Control Plan

Mojtaba Mousavi
Hossein Zeinal

AIAG
ADVANCING MOBILITY

CONTROL PLAN
Reference Manual

Issued March 2024

ISBN: 978 1 60534 481 8

FOREWORD

Effective March 1, 2024, APQP Third Edition and Control Plan Reference Manual replaces APQP and Control Plan Second Edition, unless otherwise specified by your customer.

The APQP and Control Plan Second Edition was split into separate manuals:

- Decoupling of the two will facilitate more timely updates as systems evolve.
- APQP and Control Plans are linked by requirements in APQP much like FMEA, SPC, MSA and PPAP. These links will continue.

The remainder of this manual will focus on Control Plans (CP).

Factors driving the need for this update:

- Changes to other references necessitate updates here for CP to remain relevant. Such as, new terminology and concepts consistent with IATF 16949, AIAG & VDA FMEA Handbook and other Ford, General Motors, and Stellantis core tool manuals.
- The due diligence for CP is being strengthened to avoid pitfalls from known risk factors.
- Incorporation of lessons learned from past projects and problems.
- Applications of CP are changing to meet demands imposed by higher automation and ultimately autonomous driving, electrification and expanding definition of mobility.
- Addition of content describing expectations for "Safe Launch", enhanced control/containment measures applied to early stages of mass production.
- Appropriate references to customer specifics provided without the full text.
- Supplier input was actively solicited and incorporated wherever possible.
- Allowances are included for CP functions that reside in automated systems relative to documentation requirements.

This manual continues to provide general guidelines for ensuring that control plans are implemented in accordance with the requirements of the customer. It does not give specific instructions on how to arrive at each control plan entry, a task best left to each organization.

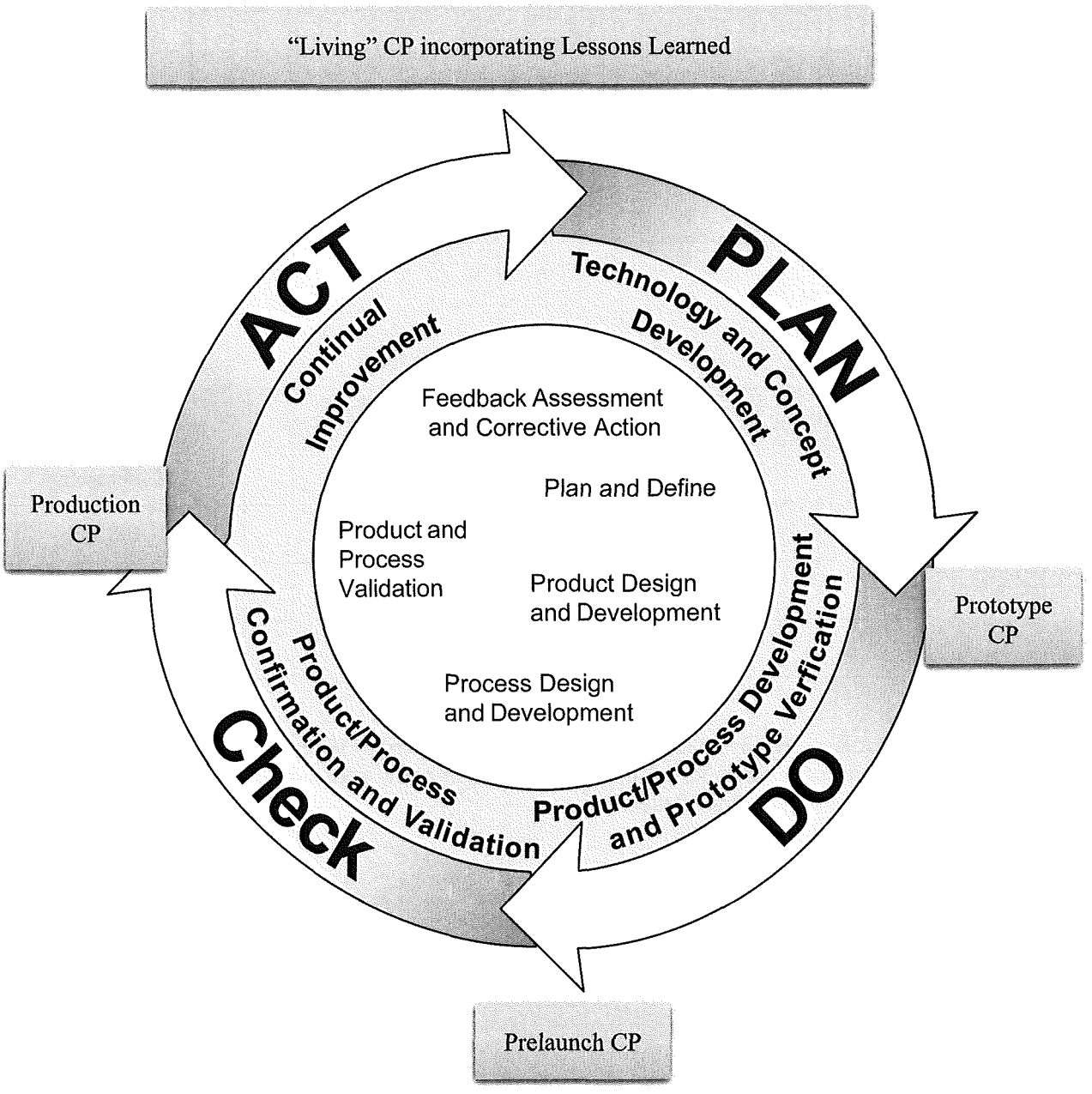
While these guidelines are intended to cover most situations normally occurring either in the early planning, design phase, or process analysis, there will be questions that arise. Please direct any questions to your authorized customer representative.

Our sponsors gratefully acknowledge the contributions of the following individuals and their respective companies for their participation in the revision process.

Meghana Nidadavolu, General Motors Company, Chair
Scott Trantham, General Motors Company
Keith Peterfeso, Ford Motor Company
Greg Szelazek, Stellantis

TABLE OF CONTENTS

PRODUCT QUALITY PLANNING CYCLE – with CONTROL PLANS



SIPOC Diagram illustrating the "Organization"

Supplier	Input	Processes	Output	Customer
Your Suppliers External or Internal		You are here You are the "Organization" You are the "CP Process Owner"		Your Customer External or Internal

Supply Chain Depiction

Tier of the organization	Supplier	Organization	Customer
0	Tier 1	OEM	Consumer
1	Tier 2	Tier 1	OEM
2	Tier 3	Tier 2	Tier 1
N	Tier N+1	Tier N	Tier N-1

Note: This is a reference manual. The visual above describes your organization within the planning process. It is important to understand who your suppliers and customers are and inputs and outputs of each.

Introduction

0.1 Purpose of this Manual

The purpose of this manual is to communicate standardized best practices for developing, using, and improving control plans.

This manual provides guidelines designed to help produce a standardized and effective product quality control plan which will support the fulfillment of a product or service that will satisfy the customer.

Some of the expected benefits in using these guidelines are:

- To create a common language for the control plan to improve communication within and between organizations and their suppliers and customers.
- A reduction in the complexity of control plans for the customers and organizations.
- To facilitate visualization and confirmation of appropriate product and process control throughout the supply chain, especially controls related to special characteristics.

This reference manual contains guidelines that support requirements as described in IATF 16949 and applicable customer specific requirements. Nothing in this manual is intended to supersede or conflict with the requirements of IATF 16949, or any customer specific requirements.

The development of a control plan is an important phase of the process for quality planning, as defined in the AIAG Advanced Product Quality Planning (APQP) manual. Control Plan is listed as an output of APQP in the following stages:

- Product Design and Development (2.5) – Protype Build Control Plan.
- Process Design and Development (3.6) – Pre-Launch Control Plan (including Safe Launch Control Plan).
- Product and Process Validation (4.7) – Production Control Plan (including Safe Launch Control Plan).

0.2 Support to Product Quality Planning Cycle

The control plan supports the Product Quality Planning Cycle shown on page vii, a graphical depiction of a typical program.

The various phases are sequenced to represent planned timing to execute the functions described.

The purpose of the Product Quality Planning Cycle is to emphasize:

- Up-front planning. The first three-quarters of the cycle is devoted to up-front product quality planning through product/process validation.
- The act of implementation. The fourth quarter is the stage where the importance of evaluating output serves two functions: to determine if customers are satisfied, and to support the pursuit of continual improvement.

Depicting product quality planning as a cycle illustrates the never-ending pursuit of continual improvement that can only be achieved by taking the lessons learned in one program and applying that acquired knowledge to all potentially impacted programs.

0.3 Control Plan Through the Product Life Cycle

The control plan is maintained and used throughout the product life cycle.

Early in the product life cycle, its primary purpose is to document and communicate the initial plan for process and product control.

Subsequently, it guides manufacturing in how to control the process and ensure product quality.

During regular production runs, the control plan provides the process monitoring and control methods that will be used to control product and/or process characteristics.

Chapter 3 Control Plan Phases gives additional detail of the purpose, content, and use of control plan at the various phases.

0.4 Control Plan Methodology

The purpose of control plan methodology is to aid in the manufacture of quality products according to customer requirements.

It does this by providing a structured approach for the design, selection, and implementation of value-added control methods for the total system.

The methodology is applicable to a wide range of manufacturing processes and technologies.

Control plans provide a written summary description of the systems used in minimizing process and product variation.

In effect, the control plan describes the actions that are required at each step of the process including receiving, in-process, out-going, and periodic requirements to ensure that all process outputs will be in a state of control. The control plan may incorporate rework processes directly, or a separate control plan for rework may be used. (See Chapter 1 Control Plan Requirements, section 1.7, for additional detail).

The control plan does not replace the information contained in detailed operator instructions.

0.5 Control Plan in Overall Quality Process

The control plan is an integral part of an overall quality process and is to be utilized as a living document, evolving to incorporate improvements and lessons learned as they occur.

Since processes are expected to be continually updated and improved, the control plan reflects a strategy that is responsive to these changing process conditions.

Therefore, the control plan is updated to reflect the latest measurement and control methods, process parameters, settings, and specifications defined in other documents such as PFMEA, work instructions, assembly/instruction drawings, etc., every time a change occurs. A review of control plan for updates must be triggered by events such as corrective actions, customer complaints, audit findings, new models, engineering changes, or other change points as defined by the customer.

0.6 Manual Structure

The manual is laid out to support the effective development and utilization of control plans:

- Chapter 1: Control Plan Requirements and Guidelines.
- Chapter 2: Control Plan Development.
- Chapter 3: Control Plan Phases (Prototype, Pre-Launch, Production).
- Chapter 4: Effective Use of Control Plans.
- Appendix A: Control Plan Examples.
- Appendix B: Forms and Checklists.
- Appendix C: Reference Material.
- Appendix D: Sector Specific Guidance.
- Appendix E: Glossary.
- Appendix F: Index.

Chapter 1
Control Plan Requirements and Guidelines

Introduction

The main purpose of this chapter is to define requirements related to the control plan, which may include information to be included or actions to be taken.

The chapter includes guidelines, which are not requirements but recommended or suggested practices that may add value to the content and utilization of the control plan.

The chapter is laid out by topic, which may include elements or aspects of the control plan, but also requirements and guidelines that apply to specific conditions or scenarios.

In every case, consult your customer to make sure your practice is in alignment with any customer specific requirements they may have.

After initial issuance of the production control plan, the organization must follow customer requirements for control plan notification and approval, including changes related to process change management and PPAP submission.

