



AEROSPACE STANDARD

AS13100™**REV. A**Issued 2021-03
Revised 2025-04

Superseding AS13100

(R) AESQ Quality Management System Requirements
for Aero Engine Design and Production Organizations

RATIONALE

This standard has been revised to update requirements, document structure, and clear up ambiguity. Additional changes to the definitions, tables, and associated notes were incorporated in response to stakeholder inputs.

FOREWORD

To assure customer satisfaction, the aviation, space, and defense industry organizations have to produce and continually improve safe, reliable products that equal or exceed customer and regulatory authority requirements.

The globalization of the industry and the resulting diversity of regional/national requirements and expectations have complicated this objective. End-product organizations face the challenge of assuring the quality of and integration of product purchased from suppliers throughout the world and at all levels within the supply chain. Industry suppliers face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

The SAE G-22 Aerospace Engine Supplier Quality (AESQ) Technical Committee was established under the SAE Aerospace Council to develop, specify, maintain, and promote quality standards relating to the aerospace engine supply chain. The principles defined within this standard may be applicable to other segments of the aviation, space, and defense industries.

The AESQ strategy is to promote defect prevention approaches across the supply chain including those associated with advanced product quality planning and process control to enable the supply chain to achieve zero defects.

INTRODUCTION

For an overview of the linkage between AS13100 and other industry standards, [Figure A1](#) shows the relationship between the current quality management system (QMS) standards and AS13100. It can be noted that 9100 follows the structure of ISO 9001 and adds its own industry specific supplemental requirements.

AS13100 now does the same by building on the elements of 9100 and 9145 to add the aero engine manufacturers' specific requirements that are not covered in the other standards.

To help demonstrate the alignment with these standards the AS13100 supplemental requirements follow the same numbering sequence (clause numbers; see [Figure 1](#)) as 9100 in [AS13100 - Chapter A](#) and 9145 in [AS13100 - Chapter B](#).

When there is a supplemental requirement to 9100 or 9145 in this document, the 9100 or 9145 clause number and title is listed.

SAE Executive Standards Committee Rules provide that: "This report is published by SAE to advance the state of technical and engineering sciences. The use of this report is entirely voluntary, and its applicability and suitability for any particular use, including any patent infringement arising therefrom, is the sole responsibility of the user."

SAE reviews each technical report at least every five years at which time it may be revised, reaffirmed, stabilized, or cancelled. SAE invites your written comments and suggestions.

Copyright © 2025 SAE International

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, or used for text and data mining, AI training, or similar technologies, without the prior written permission of SAE.

TO PLACE A DOCUMENT ORDER: Tel: 877-606-7323 (inside USA and Canada)
Tel: +1 724-776-4970 (outside USA)
Fax: 724-776-0790
Email: CustomerService@sae.org
SAE WEB ADDRESS: <http://www.sae.org>

For more information on this standard, visit
<https://www.sae.org/standards/content/AS13100A/>

Management Standards		Clause Numbers									
ISO9001	Any Industry Quality Management Standard	1	2	3	4	5	6	7	8	9	10

9100	Aviation, Space and Defense Industry Quality Management Standard	1	2	3	4	5	6	7	8	9	10
		Defines supplementary requirements to ISO9001. ISO 9001 requirements are included within 9100 in full.									

9145	APQP / PPAP Standard for Aviation, Space and Defense Industry	Clause Numbers						
		0.1	0.2	1	2	3	4	5

AS13100	Aero Engine Quality Management System Standard	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
		Defines supplementary requirements to 9100 and/or ISO9001										Defines supplementary requirements to 9145						

Figure 1 - AS13100 standard relationship to other quality management system standards

TABLE OF CONTENTS

1.	SCOPE.....	6
2.	APPLICABLE DOCUMENTS.....	6
2.1	SAE Publications.....	6
2.2	AESQ Publications.....	7
2.3	ISO Publications.....	7
2.4	EASA Publications.....	7
2.5	VDA/EN Publications.....	7
3.	TERMS AND DEFINITIONS.....	8
3.1	Background.....	8
3.2	Terms and Definitions.....	8
AS13100 - Chapter A - 9100 Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations - AESQ Supplemental Requirements.....		9
4.	CONTEXT OF ORGANIZATION.....	9
4.1	Understanding the Organization and Its Context.....	9
4.2	Understanding the Needs and Expectations of Interested Parties.....	9
4.2.1	Understanding the Needs and Expectations of Interested Parties - Supplemental Requirements.....	9
4.3	Determining the Scope of the Quality Management System.....	9
4.4	Quality Management System and Its Processes.....	12
4.4.3	Quality Management System and Its Processes - Supplemental Requirements.....	12
5.	LEADERSHIP.....	13
5.1	Leadership and Commitment.....	13
5.1.1	General.....	13
5.2	Policy.....	13
5.2.1	Establishing the Quality Policy.....	13
5.3	Organizational Roles, Responsibilities, and Authorities.....	13
5.3.1	Organizational Roles, Responsibilities, and Authorities - Supplemental Requirements.....	13
6.	PLANNING.....	13
6.1	Actions to Address Risks and Opportunities.....	13
6.1.3	Actions to Address Risks and Opportunities - Supplemental Requirements.....	13
7.	SUPPORT.....	14
7.1	Resources.....	14
7.1.3	Infrastructure.....	14
7.1.5	Monitoring and Measuring Resources.....	14
7.2	Competence.....	18
7.2.1	Competence Achieved by On-the-Job Training - Supplemental Requirements.....	18
7.2.2	Auditor Competence - Supplemental Requirements.....	18
7.2.3	Delegated Product Release Verification (DPRV) Representative Training - Supplemental Requirements.....	21
7.2.4	AS13100 Requirements Training and AESQ Quality Foundations Training - Supplemental Requirements.....	22
7.3	Awareness.....	22
7.3.1	Human Factors Awareness - Supplemental Requirements.....	22
7.5	Documented Information.....	22
7.5.2	Creating and Updating.....	22
7.5.3	Control of Documented Information.....	23
8.	OPERATION.....	24
8.1	Operational Planning and Control.....	24
8.1.3	Product Safety.....	24
8.1.4	Prevention of Counterfeit Parts.....	24

8.2	Requirements for Products and Services	24
8.2.1	Customer Communication.....	24
8.2.2	Determining the Requirements for Products and Services.....	25
8.2.3	Review of the Requirements for Products and Services	25
8.3	Design and Development of Products and Services	25
8.3.1	General.....	25
8.3.2	Design and Development Planning.....	26
8.3.3	Design and Development Inputs	26
8.3.4	Design and Development Controls	27
8.3.5	Design and Development Outputs	28
8.3.6	Design and Development Changes	29
8.4	Control of Externally Provided Processes, Products, and Services	30
8.4.1	General.....	30
8.4.2	Type and Extent of Control	31
8.4.3	Information for External Providers	33
8.5	Production and Service Provision	33
8.5.1	Control of Production and Service Provision	33
8.5.2	Identification and Traceability	38
8.5.4	Preservation	39
8.5.6	Control of Changes	39
8.6	Release of Products and Services.....	39
8.6.1	Release of Products and Services - Supplemental Requirements.....	39
8.7	Control of Nonconforming Outputs	39
9.	PERFORMANCE EVALUATION	40
9.1	Monitoring, Measurement, Analysis, and Evaluation	40
9.1.1	General.....	40
9.1.2	Customer Satisfaction	42
9.2	Internal Audit	42
9.2.3	Internal Audit - Supplemental Requirements.....	42
9.2.4	Audit Nonconformance Related to Product Quality - Supplemental Requirements	43
9.3	Management Review	44
9.3.2	Management Review Inputs	44
9.3.3	Management Review Outputs.....	44
10.	IMPROVEMENT	44
10.2	Nonconformity and Corrective Action	44
10.2.3	Problem Solving Methods for Customer Escapes - Supplemental Requirement	44
10.2.4	Customer Complaints and In-Service Failures - Supplemental Requirements	45
10.3	Continual Improvement.....	45
10.3.1	Continual Improvement - Supplemental Requirements.....	45
AS13100 - Chapter B - 9145 - Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP) - AESQ Supplemental Requirements		46
13.	(1. - 9145) SCOPE	46
13.3	Scope (APQP) - Supplemental Requirements.....	46
16.	(4. - 9145) ADVANCED PRODUCT QUALITY PLANNING (APQP) REQUIREMENTS	46
16.1	(4.1 - 9145) General Requirements	46
16.2	(4.2 - 9145) Advanced Product Quality Planning Project Management	50
16.3	(4.3 - 9145) Phase 1 Requirements - Planning	50
16.4	(4.4 - 9145) Phase 2 Requirements - Product Design and Development	50
16.5	(4.5 - 9145) Phase 3 Requirements - Process Design and Development.....	50
16.6	(4.6 - 9145) Phase 4 Requirements - Product and Process Validation	51
17.	(5. - 9145) PRODUCTION PART APPROVAL PROCESS REQUIREMENTS	51
17.1	(5.1 - 9145) Process Requirements for Production Part Approval Process	51
17.2	(5.2 - 9145) Production Part Approval Process File and Submission.....	54

18.	AESQ SUPPLY CHAIN RISK MANAGEMENT PROCESS - SUPPLEMENTAL REQUIREMENTS	56
19.	CONTROL PLAN - SUPPLEMENTAL REQUIREMENTS	57
AS13100 - Chapter C - Core Defect Prevention Quality Tools to Support APQP and PPAP - Supplemental Requirements		59
20.	OVERVIEW - SUPPLEMENTAL REQUIREMENTS	59
20.1	Key Quality Planning Tools to Support the APQP and PPAP Processes - Supplemental Requirements	59
21.	KEY REQUIREMENTS FOR THE DEPLOYMENT OF QUALITY PLANNING TOOLS - SUPPLEMENTAL REQUIREMENTS	60
21.1	Design FMEA - Supplemental Requirements	60
21.1.1	Design FMEA Purpose and Objectives - Supplemental Requirements	60
21.1.2	Design FMEA General Requirements - Supplemental Requirements	60
21.1.3	CONDUCTING Design FMEA - Supplemental Requirements	62
21.2	Product Key Characteristics (KC) - Supplemental Requirements	64
21.3	Process Flow Diagrams (PFDs) - Supplemental Requirements	64
21.4	Process FMEA - Supplemental Requirements	64
21.5	Process Key Characteristics (KC) - Supplemental Requirements	66
21.6	Control Plan - Supplemental Requirements	66
21.7	Measurement Systems Analysis (MSA) - Supplemental Requirements	67
21.8	Initial Process Capability Studies - Supplemental Requirements	67
22.	NOTES	67
22.1	Revision Indicator	67
APPENDIX A	STANDARD RELATIONSHIPS	68
APPENDIX B	AS13100 REQUIREMENTS APPLICABILITY MATRIX - ORGANIZATION TYPES AND FLOWCHARTS DEFINING TO WHOM THEY APPLY	70
APPENDIX C	ACRONYM LOG	72
Figure 1	AS13100 standard relationship to other quality management system standards	2
Figure 2	APQP and PPAP flow plan diagram	47
Figure 3	APQP and PPAP timing chart illustrations	48
Figure 4	AESQ timing of application	57
Figure 5	Key quality planning tools to support APQP and PPAP schematic	59
Table 1	AS13100 supplemental requirements applicability	10
Table 2	QMS certification requirements	12
Table 3	When to apply measurement capability assessment	15
Table 4	MSA acceptance limits	17
Table 5	Minimum requirements for quality system auditors	19
Table 6	Minimum requirements for production process or product auditors	20
Table 7	Minimum requirements for special process auditors	21
Table 8	Retention periods for retained documented information	23
Table 9	Internal audit types and frequency	43
Table 10	AESQ PPAP events	49
Table 11	Submission/retention levels	52
Table 12	Typical use of PPAP elements	53
Table 13	AESQ PPAP elements requirement	54
Table 14	Common AESQ customer-specific requirements	56
Table 15	AESQ APQP assurance framework	57

1. SCOPE

This SAE Aerospace Standard (AS) establishes supplemental requirements for 9100 and 9145 and applies to any organization receiving it as part of a purchase order or other contractual document from a customer.

