✓ Government Regulations
✓ Reliability
✓ Loading and Duty Cycles
✓ Quiet Operations – Noise, Vibration & Harshness (NVH)
✓ Fluid Retention

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✓ The functional requirements of the Design FMEA must be comprehensive and take into account the assembly or other interface requirements as well as the safety and government regulations. Reliability is most often measured in load or duty cycles and may actually require ongoing testing of components or assemblies as they are manufactured.

✓ The failure modes often complained about by the end user of vehicles are noise and leak failures. If a failure mode has the potential to create noise that is objectionable to the vehicle operator or if a fluid leak should occur it must be thoroughly assessed and resolved.

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Design FMEA

❖ Functional Requirements – Con't
➤ Both Functional and Interface Requirements
- ✓ Ergonomics
- ✓ Appearance
- ✓ Packaging and Shipping
- ✓ Service
- ✓ Design for Assembly
- ✓ Design for Manufacturability

✓ As the Design FMEA team assess the ergonomic aspects of the product or assembly the affects of failures may not only be seen by the end-user but may be a manufacturing or assembly issue, causing injury or unacceptable levels of fatigue to the operator. Injury is self evident that it must be resolved, unacceptable fatigue may in some cases lead to bottle-neck problems for manufacturing, quality issues, or other throughput restrictions that are undesirable to the organization. Appearance issues may be something as simple as rust, scratches, paint issues or other undesirable conditions to the end user. Packaging and shipping issues are not only throughput issues these may lead to product damage. The team must also remember to address the labeling requirements as called out by the design, including polymeric identification.

✓ Finally the issues of design for assembly, manufacturability must be a part of the design FMEA. Failure modes that affect these two conditions often impact throughput, scrap, rework/repair or other production issues that are undesirable conditions to manufacturing.

Design FMEA

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									Current Design							Action Results				

System
Subsystem
Component **B**
Model Year(s)/Programs(s) **D**
Core Team **G**

Potential
Failure Mode Effects Analysis
(Design FMEA)
Design Responsibility **C**
Key Date **E**

FMEA Number **A**
Page of
Prepared By **H**
FMEA Date (Orig) **F**

Item / Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Control Prevention	Occurrence	Controls Detection	Detection	RPN	Recommended Action	Responsibility & Target Completion Date	Actions Taken Completion Date	Severity	Occurrence	Detection	RPN
a1 a2	a2	b	c	d	e	f	h	g	h	i	j	k	l	m	n	n	n	n

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- ✓ This is a general look at one format for the Design FMEA, the next several pages detail how the process is documented using this form and format.

Steps to DFMEA

- ✓ A – The FMEA number is an organizationally generated number for document control purposes.

- ✓ B – Check the appropriate item to identify the scope of this DFMEA, component, system or subsystem. If this is a component the part number should be included. For a system or subsystem use the appropriate description and/or number.

- ✓ C – Design responsibility is generally assigned to the design engineer of chief design engineer when the design is a team activity. The OEM, organization, department or group may also be utilized.

- ✓ D – Model Year/Program, is the intended models or programs that will utilize the item under consideration

- ✓ E – Key Date, is the initial due date of the DFMEA and should not exceed the scheduled production design release date.

- ✓ F – FMEA dates are the original completion date and the latest revision date.

- ✓ G – Core Team, the members responsible for the completion of the DFMEA, names, job titles, phone numbers, e-mail, etc.

- ✓ H – Prepared by, is the name and contact information of the persons responsible for the completion of the DFMEA form and associated documentation.

Steps to DFMEA

Item / Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure
a1	a2	b	c

a – Item / Function / Requirement

a1 – Enter Item, Interfaces or Parts

a1 – Enter the Functions of the Items or Interfaces

a2 – Requirements – This additional column allows for further definition of the analysis of the failure mode/modes

b – Potential Failure Mode – described in technical terms not as symptom noticed by the customer

c – Potential Effect/Effects of Failure – as described by the customer

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- ✓ **a** – **ITEM/FUNCTION;** can be contained in one column or divided into two columns. Components may be listed in the Item/Function column and an additional column for Requirements.

- ✓ **a1** – **ITEM**: Enter the items, interfaces or parts identified for analysis. The terminology used should be consistent with customer requirements.

- ✓ **a1** – **FUNCTION**: Enter the function/functions of the items or interfaces being analyzed based on customer requirements. If the item has multiple functions with multiple failure modes they should be listed separately. (Function becomes **a2** if ITEM and FUNCTION are listed separately.)

- ✓ **a2** – **REQUIREMENT**: An additional column for requirements may be added to further refine the analysis. Enter the functions of each requirement, if a function has multiple requirements it is recommended that each requirement be entered separately. (Requirement becomes **a3** if ITEM and FUNCTION are split into separate columns.)

- ✓ **b** – **POTENTIAL FAILURE MODE:** Potential failure mode is defined as the method a component or item fails to meet or deliver the intended function or requirement. Failure modes should be described in technical terms and not as symptoms noticeable by the customer. Each function may have multiple failure modes and each should be listed separately. The analysis assumes the failure mode COULD occur but will not necessarily occur.

- ✓ **b** (con't) – "Potential failure modes that could occur only under certain operating 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." After determining all failure modes a validation via past experience and/or data should be completed. Potential failure modes may affect a higher level system or subsystem, or lead to the failure of a lower system or component.

- ✓ **c** – **POTENTIAL EFFECT/EFFECTS OF FAILURE;** Potential effects of failures are described in term as perceived by the customer (internal, external, or end-user). State clearly if the effect/effects impact safety or governmental regulation.

Steps to DFMEA

Severity	Classification	Potential Cause(s) of Failure	Current Design			
			Control Prevention	Occurrence	Controls Detection	Detection
d	e	f	h	g	h	i

d – Severity – scale of 1 to 10

e – Classification

f – Potential Cause/Causes or Mechanism/Mechanisms of Failure Mode

g – Occurrence – scale of 1 to 10

h – Current Design Controls (Prevention or Detection)

i – Detection – scale of 1 to 10

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✓ **d – SEVERITY:** Severity is a value of 1 to 10 based on the table defined in the AIAG/FMEA manual. The team should ensure they are using the latest revision of the AIAG documentation. The team should agree on the evaluation method and remain consistent within the FMEA.

✓ **e – CLASSIFICATION:** This column is used to identify high risk items that are designated as "Special Characteristics" by the design organization or the customer. A characteristic that is designated as "Special" without an associated design failure mode is an indication of a weakness within the design process.

✓ **f - POTENTIAL CAUSE/CAUSES OR MECHANISM/MECHANISMS OF FAILURE MODE:** This information may be contained in a single column or split into multiple columns for additional clarity.

- ✓ **g** – **OCCURRENCE:** occurrence is the likelihood that a particular cause or mechanism will occur resulting in the failure mode within the design life of the product. The likelihood is ranked 1 to 10 on the scale identified in the AIAG/FMEA manual. The team should agree on a consistent ranking system and apply the method consistently. To determine this estimate as questions such as the following;

- ❑ What is the service history or field experience with similar products?

- ❑ Is the item a carryover?

- ❑ How significant are the changes from a previous design?

- ❑ Is the item radically different from a previous design?

- ❑ Is this item completely new?

- ❑ What is the application or environmental conditions of use?

- ❑ Has an engineering analysis such as reliability testing been used to estimate the expected failure rate?

- ❑ Have preventive controls been put into place?

- ✓ **h** – **CURRENT DESIGN CONTROLS:** Design controls are those activities that assure the design is adequate for the intended use. There are two types of controls; "Prevention & Detection". Prevention eliminates or prevents the cause or mechanism of the failure mode from occurring or reduces the rate of occurrence. Detection identifies the existence of a cause or mechanism of the failure mode before the item is released for production. The preferred approach is to use prevention controls as much as possible.

- ❑ **PREVENTION CONTROLS**

- ❑ Benchmarking studies

- ❑ Fail-safe designs

- ❑ Design and material standards (internal or external)

- ❑ Documentation – records of best practices etc., from similar designs.

- ❑ Simulation studies

- ❑ Error-proofing

- ❑ **DETECTION CONTROLS**

- ❑ Design reviews

- ❑ Prototype testing

- ❑ Validation testing

- ❑ Simulation studies – for validation of design

- ❑ Design of Experiment, including reliability testing

- ❑ Mock-up using similar parts

- ✓ **i** – **<u>DETECTION:</u>** Detection is the rank (1 to 10) with the best detection control listed in the current design control detection column. A suggested approach is to assume the failure has occurred and then assess the capability of the identified control to detect the failure mode. Do not presume that the detection ranking is low because the occurrence is low. It is even more important to have effective detection methods with low occurrence incidents. Low occurrence rates are often more difficult to detect than high occurrence rates. Detection is a relative ranking within the scope of the DFMEA. The ranking value of 1 is reserved for failure prevention through proven design solutions.

Severity Table
(DFEMA)

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects save vehicle operation and/or involves noncompliance with government regulation without warning.	10
	Potential failure mode affects save vehicle operation and/or involves noncompliance with government regulation with warning.	9
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort / convenience functions inoperable).	6
	Degradation of secondary function (vehicle operable, but comfort / convenience functions at reduced level of performance).	5
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (>75%)	4
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%)	3
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%)	2
No effect	No discernible effect	1

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✓ Severity is the value given to the most serious effect for a given failure mode. Severity should be considered a relevant ranking within the scope of the current FMEA. The team should agree on the evaluation criteria and apply them consistently. If the team decides to modify the severity table they should follow the guidelines of the AIAG/FMEA manual. It is not recommended to change the severity ranking of 9 or 10 . If a particular failure mode has a severity ranking of 1, no further analysis is required.

Occurrence Table

(DFEMA)

MB Inc.

Likelihood of Failure	Criteria: Occurrence of Cause - DFMEA (Design life/reliability of item/vehicle)	Criteria: Occurrence of Cause - DFMEA (Incidents per items/vehicles)	Rank
Very High	New technology/new design with no history.	= 100 per thousand = 1 in 10	10
High	Failure is inevitable with new design, new application, or change in duty cycle/operating conditions.	50 per thousand 1 in 20	9
	Failure is likely with new design, new application, or change in duty cycle/operating conditions.	20 per thousand 1 in 50	8
	Failure is uncertain with new design, new application, or change in duty cycle/operating conditions.	10 per thousand 1 in 100	7
Moderate	Frequent failures associated with similar designs or in design simulation and testing.	2 per thousand 1 in 500	6
	Occasional failures associated with similar designs or in design simulation and testing	.5 per thousand 1 in 2,000	5
	Isolated failures associated with similar designs or in design simulation and testing	.1 per thousand 1 in 10,000	4
Low	Only isolated failures associated with almost identical design or in design simulation and testing.	.01 per thousand 1 in 100,000	3
	No observed failures associated with almost identical design or in design simulation and testing.	= .001 per thousand 1 in 1,000,000	2
Very Low	Failure is eliminated through preventive control	Failure is eliminated through preventive control	1

✓ Occurrence is the likelihood that a specific cause or mechanism will occur resulting in the failure mode and that this event happens within the design life of the product, subsystem or system under consideration. A consistent ranking system should be utilized within the FMEA. The team should agree on a consistent application of a ranking system. Occurrence should be estimated on a scale of 1 to 10 using the AIAG/FMEA manual as a guide.

Detection Table

(DFEMA)

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Opportunity for Detection	Criteria: Likelihood of Detection by Design Control	Rank	Likelihood of Detection
No Detection Opportunity	No current design control, Cannot detect or is not analyzed	10	**Almost Impossible**
Not Likely to Detect at any Stage	Design analysis/detection controls have a weak detection capability; Virtual Analysis (e.g., CAE, FEA, etc.) is **not** **correlated** to expected actual operating conditions	9	**Very Remote**
Post Design Freeze and Prior to Launch	Product verification/validation after design freeze and prior to launch with **pass/fail** testing (Subsystem or system testing with acceptance criteria such as ride and handling, shipping evaluation, etc.)	8	**Remote**
	Product verification/validation after design freeze and prior to launch with **test to failure** testing (Subsystem or system testing until failure occurs, testing of system interactions, etc.)	7	**Very Low**
	Product verification/validation after design freeze and prior to launch with **degradation** testing (Subsystem or system testing after durability test, e.g., function check)	6	**Low**

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The second half of the "Detection" table is on the following page.