1.1 Control Plan Format

The format of the control plan is not as important as the information contained within. However, care should be taken to use a format that is easy to understand and confirm the implementation of items on the control plan.

Requirements:

- Any control plan format used must contain, at a minimum, the same information as described in Chapter 2 Control Plan Development.

Guidelines:

- Using the format in this manual is recommended, but if you choose a different format, columns should be grouped logically for ease of understanding. For example, group columns related to Methods together (Specification/Tolerance, Evaluation/Measurement Technique, Sampling, Control Method). Additional columns may be added if desired.
- "Dynamic Control Plans" (i.e., a single document combining PFMEA and control plan) may be used, as long as the control plan portion includes, at a minimum, the same information as described in Chapter 2 Control Plan Development.

1.2 Special Characteristics

Special characteristics are product and/or process characteristics that may impact governmental regulatory, safety, or other aspects of the part deemed to require special attention and treatment. Special characteristics may be identified by the customer or the organization.

Requirements:

- All special characteristics (product and process) must be included in the control plan.
- At a minimum, all DFMEA items with a severity rank of 9-10 that flow to PFMEA for control must be designated as special characteristics. The customer may specify other severity ranks at their discretion.
- Special characteristics must be indicated in the "Special Characteristic Classification" column of the control plan. If the special characteristic is identified by the customer, the organization must use the appropriate classification as required by the customer. The use of organization-designated classifications is allowed if the customer agrees and there is documentation such as a correlation matrix to link to customer designation.

Guidelines:

- If the customer does not specify classification symbols for different types of special characteristics, the organization should develop their own classifications and apply them consistently.

1.3 Pass-Through Characteristics (PTC)

Pass-Through Characteristics (PTCs) are part characteristics manufactured within the supplier process and used in the organization's process without modification or further validation. PTCs are not controlled or functionally tested by the organization and would have significant impact on their customer, such as customer processing problems and/or field warranty issues. PTCs are ultimately supplied to an OEM customer (i.e., it will "pass-through"), therefore the organization must ensure there is adequate control of the characteristic at the supplier. The supplier process where the PTC is last controlled or functionally tested is the "last point of control".

Requirements:

- Organizations must identify any characteristics meeting the definition of "Pass-Through Characteristic" from this manual, or as agreed upon with their customer.

- Organizations must have a process to validate the effectiveness of the supplier's control. Based on the validation results, the organization must decide on appropriate control methods from the organization and the customer's point of view.
- Organizations must document all pass-through characteristics and the control method at the "last point of control" for each PTC. This document must be reviewed with the appropriate customer representative for agreement on control of the PTCs prior to or concurrent with pre-launch control plan review/approval.
- If the organization uses receiving inspection based on sampling (such as lot certification) to ensure quality of PTC, it must be included on the organization's control plan.

Guidelines:

- Use of the "Supplier Pass-Through Characteristic Matrix" from AIAG CQI-19 Sub-Tier Supplier Management Process Guideline is encouraged to ensure all characteristics are identified, impact assessed, and the control plan reflects process capability of the supplier. A similar format that achieves the same result is acceptable.

1.4 Error-Proofing Confirmation

Per the AIAG APQP manual, verification of effectiveness of controls designated as error-proofing (including those designated as mistake-proofing) is required.

Requirements:

- Error-proofing devices must be listed on the control plan.
- The method and frequency to confirm effectiveness or proper functioning of error-proofing devices must be included in the control plan.
- Frequency of error-proofing device verification must be based on ability to enable effective containment of product produced since the last good verification result.
- Master defect samples (e.g., "Red Rabbits") should be maintained and managed to ensure they are up to date and functional as designed. Master defect samples must be clearly identified and managed to prevent mixing with production parts or use for other purposes. To ensure effective detection and containment of nonconforming products, master defect samples must be at or just outside specification limits or tolerances.

Guidelines:

- None.

1.5 Families of Control Plans

Families of control plans are control plans for multiple parts where the parts are substantially similar in application, design, manufacture, requirements, and specification.

Requirements:

- Organization must list all related individual part numbers covered by the "Family Control Plan". If the number of individual part numbers is too great to include in fields 3 (Part Number) and 4 (Part Name/Description), the organization may refer to a separate document that indicates all parts covered by the family control plan.
- Family control plans may only be applied when all parts associated with the family control plan are run on the same manufacturing line or equipment, or when multiple lines utilize the same make and model of equipment, or similar equipment with identical controls specified on the family control plan and process flow chart.

Guidelines:

- If a family control plan is the result of applying family FMEA and family process flow, the organization should apply consistent naming or numbering to indicate the linkage of all related documents and the family of parts to which they apply.

1.6 Interdependent Processes and/or Control Plans

In some cases, processes may be interdependent, meaning they are separate but linked somehow. An example could be the process of receiving inspection for a material or component that is later used in more than one manufacturing process or to make more than one type of part. The same receiving inspection process is a precursor to the following processes. Another example is a machine process used to machine an item that is later used in more than one process to make various parts.

Requirements:

- Control plans must exist for all processes used to manufacture a given part.
- Either list all steps involved to produce a part on that part's control plan or make a separate control plan for the "interdependent" process and link that control plan to the subject part's control plan.

Guidelines:

- If interdependent processes are used, show the exit and entry points from the subject part's process to and/or from the interdependent process on the part's control plan and flow chart.

1.7 Rework and Repair Processes

Rework (including reuse of components if allowed) is planned, included in the production control plan, corrects the nonconformance to meet original specifications, and is approved by the customer during review and approval of the production control plan.

Repair is remediation that satisfies the customer's "Fitness for Use" criteria. Repair requires a control plan for the proposed remediation and customer approval. "Fitness for Use" is a decision by the customer that any deviation from the specification due to the repair will have no impact on the satisfactory performance of the product.

Requirements:

- If rework is done by reprocessing nonconforming product through the original process or a subset of steps/operations within the process, the control plan must clearly indicate the start and finish of the rework process.
- If rework is done by reprocessing nonconforming products through alternate equivalent processing, a separate rework control plan must be developed and used.
- Repairs always require customer approval/deviation.
- Any repair process must have its own control plan.
- All repairs must re-enter the main process at the point in which they were removed to complete all subsequent control plan checks.
- The organization must review the customer specific requirements or customer statement of requirements regarding acceptability of any rework or repair process prior to initiating any rework/repair activities and must consult the customer as early as possible in the planning stage.
- The organization must ensure traceability of parts that have been repaired or reworked, in accordance with customer requirements.

Guidelines:

- None.

1.8 Reaction Plan Details

Reaction plans specify not just corrective action necessary, but also who is responsible for the action. In all cases, suspect and nonconforming products must be clearly identified and quarantined, and disposition made by the responsible person designated in the reaction plan.

Requirements:

- Reaction plan area of the control plan must indicate specific action taken or refer to a specific document or system instruction that lists the specific actions to be taken in case of Out of Control and/or Out of Specification.
- Reaction plan area of the control plan must indicate the individual (by title or role) responsible to implement the action specified, or reference to document that includes all the details, including responsible owner for the action(s).

Guidelines:

- None.

1.9 100% Visual Inspection

Some processes rely on 100% Visual Inspection, which may be done by operators. Regardless of the nature, reliance on 100% Visual Inspection introduces risk of error or misinterpretation in the inspection.

Requirements:

- If 100% Visual Inspection is the method used, the control plan must include a periodic verification of the visual inspection, such as sampling audit by qualified auditor, off-line measurement to verify judgment, or similar.
- The periodic verification described above must indicate who is responsible for the verification, either by adding a column to indicate responsibility or by listing responsible individual in the method.
- If the characteristic to be evaluated is not measurable with instruments, gages or fixtures, a customer-approved master and/or boundary sample (including "book of masters" or other documented agreements) must be available to the operator and auditor and referenced in the control plan.

Guidelines:

- None.

1.10 Black-Box Processes

In some cases, the organization may not want to provide the customer with documented control plans for processes they feel are proprietary or represent a unique competitive advantage. In such cases, sometimes referred to as "Black Box" processes, the organization and its customer negotiates an acceptable solution.

Requirements:

- Control plans must exist that meet the requirements of this manual.
- Any deviation from normal customer review and approval of control plans must be documented with agreement from the customer.
- At a minimum, the control plan must be available for review by the customer, either in person or in a secure virtual environment.

Guidelines:

- Typical methods to gain customer confidence in the organization's process control and capability include in person review of the content of the control plan without providing a copy of the document; process walks demonstrating the controls of the process and product characteristics; SPC data showing capability of the process and resulting parts.

1.11 Non-Design Responsible Organizations

In cases where the organization is not design-responsible, the organization may not have ready access to DFMEA results, including special characteristics that may require action on the control plan to ensure performance to design specifications.

Requirements:

- The organization and customer must have a process to cascade DFMEA or at least special characteristics details from the design-responsible entity to the organization.

Guidelines:

- None.

1.12 Directed Supply

In cases where the customer directs the organization to source from a specified supplier, it is still the responsibility of the organization to work with the supplier to get the necessary information to develop control plans, unless otherwise specified in the mutually signed agreement (e.g., RASIC, master purchase agreement). This includes getting information from the supplier about items related to receiving and using the supplied component or material, any testing or validation to be added to the organization's control plan, and any pass-through characteristics.

Requirements:

- Information for directed supply components and materials must be available as reference when developing the organization's control plan, just as if it was self-procured.

Guidelines:

- In situations where the directed supply is from a competitor or similar situations where confidentiality is a concern, the organization and the customer should discuss how to obtain the required information.

1.13 Use of Software to Develop and Manage Control Plans

In some cases, the customer may require the use of software, or the organization may initiate the use of software to develop and manage control plans. Use of software facilitates version control and linkage of documents, which ensures if changes are made to one document the change is made to all related documents like PFMEA, flow chart, and work instructions.

Requirements:

- Confirm with your customer if there is any requirement to use software to develop and manage control plans.

Guidelines:

- Confirm with your customer the expected benefits or results of using software to develop and manage the control plan, then select software that can provide those benefits and results when integrated in your QMS.

Chapter 2
Control Plan Development

Introduction

The goal of a control plan is to facilitate communication with everyone involved to ensure that all required controls are completed on time and in full, every time.

Control plan effectiveness depends on a company's leadership commitment to the effort required to achieve customer satisfaction.

Each control plan is unique. The actual timing and sequence of execution is dependent upon customer needs and expectations and/or other practical matters.

The earlier a work practice, tool, and/or analytical technique can be implemented in the Product Quality Planning Cycle, the better.

This chapter describes how to take the output from previous steps in the product quality planning process (per the AIAG APQP manual) to develop the control plan document.

The inputs and outputs applicable to the control plan development process may vary according to the product development process, and customer needs and expectations. The list of inputs and outputs provided is not intended to be all-inclusive, but to provide examples of typical information used.

The intent of the control plan form displayed in this chapter is to provide an example of how this information can be documented. An alternate format may be used if it contains the same information, as a minimum.

2.1 Getting Started

The control plan process and team are part of the organization's product quality planning activity, as referenced in the AIAG APQP manual.

Accordingly, the control plan process starts with the steps outlined in the APQP Manual (for additional detail, see the AIAG APQP manual)

- Organize the Team: The organization's first step is to assign a process owner for the control plan. A cross-functional team (leadership, engineering, manufacturing, quality, suppliers, etc.) should be assigned. It may be necessary to have different teams or representatives for the different phases of the control plan (e.g., the pre-production CP team may differ from the production CP team).
- Define the Scope: In the earliest stage of the program, it is important for the organization's control plan development team to identify customer needs, expectations, and requirements. The team must also assess the feasibility of proposed tests and controls prescribed in the design, performance requirements, and manufacturing process. In some cases, the team may need to determine assistance required from the customer.