AS13100 also provides details of the reference materials (RM13xxx) developed by the SAE G-22 AESQ committee and listed in [Section 2](#) that can also be used by organizations in conjunction with this standard.

2. APPLICABLE DOCUMENTS

The following publications form a part of this document to the extent specified herein. The latest issue of SAE publications shall apply. The applicable issue of other publications shall be the issue in effect on the date of the purchase order. In the event of conflict between the text of this document and references cited herein, the text of this document takes precedence. Nothing in this document, however, supersedes applicable laws and regulations unless a specific exemption has been obtained.

2.1 SAE Publications

Available from SAE International, 400 Commonwealth Drive, Warrendale, PA 15096-0001, Tel: 877-606-7323 (inside USA and Canada) or +1 724-776-4970 (outside USA), www.sae.org.

AS5553	Counterfeit Electrical, Electronic, and Electromechanical (EEE) Parts; Avoidance, Detection, Mitigation, and Disposition
AS6174	Counterfeit Materiel; Assuring Acquisition of Authentic and Conforming Materiel
AS9100*	Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations
AS9102*	Aerospace Series - First Article Inspection Requirements
AS9103*	Aerospace Series - Quality Management Systems - Variation Management of Key Characteristics
AS9115*	Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations - Deliverable Software (Supplement to 9100:2016)
AS9116*	Aerospace Series - Notice of Changes (NOC)
AS9117*	Delegated Product Release Verification
AS9120*	Quality Management Systems - Requirements for Aviation, Space, and Defense Distributors
AS9145*	Aerospace Series - Requirements for Advanced Product Quality Planning and Production Part Approval Process
AS9146*	Foreign Object Damage (FOD) Prevention Program - Requirements for Aviation, Space, and Defense Organizations
AS9162*	Aerospace Operator Self-Verification Programs
AS13001	Delegated Product Release Verification Training Requirements

NOTE: *Internationally harmonized standards developed under the authority of the IAQG and listed here as SAE International AS publications. Equivalent versions may be published by other standards bodies (e.g., European Committee for Standardization [CEN], Japanese Standards Association/Society of Japanese Aerospace companies [JSA/SJAC]).

2.2 AESQ Publications

The AESQ reference manuals have been created to support the requirements of AS13100 by providing examples of preferred means of compliance. These documents provide methodologies, templates, and case studies of the application of key processes required by the standard.

Copies of RM13xxx documents are available online at <https://aesq.sae-itc.com/supplemental-material>.

RM13000	Problem Solving Methods including 8D
RM13002	Alternate Strategies to 100% Inspection
RM13003	Measurement Systems Analysis (MSA)
RM13004	Defect Prevention Quality Tools to support Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP)
RM13005	Quality Audit Methods
RM13006	Process Control Methods
RM13007	Sub-tier Management
RM13008	Design Work
RM13009	AS13100 Compliance Matrix
RM13010	Human Factors
RM13011	Managing Rework and Production Repair
RM13102	First Article Inspection Requirements (FAIR)
RM13145	Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP)

2.3 ISO Publications

Copies of these documents are available online at <https://webstore.ansi.org/>.

ISO 9001	Quality Management Systems - Requirements
ISO 31000	Risk Management - Guidelines
ISO/IEC 17025	General Requirements for the Competence of Testing and Calibration Laboratories

2.4 EASA Publications

Available from European Union Aviation Safety Agency, Konrad-Adenauer-Ufer 3, D-50668 Cologne, Germany, Tel: +49 221 8999 000, www.easa.europa.eu.

CS-E515	EASA Certification Specification - Engine Critical Parts
---------	--

2.5 VDA/EN Publications

Copies of these documents are available online at <https://www.en-standard.eu/>.

VDA 6.3	Quality Management - Automotive Industry - Process Audit
---------	--

3. TERMS AND DEFINITIONS

3.1 Background

In this SAE Aerospace Standard (AS), the following verbal forms are used:

- “Shall” indicates a requirement.
- “Should” indicates a recommendation.
- “May” indicates a permission.
- “Can” indicates a possibility, or a capability.

Information marked as “NOTE:” is for guidance in understanding or clarifying the associated requirement.

A list of acronyms has been provided (see [Appendix C](#)).

3.2 Terms and Definitions

For the purpose of this standard, the terms and definitions apply as documented in the AESQ Quality Dictionary available on the AESQ website: <https://aesq.sae-itc.com/supplemental-material>.

SAENORM.COM : Click to view the full PDF of as13100a

AS13100 - Chapter A
9100 Quality Management Systems - Requirements for Aviation, Space, and Defense
Organizations - AESQ Supplemental Requirements

4. CONTEXT OF ORGANIZATION

4.1 Understanding the Organization and Its Context

4.2 Understanding the Needs and Expectations of Interested Parties

4.2.1 Understanding the Needs and Expectations of Interested Parties - Supplemental Requirements

4.2.1.1 The organization shall ensure on-site right of entry to its customers and their respective governmental and regulatory agencies, third parties mandated by the customer and contracting parties accompanying the customer's representatives including access to documented information and the ability to conduct audits, review of quality investigations, and to verify product and processes.

4.2.1.1.1 Right of entry includes access to the applicable areas of organization facilities as well as related supplier and business partner facilities.

4.2.1.2 Where access is restricted due to export control technical requirements or organization intellectual property concerns, the organization shall facilitate to allow the customer or regulatory agency to fulfill their mandate.

4.2.1.3 Where required, the organization shall provide language translation capabilities to support such reviews.

4.3 Determining the Scope of the Quality Management System

4.3.1 Determining the Scope of the Quality Management System - Supplemental Requirements

4.3.1.1 [Table 1](#) contains the minimum requirements per organization type and shall be complied with in conjunction with additional customer requirements. It shows the applicability of the AS13100 Standard clauses to the organization's scope of approval.

4.3.1.2 [Table 1](#) takes into consideration the certification requirements in [Table 2](#). The organization shall ensure that the applicable requirements of this standard are included within their QMS.

4.3.1.3 Any significant changes shall be communicated to the customer.

4.3.1.4 For "production shop assist only" organizations, the applicable elements of AS13100 requirements shall be as defined by the customer, based upon the scope of the work undertaken.

4.3.1.5 For organization types not listed in [Table 1](#), refer to specific customer requirements.

4.3.1.6 The flowcharts can be used to illustrate how the requirements of this standard apply to the different organization types defined in [Table 1](#) of this standard; see [Figures B1](#) (hardware providers) and [B2](#) (service providers).

4.3.1.7 For the organization types and how the requirements of this standard apply, see [Tables 1](#) and [B1](#).

4.3.1.8 The flowcharts (see [Figures B1](#) and [B2](#)) can also be used by supplier (sub-tier) where AS13100 is a contractual flow down.

Table 1 - AS13100 supplemental requirements applicability

AS13100 Paragraph Reference	Organization Type					
	Type 1: Make to Print	Type 2a: Design and Manufacture	Type 2b: Design Only	Type 3: Distributor	Type 4: Special Process	Type 5: Raw Material
4.2.1	X	X	X	X	X	X
4.3.1	X	X	X	X	X	X
4.3.2	X	X	X			
4.3.3-4.3.5	X	X	X	X	X	X
4.4.3	X	X	X	X	X	X
5.1.1.1	X	X	X	X	X	X
5.2.1.1	X	X	X	X	X	X
5.3.1	X	X	X	X	X	X
6.1.3	X	X	X	X	X	X
7.1.3.1	X	X	X	X	X	X
7.1.5.1.1- 7.1.5.1.5	X	X			X	
7.2.1	X	X	X	X	X	X
7.2.2	X	X	X	X	X	X
7.2.3	X	X		X	X	X
7.2.4	X	X	X	X	X	X
7.3.1	X	X	X	X	X	X
7.5.2.1	X	X	X	X	X	X
7.5.3.3	X	X	X	X	X	X
7.5.3.4		X	X			
7.5.3.5	X	X	X	X	X	X
8.1.3.1	X	X	X	X	X	X
8.1.4.1	X	X		X	X	X
8.2.1.1	X	X	X	X	X	X
8.2.2.1	X	X	X	X	X	X
8.2.3.3	X	X	X	X	X	X
8.3.1.1-8.3.6.1		X	X			
8.4.1.2-8.4.1.3	X	X			X	
8.4.1.4	X	X		X	X	
8.4.2.1	X	X	X	X	X	X
8.4.2.2-8.4.2.4	X	X		X	X	X
8.4.2.5	X	X			X	X
8.4.2.6	X	X		X	X	X
8.4.3.1	X	X		X	X	X
8.5.1.1.1	X	X			X	X
8.5.1.2.1	X	X	X		X	X
8.5.1.4	X	X			X	X
8.5.1.5	X	X	X		X	
8.5.1.6	X	X			X	

AS13100 Paragraph Reference	Organization Type					
	Type 1: Make to Print	Type 2a: Design and Manufacture	Type 2b: Design Only	Type 3: Distributor	Type 4: Special Process	Type 5: Raw Material
8.5.1.7	X	X			X	
8.5.1.8	X	X			X	X
8.5.1.9	X	X		X	X	X
8.5.2.1	X	X				X
8.5.4.1	X	X		X	X	X
8.5.6.1	X	X	X		X	X
8.6.1	X	X			X	X
8.7.1.1	X	X			X	X
9.1.1.1-9.1.1.3	X	X			X	X
9.1.2.1	X	X	X	X	X	X
9.2.3-9.2.4	X	X	X	X	X	X
9.3.2.1	X	X	X	X	X	X
9.3.3.1	X	X	X	X	X	X
10.2	X	X	X	X	X	X
10.2.4	X	X	X	X	X	X
10.3.1	X	X		X	X	X

- 4.3.2 Organizations whose products are deliverable software, or contain deliverable software, shall comply with 9115 when planning and evaluating the software design, development, or management activities of the organization.
- 4.3.3 The organization shall be certified by an industry recognized and accredited QMS certification body for the associated scope(s) of work in accordance with [Table 2](#).
- 4.3.3.1 The organization shall cascade these certification requirements to its suppliers in accordance with [Table 2](#).
- 4.3.3.2 For Nadcap certifications, the accreditation is administered by the Performance Review Institute (PRI).
- 4.3.4 The organization shall provide access to relevant data within Online Aerospace Supplier Information System (OASIS) and provide data from the Nadcap databases (e.g., registration documentation, certification, audit reports and findings, corrective actions) to its customers.
- 4.3.5 The organization shall conduct an AS13100 compliance self-assessment to ensure that the scope of its management system includes the full scope of this standard; refer to RM13009 for recommendations on how to complete a compliance self-assessment.
- 4.3.5.1 The AS13100 compliance self-assessment review shall be reviewed at a minimum annually and updated as applicable and provided to the customer on request (refer to RM13009).
- 4.3.5.2 The organization shall identify any compliance gaps that they are unable to address and bring these to the attention of the customer for resolution.