Detection Table
(DFEMA)

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Opportunity for Detection	Criteria: Likelihood of Detection by Design Control	Rank	Likelihood of Detection
Prior to Design Freeze	Product validation (reliability testing, development or validation tests) prior to design freeze using **pass/fail** testing (e.g., acceptance criteria for performance, function checks etc.).	5	Moderate
	Product validation (reliability testing, development or validation tests) prior to design freeze using **test to failure** (e.g., until leaks, yields, cracks, etc.).	4	Moderately High
	Product validation (reliability testing, development or validation tests) prior to design freeze using **degradation** testing (e.g., data trends, before/after values, etc.).	3	High
Virtual Analysis - Correlated	Design analysis/detection controls have a strong detection capability; Virtual Analysis (e.g., CAE, FEA, etc.) **is highly correlated** with actual or expected operating conditions prior to design freeze.	2	Very High
Detection not applicable; Failure Prevention	Failure cause or failure mode can not occur because it is fully prevented through design solutions (e.g., proven design standard, best practice or common material, etc.)	1	Almost Certain

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Steps to DFMEA

RPN	Recommended Action	Responsibility & Target Completion Date
j	k	l

j – RPN (S x O x D) – Used to Prioritized Corrective Action Activities

k – Recommended Actions

l – Responsibility and Target Completion Date

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- ✓ **j** - <u>**RISK PRIORITY NUNBER (RPN)**</u>

- ✓ RPN = Severity x Occurrence x Detection

- ✓ Within the scope of the FMEA this value may range from 1 to 1000. The RPN may be utilized to prioritize corrective action/actions.

- ✓ **<u>Per the AIAG/FMEA manual it is not recommended to use a threshold value to determine action taken.</u>**

- ✓ The application of threshold values assumes that all RPNs are equal, which they are not.

- ✓ For example, if a customer or corporation applied an arbitrary threshold value of 100 to the following the supplier would be required to address characteristic 'B' when actually characteristic 'A' has the higher severity that is related to safe vehicle operation.

Item	Severity	Occurrence	Detection	RPN
A	9	2	5	90
B	7	4	4	112

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Supplier Quality Requirements Task Force.

- ✓ **k– <u>RECOMMENDED ACTIONS</u>:** Preventive actions should address the reduction of occurrence, this being preferable to an improvement in detection. The intent of recommended actions is to improve the design. In support of this objective the team should consider actions in the following order; first, reduction of (S) severity, then, improvement in (O) occurrence lastly an improvement in (D) detection. This column should also document all "rejected" recommendations.

- ✓ **l – <u>RESPONSIBILITY & TARGET COMPLETION DATE</u>:** Enter the name of the individual or organization that is responsible for the completion of each activity by the assigned target date. The responsible person/persons should ensure that all actions are completed by the due date assigned.

- ✓ **m/n** – **ACTION RESULTS**: This section records the results of actions taken and their effect on severity, occurrence and detection.

- ✓ **m** – **ACTION/ACTIONS TAKEN AND THE COMPLETION DATE:** This section contains a brief description of the action taken by an individual, organization or other group/team. This column would include documentation of rejected items.

- ✓ **n** – **SEVERITY, OCCURRENCE, DETECTION AND RPN**: After the corrective action has been taken this section records the resulting impact on severity, occurrence and detection and the resulting RPN. All revised rankings should be **validated**, it should never be assumed that action taken automatically results in reduced risk. After the validation if it is determined that additional action is needed, repeat the analysis and corrective action. The focus should always be on continuous improvement.

Chapter Two – Outputs
(Become Inputs for Chapter 3) Con't

❖Design Outputs – (con't)
- ➤2.2 Design for Manufacturability and Assembly
- ➤2.3 Design Verification
- ➤2.4 Design Reviews
- ➤2.5 Prototype Build – Control Plan
- ➤2.6 Engineering Drawings (including math data)
- ➤2.7 Engineering Specifications
- ➤2.8 Material Specifications
- ➤2.9 Drawing and Specification Changes

- ✓ **2.2 Design for Manufacturability and Assembly;** This is a simultaneous engineering activity to optimize the relationship between design features and manufacturing or assembly operations. While the AIAG/APQP manual does not endorse a specific method or formation for "design for manufacturing and assembly" at a minimum the following items should be considered;

  - ❑ **Design, concept, function, and sensitivity to manufacturing variation**
  - ❑ **Manufacturing and /or assembly process**
  - ❑ **Dimensional tolerances**
  - ❑ **Performance requirements**
  - ❑ **Number of components (strive to minimize)**
  - ❑ **Process adjustments**
  - ❑ **Material handling**

- ❑ This list may be augmented with additional considerations based on; customer requirements, team knowledge, experience, government regulations or service requirements.

- ❑ **2.3 Design Verification:** This verification confirms the product design meets the customer requirements.

- ✓ **2.4 Design Reviews:** The design review is a regularly scheduled meeting, typically lead by the design function. The review meeting should be attended and supported by top management and should include members from all affected areas of the organization. Design review are a series of verifications and should include evaluation of;

  - ❑ **Design/Functional requirement/requirements considerations**
  - ❑ **Formal reliability and confidence goals**
  - ❑ **Component subsystem/system duty cycles**
  - ❑ **Computer simulation and bench test results**
  - ❑ **DFMEA(s)**
  - ❑ **Review of the design for manufacturability and assembly effort**
  - ❑ **Design of Experiments (DOE) and assembly build variation results**
  - ❑ **Test failures**
  - ❑ **Design verification progress**

- ❑ A major function of the design review is the tracking of verification progress. Tracking via plan and report format is an effective method referred to as "Design Verification Plan and Report (DVP&R)" by some customers. The DVP&R is a formal report to assure, Design Verification and Product and Process Validation.

- ❑ **2.5 Prototype Build – Control Plan:** Prototype control plans are a description of the dimensional, material and functional test that will occur during prototype build.

- ❑ **2.6 Engineering Drawings (including math data):** Drawings should be reviewed by the organization to determine if there is sufficient information for a dimensional layout of the individual parts. Control of datum surfaces/locators should be clearly identified to support the design and development of the needed functional gauges and test equipment. If appropriate; the APQP team should assure that math data are compatible with the customer's system for effective two way communication.

- ❑ **2.7 Engineering Specifications:** A detailed review and understanding of the controlling specifications will assist the APQP team to identify the functional, durability and appearance requirements of the components or assemblies. Sample size, frequency and acceptance may be included in the "in-process test section of the engineering specification". If this information is not included the sample size and frequency are determined by the organization and may require agreement by the customer.

- ❑ **2.8 Material Specifications:** Material specifications should be reviewed for special characteristics relating to physical properties, performance, environmental, handling and storage requirements. These characteristics should also be included in the process control plan.

- ❑ **2.9 Drawing and Specification Changes:** Where drawing and specification changes are required the organization must have an adequate method of communicating the changes to the affected areas.

✓ **2.10 New Equipment, Tooling and Facilities Requirements:** The DFMEA, Product Assurance Plan, and/or design reviews may identify new equipment and facilities including the ability to meet capacity requirements. These items should be added to the teams Timing Plan. The team is responsible for ensurimg the equipment is capable and operational and is delivered on time. All facility requirements must be monitored to ensure adequate completion prior to the planned production tryout.

✓ **2.11 Special Product and Process Characteristics:** The "Preliminary Special Product and Process Characteristic list of Phase I, should be utilized and developed through consensus with the evaluation of the technical information. Many OEMs have customer specific requirements that define the selection of special product and process characteristics.

✓ **2.12 Gauges/Testing Equipment Requirements:** Gauge and test equipment may be identified at this time. The APQP team should assure that this information is added to the team's timing chart and the necessary assignments are made and the assignment includes the due dates for procurement, runoff, installation, evaluation, training and other necessary activities to be completed on-time.

✓ **2.13 Team Feasibility Commitment and Management Support:** The APQP team with the support of management must assess the feasibility of the proposed design at this time. Customer owned design responsibility does not preclude the organization from making this assessment.

APQP

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❖ Section Four

➢ APQP Chapter Two - Summary

✓ Product Design and Development

✓ Notes

APQP

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❖ Section Five
  ➢ APQP Chapter Three
    ✓ Process Design and Development

APQP Chapter Three

PRODUCT QUALITY PLANNING TIMING CHART
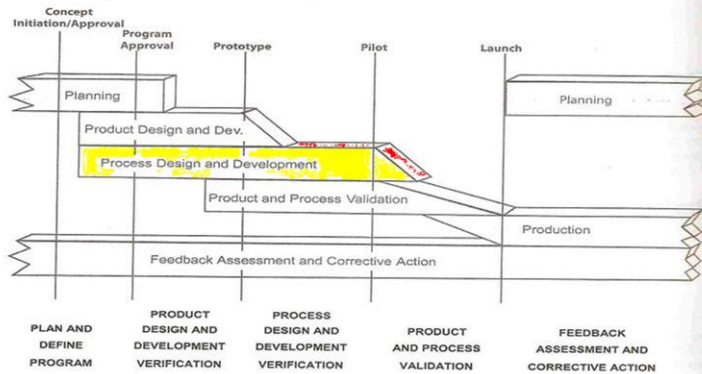
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✓ This chapter discusses the major features of developing a manufacturing process that is adequate to provide the quality and quantity required by the customer. The activities of the two previous steps are vital to the successful completion of this chapter. The manufacturing or assembly system must assure that customer requirements, expectations and needs are met.

Chapter Three – Inputs
(From the outputs of Chapter two)

❖Design
- ➢Design FMEA
- ➢Design for Manufacturability and Assembly
- ➢Design Verification
- ➢Design Reviews
- ➢Prototype Build – Control Plan
- ➢Engineering Drawings (including math data)
- ➢Engineering Specifications
- ➢Drawing and Specification Changes

Chapter Three – Inputs

(From the outputs of Chapter two

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❖ APQP

  ➢ New Equipment, Tooling and Facilities Requirements

  ➢ Special Product and Process Characteristics

  ➢ Gauges/Testing Equipment Requirements

  ➢ Team Feasibility Commitment and Management Support

  ✓ Appendix – AIAG/APQP Manual

Chapter Three – Outputs
(Become Inputs for Chapter 4)

➤ 3.1 Packaging Standards & Specifications
➤ 3.2 Product/Process Quality System Review
➤ 3.3 **Process Flow Chart**

✓ **3.1 Packaging Standards & Specifications:** The customer generally defines the packaging standards and requirements. When packaging standards are not given by the customer the organization should provide a packaging design that ensures product conformity to "point-of-use". Packaging should assure that product performance and characteristics will remain unchanged and acceptable during packing, transit and unpacking.

✓ **3.2 Product/Process Quality System Review:** The organization's APQP team should review the manufacturing sites' Quality Management System (QMS). Any additional controls, procedure revisions, enhancements, training, etc., must be addressed by the team in a timely manner. Any identified changes, etc., should be added to the quality timing plan. Specific assignments with due dates are always helpful in assuring proper follow-up and implementation of changes. The Product/Process Quality checklist in the appendix may be a helpful tool in this analysis.

✓ **3.3 Process Flow Chart:** The process flow chart is a schematic of the current or proposed manufacturing process. This charting methodology should be from receiving showing all operations, inspections, staging, storage, labeling, shipping, etc.. The flow chart is used to emphasize the impact of sources of variation and is a primary input document for the Process Failure Mode Effects Analysis (PFMEA) and Process Control Plan. The Process Flow Chart Checklist in the Appendix may be used to guide the organization.