- Team-to-Team (lines of communication): The control plan team must establish lines of communication with applicable customer, organization, and supplier teams.
- Training: Success of the control plan development is dependent upon an effective training program that communicates all requirements and development skills to fulfill customer needs and expectations.
- Customer and Organization Involvement: The primary customer may initiate the control plan development process, but the organization has an obligation to manage the control plan development and must require the same performance from their suppliers.

2.2 Timing and Coordination between APQP and CP Teams

The control plan process team must coordinate their activities with the APQP process team, primarily by assuring critical milestones and deliverables are aligned with the Product Quality Timing Plan as defined in the AIAG APQP manual.

Key items to consider include, but are not limited to (Refer to the AIAG APQP manual for details of each):

- Simultaneous Engineering: Replaces sequential series of phases where results are transmitted to the next area for execution. The organization's control plan development team assures coordination with related groups to acquire inputs and provide outputs per the overall APQP plan.
- Concern Resolution: Concerns with control plan development should be documented on a matrix with assigned responsibility and timing.
- Product Quality Timing Plan: The process owner for control plan development must support and be informed of the Product Quality Timing Plan developed by the APQP process owner, including changes to the plan. Effective status reporting supports program monitoring with a focus on identifying items requiring special attention.
- Plans Relative to the Timing Chart: The organization's control plan development team is responsible for assuring deliverable timing meets or is ahead of the Product Quality Timing Chart established and maintained by the APQP process owner.

2.3 Inputs (Numbers Indicate Section in APQP Manual)

Cross-functional/multi-disciplined team:

- Team Experience (1.1.3).
- Leadership Support (1.14, 2.13, 3.10, 4.8).
- List of all suppliers.

Product risk analysis output:

- DFMEA (2.1).
- List of product performance/functional characteristics from design (DFMEA), and corresponding testing and dimensional requirements.
- Engineering Drawings (2.6), including GD&T.
- Characteristics from Engineering drawings and Material Specifications (2.8).
- List of error-proofing devices/mechanisms for each operation/failure mode and what product/process characteristics it checks for.
- Design for Manufacturability, Assembly, and Service (2.2).
- Material Specifications (2.8), including handling and storage requirements, and those requiring inspection.

Process risk analysis output:

- PFMEA (3.5).
- PFMEA controls, including list and sequence of corresponding processes.
- Reverse PFMEA analysis and actions.
- List of error-proofing devices/mechanisms per operation/failure mode and what product/process characteristics it checks for.
- List of detection methods for each operation/type of defect.
- Repair/rework/reuse operation identification.

Operation description:

- Process Flow Chart (1.10, 3.3).
- Floor Plan Layout (3.4).
- Tool Layout.
- Considerations of workstation environment (e.g., lighting) and ergonomics.
- New Equipment, Tooling and Facilities Requirements (2.10).

Quality history knowledge:

- Lessons learned from similar parts.
- Control plan monitoring for same/similar processes at sister plants.
- Process evaluations.
- Historical Warranty and Quality Information (1.1.2).

Special Characteristics:

- Identification of Special Product and Process Characteristics (1.11, 2.11), including Safety and Regulatory Requirements.

System capability review results:

- Product/Process Quality System Review (3.2).
- Capable gages and measurement equipment.
- List of gage capabilities.
- Change management process and revision history are in place.
- Means to monitor end of line operations.
- Monitoring of process capabilities.

Sampling plan and frequency:

- Engineering Specifications (2.7), especially if "in-process test section" includes sample size, frequency and acceptance criteria.
- First-off and Last-off part validations considerations.
- Protocols for change-over and restart activities (tooling changes, maintenance, shutdown, etc.).

Outputs from product and process validation:

- Significant Production Run (4.1).
- Measurements System Analysis (4.2).
- Preliminary Process Capability Study (4.3).
- Production Validation Testing (4.5).
- Results of "Pre-Launch" and/or "Safe Launch" production.

Reaction plan strategy:

- If grouped by type of detection used (e.g., all defects detected through 100% inspection, is the operator trained to handle defect product).
- If grouped by X number of defects in a row (what is actionable by the operator who found the defect before notifying supervisor).

CONTROL PLAN

(1) ☐ Prototype ☐ Pre-Launch ☐ Production ☐ Safe Launch

Page _____ of _____

(If Safe Launch is included in Pre-Launch or Production Control Plan, check both boxes)

Control Plan Number (2)		Key Contact/Phone (7)	Date (Orig.) (9) / Date (Rev.) (10)
Part Number/Latest Change Level (3)			Customer Engineering Approval/Date (If Req'd.) (11)
Part Name/Description (4)		Supplier/Plant Approval/Date (8)	Customer Quality Approval/Date (If Req'd.) (12)
Supplier/Plant (5)	Supplier Code (6)	Other Approval/Date (If Req'd.) (13)	Other Approval/Date (If Req'd.) (13)

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE, JIG,TOOLS FOR MFG.	CHARACTERISTICS			SPECIAL CHAR. CLASS	METHODS		(23) SAMPLE			REACTION PLAN	
			NO.	PRODUCT	PROCESS		PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	EVALUATION/ MEASUREMENT TECHNIQUE	SIZE	FREQ.	CONTROL METHOD	ACTION	OWNER/ RESPONSIBLE
(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)	(22)			(24)	(25)	(26)

8. **Supplier/Plant Approval Date**

   Obtain the responsible manufacturing plant approval of the organization (if required see appropriate customer specific requirements).

9. **Date (Orig.)**

   Enter the date that the original control plan was compiled.

10. **Date (Rev.)**

    Enter the date of the latest control plan updates.

11. **Customer Engineering Approval/Date**

    Obtain the responsible customer engineering approval (if required see appropriate customer specific requirements).

12. **Customer Quality Approval/Date**

    Obtain the responsible customer supplier quality representative approval (if required see appropriate customer specific requirements).

13. **Other Approval/Date**

    Obtain any other agreed upon approval (if required).

14. **Part/Process Number**

    This item number is usually referenced from the process flow chart. If multiple part numbers exist (assembly), list the individual part numbers and their processes accordingly.

15. **Process Name/Operation Description**

    All steps in the manufacturing of a system, subsystem, or component are described in a process flow diagram. Identify the process/operation name from the process flow diagram that best describes the activity being addressed.

16. **Machine, Device, Jig, Tools for Manufacturing**

    For each operation that is described, identify the type of processing equipment, such as machine brand model, fixture type, or other relevant description of the manufacturing tool.

CONTROL PLAN

(1) ☐ Prototype ☐ Pre-Launch ☐ Production ☐ Safe Launch

Page _____ of _____

(If Safe Launch is included in Pre-Launch or Production Control Plan, check both boxes)

Control Plan Number (2)		Key Contact/Phone (7)	Date (Orig.) (9)	Date (Rev.) (10)
Part Number/Latest Change Level (3)			Customer Engineering Approval/Date (If Req'd.) (11)	
Part Name/Description (4)		Supplier/Plant Approval/Date (8)	Customer Quality Approval/Date (If Req'd.) (12)	
Supplier/Plant (5)	Supplier Code (6)	Other Approval/Date (If Req'd.) (13)	Other Approval/Date (If Req'd.) (13)	

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE, JIG,TOOLS FOR MFG.	CHARACTERISTICS			SPECIAL CHAR. CLASS	METHODS		(23) SAMPLE			REACTION PLAN	
			NO.	PRODUCT	PROCESS		PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	EVALUATION/ MEASUREMENT TECHNIQUE	SIZE	FREQ.	CONTROL METHOD	ACTION	OWNER/ RESPONSIBLE
(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)	(22)			(24)	(25)	(26)

Characteristics (17 – 19)

A distinguishing feature, dimension or property of a process or its output (product) on which variable or attribute data can be collected.

Process flow charts should be used to locate special product and process characteristics that will be addressed in the control plan. In addition, use DFMEA, if available to identify specific characteristics that may be classified as special.

All applicable documents such as, but not limited to, process flow diagrams, numbered blue-prints, FMEAs, engineering and material specifications, and drawings or other visual standards, should be used to develop a list of characteristics. The organization should determine which characteristics affect meeting functional, durability, and appearance requirements and bring it to the control plan.

Using a special characteristics worksheet, the description/rationale column includes all special process and product characteristics agreed upon by the cross-functional team. In the worksheet, a sequential number (No.) is assigned to each characteristics listed to ensure none are overlooked by the organization when the control plan is completed.

This information is carried into the control plan for each characteristic, under the appropriate "Process" and/or "Product" header. See example format in Appendix B, B-3 Special Characteristics worksheet.

17. Characteristics – Number

Assign a cross reference number to all applicable documents such as, but not limited to, process flow diagrams, numbered blue-prints, FMEAs, and drawings or other visual standards, if required. Optional example work sheets and explanation of these work sheets are located in Appendix B, B.3. Special Characteristics worksheet.

18. Characteristics – Product

Product characteristics are the features or properties of a part, component, or assembly that are described on drawings or other primary engineering information. The core team should identify the special product characteristics that are a compilation of important product characteristics from all sources. All special characteristics must be listed on the control plan. In addition, the organization may list other product characteristics for which process controls are routinely tracked during normal operations.

19. Characteristics – Process

Process characteristics are the process variables (input variables) that have a cause-and-effect relationship with the identified product characteristic. A process characteristic can only be measured at the time it occurs. The core team should identify process characteristics for which variation must be controlled to minimize product variation. There could be one or more process characteristics listed for each product characteristic. In some processes one process characteristic may affect several product characteristics.

CONTROL PLAN

(1)
☐ Prototype ☐ Pre-Launch ☐ Production ☐ Safe Launch

Page _____ of _____

(If Safe Launch is included in Pre-Launch or Production Control Plan, check both boxes)

Control Plan Number (2)		Key Contact/Phone (7)	Date (Orig.) (9)	Date (Rev.) (10)
Part Number/Latest Change Level (3)			Customer Engineering Approval/Date (If Req'd.) (11)	
Part Name/Description (4)		Supplier/Plant Approval/Date (8)	Customer Quality Approval/Date (If Req'd.) (12)	
Supplier/Plant (5)	Supplier Code (6)	Other Approval/Date (If Req'd.) (13)	Other Approval/Date (If Req'd.) (13)	

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE, JIG,TOOLS FOR MFG.	CHARACTERISTICS			SPECIAL CHAR. CLASS	METHODS					REACTION PLAN	
			NO.	PRODUCT	PROCESS		PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	EVALUATION/ MEASUREMENT TECHNIQUE	(23) SAMPLE SIZE	SAMPLE FREQ.	CONTROL METHOD	ACTION	OWNER/ RESPONSIBLE
(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)	(22)			(24)	(25)	(26)

20. Special Characteristic Classification

Use the appropriate classification as required by the customer (see the appropriate customer specific requirements), to designate the type of special characteristic or this field can be left blank for other undesignated characteristics. Customers may use unique symbols to identify important characteristics, such as those that affect customer safety, compliance with regulations, form, fit, function, etc.

Methods (Includes items 21 – 24)

A systematic plan using procedures and other tools to control a process.

21. Methods – Product/Process Specification/Tolerance

Specifications/tolerance may be obtained from various engineering documents, such as, but not limited to, drawings, design reviews, material standards, computer-aided design data, manufacturing, and/or assembly requirements.