Table 2 - QMS certification requirements

Organization Type	QMS Approval (Minimum Requirement)
Type 1: Make to print Type 2A: Design and manufacture Manufacture, inspect, test, and certify the conformance of semi-finished and/or finished products (installed on aerospace engines or a component of such a product) to proprietary engineering drawings whether customer design, or organization design. Includes castings and forgings produced to a proprietary design.	9100 registration.
Type 2B: Design only Contracted design responsible organization/partner/supplier tasks organizations.	As defined by customer's requirements.
Type 3: Distributor	9120 registration.
Type 4: Special process As part of an organization's manufacturing scope and/or special process houses.	Nadcap or customer's requirements.
Type 5: Raw material Manufacture, inspect, test, and certify the conformance of raw material to proprietary engineering specifications.	ISO 9001 registration or customer requirements.
Production shop assist only. Offload of planned manufacturing operations.	Customer defines requirements
External calibration or laboratory service provider.	ISO/IEC 17025, or the standards are traceable to national standards, e.g., UKAS, COFRAC, NIST.

4.4 Quality Management System and Its Processes

4.4.3 Quality Management System and Its Processes - Supplemental Requirements

4.4.3.1 The organization's QMS shall include management of human factors in its processes (see [5.1.1.1](#)) including:

- a. Training of employees.
- b. An open reporting culture, encouraging the sharing of mistakes without fear of retribution.
- c. Considering human factors in investigations.
- d. Considering human factors in the reporting of performance and identifying improvement plans.

4.4.3.2 Consideration of human factors shall be included in product and service design, manufacturing/assembly, and product servicing.

NOTE: For details on the deployment of human factors within the organization, refer to RM13010.

5. LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

5.1.1.1 General - Supplemental Requirements

Top management shall demonstrate a commitment to human factors in accordance with [4.4.3](#) and [7.3.1](#); refer to RM13010.

5.2 Policy

5.2.1 Establishing the Quality Policy

5.2.1.1 Establishing the Quality Policy - Supplemental Requirements

5.2.1.1.1 The organization shall have a policy that includes human factors which promotes:

- a. Open reporting.
- b. Continually improving the maturity of human factor deployment within the organization.

5.3 Organizational Roles, Responsibilities, and Authorities

5.3.1 Organizational Roles, Responsibilities, and Authorities - Supplemental Requirements

- 5.3.1.1 Personnel responsible for conformity to product requirements shall have the authority to stop and correct quality problems.
- 5.3.1.2 Where the process design prevents immediate shutdown upon detection of a quality problem, then the product or service shall be contained so that it is prevented from being delivered to the customer.

6. PLANNING

6.1 Actions to Address Risks and Opportunities

6.1.3 Actions to Address Risks and Opportunities - Supplemental Requirements

- 6.1.3.1 The organization shall implement a risk management process, e.g., ISO 31000, across their organization and ensure they:
 - a. Carry out a robust assessment of risks, in particular those that could threaten future performance, and detail these in a risk register.
 - b. Carry out a review of the effectiveness of their risk management system (including internal controls), at least annually.
 - c. Ensure appropriate risk mitigation is in place (including internal controls) that is appropriate to the risks identified.

6.1.3.2 The organization shall establish a crisis management and business continuity plan and inform its customer purchasing representative within 3 working days of becoming aware of an issue regarding the following:

- a. Major incidents affecting the organization that impact the organization's ability to meet customer commitments.
- b. Risks that could impact the continuity of the organization's business/operations, particularly single points of failure.
- c. Changes to QMS certification, including lapse/withdrawal/major audit findings to the relevant customer.
- d. Change of the nominated quality representative (usually the most senior quality leader within the organization).
- e. Significant change to the QMS.
- f. Change in ownership or discontinuation of business activities.
- g. Significant issues of breaches of information technology (IT) security systems (cyber security).
- h. Risks with the supply of materials used in the production or physical make-up of products, due to laws and regulations concerning the control or use of such materials.

7. SUPPORT

7.1 Resources

7.1.3 Infrastructure

7.1.3.1 Plant, Facility, and Equipment - Supplemental Requirements

7.1.3.1.1 The organization shall use a cross-functional approach to develop project plans when implementing a new plant, facilities, or equipment.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

7.1.5.1.1 Measurement Systems Analysis (MSA) - Supplemental Requirements

7.1.5.1.1.1 MSA guidance is available (refer to RM13003) and should be applied in conjunction with the requirements defined in this section. The organization shall obtain customer approval for equivalent methods; refer to RM13003.

7.1.5.1.1.2 The organization shall assess when to apply MSA in accordance with [Table 3](#) and provide justification when MSA is not applied.

7.1.5.1.1.3 All MSA studies shall be conducted under production conditions or equivalent (see [7.1.5.1.2](#)).

7.1.5.1.1.4 MSA is required for KCs on all Events as described in [Table 3](#). Applicability of MSA for KCs is applied independently from the classification due to the importance of KCs.

NOTE: For MSAs, apply [Table 4](#) acceptance criteria, based on KC classification of critical, major, or minor.

Table 3 - When to apply measurement capability assessment

Event	Event Description	Requirement per Characteristic Classification				Action
		KC	Critical	Major	Minor	
1	New product or characteristic	Required	Required	Required	Recommended	Perform MSA
2	New verification device or method.	Required	Required	Required	Recommended	Perform MSA
3	Any significant change to the current verification method.	Required	Required	Required	Recommended	Evaluate existing MSA and/or perform a new MSA
4	Following a product quality escape or audit finding suspected to be from the verification system.	Required	Required	Recommended	Recommended	Evaluate existing MSA and/or perform a new MSA
5	Product requirements changed (e.g., specification limit[s] changed, KC).	Required	Required	Recommended	Recommended	Evaluate current MSA
6	As part of a FAI following a lapse in use.	Required	Recommended	Recommended	Recommended	Evaluate current MSA
7	If a process monitoring method is promoted to product acceptance method.	Required	Required	Required	Recommended	Perform MSA
8	To verify a verification system meets requirements from Table 4 before applying Alternate Strategies to 100% Inspection (see 9.1.1.2).*	Required	Required	Required	Recommended	Evaluate existing MSA and/or perform a new MSA *Requirement of MSA, does not supersede any requirements in 9.1.1.2 .
9	New computer driven measurement system (CDMS) part program.	Required	Required	Required	Required	Perform CDMS study
10	Revision to computer driven measurement system (CDMS) part program	Required	Required	Required	Required	Evaluate current or perform CDMS study. Refer to RM13003 for more details.

Note: "Evaluate current or perform" is defined as reviewing any existing MSA studies to ensure it meets the requirements of this standard. Capturing additional data, rerunning the calculation on new data, applying new tolerances, or performing a new MSA study to prove the measurement system capable.

7.1.5.1.2 Conduct MSA as Planned - Supplemental Requirements

7.1.5.1.2.1 The following MSA requirements shall be met (refer to RM13003):

- a. Ensure that the personnel assigned to perform product verification activities are trained and competent in the use of the monitoring/measuring equipment.
- b. Ensure MSA tests align to industry-recognized techniques.
- c. The MSA study must follow the planned production process, and where this includes part constraint that must be included in the study.
- d. Ensure production parts, representative parts, or artifacts that represent the manufacturing process, tolerances, and dimensions are used.
- e. Ensure personnel, resources, and environment replicate the conditions in the production process and during the trial personnel do not have visibility of study results.

7.1.5.1.3 Confirm Acceptance - Supplemental Requirements

7.1.5.1.3.1 The organization shall have objective evidence to demonstrate compliance to [Table 4](#).

7.1.5.1.3.2 Use the flow diagram in RM13003 to clarify which tests are required to form a complete MSA submission.

7.1.5.1.3.3 When MSA results fail to meet the requirements in [Table 4](#), mitigation action shall be initiated to improve the measurement system. Where improvement is not practical, a containment plan that assures product conformity shall be documented and approved by the customer.

NOTE: RM13003 provides examples of mitigation action.

7.1.5.1.3.4 Customer requirements may override the values.

7.1.5.1.3.5 Where characteristic classification is unknown, assume “major” column for acceptance criteria, unless noted otherwise by the customer.

7.1.5.1.3.6 As a default, all calculations use ± 3 standard deviations (99.7% confidence). Deviations from this shall be documented and approved by customer.

7.1.5.1.3.7 For MSAs, apply [Table 4](#) acceptance criteria for KCs based on characteristic category of critical, major, or minor.

Table 4 - MSA acceptance limits

MEASUREMENT PROCESS PROPERTY		CHARACTERISTIC CATEGORY			COMMENTS
		CRITICAL	MAJOR	MINOR	
Continuous Measurement Systems - Gauge Selection	Resolution	$\leq 10\%$ of total tolerance			
	Accuracy ratio or percent	$\geq 10:1$ or $\leq 10\%$		$\geq 4:1$ or $\leq 25\%$	
Continuous Measurement Systems Analysis	Bias	$\leq 10\%$ of total tolerance			Tolerance of less than 0.05 mm are difficult to achieve; refer to RM13003 for risk mitigation.
	Repeatability (Type 1 Gauge)	$\leq 10\%$ of tolerance	$\leq 20\%$ of tolerance	$\leq 30\%$ of tolerance	Requires Customer Approval; refer to RM13003 for detail.
	Gauge Repeatability & Reproducibility (GR&R)	$\leq 10\%$ of tolerance	$\leq 20\%$ of tolerance	$\leq 30\%$ of tolerance	Required for approval unless using CDMS.
	CDMS Study (GR&R)	$\leq 10\%$ of tolerance		$\leq 20\%$ of tolerance	Used for CMM, 3D structured light, vision systems, X-Ray, etc. See above for Bias.
	Linearity	$\leq 1\%$ of total tolerance			
Attribute study: pass/fail	Overall Kappa	≥ 0.8			All appraisers agreed within and between themselves.
	Appraiser consistency	$\geq 90\%$			Appraiser agrees with himself.
	Appraiser to Appraiser	$\geq 80\%$			Appraisers between each other.
	Appraiser to Standard	$\leq 25\%$ False Fail (failing a good part) $\leq 5\%$ False Pass (passing a bad part)			For each appraiser, compare appraiser to the reference and separation between good and bad parts.
Attribute study: ordinal or count (more than two groups)	Overall ICC	ICC ≥ 0.75			Refer to RM13003.