Figure IV.2 Example Process Flow Diagram
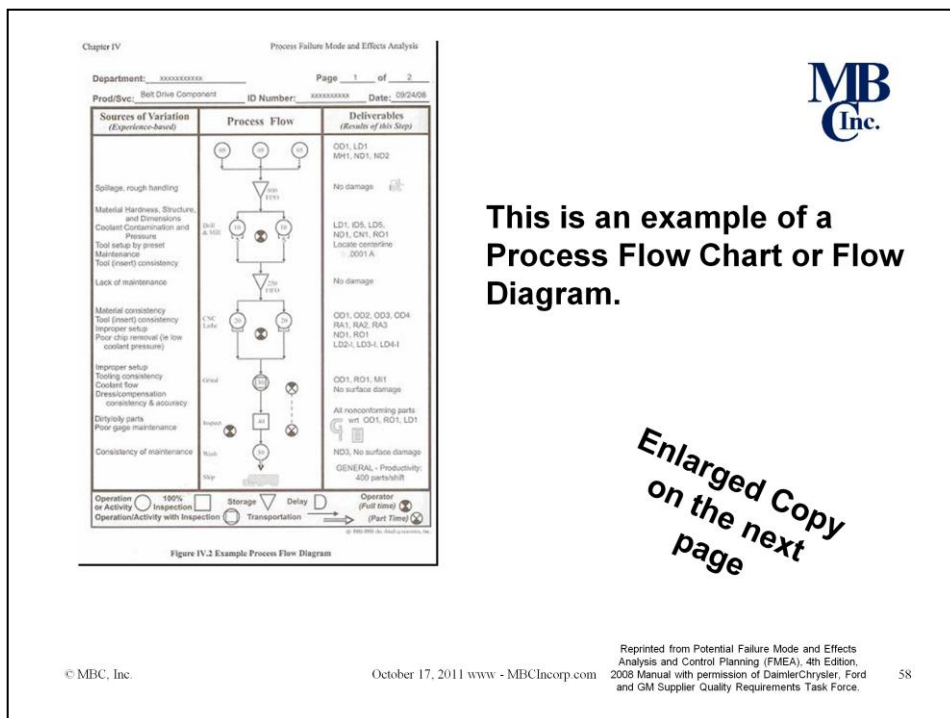
This is an example of a **Process Flow Chart or Flow Diagram.**

Enlarged Copy on the next page

✓ While there are multiple formats, approaches, requirements, information sources, etc. there is not a single required method for the documentation of the manufacturing process

✓ A comprehensive approach is to identify the entire process including but not limited to;

- ❑ Receiving
- ❑ Material Handling/Flow
- ❑ Manufacturing
- ❑ Inspection
- ❑ Labeling
- ❑ Storage and In Process Banks
- ❑ Shipping

✓ For each of these areas the flow chart may capture all the sources of input and variation. All the product characteristics should be listed as part of the process step at which they are created or modified; process parameter settings, test requirements, labeling requirements, staging, storage and shipping activities including packaging. Ambient conditions that aren't controlled but that impact process or product should be included items such as; ambient temperature, humidity, air borne contamination, vibration, etc.

✓ An enlarged Process Flow Chart/Diagram is included on the next page.

Department: ___xxxxxxxxxx___   **Page** __1__ **of** __2__

Prod/Svc: ___Belt Drive Component___   **ID Number:** ___xxxxxxxxx___ **Date:** __09/24/08__

Sources of Variation (Experience-based)	**Process Flow**	**Deliverables** (Results of this Step)
	(05) (06) (05)	OD1, LD1 MH1, ND1, ND2
Spillage, rough handling	800 FIFO	No damage
Material Hardness, Structure, and Dimensions Coolant Contamination and Pressure Tool setup by preset Maintenance Tool (insert) consistency	Drill & Mill (10) (10)	LD1, ID5, LD5, ND1, CN1, RO1 Locate centerline .0001 A
Lack of maintenance	250 FIFO	No damage
Material consistency Tool (insert) consistency Improper setup Poor chip removal (ie low coolant pressure)	CNC Lathe (20) (20)	OD1, OD2, OD3, OD4 RA1, RA2, RA3 ND1, RO1 LD2-I, LD3-I, LD4-I
Improper setup Tooling consistency Coolant flow Dress/compensation consistency & accuracy	Grind (30)	OD1, RO1, MI1 No surface damage
Dirty/oily parts Poor gage maintenance	Inspect 40	All nonconforming parts wrt OD1, RO1, LD1
Consistency of maintenance	Wash (50)	ND3, No surface damage
	Ship	GENERAL - Productivity: 400 parts/shift

Operation or Activity ◯	100% Inspection ▢	Storage ▽	Delay ▷		Operator (Full time) ⊗
Operation/Activity with Inspection ◒		Transportation ⟶			(Part Time) ⊗

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Figure IV.2 Example Process Flow Diagram

Process Flow Chart
(Assembly Example)
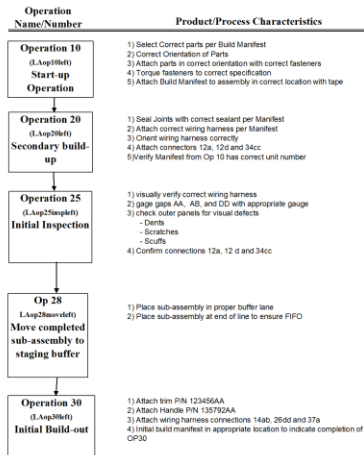
✓ This is a simplified version of a Process Flow Chart/Diagram. This example is for the "classroom-only" and lacks much information that would be required for a supplier. There is not any "header" information or other information or formatting that the customer or OEM would require of a supplier this information is omitted for simplicity and explanation.

✓ This flow chart identifies the process operation number and name (Name is both the engineering title and the operations 'common name' that is utilized in manufacturing.)

✓ Each step identifies the activities of this assembly process.

Operation Name/Number	Product/Process Characteristics
Operation 10 **(LAop10left)** **Start-up Operation**	1) Select Correct parts per Build Manifest 2) Correct Orientation of Parts 3) Attach parts in correct orientation with correct fasteners 4) Torque fasteners to correct specification 5) Attach Build Manifest to assembly in correct location with tape
Operation 20 **(LAop20left)** **Secondary build-up**	1) Seal Joints with correct sealant per Manifest 2) Attach correct wiring harness per Manifest 3) Orient wiring harness correctly 4) Attach connectors 12a, 12d and 34cc 5)Verify Manifest from Op 10 has correct unit number

Operation 25
 	
(LAop25inspleft)
 	
Initial Inspection
	1) visually verify correct wiring harness
	2) gage gaps AA, AB, and DD with appropriate gauge
	3) check outer panels for visual defects
	    - Dents
	    - Scratches
	    - Scuffs
	4) Confirm connections 12a, 12 d and 34cc

Op 28 LAop28moveleft) **Move completed sub-assembly to staging buffer**	1) Place sub-assembly in proper buffer lane 2) Place sub-assembly at end of line to ensure FIFO
Operation 30 **(LAop30left)** **Initial Build-out**	1) Attach trim P/N 123456AA 2) Attach Handle P/N 135792AA 3) Attach wiring harness connections 14ab, 26dd and 37a 4) Initial build manifest in appropriate location to indicate completion of OP30

Operation Name/Number | Product/Process Characteristics

Operation 10
(CM-Op10)
Centering Operation

1) Load Crankshaft castings in the proper orientation
2) Drill Centers to Specification
3) Rough Turn Hub end to Process Spec
3a) Rough Turn Stem End to Process Spec
4) Rough turn all Mains to Process Spec
5) Mill Locator Pad 'A-101' to Specification
6) Proper set-up
6a) Proper Spindal Speed
6b) Proper Feed Rate
7) Proper tool insert
7a) Tool insert change per schedule
8) Proper coolant flow
9) Inspection per Control Plan

Operation 20
(CM-Op20)
Rough Pins

1) Rough Turn all 4 Pins to Process Spec
2) Proper set-up
2a) Proper Spindal Speed
2b) Proper Feed Rate
3) Proper tool insert
3a) Tool insert change per schedule
4) Proper coolant flow
5) Inspection per Control Plan

Operation 30
(CM-Op30)
Final

1) Finish Turn Hub end to Spec
1a) Finish Turn Stem end to Spec
2) Finish turn all Mains to Spec
3) Proper set-up
3a) Proper Spindal Speed
3b) Proper Feed Rate
4) Proper tool insert
4a) Tool insert change per schedule
5) Proper coolant flow
6) Inspection per Control Plan

Operation 35
CM-Op35
Inspection

1) Inspect Hub End Diametere
2) Inspect Stem End Diameter
3) Inspect Main Diameter
4) Inspect Locator Pad A-101
5) Clean Parts prior to measurement
6) Calibrate Bench Gauge OP35-110 Per Instruction
7) Clamp Parts per instruction
8) Material Handling Procedure 35-110 compliance
9) Attach WIP Tag per Procedure 35-110

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Process Flow Chart

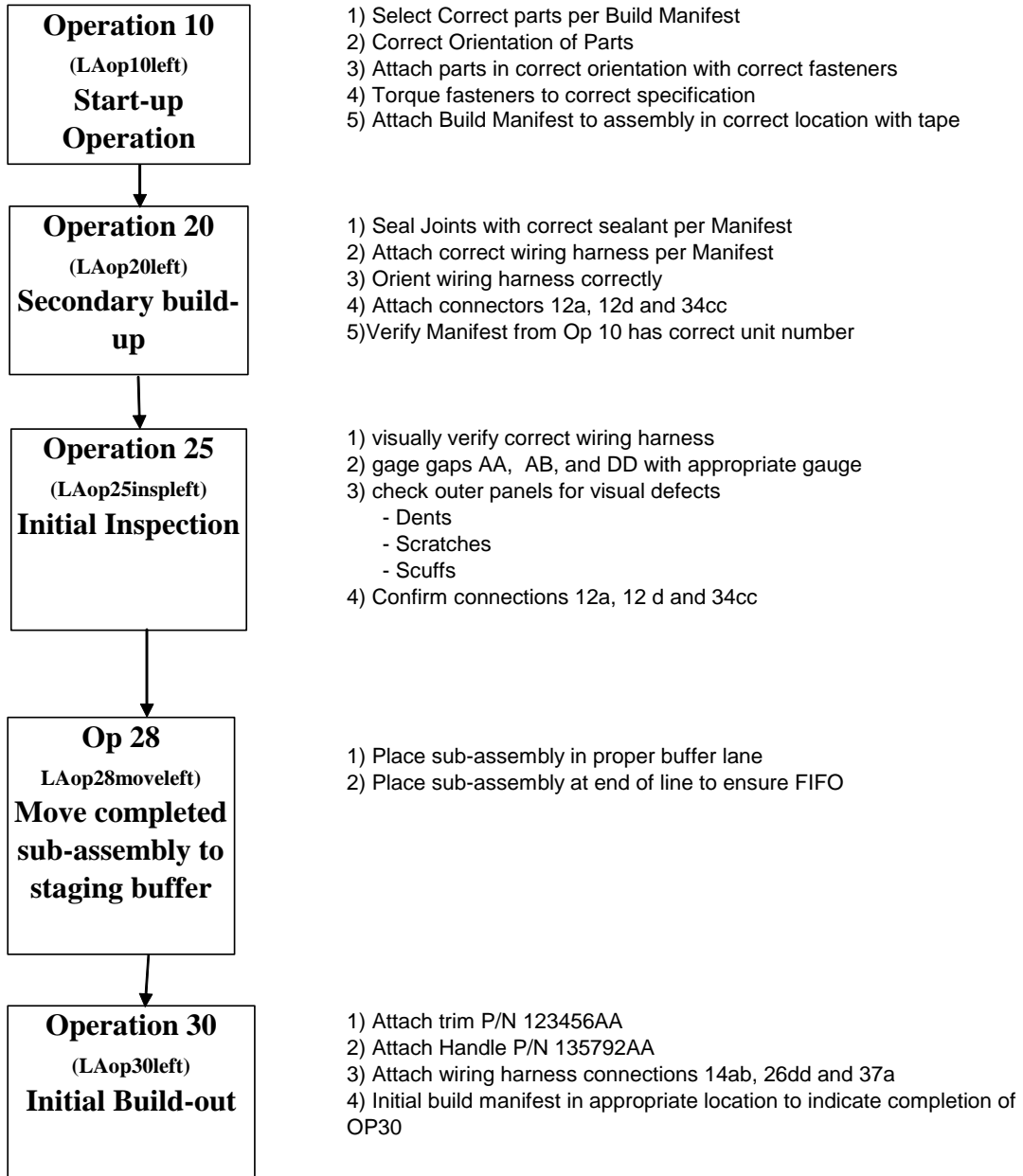**(Machining Example)**

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✓ This is a simplified version of a Process Flow Chart/Diagram. This example is for the "classroom-only" and lacks much information that would be required for a supplier. There is not any "header" information or other information or formatting that the customer or OEM would require of a supplier this information is omitted for simplicity and explanation.

✓ This flow chart identifies the process operation number and name (Name is both the engineering title and the operations 'common name' that is utilized in manufacturing.)

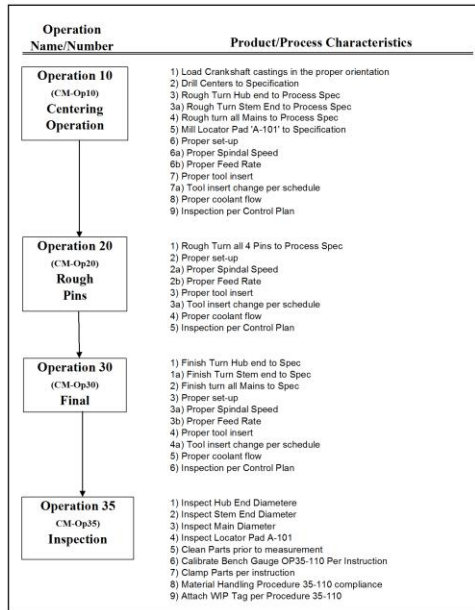✓ Each step identifies the activities of this machining process.