22. Methods – Evaluation/Measurement Techniques

This column identifies the measurement system being used. This could include gages, fixtures, tools, and/or test equipment required to measure the part/process/manufacturing equipment. The measurement equipment intended to be used should be verified and documented showing qualification for the required scope of measurement and testing. A measurement systems analysis should be done to ensure control of monitoring and measuring devices prior to relying on a measurement system. For example, an analysis of the linearity, reproducibility, repeatability, stability, and accuracy of the measurement system should be performed. Improvements to the measurement systems should be made accordingly. Refer to the AIAG Measurement Systems Analysis (MSA) reference manual for additional details.

23. Methods – Sample Size/Frequency

Sample Size: When sampling is required list the corresponding sample size. Sample sizes must be based upon industry standards, statistical sampling plan tables, or other statistical process control methods or techniques.

Frequency: Frequency of checks for a specific characteristic should be based on the thought process of effective containment actions if a defect were to escape (visual inspection, equipment failure, etc.).

The sample frequency when not 100% should be volume-based checks. Consider the method of inspection versus impact on the organization for robust containment actions for such a characteristic to determine the volume/quantity of parts run until the next check point. This could imply multiple checks within the same shift as frequency of checks would be defined by volume. Sampling sizes should be based on severity and detection mechanisms and may determine your finished goods inventory.

CONTROL PLAN

(1) ☐ Prototype ☐ Pre-Launch ☐ Production ☐ Safe Launch

Page _____ of _____

(If Safe Launch is included in Pre-Launch or Production Control Plan, check both boxes)

Control Plan Number (2)		Key Contact/Phone (7)	Date (Orig.) (9) / Date (Rev.) (10)
Part Number/Latest Change Level (3)			Customer Engineering Approval/Date (If Req'd.) (11)
Part Name/Description (4)		Supplier/Plant Approval/Date (8)	Customer Quality Approval/Date (If Req'd.) (12)
Supplier/Plant (5)	Supplier Code (6)	Other Approval/Date (If Req'd.) (13)	Other Approval/Date (If Req'd.) (13)

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE, JIG,TOOLS FOR MFG.	CHARACTERISTICS			SPECIAL CHAR. CLASS	METHODS		(23) SAMPLE			REACTION PLAN	
			NO.	PRODUCT	PROCESS		PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	EVALUATION/ MEASUREMENT TECHNIQUE	SIZE	FREQ.	CONTROL METHOD	ACTION	OWNER/ RESPONSIBLE
(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)	(22)			(24)	(25)	(26)

Example: A case where the control plan includes a periodic check to confirm a product characteristic, such as a functional test, "burn-in", destructive test, etc.

- Part cycle time equals 60 seconds (one minute)
- Control plan item specifies a non-destructive detection methodology which takes 600 minutes.
- Part #1 goes to checking station for confirmation.
- Every 600 cycles, the detection method must be used – for example, a PLC ensures part #601 of that production run goes to the checking station.
- Parts 1 - 600 can be released to the next customer (or process) once the check for part #1 has been completed and confirmed to meet specifications.

24. **Methods – Control Method**

This is one of the critical elements to an effective control plan. This column contains a brief description of how the operation will be controlled, including procedure numbers where applicable. The control method utilized should be based on effective analysis of the process. The control method is determined by the type of process and the risks identified during quality planning (e.g., FMEA). Operations may be controlled by, but are not limited to, statistical process control, inspection, attribute data, automated and non-automated error-proofing (which includes mistake-proofing, refer to the AIAG APQP manual Appendix C), and sampling plans. Mistake-proofing should be used as a technique to control repetitive tasks or actions and prevent nonconformances from being passed on to the subsequent operation and ultimately the customer. The control plan descriptions should reflect the planning and strategy being implemented in the manufacturing process. If elaborate control procedures are used, the plan will typically reference the procedure document by a specific identification name and/or number. Refer to the examples in Appendix A for how typical processes are controlled.

The method of control should be continually evaluated for effectiveness of process control. For example, significant changes in the process or process capability; quantity of issues (internal and external) coming from a control plan element, should lead to an evaluation of the control method.

CONTROL PLAN

(1) ☐ Prototype ☐ Pre-Launch ☐ Production ☐ Safe Launch

Page _____ of _____

(If Safe Launch is included in Pre-Launch or Production Control Plan, check both boxes)

Control Plan Number (2)		Key Contact/Phone (7)	Date (Orig.) (9)	Date (Rev.) (10)
Part Number/Latest Change Level (3)			Customer Engineering Approval/Date (If Req'd.) (11)	
Part Name/Description (4)		Supplier/Plant Approval/Date (8)	Customer Quality Approval/Date (If Req'd.) (12)	
Supplier/Plant (5)	Supplier Code (6)	Other Approval/Date (If Req'd.) (13)	Other Approval/Date (If Req'd.) (13)	

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE, JIG,TOOLS FOR MFG.	CHARACTERISTICS			SPECIAL CHAR. CLASS	METHODS					REACTION PLAN	
			NO.	PRODUCT	PROCESS		PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	EVALUATION/ MEASUREMENT TECHNIQUE	(23) SAMPLE SIZE	SAMPLE FREQ.	CONTROL METHOD	ACTION	OWNER/ RESPONSIBLE
(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)	(22)			(24)	(25)	(26)

25. Reaction Plan – Action

The reaction plan specifies the corrective actions necessary to avoid producing nonconforming products or operating out of control. The actions should normally be the responsibility of the people closest to the process, the operator, job-setter, or supervisor, and be clearly designated in the plan. Provisions should be made for documenting actions taken. The operator should be responsible for handling defective product as applicable, prior to notifying the supervisor. The operator should be trained to handle defective material. Training records should show evidence of such training for each operator required to handle defects.

In cases where the reaction plan defaults to "Notify Supervisor", the control plan document should indicate what the supervisor will do with the suspect product, and to correct and stabilize the operation, if the control method fails or produces a failure.

Reaction plans must include steps to contain suspect/nonconforming products, stop the process from creating more suspect/nonconforming product, and the steps necessary to bring the process back into control prior to releasing back to production.

26. Reaction Plan – Owner/Responsible

The reaction plan action must be assigned an owner, and it is recommended to indicate a single position that can be linked to a specific individual, not a shared responsibility. The "Owner/Responsible" individual is responsible for ensuring all activities called for by the reaction plan action are carried out effectively, including involvement of related individuals or departments.

Chapter 3
Control Plan Phases

Introduction

Control plans are made for different phases of the program. Just as each phase of APQP for the program has specific purpose and goals, the control plan developed and used in a phase has a specific purpose and goals. The output (data, lessons learned, etc.) of the application of the control plan from a completed phase is used to further refine and improve the control plan at the next phase, culminating in the production control plan. (See Example Process Flow for Developing Control Plan in Chapter 2 Control Plan Development)

However, after the implementation of the production control plan, refinement and improvement of the control plan continues. Lessons learned from the subject program, as well as those of similar programs in various stages of launch, are continuously applied to ensure the production control plan is a true living document, reflecting the latest process capability of the organization.

3.1 Prototype Control Plan

Prototype control plans are a description of the dimensional measurements and material and functional tests that will occur during prototype build. The organization's product quality planning team should ensure that a prototype control plan is prepared.

The manufacture of prototype parts provides an excellent opportunity for the team and customer to evaluate how well the product or service meets the Voice of the Customer objectives, per the AIAG APQP manual Chapter 2 Product Design and Development. Data acquired from application of the prototype control plan to the prototype build parts is used to:

- Ensure the product or service meets specification and report data as required.
- Establish preliminary process parameters and packaging requirements.
- Communicate any concerns, deviations, and/or cost impact to the customer.

While not required, preliminary process parameters and controls may also be included in the prototype control plan, especially if prototypes are made using existing mass production processes.

3.2 Pre-Launch Control Plan

Pre-Launch control plans are a description of the dimensional measurements and material and functional tests that will occur after prototype and before initial production launch. The pre-launch control plan must include additional product and process controls to be implemented until the production process is validated.

The purpose of the pre-launch control plan is to:

- Specify process controls, including error-proofing and mistake-proofing devices and methods.
- Specify process and part characteristic data to be collected and analyzed to determine preliminary process capability.
- Contain potential nonconformities during or prior to initial production runs.

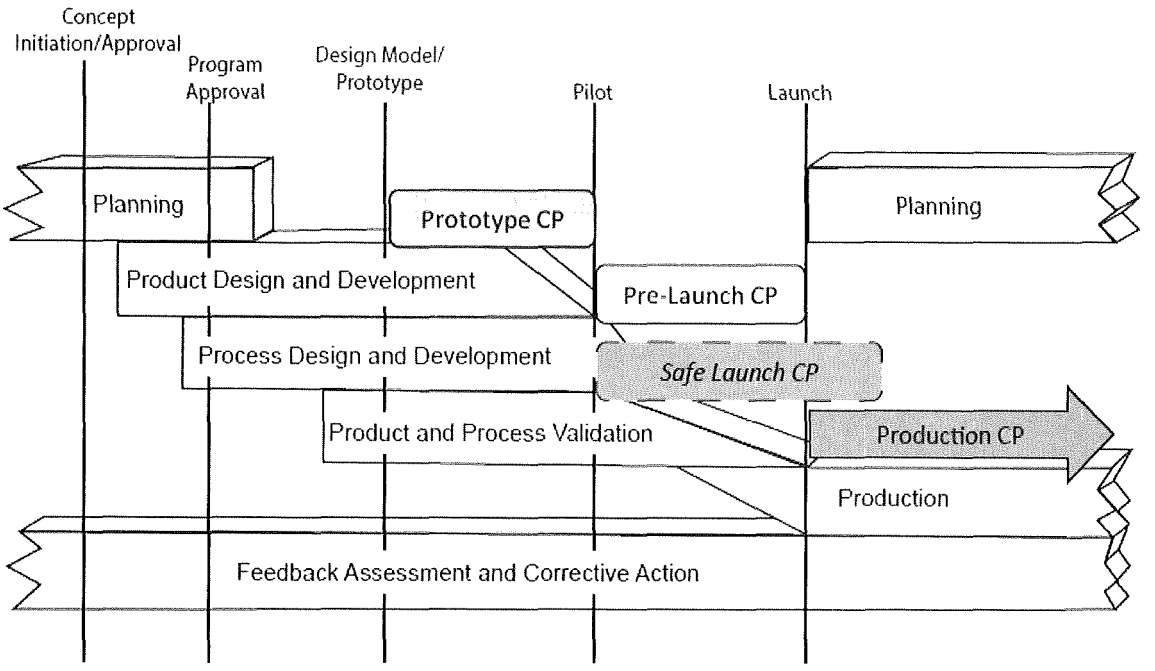
Part and process data acquired from the application of the pre-launch control plan is used for several APQP deliverables, including: (APQP Section #):

- Significant Production Run (4.1).
- Measurement Systems Analysis (4.2).
- Preliminary Process Capability Study (4.3).
- Production Validation Testing (4.5).

Outputs from the pre-launch control plan are also used for production part approval. Please refer to your customer's part approval process, and/or the AIAG PPAP manual for details.

In some cases, the customer may require a Safe Launch program to be implemented. The example below is an image of how the Safe Launch program is typically applied. The dotted outline of the Safe Launch shape indicates the start and end are flexible.

The customer may require the Safe Launch to be implemented during the pilot stage and continued into launch. The customer may require a separate Safe Launch control plan, or documentation of the additional controls as a supplement to the pre-launch control plan. The organization must provide the details of the enhanced control/containment in a customer-approved format. Additional details are explained in 3.3 Production Control Plan.