7.1.5.1.4 Agreed to Improvement Actions - Supplemental Requirements

The organization shall define and implement actions to resolve gaps in measurement system capability including mitigation actions to protect the customer.

7.1.5.1.5 On-Going MSA Requirements

The organization shall document a plan for continuing MSA needs (see [Table 3](#)).

7.2 Competence

7.2.1 Competence Achieved by On-the-Job Training - Supplemental Requirements

7.2.1.1 The organization shall provide on-the-job training in appropriate requirements.

7.2.1.2 In addition to the organization's employees, on-the-job training shall include contract or agency personnel.

7.2.2 Auditor Competence - Supplemental Requirements

7.2.2.1 The organization shall have a documented procedure to set and maintain the qualifications for all auditors that is compliant to [Tables 5, 6, and 7](#) (refer to RM13005).

NOTE: The auditor requirements of [Tables 5, 6, and 7](#) have been aligned with the four audit types identified in [9.2.3](#).

7.2.2.2 Documented information of auditor qualification shall be maintained and updated.

SAENORM.COM : Click to view the full PDF of as13100a

Table 5 - Minimum requirements for quality system auditors

Initial Training	Requirement
Lead Auditor Qualification	The Lead Auditor shall be trained in a QMS Lead Auditor training course adequate for the organization's certification level (e.g., 9100, ISO 9001, 9120) with documented content and examination. NOTE 1: This level of training is required for auditors that will be leading internal and/or supplier audits. NOTE 2: Training preferably delivered by an external body according to industry standards.
Auditor Qualification	Auditors shall be trained in audit methods and applicable industry QMS standards, by an external body, or by a qualified Lead Auditor that has successfully passed a QMS Lead Auditor training course. NOTE: It is recommended using a training provider that utilizes experienced QMS auditors, minimum 2 days, and contains audit methods and QMS standard overview.
9100 Overview Training	For all auditors that have received training against a standard that is not 9100, completion of the AS13100 Supplemental Quality Management System Requirements course (Course: PD532104) may be utilized to satisfy the requirements for both 9100 Overview Training and AS13100 Audit Proficiency.
AS13100 Audit Proficiency	All auditors shall receive training on all aspects of the AS13100 standard and the defect prevention tools (e.g. 8D, Design FMEA, Process FMEA, MSA) applicable to the scope of the auditor's audit activities.
Government or Airworthiness Authority Regulations (as applicable)	All auditors shall receive training (internal or external) on the applicable regulations.
Experience	Requirements
General Knowledge	All auditors shall have a minimum of 1 year of appropriate education and/or work experience in the application of quality management systems.
Customer-Specific Requirements	Auditors shall have a demonstrated working knowledge of the customer requirements (which may include government or airworthiness requirements) that are applicable to the product/process that is being audited. or The organization establishes checklists that include the customer requirements (which may include government or airworthiness requirements), and the auditor has been trained on the utilization of these checklists.
Quality Systems Audit Experience	Prior to an auditor completing audits alone, the auditor shall: • Witness a minimum of one Quality System audit. • Conduct a minimum of one Quality System audit evaluated by an existing qualified auditor or other subject matter expert as documented in the organization's QMS.
Maintenance	Requirements
Audit Frequency	Qualified auditors shall complete a minimum of one audit per year. NOTE: This requirement can be satisfied with a combination of internal and supplier audits.
Refresher Training	The organization's documented auditor qualification process shall ensure that all auditors receive timely refresher training when there are changes to the scope of QMS audits (e.g., customer requirement changes, industry standard changes).

Table 6 - Minimum requirements for production process or product auditors

Initial Training	Requirement
Auditor Qualification	Auditors shall be trained in audit methods and applicable QMS requirements (e.g., containment, control of nonconforming product, document control, inspection techniques) for the production process/product being audited.
9100 & AS13100 Overview Training	All auditors shall receive awareness training on the 9100 and AS13100 standards and the defect prevention tools (e.g., 8D, PPAP, Process FMEA, APQP) applicable to the scope of the auditor's audit activities. (Refer to RM13000 and RM13004.)
Experience	Requirements
Technical Knowledge	All auditors shall have a minimum of 1 year of technical knowledge of the production process or product being audited. NOTE: Additional technical knowledge may be needed for more complex production processes or products.
Process or Product Audit Experience	Prior to an auditor completing audits alone, the auditor shall: • Witness a minimum of one Process or Product audit. • Conduct a minimum of one Process or Product audit evaluated by an existing qualified Auditor or other subject matter expert as documented in the organization's QMS.
Customer-Specific Requirements	Auditors shall have a demonstrated working knowledge of the customer requirements that are applicable to the production process or product being audited. or The organization establishes checklists that include the customer requirements, and the auditor has been trained on the utilization of these checklists.
Maintenance	Requirements
Audit Frequency	Qualified auditors shall complete a minimum of one audit per year unless otherwise defined in the organization's QMS. NOTE: This requirement can be satisfied with a combination of internal and supplier audits.
Refresher Training	The organization's documented auditor qualification process shall ensure that all auditors receive timely refresher training when there are changes to the scope of audits (e.g., customer requirement changes, industry standard changes).

Table 7 - Minimum requirements for special process auditors

Initial Training	Requirement
Auditor Qualification	Auditors shall be trained in audit methods and applicable QMS requirements (e.g., containment, control of nonconforming product, document control, inspection techniques) for the special process being audited.
9100 & AS13100 Overview Training	All auditors shall receive awareness training on the 9100 and AS13100 standards and the defect prevention tools (e.g., 8D, PPAP, Process FMEA, APQP, Process control Methods) applicable to the scope of the auditor's audit activities. (Refer to RM13000 and RM13004.)
Experience	Requirements
Technical Knowledge	All auditors shall have a minimum of 5 years of combined theoretical and practical experience in the special process being audited. NOTE: Third-party special process auditors can be used to meet this requirement.
Customer-Specific Requirements	Auditors shall have a demonstrated working knowledge of the customer requirements that are applicable to the special process being audited. or The organization establishes checklists that include the customer requirements, and the auditor has been trained on the utilization of these checklists.
Special Process Audit Experience	Prior to an auditor completing audits alone, the auditor shall: • Witness a minimum of one Special Process audit. • Conduct a minimum of one Special Process audit evaluated by an existing qualified auditor or other subject matter expert as documented in the organization's QMS.
Maintenance	Requirements
Audit Frequency	Qualified auditors shall complete a minimum of one audit per year (either internal or supplier).
Refresher Training	The organization's documented auditor qualification process shall ensure that all auditors receive timely refresher training when there are changes to the scope of audits (e.g., customer requirement changes, industry standard changes).

7.2.2.3 Where it is not possible to satisfy the minimum technical knowledge and auditor qualifications in [Tables 5, 6, and 7](#) with the same individual, then the auditor shall be supported in the audit by a technical expert(s) as necessary.

7.2.2.4 Auditors shall not be assigned to, nor agree to perform any audits that they do not have the capability to properly conduct (e.g., insufficient experience and/or knowledge, conflict of interest); refer to RM13005.

7.2.3 Delegated Product Release Verification (DPRV) Representative Training - Supplemental Requirements

7.2.3.1 DPRV personnel shall be trained and certified in accordance with AS13001.

7.2.4 AS13100 Requirements Training and AESQ Quality Foundations Training - Supplemental Requirements

7.2.4.1 The organization shall define a cross-functional training plan for the organization to demonstrate that it has the right competencies to effectively implement the requirements of AS13100 and its supporting activities.

As a minimum, the training plan should include AS13100 Requirements and AS13100 Foundations Course for relevant personnel.

Employees who are responsible for implementing and maintain key quality tools should also receive formal training and development in order to demonstrate competence. The following subjects should be considered:

- a. RM13000 Problem Solving Methods (8D)
- b. RM13002 Alternate Strategies to 100% Inspection
- c. RM13003 Measurement System Analysis
- d. RM13004 Defect Prevention Quality Tools
- e. RM13005 Quality Audit Methods
- f. RM13006 Process Control Methods
- g. RM13007 Sub Tier Management
- h. RM13008 Design Work
- i. RM13009 Compliance Assessment (with Form) - Gap Assessment
- j. RM13010 Human Factors
- k. RM13011 Rework and Production Repair of Nonconforming Products
- l. RM13102 First Article Inspection

7.3 Awareness

7.3.1 Human Factors Awareness - Supplemental Requirements

The organization (see [5.1.1.1](#)) shall provide an appropriate program of training and awareness of human factors based on role; refer to RM13010.

7.5 Documented Information

7.5.2 Creating and Updating

7.5.2.1 Creating and Updating Documented Information - Supplemental Requirements.

7.5.2.1.1 When creating and updating documented information, the organization shall record, date, and ensure traceability to a responsible person making the change (e.g., name, signature, stamp, electronic signature), with a permanent marking method and the original information being legible and retrievable after the change.

7.5.2.1.1.1 Where the documented information is stored electronically, sufficiently detailed electronic records shall be maintained pertaining to the changes.

7.5.2.1.2 Documented Information such as records shall not be altered without proper traceable documented information permitting the alteration.

7.5.2.1.3 Documented information requiring submission or approval by the customer shall be written in English, unless otherwise specified by the customer.

7.5.2.1.4 Where documented information contains reference to units of measure, they are to be recorded in the same units of measure as defined on the product definition when submission or approval by the customer is required.

7.5.3 Control of Documented Information

7.5.3.3 Documented Information Retrieval Times - Supplemental Requirements

7.5.3.3.1 The organization shall ensure that documented information (data) required for review is available for the customer, the customer's customer, and/or regulatory agency within 3 working days of notification.

7.5.3.3.2 In the case of an onsite visit, actual documented information (data) shall be made available within 24 hours, unless the required documented information (data) is located off-site, then the organization needs to make every effort to retrieve the data as soon as possible, but no later than 3 working days.

NOTE: The delivery of documented information (data) to the customer, etc., does not release the organization from any requirements herein with respect to that documented information (data) except as agreed to in writing by the customer, etc.