Operation Name/Number	Product/Process Characteristics
Operation 10 **(CM-Op10)** **Centering Operation**	1) Load Crankshaft castings in the proper orientation 2) Drill Centers to Specification 3) Rough Turn Hub end to Process Spec 3a) Rough Turn Stem End to Process Spec 4) Rough turn all Mains to Process Spec 5) Mill Locator Pad 'A-101' to Specification 6) Proper set-up 6a) Proper Spindal Speed 6b) Proper Feed Rate 7) Proper tool insert 7a) Tool insert change per schedule 8) Proper coolant flow 9) Inspection per Control Plan
Operation 20 **(CM-Op20)** **Rough Pins**	1) Rough Turn all 4 Pins to Process Spec 2) Proper set-up 2a) Proper Spindal Speed 2b) Proper Feed Rate 3) Proper tool insert 3a) Tool insert change per schedule 4) Proper coolant flow 5) Inspection per Control Plan
Operation 30 **(CM-Op30)** **Final**	1) Finish Turn Hub end to Spec 1a) Finish Turn Stem end to Spec 2) Finish turn all Mains to Spec 3) Proper set-up 3a) Proper Spindal Speed 3b) Proper Feed Rate 4) Proper tool insert 4a) Tool insert change per schedule 5) Proper coolant flow 6) Inspection per Control Plan
Operation 35 **CM-Op35)** **Inspection**	1) Inspect Hub End Diametere 2) Inspect Stem End Diameter 3) Inspect Main Diameter 4) Inspect Locator Pad A-101 5) Clean Parts prior to measurement 6) Calibrate Bench Gauge OP35-110 Per Instruction 7) Clamp Parts per instruction 8) Material Handling Procedure 35-110 compliance 9) Attach WIP Tag per Procedure 35-110

✓ Notes

Chapter Three – Outputs
(Become Inputs for Chapter 4)

MB Inc.

❖ Outputs

➢ 3.4 Floor Plan Layout

➢ **3.5 Characteristics Matrix**

➢ **3.6 Process Failure Mode and Effects Analysis (PFMEA)**

✓ **3.4 Floor Plan Layout:** The floor plan layout should be developed to determine the space allocation of critical process requirements, such as: inspection points/areas, control chart location, positioning of visual aids as appropriate, interim and permanent repair stations and the material flow for repair and allocation of area for the control of non-conforming product. All material flow needs to be keyed to the process flow chart and the control plan. The floor plan checklist in the appendix may be utilized to assure content of the floor plan layout. The floor plan should be developed to optimize material flow and the best value added use of floor space through the process.

Characteristic Matrix

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Dim. Nr.	Description	Tolerance	Operation Numbers			
			05	10	20	30
1	ID		X	C		X
2	Face			X	C	C
3				X	L	L
4					X	
5					X	
6	OD				X	

C = Characteristic at an opertaion used for clamping
L = Characteristic at an operation used for locating
X = Characteristic created or changed by this operation
should match the process flow diagram form

✓ **3.5 Characteristic Matrix:** A characteristic matrix is an analytical technique for displaying the relationship between process parameters and the manufacturing stations. The analytical techniques in the AIAG/APQP Manual appendix gives additional information on the use of this tool.

Process FMEA

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❖ AIAG/FMEA – Fourth Edition

➤ Process FMEA Benefits

✓ Identify and Evaluate Process Functions
✓ Identify and Evaluate Failure Modes and Their Effect
✓ Identify Potential Process Causes
✓ Identify Process Variables for Process Control
✓ Enable a Prioritization Systems (RPN)
✓ Document Corrective Action Activities

✓ **3.6 Process Failure Mode and Effects Analysis (PFMEA):** The Process FMEA should be conducted during the product quality planning activity and before the start of production. PFMEA is a disciplined review and analysis of the manufacturing process from receiving to ship (inclusive). The following pages are a review of the process FMEA and are not intended to be a comprehensive training class needed to effectively utilize this valuable tool.

✓ Process FMEA is a risk analysis tool for manufacturing activities. This very powerful analysis enables manufacturing and operation resources to make the most value added decisions in regard to process control, inspection, training, support, etc. If your organization is **NOT** conducting **COMPREHENSIVE** Process Failure Mode Effects Analysis, you might consider additional training.

Process FMEA

MB Inc.

❖ AIAG/FMEA – Fourth Edition

➢ Process FMEA Benefits – Con't

✓ The PFMEA is a Living Document and Should:
- Be Initiated before or at feasibility stage
- Be initiated prior to tooling for production
- Take into account **all** manufacturing operations
- Include all processes in the plant that impact manufacturing;
  - » Shipping
  - » Receiving
  - » Transportation
  - » Storage, Conveyors and Labeling

Process FMEA

❖ Requirements

➢ Customer Defined

✓ Normally "end-user" but may be subsequent operations or plants

➢ Design Considerations

✓ Assume product design will meet the design intent

– Process may suggest design improvements

➢ Process Flow Diagram/Chart

✓ Primary input document to PFMEA

Process FMEA

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							Potential												

Potential
Failure Mode Effects Analysis
(Process FMEA)

FMEA Number _____ **A**

Page _____ of _____

Item _____ **B**   Process Responsibility _____ **C**   Prepared By _____ **H**

Model Year(s)/Programs(s) **D**   Key Date _____ **E**   FMEA Date (Orig) _____ **F**

Core Team _____ **G**

Process Step / Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Current Process Control Prevention	Occurrence	Current Process Controls Detection	Detection	RPN	Recommended Action	Responsibility & Target Completion Date	Action Results Actions Taken Completion Date	Severity	Occurrence	Detection	RPN
a1	a2	b	c	d	e	f	h	g	h	i	j	k	l	m	n	n	n	n

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✓ This PFMEA form is one of many different formats identified in the AIAG/FMEA manual that may be utilized by the manufacturing organization. The following pages offer some details of the content of Process FMEA, but are not designed to become comprehensive FMEA training. You may consider additional training to get the fullest benefits from FMEA.

Steps to PFMEA

	Potential		
	Failure Mode Effects Analysis	FMEA Number	**A**
	(Process FMEA)	Page	of
Item **B**	Process Responsibility **C**	Prepared By	**H**
Model Year(s)/Programs(s) **D**	Key Date **E**	FMEA Date (Orig)	**F**
Core Team **G**			

A – FMEA Number B – Item C – Process Responsibility
D – Model Year(s)/Program(s) E – Key Date F – FMEA Date (Original)
G – Core Team H – Prepared By

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- ✓ FMEA Form header, fields A-H should clearly identify the focus of the Process FMEA.

- ✓ A – **FMEA Number**; is an alphanumeric string used to identify the document and is used for document control.

- ✓ B – **Item**; enter the name and/or part number of the component, subsystem, or system being analyzed.

- ✓ C – **Process Responsibility**; enter the OEM, organization, department, group, or person responsible for the analysis.

- ✓ D – **Model Year/Years/Program/Programs**; enter the intended model year/years and program/programs that will be affected by the process FMEA (if known)

- ✓ E – **Key Date**; enter the initial due date of the PFMEA, this date should not exceed the scheduled start of production date. In the case of a supplier organization this date should not exceed the PPAP customer approval date.

- ✓ F – **FMEA Date (Original)**; enter the date the original PFMEA was completed and the latest revision date.

- ✓ G – **Core Team**; enter the name or job title of the team members responsible for the PFMEA. Contact information including, phone, e-mail, organization, etc, should be recorded. This information may be included in a referenced supplemental document.

- ✓ H – **Prepared by**; enter the name and contact information of the person responsible for completing the PFMEA forms and documentation.

Steps to PFMEA

Process Step / Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure
a1	**a2**	**b**	**c**

Process Step/Function	Requirement	Potential Failure Mode
Operation 20:	Four Screws	Fewer than four screws
	Specified Screws	Wrong screw used (larger dia.)
Attach seat cushion to track using a torque gun	Assembly sequence: First screw in right front hole	Screw placed in any other hole
	Screws fully seated	Screw not fully seated
	Screws torqued to dynamic torque specification	Screw torqued too high
		Screw torque too low

a – Process Step / Process Function/
       Requirements

a1 – Process Step

a1 – Process Function

a2 - Requirements

b – Potential Failure Mode

c – Potential Effect/Effects of Failure

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✓ **a** – **Process Step/Process Function/Requirements:** Process step/function can be separated into two or more columns or combined into a single column. The content of the combine or separated columns is defined below.

✓ **a1** – **Process Step:** Identify the process step or operation that is to be analyzed. This numbering scheme is based on the same numbering scheme utilized in the process flow chart/diagram. This carry over numbering process from the flow chart/diagram to the FMEA, to the Control Plan, to Job Instructions to Repair Instructions ensures traceability of information.

✓ **a1** – **Process Function:** Enter the process function that corresponds to the process step. The process function describes the purpose or intent of the operation being analyzed. Items such as; Operation Name or other indicators that describe the process purpose or intent.

      Process Function becomes **a2** if Process Step and Process Function are split.

✓ **a2** – **Requirements:** List the requirements for each process function of the step being analyzed. Requirements are the inputs to the process to meet design intent and other customer requirements. Items such as; print specifications, machine settings, set-up requirements, etc.

      Requirements become **a3** if Process Step and Process Function are split.

✓ **b** – **Potential Failure Mode:** The potential failure mode is the manner in which the process would potentially not meet the process requirement, this includes failing to meet design intent or requirement.

✓ **c** – **Potential Effect/Effects of Failure:** Effects of the failure are defined as the effect on the customer, either the end user or subsequent process or subsequent factory. The effects should be expressed in terms that are experienced by the customer, remembering that the customer may be the end user or subsequent operation or subsequent facility. If the failure mode could impact safety or noncompliance to government regulation this must be clearly identified in the PFMEA. If the affected customer is the end user the effects should be described in language of component or system failure. If the affected customer is subsequent operation or facility the impact on process or operations should be described. The following is an example;

Requirement	Potential Failure Mode	Effect
Four Screws	Fewer than four screws	*End User*: Loose seat cushion and noise. *Manufacturing and Assembly:* Stop Shipment and additioan sort and rework due to affected portion.
Specified Screws	Wrong screw used (larger dia.)	*Manufacturing and Assembly:* Un able to install screw in statin.
Assembly sequence: First screw in right front hole	Screw placed in any other hole	*Manufacturing and Assembly:* Difficult to install screw in station.
Screws fully seated	Screw not fully seated	*End User: Loose Seat cushion and noise. Manufacturing and Assembly: Sort and rework due to affected portion.*
Screws torqued to dynamic torque specification	Screw torqued too high	*End User:* Loose Seat cushion due to subsequent fracture of screw and noise. *Manufacturing and Assembly;* Sort and rework due to affected portion.
	Screw torque too low	*End User:* Loose Seat cushion due to gradual loosening of screw and noise. *Manufacturing and Assembly;* Sort and rework due to affected portion.

Steps to PFMEA

Severity	Classification	Potential Cause(s) of Failure	Current Process			
			Control Prevention	Occurrence	Controls Detection	Detection
d	**e**	**f**	**h**	**g**	**h**	**i**

d – Severity 1 – 10

e – Classification

f – Potential Cause/Causes of Failure Mode

g – Occurrence 1 – 10

h – Current Process Controls (Prevention / Detection)

i – Detection 1 - 10

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✓ **d** – **SEVERITY:** Severity is a value of 1 to 10 based on the table defined in the AIAG/FMEA manual. The team should ensure they are using the latest revision of the AIAG documentation. The team should agree on the evaluation method and remain consistent within the FMEA.

✓ **e** – **CLASSIFICATION:** This column is used to highlight high priority failure modes or causes, these may require additional assessment. This column may also be used to classify any special product or process characteristic that may require additional process controls. Customer specific requirements may require the use of specific symbols and their usage. The AIAG/FMEA manual identifies that a special characteristic with a severity ranking of 9 or 10 requires the notification of the responsible design engineer as this may affect certain engineering documents.

✓ **f** - **POTENTIAL CAUSE/CAUSES OF FAILURE MODE:** Potential cause of failure is the method defining how the failure could occur, this is described as something that can be corrected or controlled. The APQP team should strive to identify all failure modes and should be as detailed as possible. There may be and often are multiple causes for each failure mode identified. All these should be listed, analyzed, and resolved. Only specific errors should be listed (e.g. part assembled in the wrong orientation or "right" and "left" side components reversed). Ambiguous language such as; "operator error" or "machine malfunction" should not be used. See the example of Causes and Controls on the next page.