Typical Application of Safe Launch Control Plans

3.3 Production Control Plan

The production control plan is a written description of the systems for controlling production parts and processes. Approval of the authorized customer representative may be required.

The Start of Production will include a "Safe Launch" or "Enhanced Containment" period to ensure containment of potential nonconformities. The Safe Launch period typically incorporates added inspection items or increased frequency of checks and monitoring and may include tighter control of specification limits. Consult your customer for specific requirements related to Safe Launch.

The organization must provide the details of the enhanced control/containment in a customer-approved format. Typically, an addendum is attached to the production control plan, or items and frequencies of Safe Launch are indicated on the production control plan as "special control period" items.

The organization must establish judgment criteria to determine when it is acceptable to end the Safe Launch period and have a decision-making process in place that ensures adequate management oversight of the decision. If the customer provides judgment criteria or requires authorization to end Safe Launch and implement the production control plan, the organization's decision-making process must confirm the criteria are met and/or the customer has provided authorization.

A typical judgment criteria applied to decision-making is 90 days from production (from customer-defined start point) with no quality issues identified by the customer or by application of the Safe Launch items at the organization. If any quality issues are found within 90 days, the Safe Launch period starts again and continues until 90 days of production with no issues. Customers may apply additional or different judgment criteria.

Mass production provides the organization with the opportunity to evaluate output, review the control plan, and make appropriate changes. Various data sources and lessons learned should be applied to continuously improve the control plan, including but not limited to:

- Statistical analysis of data collected as a result of applying the production control plan.
- Customer quality reports and data.
- Warranty data and part returns.
- Lessons learned from similar part programs and following launches.
- Evolution/refinement of FMEAs for the part and similar parts.
- Evolution/refinement of process and product controls technology and methods (best practices).

The production control plan is a living document and should be updated to reflect the addition or deletion of controls based on experience gained by producing parts, as described in the list above.

Chapter 4
Effective Use of Control Plans

Introduction

As stated in the Introduction to this Control Plan Reference Manual, the control plan is an integral part of an overall quality process and is to be utilized as a living document, evolving to incorporate improvements and lessons learned as they occur, are verified and countermeasures are finalized.

This chapter gives guidance on the effective use of control plans, especially in relation to other elements of the overall quality process. While some of the topics described are directly related to control plans (e.g., Use of Software to Develop/Link/Maintain, Reverse FMEA, Family/Foundation FMEA), several give guidance on how other elements of the "overall quality process" should be used to improve or complement control plans to ensure robust quality and minimize variation.

Each topic's section is laid out in simple bullet point form to explain:

- Definition/Key Concept of the topic.
- Why the topic is important.
- What to do and how to do it.

The examples presented are given to illustrate an approach that is consistent with good or best practices, from the point of view of Ford, General Motors and Stellantis. It is not intended to define a specific approach taken, just to give guidance and consideration points to pursue continuous improvement of your overall quality process.

As always, consult your customer for any specific requirements related to these topics.

4.1 Reverse PFMEA

Definition/Key Concept(s):

- Reverse PFMEA is a documented continuous improvement tool designed to find gaps or weaknesses in the prevention and detection controls of a process.
- Reverse PFMEAs can be applied reactively as well as proactively.

Why is this important:

Reverse PFMEA's are an important tool that can:

- Help identify previously overlooked processes.
- Find additional failure modes in identified processes.
- Develop more realistic Risk Priority Numbers (RPNs) or Action Priorities (APs).
- Improve robustness of corrective actions.

What to do and how to do it:

- Teams conducting a reverse PFMEA test the process by attempting to make bad parts, defeat error-proofing, and finding new failure modes in the process.
- Reverse PFMEAs may be conducted during equipment buy-off/tool tryouts, during launch, and during production.
- Any improvements must be input to PFMEA and cascaded through all related documents (control plan, work instruction, etc.).

Example or illustration of good practice:

Reverse PFMEAs will be process-specific, and therefore unique questionnaires or check sheets should be developed for each process.

Proactive questionnaires or check sheets should ask questions such as: (assembly process example)

- Can this component be installed incorrectly?
- Is there a detection method for incorrectly installed components?
- Can a similar but different component be used i.e., different size screw?
- Is there potential for unintended parts/components to be included in a part shipment?
- Can error-proofing be circumvented?

Reactive questionnaires or check sheets may start with a production quality defect and look for ways to duplicate the defect or test the system for similar defects throughout the process.

4.2 Using Software to Develop and Manage Control Plans and Related Documents

Definition/Key Concept(s):

- Software to develop and manage FMEAs, control plans, and related documents is much more efficient and effective than "paper-based" or "linked individual electronic file" systems.
- Software specifically designed for this function is widely available, and the benefits justify the added expense of purchase or subscription.
- The scope of a software system typically includes FMEA and control plan but many include the ability to develop and maintain linkage to related downstream documents, such as work instructions and corrective actions.

Why is this important:

- Provides real-time updates between FMEAs by linking Foundation/Family/Part specific FMEAs.
- Automatic linkage between your process flow, PFMEA and control plan.
- Ease of including improvement updates in future designs and processes.
- Improves flow of content into FMEAs and control plans after launch.
- Web-based – Promotes document revision control and eliminates local copies of documents on personal computers to ensure all users are accessing the latest version.
- Improves migration of learning.
- Security controls can be integrated into software and any web-based platform (Intellectual Property protection).
- Automated notifications can alert process owners of actions needed or changes that may impact them.
- Your customer may require the use of a software-based system to minimize risk from unconnected or out-of-date information.

What to do and how to do it:

- Define your current state system, and desired functionality that will be compatible with other internal systems.
- Work with a reputable vendor that can provide a solution that meets your needs and requirements.
- Involve a cross-functional team in development and/or use testing to confirm all related groups have input and can confirm ease of use, especially the "cascade" of changes to one document that should trigger or populate change to related documents.
- Specify how to use the software at development, maintenance and corrective action stages to ensure a "living system" is created and maintained.

4.3 Layered Process Audits as Control Plan Verification

Definition/Key Concept(s):

- Layered Process Audits (LPAs) are verifications that the most important standards and controls are in place, including the organization's control plan.
- LPAs verify work is done according to established standards, emphasize importance of those standards, and identify opportunities for continuous improvement.
- "Layered" means different levels of participants from the working level to top management. Different perspectives, fresh eyes, etc. Top management participation reinforces importance and commitment.
- LPA is not a control but a verification of control and does not belong in a process control plan.

Why is this important:

- Verifies improvements to control plan and work instructions are implemented and maintained, especially improvements as a result of corrective action or "read across" of lessons learned.

What to do and how to do it: (Assumes LPA practice is already established at facility)

- Prioritize processes to apply LPA based on impact on customer and internal operations.
- Develop audit check sheet based on control plan content.
- "Fine Tune" check sheet questions to ensure it verifies what is happening in real time based on direct observation and can be answered with yes or no.
- Consult your customer for customer specific requirements related to LPA.
- Refer to the AIAG CQI-8 Layered Process Audit Guideline for additional details.

4.4 Control Plans in Highly Automated Processes

Definition/Key Concept(s):

- The purpose of a control plan is to minimize variation in a process. Highly automated processes (e.g., semiconductor fabrication) have the same goal of minimized variation, but "traditional" control plans are impractical in such an environment.
  - Manufacturing operations have very little human interaction. The manufacturing line has been fully automated including product delivery, processing tools, and process controls.
  - Processes typically have self-adjusting parameters using automated feed-forward and feed-back loops to keep the process on target. Numerous sensors and controls are constantly monitoring and measuring the process and charting the measurements.
    - Self-adjusting parameters have "hard limits" applied by engineering. If the parameters try to self-adjust beyond the established "hard limit", then the process goes offline for engineering to investigate.
    - Control systems (FDC – Fault Detection and Classification, SPC, etc.) monitor results and are connected back to a manufacturing execution system (MES). The controls will self-inhibit the process, automatically log tools down, and put the product on hold for disposition if the process controls are flagged.
- Controls are defined (sample size, frequency, gage tool, control limits, reaction plan) within the MES. These parameters are defined and housed within the automated system. Therefore, trying to keep a redundant paper control plan in sync with the automated "MES" system is not feasible.

Why is this important:

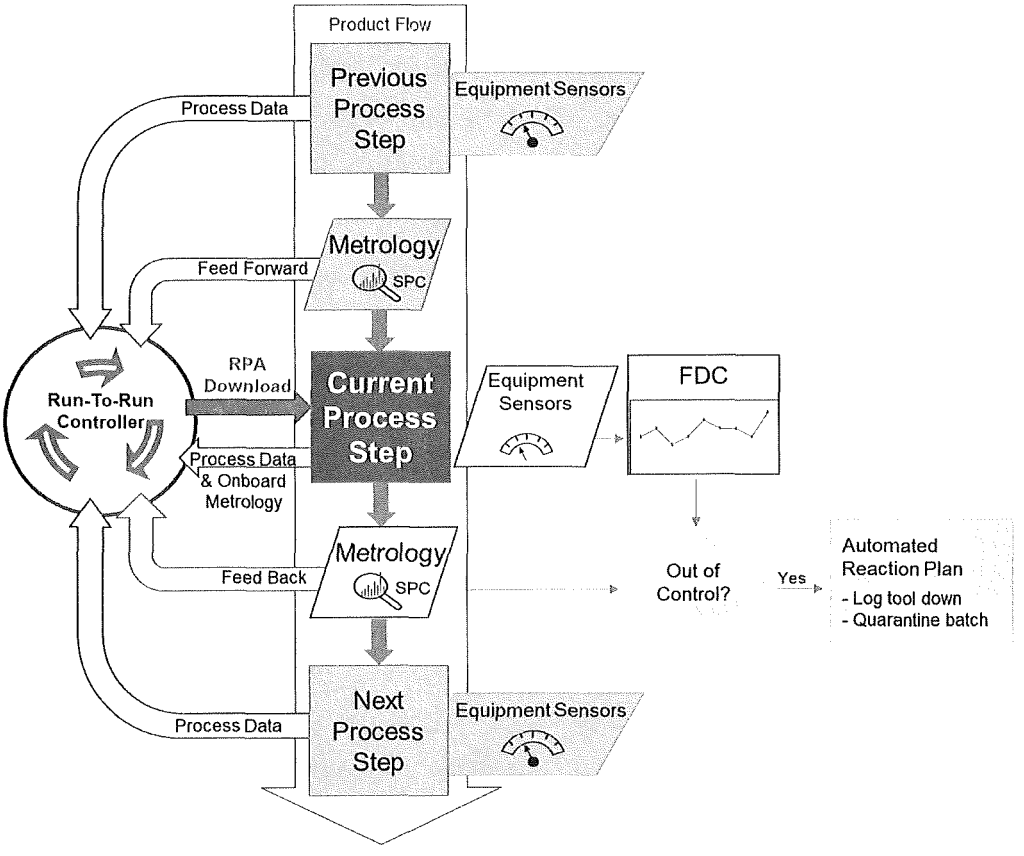
- Processes and control strategies are not static. The strategies are continuously being monitored and adjusted to reduce variation in the process. A paper control plan cannot accurately portray the details (optimum parameters) of such dynamic controls.
- Paper is a major source of contamination in a cleanroom environment, which is common for many highly automated processes. Paper control plans, even if feasible, could not be used during the process.
- You cannot "walk the process" to observe the line and its controls the way you can in most processes – you can only see the results of the controls. You can still achieve the goal of the traditional process walk by confirming the control plan is effectively implemented.