7.5.3.4 The organization shall inform the customer within 3 working days and confirm in writing when damage to documented information of the design and development output under their responsibility occurs or following termination of activity.

7.5.3.5 Documented Information Retention Periods - Supplemental Requirements

7.5.3.5.1 Unless otherwise specified by the customer, documented information shall be retained from the date of manufacture for the time periods defined in [Table 8](#).

7.5.3.5.2 If a contract is open, all documented information shall be retained. If the contract is closed, then the documented information (data) becomes a candidate for disposition in accordance with retention time period requirements. For questions related to this requirement, contact your assigned customer quality representative.

Table 8 - Retention periods for retained documented information

Retention Time Period (from Date of Manufacture)	Part Type
40 years	Critical safety item(s).
10 years	All other parts.

7.5.3.5.3 Design Technical Data Package (DTDP) shall be retained for end of life of product operation plus 10 years, if not otherwise required by the customer.

NOTE: End of life of product operation meaning notification of withdrawal of type certificate for civil aerospace applications or notification of the withdrawal for support in the case of military aerospace products. Documented information (design records) typically includes the contents of the design technical data package (DTDP) (see [8.3.5.3](#)) as well as any records of design support to nonconformance approval, e.g., analysis, calculations.

7.5.3.5.4 Sources performing nondestructive evaluation/testing shall ensure inspection records including, but not limited to, radiographic film, are maintained in accordance with the retention period specified in [Table 8](#).

8. OPERATION

8.1 Operational Planning and Control

8.1.3 Product Safety

8.1.3.1 Product Safety - Supplemental Requirements

The organization shall plan, implement, and control the processes needed to assure product safety. These processes include, as appropriate:

- a. Identification of hazards, including reactive and proactive methods.
- b. Analysis, assessment, and control of safety risks associated with identified hazards.
- c. Identification and management of changes that may impact product safety.
- d. Assessment of the effectiveness of safety processes.
- e. Provision of training on product safety responsibilities to relevant personnel.
- f. Communication and awareness of product safety information, including safety-critical information, safety events, and changes to safety procedures, as applicable.
- g. Reporting of safety events to the customer, authorities, and type certificate holder in accordance with customer and regulatory requirements.

NOTE: The OEM or engine type certificate holder is responsible for making the final judgment on whether there is an actual risk to safe and reliable operation.

8.1.4 Prevention of Counterfeit Parts

8.1.4.1 Prevention of Counterfeit Parts - Supplemental Requirements

- 8.1.4.1.1 The organization shall plan, implement, and control counterfeit part prevention processes in accordance with AS6174 or AS5553, as applicable.
- 8.1.4.1.2 The organization shall ensure that the counterfeit part prevention process includes a mechanism for reporting counterfeit parts to the customer purchasing representative within 24 hours of it being confirmed.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

8.2.1.1 Customer Communication - Supplemental Requirements

- 8.2.1.1.1 The organization shall only accept privileges, agreements, and instructions in writing (e.g., interface documents, purchase order, purchase order supplements/amendments).
- 8.2.1.1.2 Verbal agreements and instructions shall not be construed as customer approval or authorization.
- 8.2.1.1.3 The organization shall agree with the customer the method of formal communication (e.g., for approval, authorization, agreement) to be used and the applicable traceability requirements such as pro forma, coordination memorandum, etc.

8.2.1.1.4 The organization shall provide access to relevant data within OASIS and provide data from the Nadcap databases (e.g., registration documentation, certification, audit reports and findings, corrective actions) to its customers.

8.2.1.1.5 The organization shall notify its customer if there are any changes to certification, registration, or accreditation within 3 working days of the change.

8.2.2 Determining the Requirements for Products and Services

8.2.2.1 Determining the Requirements for Products and Services - Supplemental Requirements

8.2.2.1.1 The organization shall ensure that it uses the latest revisions of the customer-specific procedures/forms/templates where specified by and agreed with the customer.

8.2.3 Review of the Requirements for Products and Services

8.2.3.3 Engineering Standards/Specifications - Supplemental Requirements

8.2.3.3.1 The organization shall have a documented process describing the review, distribution, and implementation of all customer engineering standards/specifications and related revisions based on customer schedules, as required.

8.2.3.3.2 The organization shall comply with customer requirements for designation, approval documentation and control of KCs.

8.3 Design and Development of Products and Services

8.3.1 General

8.3.1.1 Design and Development of Products and Services - Supplemental Requirements

8.3.1.1.1 The organization shall have a documented process that describes the design and development process.

8.3.1.1.2 The design and development process shall comply with applicable elements of the advanced product quality planning (APQP) and production part approval process (PPAP) as defined by 9145 and [AS13100 - Chapters B and C](#).

8.3.1.1.3 The organization shall have an appointed person, or equivalent, who is responsible for coordination of all design and development activities and who can act as a single point of contact for the customer.

8.3.1.1.4 The organization shall update and maintain the traceability of customer technical requirements, transfer them into the technical specifications of their product, and manage the data validation and verification of these requirements.

8.3.1.1.5 The organization shall maintain an active list of authorized design approvers, as applicable to the organization's scope of work.

8.3.1.1.6 The organization, when applicable, shall have a documented system to handle formal technical delegation; refer to RM13008.

8.3.2 Design and Development Planning

8.3.2.1 Design and Development Planning - Supplemental Requirements

8.3.2.1.1 The organization shall ensure that design and development planning includes all relevant stakeholders within the organization and, as appropriate, its supply chain. Examples of areas for using such a cross-functional approach include, but are not limited to, the following:

- a. Project management, e.g., APQP.
- b. Product and manufacturing process design activities, e.g., design for manufacture (DFM) and design for assembly (DFA).
- c. Development and review of design FMEA including actions to reduce potential risks.

NOTE: A cross-functional approach typically includes the design, manufacturing, engineering, quality, production, purchasing, customer (internal and external), supplier, maintenance, and other appropriate functions.

8.3.2.2 The organization shall identify any associated dependencies needed for the successful progression of the design and development activity, e.g., where the organization needs information from the customer and include those milestone dates in the design and development plan. The organization is required to formally communicate those milestone dates to the customer for acceptance.

8.3.2.3 The organization shall configure and plan design reviews appropriate to the project considering magnitude, complexity, novelty, risk, etc., (see [8.3.4.3](#)) and include those milestone dates in the design and development plan.

8.3.3 Design and Development Inputs

8.3.3.1 Design and Development Inputs - Supplemental Requirements

The following requirements shall be identified and reviewed, as applicable:

- a. Safety requirements, e.g., safety assessment output, part classifications.
- b. Customer requirements, e.g., project timescales, aftermarket strategy including component lives, service intervals.
- c. Operational requirements, e.g., fluid dynamics, loads, speeds, operating environments, maneuvering characteristics, and gyroscopic loads.
- d. Boundary and interface requirements.
- e. Requirements for identification, traceability, and packaging.
- f. Consideration of design alternatives.
- g. Embedded software requirements.
- h. Lessons learned, design procedures, and best practice.

8.3.3.2 Design Risk Analysis - Supplemental Requirements

8.3.3.2.1 When APQP has been required by the customer, the organization shall conduct design FMEA on the product design, see [AS13100 - Chapter C](#) (see [21.1](#)). Refer to RM13004.

8.3.3.2.2 The organization shall retain documented information as evidence of the results of the design FMEA (see [7.5.3.5.3](#)).

- 8.3.3.2.3 Alternative approaches to design FMEA shall only be used with customer approval.
- 8.3.3.2.4 Where the organization identifies a requirement for new or novel technologies associated with the design, the organization shall conduct an appropriate risk assessment and identify mitigating actions.
- 8.3.3.2.4.1 The technical aspects of the risk assessment shall be available to the customer upon request. If there are Intellectual Property (IP) restrictions, objective evidence can be viewed virtually or on-site, with IP redacted.
- 8.3.3.3 Foreign Object Damage (FOD) - Supplemental Requirements
- 8.3.3.3.1 The organization shall comply with the requirements of 9146 for FOD prevention programs and design for the prevention, detection, and safe removal of foreign objects and contamination being trapped during manufacture in such features as apertures, orifices, sharp bends, corners, etc.
- 8.3.4 Design and Development Controls
- 8.3.4.2 Progressive Product Definition Release - Supplemental Requirements
- 8.3.4.2.1 The organization shall employ an appropriate, traceable, progressive product definition release process that enables formal advance information to be provided to stakeholder functions (e.g., manufacturing, external providers).
- 8.3.4.2.2 Product definitions shall be associated with the correct approval status of the design data (either approved or nonapproved) by aviation authority or under their delegation.
- 8.3.4.3 Design Reviews - Supplemental Requirements
- 8.3.4.3.1 The organization shall conduct or support design reviews in accordance with arrangements planned and agreed with the customer (see [8.3.2.3](#)), formally documenting the output from design reviews including action owners and timeline for closure; refer to RM13008.
- 8.3.4.3.2 The organization shall agree the applicability of each appropriate design review with the customer in relation to the scope of the design work and agree with the customer the roles, accountabilities, responsibilities, deliverables, attendees, and agenda for each design review.
- 8.3.4.4 Design Verification and Product Validation - Supplemental Requirements
- 8.3.4.4.1 The organization shall create a verification strategy documenting the activities necessary to verify that the design outputs meet the design inputs (requirements) using established methods and techniques such as, but not limited to, analysis, compliance to standards, comparison to existing established designs, inspection, test, etc., and agree on the verification strategy with the customer prior to commencement of any verification activity; refer to RM13008.
- 8.3.4.4.2 The organization shall agree with the customer the material property data to be used and its source prior to launching any design verification activity that requires the input of material property data, e.g., analysis, modeling.
- 8.3.4.4.3 The organization shall identify and formally document the activities necessary to validate that the product operates as intended in accordance with the requirements and agree on the validation strategy with the customer prior to commencement of any validation activity.

8.3.4.4.4 Where validation involves incorporation of the designed product into the customer's product, (e.g., engine test), the following applies:

8.3.4.4.4.1 The organization shall agree on the level of support required with the customer, for the following examples:

EXAMPLE 1: When a part is supplied with installed instrumentation (e.g., pressure tapping, thermocouple, or accelerometer) to validate the installed environment specification, or

EXAMPLE 2: A modified version of a part is supplied to support the specific needs of an engine test (e.g., a choked-open valve, a higher-pressure relief valve cracking pressure), or

EXAMPLE 3: Where verification of compliance with performance requirements for a part is required, but that verification cannot be done via rig test (e.g., due to physical size, or because operating conditions cannot be reproduced in a rig).

8.3.4.4.5 The organization shall ensure that any specific regulatory requirements associated with the verification and validation activities are agreed with the customer.

8.3.4.4.6 The organization shall capture and formally document the output from verification and validation activities as agreed with the customer.