✓ The following example describes the relationship between; Requirement, Failure Mode, Cause, Prevention Control and Detection Control.

Requirement	Failure Mode	Cause	Prevention Control	Detection control
Screws Torqued Until fully seated	Screw not fully seated	Nut runner not held perpendicular to work surface by operator	Operator training	Angle sensor included in nut runner to detect cross-threading not allowing part to be removed from fixture until value is satisfied
Screws torqued to dynamic torque specification	Screw torqued too high	Torque setting set too high by non-set-up personnel	Password protected control panel (only set-up personnel have access)	Torque validation box included in set-up procedure to validate setting prior to running
		Torque setting set too high by non-set-up personnel	Training of set-up personnel	Torque validation box included in set-up procedure to validate setting prior to running
			Settings added to set-up instructions	
	Screw torqued too low	Torque setting set too low by non-set-up personnel	Password protected control panel (only set-up personnel have access)	Torque validation box included in set-up procedure to validate setting prior to running
		Torque setting set too low by non-set-up personnel	Training of set-up personnel	Torque validation box included in set-up procedure to validate setting prior to running
			Settings added to set-up instructions	

Severity Table

MB C Inc.

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank	Effect	Criteria: Severity of Effect on Process (Manufacturing/Assembly Effect)
Meet Safety and/or Regulatory Requirements	Potential failure mode affects save vehicle operation and/or involves noncompliance with government regulation without warning.	10	Meet Safety and/or Regulatory Requirements	May endanger operator (machine or assembly) without warning.
	Potential failure mode affects save vehicle operation and/or involves noncompliance with government regulation with warning.	9		May endanger operator (machine or assembly) with warning.
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship.
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7	Significant Disruption	A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort / convenience functions inoperable).	6		100% of production run may have to be reworked off line and accepted.
	Degradation of secondary function (vehicle operable, but comfort / convenience functions at reduced level of performance).	5	Moderate Disruption	A portion of the production run may have to be reworked off line and accepted
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (>75%)	4		100% of production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%)	3	Moderate Disruption	A portion of the production run may have to be reworked in-station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%)	2	Minor Disruption	Slight inconvenience to process, operation, or operator
No effect	No discernible effect	1	No effect	No discernible effect

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Occurrence Table

MB Inc.

Likelihood of Failure	Criteria: Occurrence of Cause - PFMEA (Incidents per items/vehicles)		Rank
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
	.5 per thousand 1 in 2,000		5
	.1 per thousand 1 in 10,000		4
Low	.01 per thousand 1 in 100,000		3
	= .001 per thousand 1 in 1,000,000		2
Very Low	Failure is eliminated through preventive control		1

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Detection Table

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Opportunity for Detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
No Detection Opportunity	No current process control, Cannot detect or is not analyzed	10	**Almost Impossible**
Not Likely to Detect at any Stage	Failure Mode and/or Error (Cause) is not easily detected (e.g., random audits)	9	**Very Remote**
Problem Detection Post Processing	Failure Mode detection post-processing by operator through visual/tactile/audible means	8	**Remote**
Problem Detection at Source	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.).	7	**Very Low**
Problem Detection Post Processing	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).	6	**Low**

Detection Table

MB **C Inc.**

Opportunity for Detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
Problem Detection at Source	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).	5	**Moderate**
Problem Detection Post Processing	Failure Mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing.	4	**Moderately High**
Problem Detection at Source	Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing	3	**High**
Error Detection and/or Problem Prevention	Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made.	2	**Very High**
Detection not applicable; Error Prevention	Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant pars cannot be made because item has been error-proofed by process/product design.	1	**Almost Certain**

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Steps to PFMEA

RPN	Recommended Action	Responsibility & Target Completion Date
j	k	l

j – RPN (S x O x D) Used to Prioritize Action/Actions

k – Recommended Action/Actions

l – Responsibility & Target Completion Date

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- ✓ **j** - **RISK PRIORITY NUMBER (RPN)**

- ✓ RPN = Severity x Occurrence x Detection

- ✓ Within the scope of the FMEA this value may range from 1 to 1000. The RPN may be utilized to prioritize corrective action/actions.

- ✓ **Per the AIAG/FMEA manual it is not recommended to use a threshold value to determine action taken.**

- ✓ The application of threshold values assumes that all equal RPNs are indeed equal in importance, which they are not.

- ✓ For example, if a customer or corporation applied an arbitrary threshold value of 100 to the following. The supplier in this example would be required to address characteristic 'B' when actually it is characteristic 'A' with the higher severity is related to safe vehicle operation that should get the attention first.

Item	Severity	Occurrence	Detection	RPN
A	9	2	5	90
B	7	4	4	112

- ✓ **k– <u>RECOMMENDED ACTIONS:</u>** Preventive actions should address the reduction of occurrence, this being preferable to an improvement in detection. The intent of recommended actions is to improve the design. In support of this objective the team should consider actions in the following order; first, reduction of (S) severity, then, improvement in (O) occurrence lastly an improvement in (D) detection.

- ✓ **l – <u>RESPONSIBILITY & TARGET COMPLETION DATE:</u>** Enter the name of the individual or organization that is responsible for the completion of each activity by the assigned target date. The responsible person/persons should ensure that all actions are completed by the due date assigned.

- ✓ This column is also a fine input to a management review application.

Steps to PFMEA

Action Results				
Actions Taken Completion Date	Severity	Occurrence	Detection	RPN
m	**n**	**n**	**n**	**n**

m/n – Action Results

m – Action/Actions Taken and Completion Date

n – Severity, Occurrence, Detection and RPN

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- ✓ **m/n** – <u>**ACTION RESULTS:**</u> This section records the results of actions taken and their effect on severity, occurrence and detection.

- ✓ **m** – <u>**ACTION/ACTIONS TAKEN AND THE COMPLETION DATE:**</u> This section contains a brief description of the action taken by an individual, organization or other group/team.

- ✓ **n** – <u>**SEVERITY, OCCURRENCE, DETECTION AND RPN:**</u> After the corrective action has been taken this section records the resulting impact on severity, occurrence and detection and the resulting RPN. All revised rankings should be <u>**validated**</u>, it should never be assumed that action taken automatically results in reduced risk. After the validation if it is determined that additional action is needed, repeat the analysis and corrective action. The focus should always be on continuous improvement.

Notes

Chapter Three – Outputs
(Become Inputs for Chapter 4)

MB Inc.

❖ **Outputs (Con't)**
- ➤ 3.7 Pre-Launch Control Plan
  - ✓ (Including Error-Proofing Devices)
- ➤ 3.8 Process Instructions
- ➤ 3.9 Measurement System Analysis Plan
- ➤ 3.10 Preliminary Process Capability Study Plan
- ➤ 3.11 Management Support
  - ✓ (including operator staffing and training plan)

✓ **3.7 Pre-Launch Control Plan:** The pre-launch control plan's purpose is to contain any non-conformities during or before the initial production runs related to PPAP. The pre-launch plan is a description of the controls for dimensional, material and functional testing required between the prototype control plan and the predecessor of the production control plan. The pre-launch plan has additional product and/or process controls needed until the manufacturing process is validated. Some of the examples of potential enhancements are; increased inspection frequency, additional in-process and final inspection checks, more statistical analysis, additional audits, and identification of error-proofing devices or items. Additional checklists and information about control plans are found in the AIAG/APQP manual appendix.

✓ **3.8 Process Instructions:** The APQP team assures the process, job or work instructions provide sufficient information that all persons responsible to operate the process are able to do so in a consistent, correct and efficient manner. The APQP team should take information from many sources into account when developing instructions. Sources such as; FMEAs, control plans, Engineering information, process flow chart, floor plan layout, characteristic matrix (as appropriate) packaging information, acceptable process parameters, team knowledge, handling requirements, operators of the process or similar processes.

✓ **3.9 Measurement System Analysis (MSA) Plan:** The APQP team assures a plan for MSA is comprehensive. The plan must include all required gauges including checking aids. The plan should at a minimum include a laboratory scope appropriate to the gauges and test equipment affected. The responsibilities to assure all studies are completed. You may reference the AIAG/MSA manual for additional detail, requirements, methods and acceptance criteria. It should be noted that customers may define studies to be completed and the acceptance criteria.

- ✓ **3.10 Preliminary Process Capability Study Plan:** The APQP team should assure the development of the preliminary process capability study plans. These characteristics may be identified in the Process Control Plan and are influenced by the customer requirements for Production Part Approval Process (PPAP). There is additional information in customer specific requirements and in the AIAG/PPAP Manual.

- ✓ **3.11 Management Support:** The organization's APQP team should schedule a formal management review as they prepare to exit this chapter. This review keeps upper management informed and brings them into the support activity that is often required to resolve issues where resource support is needed or required, including the staffing requirements of the organization.

APQP

MB C Inc.

❖ Section Five - Summary

➢ APQP Chapter Three

✓ Process Design and Development

APQP

MB Inc.

❖ Section Six

➢ APQP Chapter Four

✓ Product and Process Validation

APQP Chapter Four
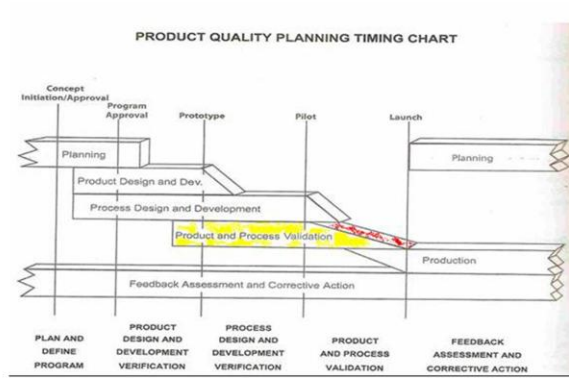
PRODUCT QUALITY PLANNING TIMING CHART

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Chapter Four – Inputs

(From the outputs of Chapter three)

MB **Inc.**

❖ Process

➢ Packaging Standards & Specifications

➢ Product/Process Quality System Review

➢ Process Flow Chart

➢ Floor Plan Layout

➢ Characteristics Matrix

➢ Process Failure Mode and Effects Analysis (PFMEA)

Chapter Four – Inputs
(From the outputs of Chapter three)

❖ Process – Con't
  ➢ Pre-Launch Control Plan
    ✓ (Including Error-Proofing Devices)
  ➢ Process Instructions
  ➢ Measurement System Analysis Plan
  ➢ Preliminary Process Capability Study Plan
  ➢ Management Support
    ✓ (including operator staffing and training plan)

Chapter Four – Outputs
(Become Inputs for Chapter 5)

MB Inc.

❖ Process/Product Validation
- ➤ 4.1 Significant Production Run
- ➤ 4.2 Measurement System Evaluation
- ➤ 4.3 Preliminary Process Capability Study
- ➤ **4.4 Production Part Approval (PPAP)**

- ✓ **4.1 Significant Production Run:** This production run is part of the validation activity and the organization, led by the APQP team, must conduct this run using; production tooling, production equipment, production environment, production operators, facility, production gauges and run at production rate. The team may refer to the AIAG/PPAP Manual and customer specific requirements for this production run. The minimum quantity is set by the customer but the organization's APQP team may authorize additional run time or volume. The output of this production run is used for;

- ❑ Preliminary process capability study   - Measurement System Analysis
- ❑ Production rate demonstration   - Process review
- ❑ Production Validation testing   - Production Part Approval
- ❑ Packaging evaluation   - First time capability
- ❑ Quality planning sign-off   - Sample Production Parts
- ❑ Master Sample (as required)

- ✓ **4.2 Measurement System Analysis:** The required measuring and testing devices should be analyzed per the requirements of the AIAG/MSA Manual and customer requirements.

- ✓ **4.3 Preliminary Process Capability Study:** These preliminary studies should be conducted on characteristics identified in the control plan and required by the customer. The organization may refer to the AIAG/PPAP Manual, the AIAG/SPC Manual, and customer requirements for requirements and acceptance criteria.

- ✓ **4.4 Production Part Approval (PPAP):** The purpose of PPAP is to verify that the supplier fully understands the customer requirements and that the supplier's manufacturing process has the potential to consistently meet the customer's needs and requirements. Refer to the AIAG/PPAP Manual.

PPAP 4th Edition

❖ PPAP Saleable Parts From a "Significant Production Run"

❖ Completed by the Supplier

❖ Defined by the Customer

❖ Completed for Each Part Number

➢ Family of Parts may be Approved by the Customer at Their Discretion.