What to do and how to do it:

- Process walks to verify controls and reaction plans are still performed, but watching the product during processing as it flows from station to station is only part of the process walk. It is also critical to follow the automation by watching the electronic flow of data and the system flow and verifying the system interfaces and automated decision branches function as designed.

Example or illustration of good practice:

- Process control systems are built into the MES. These are identified in the pre-launch control plan and are validated prior to volume manufacturing.
- Engineering sets up the automation for each process step including measurement steps, process and measurements tools in place, gage capability and capacity, recipes set up, charts created with limits set, initial sampling levels defined, feed-forward and feed-back loops set up, etc.
- Process engineers periodically monitor the correct functioning of the control plan (the MES) by observing material flow, data flow and product disposition actions, as shown in the flow diagram below.



Semiconductor Automation – Advanced Process Control (APC)

Key Points to Remember:

- Semiconductor processes are highly equipment centric (equipment must be tightly controlled to limit variation).
  - The equipment sensors are, by extension, monitoring the process.
  - One manufacturing tool may include hundreds of sensors monitoring all the inputs and outputs.
- Metrology includes product dimension measurements, thickness measurements, defectivity measurements, etc.
- Run-to-Run (R2R) controllers are best in situations when the process is linear or there is a known process/equipment drift. R2R is not meant to control unexpected disturbance (variation) such as excursions, etc.

Acronyms:

- MES – Manufacturing Execution System.
- APC – Advanced Process Control.
- R2R – Run to Run.
- RPA – Recipe Parameter Adjustment.
- BiRD – Binary Recipe Download.
- FDC – Fault Detection Classification.
- SPC – Statistical Process Control.
- OOC – Out of Control.
- NPI – New Product Introduction.
- HVM – High Volume Manufacturing.

4.5 Using Family and Foundation FMEAs

Definition/Key Concept(s):

- Foundation FMEAs (also known as generic, baseline, template, core, master, or best practice FMEAs) are FMEAs that contain knowledge of the organization from prior developments which make them useful as a starting point for new FMEAs. The foundation FMEA is not program-specific, therefore the generalization of the requirements, functions, and measures is allowed.
- Family FMEAs are specialized foundation FMEAs. It is common to develop products that generally contain common or consistent product boundaries and related functions (a product family) or processes that contain a series of operations that produce multiple products or part numbers. In these cases, it is appropriate to develop family FMEAs which cover the commonalities for these families.

Why is this important:

- Foundation FMEAs provide a comprehensive starting point for control plan development, incorporating lessons learned while reducing effort and expenditure.
- Family/Foundation FMEAs are vital to development and use of "family control plans."

What to do and how to do it:

- Identify and verify which, if any, existing family/foundation FMEAs can be used as a baseline for the new part/project control plan.
- When using the family or foundation FMEA approach for the new product or process under development, the team should identify and focus the analysis on the difference between the existing (baseline) and the new product, process, or application.
- After adding a new product in the "family", the new project-specific process elements would be added to the family control plan and PFMEA. It is recommended to wait for customer approval (e.g., PPAP approval) before this step.
- It is recommended that lessons learned and best practices be incorporated into foundation or family DFMEAs and PFMEAs as applicable. The use of databases or software that facilitate documentation of lessons learned and their application across related control plans and other quality documents including work instructions, will make this step easier.
- Reference the AIAG & VDA FMEA Handbook for information.

4.6 Control of Storage and Handling Related Risk

Definition/Key Concept(s):

- Storage and handling related risks include failure modes such as:
  - Damage due to improper handling or logistics, or use of packaging or conveyance methods that do not offer robust protection.
  - Contamination or damage due to inadequate cleanliness or environmental controls, or cross contamination from storage or handling process/methods/materials.
  - Changes to properties or performance due to inadequate shelf-life controls.
- Process elements related to received materials/components, in-process product and finished product storage and handling are sometimes not included in process flow charts, as these tend to focus on "value-added" processing steps (actual part manufacturing process).

Why is this important:

- Failure to include perceived "non-value-added" processes to risk management (DFMEA→PFMEA→Control Plan→Work Instruction) leaves potential "special cause" variation uncontrolled.
- Increasing use of electronics and "new technology" associated with autonomous, connected, and electrified vehicles leads to increased risk due to sensitivity of parts and processes to failure modes related to storage and handling, such as:
  - Temperature and humidity sensitive materials and components.
  - Electrostatic discharge.
  - Contamination.
  - Damage to connectors or other sensitive components.
- Continued occurrence of problems related to handling/logistics damage, inadequate shelf-life control, and storage environment.

What to do and how to do it:

- Ensure all storage and handling related risks are considered in the early stages of risk management planning, engaging cross-functional teams that include logistics related operations and technical experts familiar with sensitivities of materials, components, and finished product.

- Once sensitivities are identified, include related failure mode planning in DFMEA and PFMEA, and document impacted processes on the process flow chart. This ensures the risks will be addressed through the normal process to develop robust control plans and work instructions.
- Implement audits to confirm effective maintenance and management of systems that prevent failure modes related to storage and handling. Incorporate Layered Process Audits and Finished Product Audits that include elements like:
  - Shelf-life management and FIFO.
  - Adherence to operator practices that are key to risk mitigation (e.g., use of clean suits and proper hygiene, use of ESD grounding devices).
  - Periodic confirmation of racks, conveyors and work in-process storage containers for aging or damage.
  - Periodic audits of product to confirm no damage or exposure to environmental conditions downstream of manufacturing process.

4.7 Abnormality Management in Relation to Control Plans

Definition/Key Concept(s):

- Control plans assume supporting operations, resources, and conditions are in a "normal" state; however, several factors can result in abnormal conditions the control plan is not set up to mitigate.
- Such abnormal conditions may include:
  - Absenteeism – assuring properly trained operator/inspector when controls/inspections and reaction plans rely on responsible person's skill.
  - Line stop and restart mid-process – assuring completion of process with no skipped or duplicated steps.
  - Equipment breakdown – assuring equipment functionality is fully restored prior to resumption of process control via control plan; or deciding alternate processing is required.
  - Process shutdown and restart after plant shutdowns due to pandemic, part shortage, maintenance/retooling, etc. – assuring all support operations, infrastructure and facilities are fully restored to "normal".

Why is this important:

- "Abnormality Management" relies on shop floor management systems and practices, which are outside the scope of control plan development.
- Equal attention and a similar risk-based approach is required to develop shop floor management systems/practices that ensure the "normal state" is in place or alternate/additional controls are in place prior to start or resumption of the process and the normal control plan.

What to do and how to do it:

- Is the control plan content sufficient to mitigate risk from the abnormality, or do you need to implement supplemental controls to mitigate until "back to normal"?
- Use the control plan to evaluate impact/risk of abnormalities, and plan appropriate mitigation:
  - Could the abnormality negatively impact special characteristic controls?
  - Do control item frequencies still make sense given the impact of the abnormality?
- Ensure all related aspects (contamination, return of effectiveness of equipment, etc.) are brought back to "normal" condition before you revert to the production control plan.

Appendix A
Control Plan Examples

Introduction

To provide an illustration of the application of the methodologies, requirements, and guidelines explained in this manual, the following examples are provided for reference. They are not intended to specify specific controls or other content to the processes described, just provide points for consideration when developing control plans.

A-1 General Example

This example illustrates the application of some requirements detailed in the manual as applied to any type of part or process.

CONTROL PLAN

☐ Prototype ☐ Pre-Launch ☐ Production ☐ Safe Launch

Page 2 of 4

Control Plan Number	Key Contact/Phone	Date (Orig.)	Date (Rev.)
CP-215128	John Doe / 555-543-7809	7/11/2021	5/26/2023 (Rev. 3)
Part Number/Latest Change Level		(1) Customer Engineering Approval/Date (If Req'd.)	
12345678AC		N/A	
Part Name/Description	Supplier/Plant Approval/Date	Customer Quality Approval/Date (If Req'd.)	
Stabilizer Bar, Rear	2/14/2021	2/15/2021	
Supplier/Plant	Supplier Code	Other Approval/Date (If Req'd.)	Other Approval/Date (If Req'd.)
Stab Bar Inc.	82842 MK	N/A	N/A

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE, JIG,TOOLS FOR MFG.	CHARACTERISTICS NO.	CHARACTERISTICS PRODUCT	CHARACTERISTICS PROCESS	SPECIAL CHAR. CLASS	METHODS PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	METHODS EVALUATION/ MEASUREMENT TECHNIQUE	METHODS SAMPLE SIZE	METHODS SAMPLE FREQ.	METHODS CONTROL METHOD	REACTION PLAN (8) ACTION	REACTION PLAN (9) OWNER/ RESPONSIBLE
10	Gauging	Check Fixture		Part Shape / Dimensions			Correct Contour / Eye Locations Per Part Drawing	Contour Gauge	1 Piece	100%	Work Instruction: QI-PRD-01	Follow Instructions In QI-PRD-11	Gauging Associate
								Verify Gauge with Master Part (2)	1 Piece	Prior to first piece	Work Instruction: QI-PRD-01 Check Sheet: PRD-030	Follow Instructions In QI-PRD-03	Gauging Associate
-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	(3) Fitting (Rework)	Fitting Press		Part Shape / Dimensions			Correct Contour / Eye Locations Per Part Drawing	Contour Gauge	1 Piece	100% (Each Reworked Part)	Work Instruction: QI-PRD-01	Follow Instructions In QI-PRD-11	Gauging Associate
				Appearance			No Detrimental Marks	Visual Inspection	1 Piece	100%	Work Instruction: QI-PRD-01	Follow Instructions In QI-PRD-11	Gauging Associate
				Eye Hole Diameter			16.0 +/-.25mm	Contour Gauge / Plug Gauge	1 Piece	100%	Work Instruction: QI-PRD-01	Follow Instructions In QI-PRD-11	Gauging Associate
-	-	-	-	-	-	-	-	-	-	-	-	-	-
60	Rework - Shot Peen (3)	Shot Peen		Part Without Paint			Bar with All Paint Removed	Visual	Every Bar	100%	Work Instruction: QI-STP-01	Run Bar(s) Through Shot Peen Process Until All Paint Has Been Removed	Operations Manager
-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	Caliper Assembly	Assembly Dial		Bracket and Housing Assembly			Correct Caliper Housing	In-line Vision System	1 Piece	100%	Work Instruction: QI-AH-02	Follow Instructions In KAO-CC6	Assembly Associate
					Error-Proofing Confirmation	(4)	Proper Function of Vision System	Red Rabbit	1 Piece	Start of Each Shift / Changeover / Tooling Change	Work Instruction: QI-RR-01 Check Sheet: Form RR-001	Follow Instructions In KAO-RR9	Assembly Associate
-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	Brake Rotor Machining	CNC		Brake Plate Surface Finish			.4 - 1.8 Ra	Profilometer	1 Piece (5)	Every 30 Parts	Work Instruction: WI-CNC-01 Check Sheet: CS-012	Follow Instructions in RP-9	Quality Assurance Manager
6 (SLP) (6)	Brake Rotor Machining	CNC		Brake Plate Surface Finish			.4 - 1.8 Ra	Profilometer	1 Piece	100%	Work Instruction: WI-CNC-01 Check Sheet: CS-012	Follow Instructions in RP-9	Quality Assurance Manager
-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	Eye Hole Punch	Press 15		Hole Diameter			36.0 +/-.05mm	Bore Gauge	1 piece	Every 10 Parts	Work Instruction: OI-23, SPC: X&R Chart CAP-3 (7)	Follow Instructions in RP-6	Quality Assurance Manager
-	-	-	-	-	-	-	-	-	-	-	-	-	-

Control Methods and Requirements illustrated:

1. "N/A" to be documented in non-applicable top fields rather than leaving the fields blank.
2. Master part qualifications.
3. Rework (how it appears/fits in CP and customer approval). Repair requires its own CP.
4. Error-proofing/red rabbit confirmation.
5. Sample size/frequency: utilize lot inspection (quantity) rather than time based.
6. Stand-alone example and an example of safe launch plan included in CP (Chapter 2).
7. SPC is an acceptable control method.
8. "Follow instructions...xxx" is recommended rather than simply listing a number or referencing a document.
9. "Owner Responsible" is who initiates the reaction plan.