8.3.4.4.7 The organization shall report all verification and validation test failures to the customer.

8.3.4.5 Design for "X" (DfX) - Supplemental Requirements

8.3.4.5.1 The organization shall utilize DfX (refer to RM13008) or an alternate approach, as a tool for a cross-functional design optimization. Such criteria may include:

- a. Manufacturing capability (design for manufacture).
- b. Ease of assembly/strip (design for assembly).
- c. Cost (design for cost).
- d. Weight.
- e. Aftermarket including overhaul strategy, product lifing.
- f. Other design drivers and threats including accounting for variability and uncertainty, e.g., robust design, 6-sigma.

8.3.4.6 Failure Reporting - Supplemental Requirements

The organization's quality procedures shall include failure reporting, analysis, and corrective action as set out in [10.2.4](#), unless otherwise agreed with the customer.

8.3.5 Design and Development Outputs

8.3.5.1 Design Rationale - Supplemental Requirements

The organization shall create and retain comprehensive technical documented information of all the aspects that influenced the design throughout its development, e.g., alternative designs, key decisions, problems encountered and how they were resolved, considerations, trade-offs, design procedures used.

8.3.5.2 Critical Items (CIs) and Key Characteristics (KCs) - Supplemental Requirements

8.3.5.2.1 The organization shall document CIs and KCs and:

- a. Ensure they are agreed with the customer, if required.
- b. Comply with any customer requirements for symbols and notations.
- c. Ensure KCs are identified on relevant documentation as agreed by the customer.
- d. Ensure Feature Unique Identification is applied; refer to RM13008.

8.3.5.3 Design and Development Outputs - Supplemental Requirements

8.3.5.3.1 The product design outputs, commonly known as the design technical data package (DTDP), shall be communicated to the customer; refer to RM13008.

8.3.5.3.2 The organization shall ensure that contents of the DTDP are independently reviewed by suitably qualified individuals other than the authors.

8.3.5.4 Product End of Life - Supplemental Requirements

8.3.5.4.1 The organization shall, if applicable, define and document appropriate procedures and instructions for the disposal of “end of life” products that they have designed and provide this information for inclusion in the applicable maintenance manual. Including giving consideration to:

- a. Prevention of unauthorized reuse.
- b. Minimization of environmental impact.
- c. Compliance with national or international health, safety, and environmental regulations.
- d. Compliance with any national security regulations.
- e. Safeguarding of customer intellectual property.

8.3.5.4.2 If requested, the organization shall agree on the disposal procedures with the customer.

8.3.6 Design and Development Changes

8.3.6.1 Design and Development Changes - Supplemental Requirements

8.3.6.1.1 The organization shall operate a design change process that complies with 9116 and any customer-specific requirements.

8.3.6.1.2 The customer shall approve all design changes unless formal delegation has been given to the organization.

8.3.6.1.3 The scope and level of authorization shall be defined within an agreed delegation document from the customer.

8.3.6.1.4 The organization shall issue Notice of Change (NOC) data using the customer's templates/forms or alternative as agreed with customer.

8.3.6.1.5 The organization, when required by the customer shall have a system to ensure:

- a. All Class I and Class II design changes are submitted to the customer for change approval, unless the customer has granted written authorization to proceed differently.
- b. Rejected design changes are not incorporated into the supplier's drawing or into hardware shipped to the customer.
- c. All requested design change documentation is retained on file (including accepted and rejected dispositions).

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

8.4.1.2 Supplier Evaluation - Supplemental Requirements

8.4.1.2.1 Prior to supplier approval or issuance of a contract, the organization shall conduct an evaluation of the supplier.

8.4.1.2.2 The level of evaluation shall be determined by the Organization dependent on the risks, product or process criticality, and expectations.

8.4.1.2.3 Where there is significant risk identified, the organization shall perform an on-site evaluation.

8.4.1.2.4 The supplier evaluation shall include the following topics, as applicable:

- a. Engineering and manufacturing capabilities: Capability to manufacture the product to be contracted and control changes to design and processes.
- b. Quality control capabilities: Capability to meet quality requirements and deliver conforming product.
- c. Purchasing, planning, and capacity: Ability to meet current and future requirements considering all resources as well as management of the supply chain.
- d. Commercial, legal, and environmental: Ability to meet commercial, regulatory business, and customer requirements.

8.4.1.2.5 The organization shall consider all the evaluation criteria as required by the supplier scope of work to be undertaken and retain the assessment information as a record, including if the criterion is not considered relevant; refer to RM13007.

8.4.1.3 Supplier Selection - Supplemental Requirements

The organization shall document a risk mitigation plan to manage any identified risks resulting from the evaluation.

8.4.1.4 Supplier Register Maintenance - Supplemental Requirements

8.4.1.4.1 The organization shall have a documented process to assure that the QMS and other required certifications and approvals of the supplier remain valid.

8.4.1.4.2 When notified of any supplier change in quality leadership personnel or reporting structure, changes in scope, name, address, or approval status of QMS registrations (see [Table 2](#)), applicable production organization holder approvals, and special process accreditations, the organization shall assess the impact and implement appropriate mitigation actions. This shall include notification to the customer.

8.4.1.4.2.1 For 9100 certified suppliers, the OASIS database, and the OASIS Next Generation (NG) Feedback Process shall be used.

NOTE: For more information of the OASIS NG Feedback Process, refer to <https://oasishelp.iagg.org/> under the [OASIS Feedback Guidance](#).

8.4.2 Type and Extent of Control

8.4.2.1 Type and Extent of Control - Supplemental Requirements

8.4.2.1.1 The supplier's QMS Certification shall be defined by the organization type and comply with [Table 2](#).

8.4.2.1.2 The supplier shall establish and maintain an effective FOD prevention program that meets the requirements of 9146.

8.4.2.1.3 The supplier shall plan, implement, and control counterfeit part prevention processes in accordance with AS6174 or AS5553, as applicable.

8.4.2.1.4 The supplier shall ensure that the counterfeit part prevention process includes a mechanism for reporting counterfeit parts to the organization's purchasing representative within 3 working days of it being confirmed.

8.4.2.1.5 The supplier shall notify the organization of any significant change in QMS or business operations.

8.4.2.1.6 The supplier shall comply with the organization's specific requirements for control of work transfer.

8.4.2.1.7 The organization shall develop a risk analysis and mitigation plan to be implemented between the supplier and the organization to deal with any restrictions to right of access to the supplier's facility.

8.4.2.2 Verification of Purchased Product - Supplemental Requirements

8.4.2.2.1 Where the organization delegates verification activities to the supplier, usage of customer defined delegated product release verification shall only be further delegated if it has been formally approved by the customer.

8.4.2.2.2 Where the organization delegates product release, delegated qualification shall require the completion of training for self-release delegates. Supplier self-release training requirements may be implemented to satisfy this requirement (refer to AS13001 and 9117).

8.4.2.3 Material and Special Process - Supplemental Requirements

8.4.2.3.1 Material and special process test results shall reflect all requirements of the drawing and/or specification and conform to drawing and/or specification limits. Documented evidence of this conformity including listing of each material element or test result in the applicable test report.

8.4.2.3.2 The applicable test report shall be signed by a cognizant test laboratory person, clearly confirming which of the following is correct:

- a. All tests and inspections have been performed and results meet the drawing and/or specification requirements, or
- b. All tests and inspections have been performed and the results meet all the drawing and/or specification requirements, except _____, which does not meet requirements, or
- c. All tests and inspections have been performed and the results meet all drawing and/or specification requirements, except test(s) _____, which was not performed in accordance with the drawing and/or specification requirements.

8.4.2.4 Product Acceptance - Supplemental Requirements

8.4.2.4.1 When product acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the supplier shall establish controls for the media appropriate to:

- a. Avoid misuse.
- b. Establish traceability to the authorized user.
- c. Avoid duplication.
- d. Align to responsibilities and authorities defined within the quality system.
- e. Maintain good condition and legibility.

8.4.2.5 Supplier Surveillance - Supplemental Requirements

8.4.2.5.1 The organization shall perform supplier risk assessments, which, at a minimum, include evaluation of results of supplier's audits (e.g., internal, supplier surveillance), supplier's current quality performance, and part complexity.

8.4.2.5.2 The organization shall establish and execute appropriate surveillance methods to monitor supplier systems, processes, and products based on the risk evaluations.

8.4.2.5.3 When audit is used as a surveillance method, refer to RM13005 on how the audit can be conducted.

NOTE: Some examples of potential surveillance methods are quality system audits, product audits, inspections, and review of conformance documentation.

8.4.2.5.4 The organization shall establish and maintain an effective process to identify and mitigate delivery and capacity risk within the supply chain.

8.4.2.6 Supplier Performance Monitoring - Supplemental Requirements

8.4.2.6.1 Performance monitoring shall be performed and contain minimum key performance indicators (KPIs) that can encompass quality (e.g., disruptions, concessions, escapes) and delivery (e.g., schedule performance).

8.4.2.6.2 The organization shall provide the performance monitoring results to the supplier on an annual basis, (e.g., posted on supplier portal, communicated regularly to the supplier).

8.4.2.6.3 Performance monitoring review frequency shall be increased as appropriate (e.g., unacceptable performance).

8.4.2.6.4 Where unacceptable performance at customer directed suppliers exists, the customer shall be notified.

8.4.2.6.5 When improvement actions have not been effective, the issue shall be escalated within the organization until resolved.

8.4.3 Information for External Providers

8.4.3.1 Information for External Providers - Supplemental Requirements

8.4.3.1.1 The organization shall have a process to ensure that its suppliers understand contract requirements and flow the applicable specifications and requirements down the supply chain.

8.4.3.1.2 The purchasing document shall state the OEM for all part numbers except supplier designed part numbers.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

8.5.1.1 Control of Equipment, Tools, and Software Programs

8.5.1.1.1 Control of Equipment, Tools, and Software - Supplemental Requirements

8.5.1.1.1.1 A Software Quality Assurance program for all non-deliverable software shall be implemented, documented, and maintained.

8.5.1.1.1.2 The Software Quality Assurance program (documented process) shall include:

- a. Responsibility and authority within the organization.
- b. Identification of requirements.
- c. Analysis of risks and criticality.
- d. Coding: Ensure coding standards are defined and include, but are not limited to:
 1. Software naming conventions (e.g., modules and executable software).
 2. Naming conventions including developmental and production file names.
 3. Header information with unique identifier and revision as a minimum.
- e. Documented change history for modifications.
- f. Verification: The intent of the verification phase is to ensure undetected errors from the coding process are found and corrected.
- g. Requirements for each new or revised software program to be tested prior to use and control of unapproved programs to prevent usage for production purposes.
- h. Verification of software for automated inspection (e.g., CMM) by correlation of the test results with the results from an independent method of inspection.
- i. Version and change control: Each version of the software program is uniquely identified.