✓ **4.4 Production Part Approval Process (PPAP):** The AIAG/PPAP Manual defines the generic requirements the supplier organization follows to obtain customer approval of production process, production parts, and bulk materials. PPAP applies to both internal and external suppliers of production parts, service parts, production material or bulk material.

✓ The APQP team guiding the organization through the APQP process ensures the completion of the PPAP activity. While it is generally true that most supplier's have people dedicated to managing the PPAP activity, PPAP does fall within the APQP process.

✓ While the AIAG/PPAP Manual defines the generic requirements for PPAP there are also customer specific requirements and interpretations to be considered.

✓ The PPAP process is completed by the supplier and defined by the customer. PPAP is generally completed for each production part number. Family of parts may be approved at the discretion of the customer.

1. Design Record
2. Engineering Change Documents – If Any
3. Customer Engineering Approval – If Req.
4. Design FMEA
5. Process Flow Diagram/Diagrams
6. Process FMEA

- ✓ **2.2.1 Design Record:** The organization has a design record for each saleable part or product, including design records for components or details of the saleable parts. For electronic design record a hardcopy may be produced. The organization supports the requirements of **2.2.1.1. Reporting of Part Material Composition;** The organization provides evidence that material or substance composition reporting required by the customer is completed for each part number. **2.2.1.2 Marking of Polymeric Parts;** The organization complies with the appropriate ISO symbols as specified in ISO11469, "Plastics – Generic Identification and marking of plastic products" and/or ISO1629, "Rubber and lattices – Nomenclature." The weight criteria is defined in the AIAG/PPAP manual as;

- ❑ **Plastic parts weighing at least 100g (using ISO11469/1043-1)**

- ❑ **Elastomeric parts weighing at least 200g (using ISO11469/1629)**

- ❑ **2.2.2 Authorized Engineering Change Documents:** The organization must have a authorized change process for engineering documents.

- ❑ **2.2.3 Customer Engineering Approval:** If the customer specifies such the organization shall have evidence of customer engineering approval.

- ❑ **2.2.4 Design Failure Mode and Effects Analysis (Design FMEA) if the organization is product design-responsible;** The design responsible organization develops the DFMEA compliant to AIAG/FMEA Manual and customer specific requirements.

- ✓ **2.2.5 Process Flow Diagram/Diagrams:** The process flow diagram compliant to the customer specific requirements is completed by the supplying organization. The flow chart is comprehensive and includes all activities from receiving to shipping; for bulk materials the supplier provides the process flow description.
- ✓ **2.2.6 Process Failure Mode and Effects Analysis (Process FMEA):** The supplying organization develops a process FMEA compliant to the customer specific requirements and the AIAG/FMEA Manual. If approved by the customer the organization may provide a single PFMEA for a family of parts.

7. Control Plan
8. Measurement System Analysis Studies
9. Dimensional Results
10. Material, Performance Test Results

- ✓ **2.2.7 Control Plan:** The supplying organization develops a process control plan compliant with customer requirements and the AIAG/APQP Manual. The control plan lists all the process control requirements of the organization.

- ✓ **2.2.8 Measurement System Analysis (MSA) Studies:** The organization shall have appropriate MSA studies (i.e. GR&R, Bias, Linearity, stability for all new or modified gauges, measurement and test equipment. The studies shall be compliant to the customer requirements and to the AIAG/MSA Manual.

- ✓ **2.2.9 Dimensional Results:** dimensional results as defined by the AIAG/PPAP Manual and customer requirements. Results are reported in the customer specified format.

- ✓ **2.2.10 Records of Material / Performance Test Results:** The organization has records of material and/or performance results, compliant to customer requirements and the AIAG/PPAP Manual

- ❑ **See reporting formats for dimensional, Material and Performance test results on following pages;**

Appendix C – Production Part Approval, Dimensional Results

Production Part Approval
Dimensional Test Results

MB Inc.

		ORGANIZATION:				PART NUMBER:		
		SUPPLIER/VENDOR CODE:				PART NAME:		
		INSPECTION FACILITY:				DESIGN RECORD CHANGE LEVEL:		
						ENGINEERING CHANGE DOCUMENTS:		

ITEM	DIMENSION / SPECIFICATION	SPECIFICATION / LIMITS	TEST DATE	QTY. TESTED	ORGANIZATION MEASUREMENT RESULTS (DATA)	OK	NOT OK

Blanket statements of conformance are unacceptable for any test results.

March 2006   CFG-1003

SIGNATURE	TITLE	DATE

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Appendix C – Production Part Approval, Dimensional Results

Production Part Approval
Dimensional Test Results

DAIMLERCHRYSLER Ford GM

ORGANIZATION:					PART NUMBER:		
SUPPLIER/VENDOR CODE:					PART NAME:		
INSPECTION FACILITY:					DESIGN RECORD CHANGE LEVEL:		
					ENGINEERING CHANGE DOCUMENTS:		

ITEM	DIMENSION / SPECIFICATION	SPECIFICATION / LIMITS	TEST DATE	QTY. TESTED	ORGANIZATION MEASUREMENT RESULTS (DATA)	OK	NOT OK

Blanket statements of conformance are unacceptable for any test results.

SIGNATURE	TITLE	DATE

March 2006   CFG-1003

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Appendix D – Production Part Approval, Material Test Results

Production Part Approval
Material Test Results

DAIMLERCHRYSLER [Ford] [GM]

ORGANIZATION:						
SUPPLIER/VENDOR CODE:						
MATERIAL SUPPLIER:						
*CUSTOMER SPECIFIED SUPPLIER/VENDOR CODE:						
* If source approval is req'd, include the Supplier (Source) & Customer assigned code.						

PART NUMBER:
PART NAME:
DESIGN RECORD CHANGE LEVEL:
ENGINEERING CHANGE DOCUMENTS:
NAME of LABORATORY:

MATERIAL SPEC. NO. / REV / DATE	SPECIFICATION / LIMITS	TEST DATE	QTY. TESTED	SUPPLIER TEST RESULTS (DATA)	OK	NOT OK

Blanket statements of conformance are unacceptable for any test results.

March 2006   CFG-1004

SIGNATURE	TITLE	DATE

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Appendix D – Production Part Approval, Material Test Results

Production Part Approval
Material Test Results

DAIMLERCHRYSLER Ford GM

ORGANIZATION:	PART NUMBER:
SUPPLIER/VENDOR CODE:	PART NAME:
MATERIAL SUPPLIER:	DESIGN RECORD CHANGE LEVEL:
*CUSTOMER SPECIFIED SUPPLIER/VENDOR CODE:	ENGINEERING CHANGE DOCUMENTS:
* If source approval is req'd. Include the Supplier (Source) & Customer assigned code.	NAME of LABORATORY:

MATERIAL SPEC. NO. / REV / DATE	SPECIFICATION / LIMITS	TEST DATE	QTY. TESTED	SUPPLIER TEST RESULTS (DATA)	OK	NOT OK

Blanket statements of conformance are unacceptable for any test results.

March 2006   CFG-1004

SIGNATURE	TITLE	DATE

Appendix E – Production Part Approval, Performance Test Results

Production Part Approval
Performance Test Results

DaimlerChrysler · Ford · GM

ORGANIZATION:		PART NUMBER:		
SUPPLIER/VENDOR CODE:		PART NAME:		
NAME of LABORATORY:		DESIGN RECORD CHANGE LEVEL:		
*CUSTOMER SPECIFIED SUPPLIER/VENDOR CODE:		ENGINEERING CHANGE DOCUMENTS:		

* If source approval is reqd, include the Supplier (Source) & Customer assigned code.

TEST SPECIFICATION / REV / DATE	SPECIFICATION / LIMITS	TEST DATE	QTY. TESTED	SUPPLIER TEST RESULTS (DATA)/ TEST CONDITIONS	OK	NOT OK

Blanket statements of conformance are unacceptable for any test results.

March 2006 CFG-1005

SIGNATURE	TITLE	DATE

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Appendix E – Production Part Approval, Performance Test Results

Production Part Approval
Performance Test Results

DaimlerChrysler Ford GM

ORGANIZATION:				PART NUMBER:		
SUPPLIER/VENDOR CODE:				PART NAME:		
NAME of LABORATORY:				DESIGN RECORD CHANGE LEVEL:		
*CUSTOMER SPECIFIED SUPPLIER/VENDOR CODE:				ENGINEERING CHANGE DOCUMENTS:		

* If source approval is req'd, include the Supplier (Source) & Customer assigned code.

TEST SPECIFICATION / REV / DATE	SPECIFICATION / LIMITS	TEST DATE	QTY. TESTED	SUPPLIER TEST RESULTS (DATA) / TEST CONDITIONS	OK	NOT OK

Blanket statements of conformance are unacceptable for any test results.

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✓ **2.2.11 Initial Process Studies:**

✓ **2.2.11.1 General:** The level of process capability shall be determined with the customer **prior to submission** for special characteristics designated by the customer. MSA must be conducted to obtain the impact of measurement error on the study, i.e. Number of Distinct Categories, (ndc). When no special characteristics exist the customer has the right to require studies on other characteristics. The study determines if the supplier's process is likely to produce product that meets customer requirements. The initial studies are conducted focused on variable data not attribute data. Initial studies are short term and may not reflect the effects of time and variation in the process. For studies using an X-bar and R chart the short term study is based on a minimum of 25 sub-groups containing at least 100 readings from consecutive parts.

✓ **2.2.11.2 Quality Indices:** The initial studies shall be summarized with capability or performance indices that are applicable.

✓ **2.2.11.3 Acceptance Criteria for Initial Study:** The following are used as acceptance criteria for evaluating initial study results when the process appears to be stable.

Index > 1.67 –   meets acceptance criteria

$1.33 \leq$ Index ≤ 1.67 – may be acceptable, contact the customer for a review of study
                         results.

Index < 1.33 -   does not meet acceptance criteria, contact the customer for a
                         review of study results

- ✓ **2.2.11.4 Unstable Processes:** Contact the customer about corrective action requirements prior to any submission

- ✓ **2.2.11.5 Processes With One-Sided Specifications or Non-Normal Distributions:** The supplier determines with the customer representative the action/actions to be taken.

- ✓ **2.2.11.6 Actions To Be Taken When Acceptance Criteria Are Not Satisfied:** The supplier contacts the customer representative if the acceptance criteria cannot be obtained.

- ✓ **2.2.12 Qualified Laboratory Documentation:** Inspection and testing for PPAP shall be conducted by qualified laboratory as defined by the customer.

- ✓ **2.2.13 Appearance Approval Report (AAR):** A separate AAR is completed for each part or series of parts if the product/part has appearance requirements on the design record. The completed AAR and representative production parts are submitted to the customer to receive disposition.

- ✓ **2.2.14 Sample Production Parts:** The supplier provides sample product as specified by the customer.

- ✓ **2.2.15 Master Sample:** The supplying organization shall retain a master sample for the same period as the PPAP records or until a new master sample is produced for the same customer part number for customer approval. The master sample shall be identified as such and shall show the customer approval date. The supplier retains a sample part for each position of a multiple cavity die, mold, tool or pattern, or production process unless waived by the customer.

- ✓ **2.2.16 Checking Aids:** The supplying organization certifies the checking aids to meet the print requirements. The supplier provides a PM program for the checking aid for the life of the part.

- ✓ **2.2.17 Customer Specific Requirements:** The supplying organization shall have evidence of compliance to all customer specific requirements.

- ✓ **2.2.18 Part Submission Warrant (PSW):** Upon completion of PPAP the organization shall complete the Part Submission warrant. A separate warrant is completed for each customer part number unless otherwise agreed to by the customer's authorized representative.

- ✓ **2.2.18.1 Part Weight (Mass):** The supplying organization shall record on the PSW the part weight of the part as shipped, expressed in kilograms to four decimal places unless otherwise specified by the customer. To determine the part weight the supplier shall randomly select 10 parts and report the average weight. At least one part from each cavity, tool, line or process to be used in product realization.

❖ Process/Product Validation
  ➢ 4.5 Production Validation Testing
  ➢ 4.6 Packaging Evaluation
  ➢ **4.7 Production Control Plan**

- ✓ **4.5 Production Validation Testing:** Production validation testing are engineering tests that validate that products made from the supplier's tooling and manufacturing processes meet the customer engineering standards including appearance requirements.

- ✓ **4.6 Packaging Evaluation:** When test shipments are required by the customer the test results must validate the ability of packaging to protect the product from normal shipping damage, including environmental factors. Customer specified packaging must still be evaluated for effectiveness by the supplier.