A-2 Process Dependent Examples

Different types of processes provide challenges and opportunities for control and reduction of variation. The process types can be related to their most common sources of variation from aspects of process dependencies.

The table below provides descriptions of different process dependencies. A given part may include one or more of these dependencies, so the table gives points to consider for each type when developing the control plan.

A-2 Process Dependency Table

	Points to Consider When the Process is Dependent Upon:	
	A. Set-Up	B. Machine
Description of the example Process dependency, including:	Automotive grills are produced on plastic injection molding machines.	A supplier manufactures a circuit board with electronic components soldered on the board, and wire bonded connections to a chip.
Part Characteristic(s), including special and/or "critical characteristics"	After set-up of the mold, the machine must be adjusted to produce a dimensionally-correct part. Parts must also be free of blemishes, flow lines and sink marks on the surface.	The special product characteristic is electrical continuity of the soldered joints.
Process Characteristic(s), including special and/or "critical characteristics"	A set-up card provides specifications for setting all controls on the machine. After setting the machine to the specifications a sample part is produced. This part is checked for the key control dimensions for mounting holes and perimeter fit, and visually inspected.	Two major process characteristics for the wave solder machine, are solder level and flux concentration. An automated feeder controls the solder level by sensing the level of solder and feeding in additional solder as the level is reduced. The flux must be sampled and tested for the concentration level. An automated Wire Bonding machine feeds the wire, bonds the wire to heated connections, and checks the bond strength.
Rationale for the Process and Part Controls described below, such as: • Capability of Process based on studies • Inspection Frequency • Use error-proofing devices or methods • Factors influencing variation or defect production	Capability studies on the product characteristics show that when properly set-up, the operation is highly capable and stable.	The Special Product Characteristic is measured 100% by checking electrically for continuity, which is built in to the automated control of the process (Manufacturing Execution System).
Typical Process Characteristic for this type process.	The set-up is the critical variable in this type process.	Machine settings are the variables that have the major effect on the output for this type process.
Comments giving rationale supporting the control methods.	The set-up specifications become the process characteristics that affect the product characteristic.	In highly automated systems, the controls and measures may be automated, such as in a Manufacturing System that specifies, monitors and controls hundreds or thousands of variables with no human interaction.
Types of Process Characteristics controls for this type process:	Types of controls for the process characteristic include "first piece check" procedures, and verifications that machine settings are correct to authorized set up cards.	Types of controls include self-adjusting devices on the parameters and statistical measurements taken on the process parameters and recorded on control charts and automatically managed via the automated control (Manufacturing Execution System). Reaction Plans may also be automated into the MES, such as the link to Out of Control Action Plan (OCAP) in this example.
Product Characteristics control methods, including if lot control is appropriate/required.	Product characteristics are measured to ensure the set-up is correct and that no unusual special cause has occurred. In some cases, lot control may be appropriate between checks.	Product characteristics are measured using error proofing methods or statistical sampling to ensure that all products meet the customer's requirements. In this example, 100% sampling of the part critical characteristic is built-in to the MES.

A-2 Process Dependency Table (continued)

	Points to Consider When the Process is Dependent Upon:		
	C. Fixture/Pallet	D1. Tooling	D2. Tooling
Description of the example Process dependency, including:	Metal castings are loaded on a seven-stage rotary machine with several fixtures which rotary machine rotates under a cutting head.	A sheet metal stamping die is used to form a steel bracket that has several angles and a pierced hole.	A broach is used to form the internal spline teeth on a steel prop shaft yoke.
Part Characteristic(s), including special and/or "critical characteristics"	Each part has a machined surface on which perpendicularity and depth of cut are critical.	The pierced hole diameter will not vary significantly, therefore it is not marked as a Special Characteristic. The presence of the hole is critical to the part. The angles on the part are critical and two angles are marked as Special Characteristics.	The pitch diameter of internal spline is the Special Product Characteristic.
Process Characteristic(s), including special and/or "critical characteristics"	Location of part in fixture/pallet, location of fixture/pallet in machine or cell.	Condition of tooling, placement and movement of tool parts.	Pitch diameter and relief angle (sharpness) of the broach tool.
Rationale for the Process and Part Controls described below, such as: • Capability of Process based on studies • Inspection Frequency • Use error-proofing devices or methods • Factors influencing variation or defect production	Besides the cutting tool, the removal of debris and proper placement of the fixtures/pallet can significantly affect the special product characteristic.	Historically, broken hole punches are a problem with this type tooling. Further, moving parts in the tool can vary when forming the angles in the bracket.	Studies have correlated spline pitch diameter and sharpness of tool to pitch diameter.
Typical Process Characteristic for this type process.	Part location on fixture/pallet and proper placement of the fixture or pallet into a machine or cell.	The process characteristic is the condition of tooling and the location/movement of moving parts.	The process characteristic is the condition of the tooling.
Comments giving rationale supporting the control methods.	The dimensional differences between fixtures or pallets and part location contribute to product variation. In addition, debris accumulated on the fixture can cause fixture-to-fixture variation of part location.	Tools can have details that break or moving parts that intermittently/permanently fail to move. Tools can also wear or be repaired incorrectly. The product characteristics are affected by these tooling problems.	Tools can have details that break or moving parts that intermittently/permanently fail to move. Tools can also wear or be repaired incorrectly. The product characteristics are affected by these tooling problems.
Types of Process Characteristics controls for this type process:	Types of controls for fixture/pallet process characteristics are driven by loading procedures, fixture/pallet placement sensors, and fixture/pallet adjustments and maintenance (i.e., cleaning).	Types of controls for tooling dominant processes are mainly seen in the product. First piece check can verify that the tool has been properly repaired.	The sharpened tool is checked on a visual comparator for correct pitch diameter and relief angle prior to being approved for production. First piece check can verify that the tool has been properly repaired.
Product Characteristics control methods, including if lot control is appropriate/required.	Product characteristics are often difficult to measure in fixture/pallet dominant processes. Therefore, frequent statistical product sampling may be required for Special Product Characteristics.	Product characteristics trends are a very important measure of proper tool life performance. Sampling frequency should reflect expected tool wear. When in operation a tool failure may go unnoticed except in the part, therefore lot control is appropriate and error proofing for Special Characteristics should be used.	First piece of a production run is checked for sharpness of cut and correct pitch diameter. Product characteristics trend are a very important measure of proper tool life performance. Sampling frequency should reflect expected tool wear. When in operation a tool failure may go unnoticed except in the part, therefore lot control is appropriate.

A-2 Process Dependency Table (continued)

	Points to Consider When the Process is Dependent Upon:	
	E. Operator	F. Material or Component
Description of the example Process dependency, including:	Headlamp aim is one of the final operations during car and truck assembly. An aiming device, which contains two bubble levels, attaches to the headlamp. The operator adjusts the headlamps by turning aiming screws until the bubbles center in the level.	An automobile hood is made of SMC. SMC is a molding compound that is temperature sensitive, has a specific shelf life, and for which mixing is critical. The parts produced from this material can become brittle when the material is improperly mixed, handled, or rotated.
Part Characteristic(s), including special and/or "critical characteristics"	Proper headlamp aim is an FMVSS requirement and therefore a Special Product Characteristic.	A force specification on one end of the bracket is a Special Product Characteristic.
Process Characteristic(s), including special and/or "critical characteristics"	Operator knowledge and control, ensuring the two bubble levels center during aiming.	The Special Process Characteristics are the proper formulation, storage, and use of material date control (shelf-life).
Rationale for the Process and Part Controls described below, such as: • Capability of Process based on studies • Inspection Frequency • Use error-proofing devices or methods • Factors influencing variation or defect production	Skill, knack or knowledge of the operator may directly influence variation of part characteristics and the ability to correctly judge "good or no good" process or part characteristics.	The organization requires a laboratory report from the material supplier on each lot of compound. Lots of material are dated for proper rotation (inventory FIFO).
Typical Process Characteristic for this type process.	Operator control/adjustment of tools, materials, conditions to achieve desired process characteristic.	The materials or components are the process characteristics for this process.
Comments giving rationale supporting the control methods.		The variation found in the materials or components will affect the output of the process.
Types of Process Characteristics controls for this type process:		Types of controls for the process characteristics include the various ways of testing and controlling the specification on the material or component being used (i.e., control charts, lab reports and error proofing). Shelf life confirmation checks (operator checks, date code scanning etc.).
Product Characteristics control methods, including if lot control is appropriate/required.	Operator judgment of product characteristic (100% inspection). Periodic audits of operator judgment (precision measuring, expert auditors, etc.) to confirm consistency of correct judgment, with lot control based on frequency of the audit.	Periodic testing of the product characteristic based on material or component lot/container changes. If product testing is infrequent (such as in destructive testing or testing which takes a long time), lot control of the product is advisable. Lot release is tied to acceptable result of test.

A-2 Process Dependency Table (continued)

	Points to Consider When the Process is Dependent Upon:	
	G. Preventive Maintenance	H. Climate
Description of the example Process dependency, including:	A painting operation for decorative parts requires clean equipment and a dirt-free work area.	Semiconductor chip production is carried out in "clean room" and ESD-controlled setting.
Part Characteristic(s), including special and/or "critical characteristics"	Dirt-free paint is a Special Product Characteristic.	Chip function is the part characteristic, as measured by functional, electrical and mechanical testing of samples.
Process Characteristic(s), including special and/or "critical characteristics"	The process characteristic is a scheduled routine cleaning, repair and replacement.	Temperature and humidity need to be controlled to prevent electrostatic discharge; humidity impacts adhesion of coating processes used to create circuits, encapsulate components in protective coatings, etc. Debris in air can result in short term and/or long term functional failure due to contamination.
Rationale for the Process and Part Controls described below, such as: • Capability of Process based on studies • Inspection Frequency • Use error-proofing devices or methods • Factors influencing variation or defect production	Periodic cleaning of the paint equipment and paint room prevents the problem of dirt in the paint.	Temperature, humidity and air cleanliness can negatively impact product characteristics of electronic components, such as semiconductors, PCBs, sensors and more complex electronic assemblies using such components.
Typical Process Characteristic for this type process.	Periodic maintenance is the process characteristic.	The proper functioning of the "clean room" climate controls are the process characteristics to be controlled, and resulting conditions confirmed.
Comments giving rationale supporting the control methods.	Where input variables exist, replacing worn out parts, cleaning, calibration, tool adjustments, and other maintenance activities have an effect on the product characteristics, and must be controlled.	
Types of Process Characteristics controls for this type process:	Product characteristics are checked after each maintenance to verify the process is properly performed.	Type of control for this process characteristic is continuously or periodically monitored temperature and humidity, and periodic checks with an air particle counter.
Product Characteristics control methods, including if lot control is appropriate/required.	Periodic testing of related product characteristic (dirt in paint, etc.) between Preventive Maintenance events.	Product characteristics are checked by visual examination during first piece check and by subsequent periodic checks, or may have automated inspection checks built into an automated control system (Manufacturing Execution System). Reaction Plan related to automated controls may be automated into the MES, such as the link to Out of Control Action Plan (OCAP) in this example.