8.5.1.1.1.3 The Software Quality Assurance program shall include a change control process that documents all software changes are appropriately reviewed for:

- a. Access control: The Software Quality Assurance program ensuring that the software is uniquely identified in the appropriate work instructions (e.g., routers, test plans):
 - 1. Access control restrictions being defined and implemented to ensure no obsolete or unapproved software resides in a production accessible library or machine memory.
- b. Software control: The Software Quality Assurance program ensuring protection of the software media from unauthorized changes.
- c. Training and maintenance.
- d. Documentation: Confirming compliance with export control and classification requirements.
- e. Supplier requirements (purchased/procured software): Purchase documentation (PO/statement of work), ensuring they describe the product to be purchased and that it is approved prior to communication to the supplier.
- f. Oversight (audit).

8.5.1.1.1.4 The organization shall establish a system for the management of pre-production and production tooling, jigs, and fixtures that includes (but is not limited to) the following:

- a. Unique tool identification.
- b. Validation of tool prior to release for production.
- c. Protection from damage and deterioration during storage.
- d. Maintained as fit for purpose.
- e. Storage and recovery.
- f. Tool setup.
- g. Tool life control/tool-change programs.
- h. Tool design modification documentation, including engineering change level.
- i. Tool modification and revision.

NOTE: The requirements in this paragraph can be applied at the individual site, individual division, or corporate levels within an organization.

8.5.1.2 Validation and Control of Special Processes

8.5.1.2.1 Validation and Control of Special Processes - Supplemental Requirements

Sampling of NDT is not permitted when the NDT is performed to fulfill a drawing or specification requirement, unless approved by the customer. This does not apply to in-process NDT used to increase yield.

8.5.1.3 Production Process Verification

8.5.1.4 Control of Production and Service Provision - Supplemental Requirements

8.5.1.4.1 The organization shall have a process to verify the correct metallic raw material is used when issued for production or concurrent with the start of the first operational process step in the manufacturing process.

8.5.1.4.1.1 Handheld spectrometry devices, or equivalent, shall be utilized to verify 100% of material. Industry sampling plans or equivalent zero-based acceptance sampling plans as described in alternate strategies to 100% (see [9.1.1.2](#)) may only be used for high volume purchases of material.

8.5.1.4.1.1.1 Exclusions to this requirement are:

- Product with a unique identifier linking to the material origin (e.g., serial number, lot number) unless otherwise agreed with the customer.
- Hardware (fasteners, bolts, nuts) or standard components at the point of assembly.

NOTE: The intent of the requirement is not to measure or control the manufacture of raw material but to ensure the material input at the part manufacturer is correct.

8.5.1.4.2 The organization, when applicable, shall have a documented process for managing the transfer of approved product definition from the design organization to the production organization, including prototypes. The documented process identifying the product definition is shared with the customer, as requested.

8.5.1.4.2.1 The organization shall ensure that all transfers of data comply with export control requirements.

8.5.1.4.3 The organization shall:

- a. Create a control plan (also referred to as a test/inspection plan) for all product characteristics and production operations (refer to RM13004), including:
 1. Where in the sequence the testing/inspection operations are performed.
 2. A reference to each product characteristic to be tested/inspected at each operation.
 3. The type of equipment required, and any specific instructions associated with their use.
 4. Criteria for acceptance and/or rejection.
 5. A reference to product test/inspection activities to be witnessed by the customer.
 6. Control plans for characteristics that are not tested/inspected when the product is in the final condition, e.g., inaccessible characteristics, characteristics tested/inspected before the product is in its final condition, characteristics that cannot be measured directly, characteristics subject to alternate strategies to 100% inspection (see [9.1.1.2](#)).
- b. Ensure 100% verification of all product characteristics in their final condition, i.e., at a stage where it is ensured that subsequent processing cannot affect the product characteristic verification result. This is not required for purchased standard catalogue hardware or sample or reduced inspection being applied in accordance with alternate strategies to 100% inspection requirements (see [9.1.1.2](#)).
- c. Ensure product test/inspection activities are conducted in an acceptable environment. This includes a requirement that lighting conditions provide at least 700 lx, and where visual inspections are performed, a white light intensity of at least 1000 lx is provided (requirement not applicable to NDT).

- d. Produce documented information of test and inspection, that includes as a minimum:
 - 1. Item inspected.
 - 2. Activity performed.
 - 3. Procedure/Instruction for the inspection activity.
 - 4. Date of inspection or surveillance activity.
 - 5. Personnel who performed the inspection or surveillance.
 - 6. Results of the inspection/surveillance.
 - e. Ensure when actual measurement values are routinely recorded during inspection, they are not being deliberately destroyed, deleted, altered, or exposed to hazards detrimental to record retention (e.g., fire or water hazard). This includes characteristics inspected:
 - 1. Using equipment where a report containing actual measurement values is automatically created (e.g., coordinate measurement machines, computer-connected digital equipment).
 - 2. Where measurement values are already routinely recorded for other reasons, e.g., statistical process control (SPC), KCs.
- 8.5.1.5 APQP and PPAP Process Verification - Supplemental Requirements
- 8.5.1.5.1 APQP and PPAP Process Verification requirements shall be met through compliance to 9145 APQP and PPAP; and [AS13100 - Chapters B and C](#).
- 8.5.1.5.2 APQP applies to new part introductions unless a pre-existing customer agreement exists.
- 8.5.1.6 First Article Inspection (FAI) - Supplemental Requirements.
- 8.5.1.6.1 The organization shall:
- a. Perform FAI in compliance to 9102; refer to RM13102.
 - b. In addition to the requirements of 9102 apply FAI to:
 - 1. A kit with a defined “bill of parts” to provide evidence all parts in the “kit” have an approved FAIR.
 - c. Perform FAI when:
 - 1. The production source is not able to provide evidence of an approved FAI report. Where the product predates the requirement for FAI, then an approved configuration or equivalent process that was agreed with the customer will be acceptable.
 - 2. Product is to be resourced and the customer requires a FAIR prior to production ceasing in the existing source. This can be referred to as Last Article Inspection (LAI) report.
 - 3. Requested by a customer.

- d. Conduct an evaluation, to determine the required verification when changes occur that can invalidate a previous FAI. The evaluation is to consider:
 - 1. The impact of the change on the ability of the production method to meet product design characteristics.
 - 2. Equipment and associated software programs, personnel, and environment.
 - 3. The accumulation of changes covered by partial FAI or dimensional/non-dimensional reports which may warrant a repeat full FAI being performed.
- e. Retain a formal record of the evaluation for audit purposes (see [8.5.6](#)).
- f. Verify characteristics in the final product, i.e., after all production activities have been completed (unless otherwise instructed by the product definition), including:
 - 1. Ensuring inspection equipment is:
 - i. Traceably calibrated, within its valid calibration period, and measurement systems to be assessed are in accordance with [7.1.5.1.1](#).
 - ii. Independent of production inspection equipment. Exceptions must be approved by the customer.
 - 2. Ensuring characteristics not accessible in the final product are measured during the production process.
 - i. When subsequent production activities can affect the characteristics, ensuring they are verified by destructive means, unless it can be shown (with evidence included in the FAIR) that the characteristic in the final product is not different (is equivalent) to the characteristic verified during the production process. This does not apply when the product definition instructs the characteristics to be verified prior to the production activity, e.g., coating, painting, shot peening.
- g. Compile and submit a FAIR using the customer electronic system for FAIR submittal (e-FAIR), ensuring:
 - 1. The submission follows the purchase order cascade, e.g., Tier-2 to Tier-1 to OEM customer, unless otherwise instructed.
 - 2. When a supplier does not have access to e-FAIR, that the forms in 9102 are used, in conjunction with any customer-specific forms (e.g., customer checklist).

8.5.1.7 Fixed Production Methods - Supplemental Requirements

- 8.5.1.7.1 Fixed Production Method applies to all the organizations, when the product definition specifies “fixed process control” or similar, e.g., production process, frozen process, engineering source approval/substantiation.
- 8.5.1.7.2 The organization shall implement the necessary fixed production controls as defined by the customer.

8.5.1.8 Vision Standards - Supplemental Requirements

The organization shall:

- a. Ensure non-NDT personnel engaged in product verification and inspection activities (e.g., certified operators and/or final inspectors) are examined annually. Eyesight acuity requirements being a minimum of Curpax N5, Jaeger #2, or equivalent in at least one eye or when using both eyes together at a distance not less than 16 inches. These non-NDT inspectors shall also be required to pass a one-time color vision perception test as required in the process involved.
- b. Ensure vision tests are performed by suitably trained and qualified personnel.
- c. Ensure vision correcting eyewear (e.g., glasses, contact lenses) used by personnel to pass the vision examination are worn when performing product verification/inspection activities.
- d. Ensure the use of any tinted or darkened lenses or those that darken on exposure to light are prohibited.

8.5.1.9 Appointment of Competent Persons, Including Any Required Qualification - Supplemental Requirements

8.5.1.9.1 The organization shall:

- a. Ensure employees directly inspecting product are formally authorized.
- b. Ensure product is released by authorized personnel.
- c. Ensure when an operator self-verification program is implemented, it conforms to 9162 requirements.

NOTE: All elements of the operator self-verification program and plan are subject to customer approval.

8.5.1.9.2 Personnel responsible for the review of material and special process test reports shall be trained to read, interpret, and evaluate test results for the purpose of assuring that all drawing and/or specification requirements of the final product are met.

8.5.1.9.3 The method employed to evaluate material and special process test report results shall be documented and provided for the review of each test, as required, per the applicable drawing and/or specification. The methodology to be employed may be subject to customer approval.

8.5.2 Identification and Traceability

8.5.2.1 Identification and Traceability - Supplemental Requirements

8.5.2.1.1 The system for assigning serial numbers shall provide traceability to the following information:

- a. Higher configuration level part or assembly identification numbers.
- b. Date of assignment.
- c. Explanation for deviations from expected sequence or practice.
- d. Record of serial numbers assigned to rejected items.

8.5.2.1.2 If serialized or lot numbered parts are manufactured from serialized or lot numbered material, then traceability shall be maintained to those details and their product acceptance records.

8.5.4 Preservation

8.5.4.1 Preservation - Supplemental Requirements

The organization shall develop and establish a FOD prevention program in accordance with 9146.

8.5.6 Control of Changes

8.5.6.1 Control of Changes - Supplemental Requirements

8.5.6.1.1 The organization shall have a process to manage shift and task handovers including rapid escalation and resolution of associated issues.

8.5.6.1.2 Where customer approval of changes to production or service provision are contractually required, then the organization shall ensure that the changes are managed through 9145, configured to the type of change and that the proposed change are approved by the customer prior to implementation; see [AS13100 - Chapters B and C](#).