- ✓ **4.7 Production Control Plan (PCP):** The PCP is a written description of the systems for controlling production. The PCP is a living document and must be updated to reflect the current manufacturing process. Changes to the PCP may require approval of the customer. The PCP is a logical extension of the pre-launch control plan. The AIAG/APQP manual appendix has additional information about the content, examples, structure and application of manufacturing process control plans.

Process Control Plan

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❖ PCP

➤ Aid in the Manufacture of Quality Products According to Customer Requirements

➤ Provide a Written Summary of the Systems Used to Minimize Variation

➤ Is a Living Document

➤ Operator Instructions are in Addition to Process Control Plans

➤ A Documentation Tool of Continuous Improvement

✓ The Control Plan is an aid to manufacturing and provides a written description of the systems used for the control of products and processes. The control plan provides a structured approach to the design, selection and implementation of value-added control methods. The control plan may be in any form or format but **MUST** contain the information as reflected in the AIAG/APQP Manual and if the using organization is registered to ISO/TS16949 the identified content of section A.2 must be applied. In support of the control plan operator and process monitoring instructions should be provided and used continually. The control plan describes the action required at each phase or step of the process including receiving, in-process, out-going and all periodic requirements to assure the process output remains in a "state of control". The control plan is maintained and used throughout the life of the product and remains a living document.

Process Control Plan

❖ PCP
  ➤ Developed by a Multi-Disciplined Team
  ➤ Utilize all Available Information
  ✓ Process Flow Diagram
  ✓ System/Design/Process FMEA
  ✓ Special Characteristics
  ✓ Lessons Learned
  ✓ Team Knowledge
  ✓ Optimization Methods (e.g., QFD, DOE, etc.)

✓ For process control to be effective a basic understanding of the process must be obtained by the organization. This is most often achieved by the utilization of a multi-disciplined team utilizing all available information.

✓ The benefits of developing and implementing a control plan are the reduction of waste and the improvement in the quality of products. This structured and disciplined process provides the organization with a thorough evaluation of the product and the manufacturing or assembly process. Control plans are an effective method of identifying process characteristics and the identification of control methods for the various sources of process or product variation.

✓ Control plans focus the use of available resources on the product and process related items of greatest importance to the organization and the customer. This proper allocation of available resources helps to keep cost to a minimum without sacrificing quality.

Process Control Plan

MB Inc.

Prototype	Pre-Launch	Production	Key Contact/Phone (1) (7)		Date (Orig) (10)	Date (Rev) (11)
Control Plan Number (2)						
Part Number/Latest Change Level (3)			Core Team (8)		Customer Eng. Approfval/Date (if req) (12)	
Part Name/Discription (4)			Organization/Plant Approval/Date (9)		Customer Quality App. Date (if req) (13)	
Organization Plant (5)		Organization Code (6)	Other Approval Date (if req) (14)		Other Approval Date (if req) (14)	

Part/ Process Number	Process Name/ Operation Discription	Machine Device, Jig, Tools For Mfg.	Characteristics				Product/Process Specification/ Tolerance	Evaluation Measurement Technique	Methods — Sample		Control Method	Reaction Plan
			No.	Product	Process	Special Char. Class.			Size	Freq.		
(15)	(16)	(17)	(18)	(19)	(20)	(21)	(22)	(23)	(24)		(25)	(26)

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- ✓ Here we have the formatted process control plan. There are many formats available any of which the organization may utilize. The only criteria is the organization MUST ensure the content of the control plan is compliant to AIAG/APQP Manual and to ISO/TS16949 if your organization is registered to that standard.
- ✓ Customer specific requirements of specific content must also be addressed by the organization. As well as customer approval of the completed control plan and the customer approval of changes to the plan.
- ✓ The following pages give some information about the content of each field. It should be noted that this manual, as previously stated, will only give a brief paraphrased description of the content of each field.
- ✓ The organization **MUST** consult the AIAG/APQP Manual as well as customer specific requirements. For this, the best approach may be to work closely with the customer representative about content and scope of the PCP.

Process Control Plan
(Description)

MB Inc.

1 — Prototype	Pre-Launch	Production	Key Contact/Phone 7	Date (Orig)	Date (Rev) 11
Control Plan Number 2				10	
Part Number/Latest Change Level 3		Core Team 8		Customer Eng. Approval/Date (if req) 12	
Part Name/Discription 4		Organization/Plant Approval/Date 9		Customer Quality App. Date (if req) 13	
Organization Plant 5	Organization Code 6	Other Approval Date (if req) 14		Other Approval Date (if req) 14	

1 – Prototype/Pre-Launch/Production
2 – Control Plan Number
3 – Part Nr/Change Level
4 – Part Name/Description
5 – Organization/Plant
6 – Organization Code (Supplier Code)
7 – Key Contact/Phone etc

8 – Core Team
9 – Org/Plant Approval Date
10 – Date (Orig.)
11 – Date (Rev.)
12 – Customer/Eng. App. Date
13 – Customer / Qlty. App. Date
14 – Other Approval Date

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1. Identify this document as to the type of PCP "Prototype", "Pre-Launch" or "Production" control plan, (check the appropriate box).

2. This number is used for tracking and document control. For multiple page control plans a page numbering system such as (page __ of __), may be used.

3. Enter the system, subsystem or component to be controlled. When required enter the engineering change level and/or the issue date of the drawing.

4. Enter the name and other information describing the part or assembly.

5. Enter the appropriate plant information.

6. Enter the appropriate plant identification number; such as, DUNS, Customer Supplier Code. (See customer representative for any clarification needed).

7. Enter the necessary contact information for the primary contact person.

8. Enter the appropriate contact information of the team members responsible for the latest revision level of the PCP. It is recommended in the AIAG/APQP Manual that an attached list maintain the contact information of ALL core team members. This would include past members.

9. Obtain the appropriate manufacturing plant approval.

10. Enter the date the original control plan was completed.

11. Enter the date of the latest revision/update.

12. Obtain the responsible customer engineering approval.

13. Obtain the appropriate customer supplier quality representative approval.

14. Obtain any other agreed upon approvals as required.

Process Control Plan
(Description)

Part/ Process Number	Process Name/ Operation Discription	Machine Device, Jig, Tools For Mfg.
15	16	17

15 – Part/Process Number

16 – Process Name/Operation Description

17 – Machine, Device, Jig, Tools for Manufacturing

15. This item number is generally reference to the Process Flow Diagram/Chart. If multiple part numbers exist list the part numbers and their processes accordingly.

16. All steps in the manufacturing or assembly process are identified in the Process Flow Diagram/Chart. Identify the process name from the appropriate Flow Chart that best describes the process step being addressed.

17. For each operation of the manufacturing or assembly process being addressed identify the various equipment, machines, lines, jigs and other tools for manufacturing.

Process Control Plan
(Description)

MB **C** **Inc.**

Characteristics			Special Char. Class.
No.	Product	Process	
(18)	(19)	(20)	(21)

18 – Number

19 – Product

20 – Process

21 – Special Characteristic Classification

✓ Characteristics – Items 18, 19, & 20

18. Assign a cross reference number to applicable documents. These documents may include such items as; Process Flow Diagram/Chart, Numbered blue print, FMEA's both Process and/or Design, Drawing, or other visual standards as required. Additional information is available in the AIAG/APQP Manual supplements.

19. Product characteristics are the features of the part, component or assembly that are defined on the drawings or other engineering documents. The PCP team should identify the special product characteristics from all sources and ensure they are ALL included in the control plan. Other product characteristics may be added as necessary.

20. Process characteristics are the process parameters that must be controlled to reduce the variation and effect on the product. A process characteristic can only be measured at the time it occurs. The core team should identify the process characteristics for which variation must be controlled. There may be more than one process characteristic for each product characteristic.

21. For special characteristics use the identification method required by the customer.

✓ For items 18 and 19 the following also applies:

✓ For an organization that is registered to ISO/TS16949, the standard requires in clause 7.5.1.1 "…The control plan shall; list the controls used for the manufacturing process control…".

✓ This is a much more comprehensive requirement than the AIAG/APQP Manual or customer required definition of process control.

Process Control Plan
(Description)

MB Inc.

Product/Process Specification/ Tolerance	Evaluation Measurement Technique	Methods		Control Method	Reaction Plan
		Sample			
		Size	Freq.		
(22)	(23)	(24)		(25)	(26)

22 – Product/Process Specification/Tolerance

23 – Evaluation/Measurement Technique

24 – Sample Size/Frequency

25 – Control Method

26 – Reaction Plan

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22. Product/Process Specification/Tolerance: Specifications and tolerances are found on various engineering documents, such as; drawing, design reviews, material standards, CAD data, manufacturing and/or assembly requirements and/or parameters. Specifications and tolerances may also come from other sources.

23. Evaluation/Measurement Technique: This section identifies the measurement system being used for process control/verification. This may include gauges, fixtures, tools and/or tests and other equipment used to measure the product or process. A Measurement System Analysis (MSA) should be completed to verify the measurement system prior to relying on the system to control the product or process. For definition of the analysis of; Repeatability, Reproducibility, Bias (accuracy) linearity, stability, refer to the AIAG/MSA Manual and AIAG/PPAP Manual for additional requirements.

For item 23 the following also applies:

✓ For an organization that is registered to ISO/TS16949, the standard requires in clause 7.6.1 – "Statistical studies shall be conducted to analyse the variation present in the results of each type of measuring and test equipment system. This requirement shall apply to measurement systems **referenced in the control plan…".**

24. Sample Size/Frequency: When sampling is required the organization should list the sample size and frequency in this section.

25. Control Method: This critical section of an effective PCP contains a brief description of how the operation will be controlled, including procedure or instruction numbers when applicable. The column method is determined during the Process FMEA process or other sources. Some examples are but not limited to; Statistical Process Control (SPC), inspection, attribute data, mistake-proofing, and other sampling plans. The method of control should be continually evaluated for effectiveness.

26. Reaction Plan: This section documents the corrective actions necessary to avoid producing nonconforming products or operating the process out of control or out of specification.
The actions defined are normally the people closest to the process, persons such as operators, set-up personnel, supervisors or others. All Reaction plans MUST assure that suspect or nonconforming material is clearly identified and quarantined with final disposition made by the appropriated responsible person designated in the reaction plan.

✓ Notes

Chapter Four – Outputs
(Become Inputs for Chapter 5)

MB Inc.

❖ Process/Product Validation

➢ 4.8 Quality Planning Sign-Off & Management Support

✓ **4.8 Quality Planning Sign-Off and Management Support:** The organization's APQP team should perform a review at the manufacturing location and coordinate a formal sign-off. The quality sign-off indicates to management that the appropriate APQP activities have been completed. The sign-off is prior to the first production shipments and contains a review of the following;

❑ **Process Flow Charts**, Verify the flow charts that exist are accurate **and are being followed.**

❑ **Control Plans**, Verify that control plans are available, complete and **are followed at all times** for affected processes.

❑ **Process Instructions**, Verify that these documents exist, contain all special characteristics that are specified in the control plan and that all PFMEA recommendations are addressed. Compare the Process Instructions, PFMEA and Process Flow Chart to the Process Control Plan.

❑ **Monitoring and Measuring Devices**, Where special gauges, fixtures, test equipment or devices are required per the control plan, verify Gauge Repeatability and Reproducibility (R&R) and proper usage.

❑ **Demonstration of required Capacity**, using production processes and personnel.

❑ Upon completion of the sign-off a formal management review should be scheduled to inform management of the program status and gain support for any open issues. The "Quality Planning Sign-Off" in the appendix of AIAG/APQP Manual may be used as a guide for this activity.