APPENDIX B
FORMS AND CHECKLISTS

Introduction

The form, checklist, and worksheet demonstrated in this document are provided as a guide to assist the organization in developing and verifying the control plan to ensure completeness and accuracy. They are not intended to fully define or represent all the elements of the control plan process.

B-1 Control Plan Form

As explained in Section 1.1, the control plan format provided is not mandatory but does illustrate the minimum required content and a recommended layout.

Consult your customer for any requirements they may have related to the control plan format.

B-2 Control Plan Checklist

Use of the Control Plan Checklist should be one of the activities to confirm the full application of the control plan process. The checklist is designed to allow users to "check-the-box" when completing. In reviewing the questions in the checklist, where "No" is identified as the appropriate response, the column "Comment/Action Required" is used to identify the action required to close the gap, including the impact on the APQP process. The follow-up action should include the identification of an individual responsible and schedule. Use the "Person Responsible" and "Due Date" columns. All follow-up actions should always be completed as quickly as possible. Where change management is affected, this needs to be noted.

B-3 Special Characteristic Worksheet

The Description/Rationale column includes all special process and product characteristics agreed upon by the cross-functional team. A sequential number (No.) is assigned to each characteristics listed to ensure none are overlooked by the organization when the control plan is completed. Develop a rationale for each special characteristic and add this information to the list for clarification.

CONTROL PLAN

☐ Prototype ☐ Pre-Launch ☐ Production ☐ Safe Launch

(If Safe Launch is included in Pre-Launch or Production Control Plan, check both boxes)

Control Plan Number		Key Contact/Phone	Date (Orig.)	Date (Rev.)
Part Number/Latest Change Level			Customer Engineering Approval/Date (If Req'd.)	
Part Name/Description		Supplier/Plant Approval/Date	Customer Quality Approval/Date (If Req'd.)	
Supplier/Plant	Supplier Code	Other Approval/Date (If Req'd.)	Other Approval/Date (If Req'd.)	

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE, JIG,TOOLS FOR MFG.	CHARACTERISTICS			SPECIAL CHAR. CLASS	METHODS					REACTION PLAN	
			NO.	PRODUCT	PROCESS		PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	EVALUATION/ MEASUREMENT TECHNIQUE	SAMPLE SIZE	SAMPLE FREQ.	CONTROL METHOD	ACTION	OWNER/ RESPONSIBLE

CONTROL PLAN CHECKLIST

Applicable Control Plan Stage: Prototype ☐
Pre-Launch ☐
Safe Launch ☐ (If Safe Launch is included in Pre-Launch or Production Control Plan, check both)
Production ☐

Customer or Internal Part No _____ Revision Level _____

	Question	Yes	No	N/A	Comment / Action Required	Person Responsible	Due Date
1	Was the control plan developed according to the methodology described in the AIAG Control Plan Manual?						
2	Were DFMEA, PFMEA and Process Flow Chart used to prepare the control plan?						
3	Have all the controls identified in the PFMEA been included in the control plan?						
4	Are all DMFEA items with severity rank of 9-10 that flow to PFMEA for control designated as special characteristics?						
5	Are all special product/process characteristics included in the control plan?						
6	Are material specifications requiring inspection identified?						
7	Does the control plan address incoming (material/components) through processing/assembly including packaging?						
8	Are all pass-through characteristics with last point of control at the organization that may impact the customer on this control plan?						
9	Are all interdependent processes included on this control plan, or linked to this control plan?						
10	If there are repair or rework processes, are they included on this control plan or on a separate control plan linked to this control plan?						
11	Have repair and rework processes been approved by customer?						
12	Are engineering performance testing and dimensional requirements identified?						
13	Are all error-proofing devices listed on the control plan, with method and frequency to confirm effectiveness or proper functioning?						
14	Does the frequency to confirm effectiveness or proper functioning of error-proofing devices enable effective containment of product produced since the last good verification check?						
15	Are sample sizes based upon industry standards, statistical sampling plan tables, or other statistical process control methods or techniques?						
16	If sampling frequency is not 100%, is the frequency based upon volume produced to support effective containment?						
17	Are gages and test equipment available as required by the control plan?						
18	Are the gage methodology and compatibility appropriate to meet customer requirements?						
19	Have measurement systems analysis been completed in accordance with customer requirements?						
20	If required, has the customer approved the control plan?						
21	Have lessons learned and "Read Across" actions been implemented?						

Revision Date _____

Prepared By: _____

CONTROL PLAN SPECIAL CHARACTERISTICS

☐ Prototype ☐ Pre-Launch ☐ Production ☐ Safe Launch

Control Plan Number		Key Contact/Phone	Date (Orig.)	Date (Rev.)
Part Number/Latest Change Level		Core Team	Customer Engineering Approval/Date (If Req'd.)	
Part Name/Description		Supplier/Plant Approval/Date	Customer Quality Approval/Date (If Req'd.)	
Supplier/Plant	Supplier Code	Other Approval/Date (If Req'd.)	Other Approval/Date (If Req'd.)	

No.	Description/Rationale	Specification/Tolerance	Class	Process/Product	Illustration/Pictorial

APPENDIX C
REFERENCE MATERIAL

The following publications can be obtained from AIAG at www.aiag.org.

AIAG & VDA Failure Mode and Effects Analysis (FMEA) Handbook

This reference manual can be used as a guide to assist in the development of Design FMEA, Process FMEA, and Supplemental FMEA for Monitoring and System Response.

Advanced Product Quality Planning (APQP) Reference Manual

This reference manual describes general guidelines for ensuring that Advanced Product Quality Planning is implemented in accordance with the requirements of the customer.

Measurement Systems Analysis (MSA) Reference Manual

This reference manual describes common methods of evaluating measurement system variation and gives general guidance in the application of techniques.

Production Part Approval Process (PPAP)

This requirements document covers generic requirements for production part approval for all production and service commodities.

Statistical Process Control (SPC) Reference Manual

This reference manual provides a unified reference for statistical process control and gives general guidance in the application of techniques.

CQI-8 Layered Process Audit Guideline

This guideline integrates LPA with management of Key Performance Indicators (KPIs) and includes recommendations for expanding ownership beyond the Quality function, for writing effective LPA check sheet questions, and explains the audit process in more detail.

CQI-19 Sub-Tier Supplier Management Process Guideline

This guideline defines the minimum quality-related requirements for Sub-Tier suppliers and provides explicit guidance on effective identification and control of Pass-Through Characteristics (PTC).

APPENDIX D
SECTOR SPECIFIC GUIDANCE

Introduction

Experience has shown that variation in the interpretation of APQP, Control Plans (CP), and PPAP in non-traditional parts manufacturing sectors causes significant waste throughout the supply chain. Suppliers get different interpretations of what is expected from customers, supplier quality engineers, auditors, and internally between departments.

Goal

Improve the applicability of APQP/CP/PPAP by clarifying requirements for specific sectors or commodities with significant differences in design and manufacturing operations. Provide a means for developing, documenting, and distributing clarifications. Clarifications may include changes in terminology, alternate requirements, or change in applicability.

Rules for successful sector requirements:

- Sector clearly defined.
- Broadly applicable across the sector and possibly beyond that.
- Sector consensus on agreement to use the revised definitions.
- OEM agreement.

Method

Sector proposes clarifications indexed to the APQP/CP/PPAP requirements through the following process: All referenced forms are available at https://www.aiag.org/quality/automotive-core-tools/apqp

1. The sector identifies and justifies the need for clarification (typically initiated by a few motivated representatives).
2. The sector, to proceed with development of the guidance table, completes and submits a petition to AIAG using the on-line petition form.
3. AIAG reviews the petition and works with the author to prepare it for submission.
4. When all requirements are met, AIAG manages the review and approval process with the appropriate oversite team for the approval to start.
5. AIAG, or the appropriate sector association, conducts a call to action for volunteers and forms a team to draft the guidance table.
6. The sector team reaches consensus on the significant clauses in the APQP/CP/PPAP and develops the guidance table.
7. The sector team submits the draft guidance table to AIAG for review with the appropriate oversite team for disposition.
8. If rejected, AIAG provides feedback to the sector team.
9. If approved, return to sector team for stakeholder review and reconciliation of comments.
10. After final approval, AIAG announces and posts the guidance table as a free download.
11. Ongoing edits and periodic reviews are managed by AIAG.

APPENDIX E
GLOSSARY

Glossary

Core Team: Individuals within the organization responsible for preparing the control plan to the latest revision.

Customer: The entity that is receiving the output of the organization.

Design Failure Mode and Effects Analysis (DFMEA): An analytical technique used by a design responsible organization as a means to ensure, to the extent possible, that potential failure modes and their associated causes/mechanisms have been considered and addressed. See the current edition of FMEA.

Design for Manufacturability and Assembly: A simultaneous engineering process designed to optimize the relationship between design function, manufacturability, and ease of assembly.

Design Reviews: Milestone checkpoints to review progress of the design process, a proactive process.

Durability: The probability that an item will continue to function at customer expectation levels, at the useful life without requiring overhaul or rebuild due to wear-out.

Dynamic Control Plans: A single document combining elements of PFMEA with those of the control plan to facilitate linkage between the two.

Error-proofing: Describes designs, devices and/or methodologies to prevent defective parts from being produced, or to detect defective parts and ensure they are contained with the process or prevented from shipping to customers. See the AIAG APQP manual for additional detail.

Failure Modes Effects Analysis (FMEA): See current edition of FMEA.

Leadership (Upper): In the context of control plan, leadership has responsibility for sponsoring and assuring the completion of all aspects of the control plan process. This is accomplished by ensuring adequate resources, setting priorities, and challenging the team to meet all timing and KPI goals.

Management (Project): In the context of control plan, management applies to decision makers and process owners who are accountable for the successful completion of the control plan. Success is achieved through the manager's knowledge, commitment, engagement, and attention to detail.

Mistake-proofing: A subset of error-proofing that tends to focus on detecting the presence of a defect, and either stopping further production or assuring all defective and suspect parts are contained. See the AIAG APQP manual for additional detail.

Organization: Control plan process owner.

Packaging: A unit that provides protection and containment of items plus ease of handling by manual or mechanical means.

Pass-through Characteristics: Characteristics manufactured within the supplier process and used in the organization's process without modification or further validation.

Process Failure Mode and Effects Analysis (PFMEA): An analytical technique used by a manufacturing responsible engineer/team as a means to ensure that, to the extent possible, potential failure modes and their associated causes/mechanisms have been considered and addressed. See the current edition of FMEA.

Reaction Plan Strategy: An organization's approach to reaction plans based on sampling frequency, amount or pattern of defects detected, SPC rules, etc.

Significant Production Run: Product made using all production tools, processes, equipment, environment, facility, and cycle time.

Special Characteristics: Product and process characteristics designated by the customer, including governmental regulatory and safety, and/or selected by the organization through knowledge of the product and process. Subsets of special characteristics may be identified and classified using terms such as critical or key, as defined by organizations.

Subsystem: A major part of a system which itself has the characteristics of a system, usually consisting of several components, or processes.

Supplier: The entity that supplies a product or service to the organization.

System: A combination of several components, processes or pieces of equipment integrated to perform a specific function.

Voice of the Customer: Customer feedback both positive and negative, including likes, dislikes, problems, and suggestions.

Appendix E

Glossary

APPENDIX F
INDEX

Appendix F

Index