APQP

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❖ Section Six - Summary

➢ APQP Chapter Four
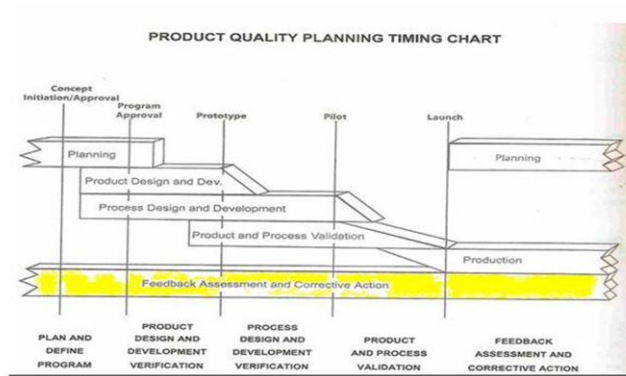
✓ Product and Process Validation

✓ Notes

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APQP

❖Section Seven

➢APQP Chapter Five

✓Feedback, Assessment and Corrective Action

PRODUCT QUALITY PLANNING TIMING CHART

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Chapter Five – Inputs
(From the outputs of Chapter four)

❖ Process

➢ Significant Production Run

➢ Measurement System Evaluation

➢ Preliminary Process Capability Study

➢ Production Part Approval (PPAP)

➢ Production Validation Testing

➢ Packaging Evaluation

➢ Production Control Plan

➢ Quality Planning Sign-Off & Management Support

Chapter Five – Outputs

❖ Chapter Five – Outputs
- ➢ 5.1 Reduced Variation
- ➢ 5.2 Improved Customer Satisfaction
- ➢ 5.3 Improved Delivery and Service
- ➢ 5.4 Effective Use of Lessons Learned/Best Practices

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✓ **5.1 Reduced Variation:** Control charts and other techniques should be used as methods of identifying process variation. Analysis and corrective action activities should then be used to reduce the product or process variation. Continual improvement requires attention to detail and not only the corrective action activity for addressing special cause of variation, but the understanding and improvement of common cause variation as appropriate. Information should be developed not only for management review, but for customer review as well. Not only does the organization benefit from improved customer satisfaction, but reduction of cost may also be realized.

✓ **5.2 Improved Customer Satisfaction:** The organization and customer become partners in making changes to improve customer satisfaction. Planning activities and the demonstration of process capability are important aspects to customer satisfaction. The product or service must still perform to the customer expectations in the customer environment. The effectiveness of the APQP process may also be evaluated at this time.

✓ **5.3 Improved Delivery and Service:** The delivery and service activities continue and the organization and the customer are involved in a partnership of problem solving. The customer's service and replacement parts must meet the requirements for quality, cost and delivery. As always the goal for every supplier is "First-Time-Quality", where problems occur in the field it is the important that the customer and the supplier respond in partnership to find resolution for the end-user customer.

✓ **5.4 Effective Use of Lessons Learned, Best Practices:** A robust lessons learned or best practices is helpful in capturing, retaining and applying knowledge to future activities. Input to lessons learned and best practices can be obtained through multiple methods including

- ❑ The use of; Things Gone Right or Things Gone Wrong reports or databases.
- ❑ Warranty data and other customer satisfaction information
- ❑ Corrective action plans
- ❑ Read-Across with similar products and process
- ❑ The analysis and use of DFMEA and PFMEA

APQP

❖ Section Seven - Summary

➢ APQP Chapter Five

✓ Feedback, Assessment and Corrective Action

APQP

❖Section Eight

➤APQP Team Implementation

✓Team Organization
- Define the Scope

✓Team Training

✓Team Support

✓Team Communication

✓Team Documentation

✓Team Effectiveness

✓Management Support

Team Organization

❖ Assign a Process "Owner" to the APQP Project

❖ Assign a Cross Functional Team

❖ Representatives such as;
- ➢ Engineering, Manufacturing, Material Control
- ➢ Purchasing, Quality, Human Resources
- ➢ Sales, Field Services
- ➢ Suppliers and Customers – as Appropriate

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✓ The organization's APQP team should be given careful consideration by management, as this process may become critical to the organization's successful launch of a new or revised product. The communication with all parties concerned must take a high priority. One of the organization's first steps is to assign a process owner for the APQP project. It must be remembered that this cross functional or multi-disciplined team is needed to assure effective quality planning.

✓ The make-up of the team should reflect the organization's needs. Team members from many disciplines ensures a well balanced "knowledge-base". The members selected from the various departments or areas MUST have knowledge of their department or area. It is also helpful if the selected persons have, or are given, decision making authority. If the team members cannot make management decisions for their area of responsibility, they **MUST** have access to those person that are able to make, implement, enforce and follow-up on decisions, including financial needs.

Define the Scope

❖ Define Customer;
  ➤ Needs, Expectations, Requirements
❖ Define Team Member Roles & Responsibilities
❖ Identify Customers (Internal & External)
❖ Assess the Feasibility
❖ Identify Cost, Timing, & Constraints
❖ Determine Assistance Needed From Customer

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✓ While many APQP teams want to 'jump' directly to the work of "manufacturing process development or revision", there is actually much work to do prior to that step.

✓ Defining the customer's needs, expectations and requirements is the proper starting point for most APQP projects. This communication with the customer is a vital start and a communication link that MUST not be broken during the entire APQP project. (Remember APQP is a customer driven process. The large umbrella under which resides the quality tools, DFMEA, PFMEA, SPC, MSA, Process Flow Chart, Process Control Plan, PPAP, Corrective Action, and all the other activities that must be completed for a successful launch.)

✓ The assignment of a team leader or project manager is probably the first step for most projects. Another early step is the definition of roles and responsibilities of team members. In addition to the definition of roles and responsibilities is the understanding of the workload involved in the APQP project. For most organizations this is an additional assignment to an individual's normal work load. When selecting members the team leader should inform them of the approximate number of hours per week or month the project will require. With this understanding and agreement of the selected team member, it is also important to talk with the selected team members immediate supervisor, and obtain there support for the workload expectations. If the supervisor is unable to commit there subordinate to the required work load, another team member should be selected.

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- ✓ With the organization of the team complete, the identification of customers both internal and external is a vital step. With the identification complete a thorough documentation of each customer's requirements, needs, and expectations agreed upon by the customer and the APQP team defines the work, scope and depth of the project.

- ✓ With this information gathered, communicated and understood the team is able to assess feasibility. Make the proper documentation and necessary presentations to top management about the cost, timing, and constrains on the organization. This initial review with top management is another vital step in obtaining the necessary support of the organization.

- ✓ This presentation will also aid in the identification of support, resources and needs that may be obtained from the customer.

- ✓ Keeping all this activity documented and communicated to all appropriate persons within the organization and the affected customers and suppliers supports a successful completion of even the most complex APQP projects.

- ✓ Additionally all the planning and definition activity is an effective step in establishing all the communication links and channels that will be vital to a successful APQP project.

KEY POINT

- ✓ **An important question to address to all persons, teams and organizations involved in the APQP Process is to ask. "What information do you need and when do you need the information?" With this defined it should be someone's task on the team to ensure that the proper communications are made, by whatever method is appropriate.**

Team Training

❖ What Skills does the Team have?

❖ What Skills are Required for the APQP Project at Hand?

❖ Where is Training Available?

✓ The APQP project manager or the team leader has a great obligation of finding out what skills the team already has, and what skills are needed that may not reside within the team. With this piece of information complete then the task is simple, either someone has to be trained in the skills that are lacking OR you need to select additional team members that have the skills required.

✓ Keep It Simple, it is often easier and cheaper to find the skills internally than it is to train a team member. If additional training is the decision, then is it internal or external training you are seeking?

Team Support

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❖Team Members:

➤Commit to the Work Load as Defined by the Project Leader

➤Team Member's Direct Supervisor Also Commits to the Work Load

➤Attend Meetings

➤Participate

➤Identify; Obstacles, Training, Cost, Time Line Adherence, etc.

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✓ Now the team has been assembled and the project has definition. You have already obtained the commitment to support the workload defined.

❑ (It should be noted that the team members and their supervisors have committed to a specific amount of hours per day/week/month. If it is found that a particular team members workload is increasing, the project leader should go back to that individual and their supervisor, redefine the work and negotiate the newly identified needs.)

✓ It is now expected that all persons will attend the needed meetings and will come to all meetings with assignments completed and prepared for the meeting. Meetings **MUST** be scheduled, with agendas and time frame. It is the responsibility of the team leader to ensure agendas and time are strictly followed. (Many organizations waste a great deal of time in poorly organized meets. As an organization you may find the need to have some training in "Effective Meetings")

✓ Participation of team members in meeting discussions is important. The team members MUST feel free and open to the identification of obstacles, training needs, cost, time line and all the other items and issues that will come-up during the course of any major project. Again, it is the responsibility of the team leader to assure all members are effectively communicating in and out of the meeting environment.

Team Communication

❖ Communication Within the Team
❖ Communication to Other Teams in the Organization
❖ Communication with Customers
❖ Communication with Suppliers
❖ Communication with External Resources
❖ Team Documentation of Communication

✓ Communication; we have already spoke considerably about communication. Many APQP projects, especially those that involve a new product vs. a revised product may become very complex. This complexity may involve multiple suppliers, customers, design centers, testing facilities, equipment manufactures, internal departments, purchasing activities, training, etc. It is no wonder communication becomes vital and complex. It is advisable to have a team member dedicated to address communication issues. As is apparent from the list above there are many levels of communication to be addressed. While this list is only partial and only addresses "communication links or points" **it does not address content of the communication.**

✓ With all the tools of communication available to today's organization this still becomes a complicated problem that must be successfully addressed by the APQP Project team.

✓ As important as the point-to-point is the content of the information. The team MUST devise a method to know what information is needed by which resources at which time. Sometimes this is as simple as asking "What do you need to know and when do you need the information?"

✓ Documentation of all communication is maintained by the appropriate member of the team. While most communication today is electronic, e-mail, etc; Other methods of communication also needs documentation. Methods such as; phone, test message, memo, meeting minutes, etc. all require attention and distribution.

Team Documentation

❖ Training Documentation
❖ Meeting Documentation
❖ Project Time Line With Critical Path Identification
❖ Customer Requirements
❖ Supplier Requirements and Capability

✓ There are many levels of documentation that need to be considered by the APQP Project team.

❑ **Training documentation**, whether that is team member training for skill enhancement, organization training, maintenance, operators, supervisors, quality, engineering, etc.

❑ **Meeting documentation**, all meetings should have agendas, minutes, follow-up, etc.

❑ **Project Time Line**, this is a critical item and must be developed, review, supported by management and the customer as well as suppliers, labs, design centers, etc. Many organizations use a GANT chart for this task, though there are other tools for "time-line" tracking.

❑ **Customer Requirements**, all customer requirements MUST be defined, the part or assembly print, production quantities, schedule requirements, packaging, special characteristics, etc. It is critical the supplier understands the customer requirements. This is one of the primary objectives of APQP.

❑ **Supplier Requirements and Capability,** this area of understanding is enhanced by requiring the same future planning of suppliers as your customers require of your organization. This is also one of the communication links your team is charged with developing.

Team Effectiveness

❖ Metrics;

➢ How do you Measure the Effectiveness of the APQP Project

➢ Team Member Measure's (Individual)

➢ Tracking Effectiveness

➢ Reporting Effectiveness to Management

   ✓ Is this a part of "Management Review"?

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✓ The APQP team needs to have means of measuring the effectiveness of their efforts. While every organization is different and each APQP Project is different; the team will find a method of measuring the quality of the progress made by the APQP Team and the organization overall.

✓ This tracking is best if it focuses on interim steps not just the end result and the meeting of key dates along the way, not just making the delivery date. Management reviews along the way are important steps and opportunities to show this tracking methodology.

Management Support

MB Inc.

❖ Has Management Assigned the Project Leader?

❖ Has Management Been Kept Up to Date as the Project Advances?

❖ Is Management Involved?

❖ Does Management Understand the Training Needs of the Team?

❖ Other Management Involvement!

✓ Finally we have the top management involvement in this process.

✓ It is the duty of top management to assign a project leader.

❑ AIAG/APQP 2nd Edition page 3, "…Effective product quality planning depends on a company's top management commitment to the effort required in achieving customer satisfaction…"

✓ Management should not just attend "management reviews", top managers should be actively involved in these reviews, questioning data, time lines, resources needs, projected dates, critical path timing, training and training needs, etc.

✓ For the company that is registered to ISO/TS16949:2002
clause 5.2 "Top management <u>shall</u> ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1."
clause 5.4.2 "Top management <u>shall</u> ensure that…b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented."

APQP

❖ Section Eight - Summary

➢ APQP Team Implementation

- ✓ Team Organization
- ✓ Team Training
- ✓ Team Support
- ✓ Team Communication
- ✓ Team Documentation
- ✓ Team Effectiveness
- ✓ Management Support

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Course Summary

❖ Understand the APQP – 2nd Edition

❖ Understand the Five Phases of APQP

❖ Understand the Tools of APQP
  ➢ DFMEA, PFMEA, Process Flow Chart, Process Control Plan, PPAP, etc.

❖ Understand the Planning Requirements

❖ Understand the Team Benefits Applied to APQP

Course Evaluation

- ❖ Complete the Course Evaluation Questionnaire.
- ❖ Thank You to all Participants
- ❖ Ask Any Final Questions

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