8.5.6.1.2.1 APQP applies when agreed between the customer and the organization.

8.6 Release of Products and Services

8.6.1 Release of Products and Services - Supplemental Requirements

8.6.1.1 Controls to manage the risks associated with “releasing products and services at risk” shall be documented by the organization and define the key accountabilities to ensure that the required controls are implemented, including those of external stakeholders.

8.6.1.2 The risk release of products and services throughout the supply chain shall only take place once the required approvals, including the customer, if applicable, have been received.

NOTE: Risk release typically is used to describe all actions taken in advance of full completion and/or approval of a process step, an operation, an inspection, or a test.

8.6.1.3 Product subject to risk release shall be clearly identified as being subject to risk release with traceability to the approval document.

8.6.1.4 When required by the customer, the organization shall work in accordance with 9117 and AS13001 in defining its minimum system and personnel requirements for customer product release programs.

8.7 Control of Nonconforming Outputs

8.7.1.1 Control of Nonconforming Outputs - Supplemental Requirements

8.7.1.1.1 For product subject to frozen process control, the supplier shall have a process for rework.

8.7.1.1.1.1 The organization shall review the nonconformance to determine if it is possible to rework the product to meet the product definition.

8.7.1.1.1.2 All product rework shall have documented work instructions.

NOTE 1: Where rework is not possible, the organization should evaluate if repair is appropriate.

NOTE 2: If repair is required, then the design responsible organization determines if a repair is appropriate.

8.7.1.1.2 The organization shall obtain authorization approval for all repair instructions for the correction of nonconforming product. When repair or rework is necessary, refer to RM13011.

9. PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

9.1.1.1 Monitoring and Measurement of the Manufacturing Process - Supplemental Requirements

- 9.1.1.1.1 The organization shall determine, document, and deploy the most appropriate process control methods to ensure continued conformity of each product characteristic (e.g., process development, process FMEA, capability study, and control plan creation).

NOTE 1: For a range of industry recognized process control methods and methods for capability studies, refer to RM13006.

NOTE 2: For a range of industry recognized risk identification and mitigation methods, refer to RM13004.

NOTE 3: Validation of the production process and key characteristics is through the application of initial process studies; see [16.6.9](#).

- 9.1.1.1.2 Process/operation specific controls shall be captured in the control plan and/or work instruction for the operation or alternative plan if the control is not operation specific (e.g., routine maintenance activity).

NOTE: Control activities not directly aligned to a specific product or process step may be included in separate plans for those activities (e.g., machine tool maintenance plan, fixture, tooling inspection/qualification plan).

- 9.1.1.1.3 The organization shall demonstrate the effectiveness of the process control methods for high-risk items as identified in the PFMEA using process capability studies.

- 9.1.1.1.4 When process capability studies are utilized, the process stability shall be analyzed using SPC control charts.

- 9.1.1.1.5 Process stability (i.e., statistical control) shall be understood prior to process capability analysis using SPC control charts. Wherever possible, the data collection and monitoring activity through the use of SPC control charts shall be done at the transformation operation. Refer to RM13006.

- 9.1.1.1.5.1 Where stability is not achieved, the organization shall investigate the causes for instability, take appropriate actions to establish best possible stability and ensure product meets customer requirements.

- 9.1.1.1.6 In addition to the PFMEA high risk items, process capability studies shall be performed on all KCs.

- 9.1.1.1.7 The organization shall implement Temporary Key Characteristics (TKCs) to validate the effectiveness of corrective actions for dimensional escapes upon request of the customer.

- 9.1.1.1.8 KCs shall be monitored continuously with the information being made available to the customer upon request.

- 9.1.1.1.9 When a process capability study is required, the process shall first be determined to be stable, followed by a capability index value greater than or equal to 1.33 (or equivalent attribute value, if appropriate).

NOTE 1: The customer may require higher minimum capability thresholds; see [16.6.9](#).

NOTE 2: Ppk is the standard capability index. If a different capability index is agreed upon by the customer (such as Cpk), the same requirement for stability applies.

- 9.1.1.1.10 In addition to customer identified KCs, the organization shall assess the need for their own KCs that are important for their process or are related to high FMEA risk areas.

- 9.1.1.1.11 Personnel using SPC control charts shall be trained in data collection, monitoring, the use of tests for special cause variation (Western Electric Rules, refer to RM13006) to determine process stability, and how to react to out-of-control process situations.

9.1.1.1.12 Where capability or stability is lost in manufacturing, the organization shall identify root cause(s) and implement mitigation actions with all corrective actions being formally recorded.

NOTE: The reaction plan (refer to RM13004 and RM13006) or a systematic problem-solving method such as 8D can be used (refer to RM13000).

9.1.1.1.13 The effectiveness of the corrective action shall be validated by the reestablishment of the process stability and capability.

9.1.1.1.14 If process capability does not reach the minimum capability but has reached a point where it cannot be improved further (or further improvement is prohibitively costly), the organization shall develop a control plan that assures the customer receives conforming product without supply disruption.

9.1.1.1.15 The control plan shall be updated to reflect any changes to the process control system used to monitor the process.

9.1.1.2 Alternate Strategies to 100% Inspection (Alternate Strategies) - Supplemental Requirements

9.1.1.2.1 The organization shall have a documented process within its own quality system to control inspection which meets the requirements set forth by the customer.

9.1.1.2.2 Product acceptance for drawing characteristics shall be 100% inspected unless customer-specific alternate strategies to 100% inspection (e.g., sampling plans) are flowed down to the organization, or the organization has a customer approval for use of an alternate strategy. Refer to RM13002 for guidance on alternate strategy options.

9.1.1.2.3 The organization shall receive documented approval for the alternate inspection strategies.

9.1.1.2.4 One customer's approval shall not be extended to another customer's product without that customer's approval.

9.1.1.2.5 The organization shall define the characteristics which use the alternate strategy to 100% inspection and the associated process controls to ensure continued conformance.

9.1.1.2.6 The approved alternate strategy to 100% inspection and the reaction plan shall be documented within the control plan or equivalent documentation. Refer to RM13004 and RM13006 for guidance.

9.1.1.2.7 The reaction plan shall be followed whenever an agreed acceptance criterion is not met.

9.1.1.2.8 For features under alternate strategies to 100% inspection, the control plan shall include a periodic check of product features that are not routinely verified (e.g., when the mold, fixture, or tooling is inspected).

9.1.1.2.9 Inspection shall return to 100% (or other agreed inspection level) until the corrective actions have been implemented and requalification requirements (if necessary) are met for the relevant drawing characteristics. Validation of the corrective actions by the customer may be required.

9.1.1.2.10 Any change to the approved alternate strategy to 100% inspection shall be subject to the customer's standard change control requirements.

9.1.1.3 Understanding of Statistical Concepts - Supplemental Requirements

9.1.1.3.1 The organization shall ensure that the statistical concepts of variation are understood in the context of manufacturing capability and measurement capability.

9.1.1.3.2 All employees engaged in the collection, analysis, and management of statistical data, including control charting, establishing inspection frequency, process capability, and measurement capability, shall be able to demonstrate their competency through training or other means. For specific training syllabus guidance and details, refer to RM13006.

NOTE: Examples of statistical data used in AS13100 are control charting, establishing inspection frequency, Alternate Strategies to 100% Inspection, process capability, and measurement capability.

9.1.2 Customer Satisfaction

9.1.2.1 Customer Scorecards - Supplemental Requirements

9.1.2.1.1 The organization shall ensure that customer scorecards are used as a focus for customer satisfaction monitoring.

9.1.2.1.2 Improvement plans shall be developed to address identified performance gaps.

9.1.2.1.3 The organization shall strive to achieve and maintain 100% quality products and delivered on time.

9.1.2.1.3.1 Where this is not being achieved, the organization shall define an improvement program to address deficiencies.

9.2 Internal Audit

9.2.3 Internal Audit - Supplemental Requirements

9.2.3.1 The organization shall have a documented process that describes the internal audit process.

NOTE: The audit types described in this section can also form the basis for supplier audit activities (see [8.4.2.5](#))

9.2.3.2 The audit plan shall include all elements within the scope of the management system (refer to RM13005) and include:

- a. Quality system audits.
- b. Production process audits.
- c. Product audits.
- d. Special process audits.

9.2.3.3 For default frequency for each type of internal audit, see [Table 9](#).

Table 9 - Internal audit types and frequency

Audit Type	Scope	Frequency
Quality system audits	Entire Quality Management System.	Within 3 years
	▪ Internal audit management. ▪ Contract review and flow down of customer requirements. ▪ Control of work transfers. ▪ Control of suppliers. ▪ Control of design and development changes. ▪ Control of nonconforming product. ▪ Management of fixed processes.	Annually
Production process audits	Every production process.	Within 3 years, unless otherwise agreed with customer
Product audits	As required by the customer.	
Special process audits	All processes classified as special processes.	Annually

9.2.3.4 Quality system audits shall include the review of compliance to the appropriate Industry QMS standard, i.e., 9100, ISO 9001, and this standard.

9.2.3.5 The organization shall ensure that regulatory and customer-specific quality system requirements are included within the audit scope, as applicable.

9.2.3.6 The production process audit shall be conducted using a defined checklist appropriate to the complexity of the production of the product or equivalent to the VDA 6.3 checklist (see [2.5](#)), or provided by customers; refer to RM13005. Production process audits should include samples from all standard shifts operated by the organization over the course of the audit cycle.

9.2.3.7 The special process audit shall be conducted annually (regardless of the Nadcap merit scheme status) using a Nadcap Audit Criteria (AC), customer or an internally developed checklist.

NOTE: If the special process is not Nadcap accredited, then the organization can use either the Nadcap AC for that process, supported by customer specifications, or a checklist developed by the customer or the organization that fully evaluates the conformity of the process.

9.2.3.7.1 The frequency of audits shall be reviewed and be increased, if required, due to process changes, quality performance, or risk.

9.2.4 Audit Nonconformance Related to Product Quality - Supplemental Requirements

9.2.4.1 If any audit identifies a nonconformance impacting product conformity, the nonconformance shall be addressed (see [8.7](#) and [10.2](#)).

9.3 Management Review

9.3.2 Management Review Inputs

9.3.2.1 Management Review Inputs - Supplemental Requirements

9.3.2.1.1 Management Reviews shall be conducted at least annually and include the following performance topics:

- a. Cost of poor quality (COPQ).
- b. Manufacturing/assembly right first time/first pass yield.
- c. Customer scorecards (where available).
- d. Human factors reporting.

9.3.3 Management Review Outputs

9.3.3.1 Management Review Outputs - Supplemental Requirements

9.3.3.1.1 The organization shall document and implement an action plan when agreed customer performance targets are not met.

10. IMPROVEMENT

10.2 Nonconformity and Corrective Action

10.2.3 Problem Solving Methods for Customer Escapes - Supplemental Requirement

- 10.2.3.1 When a nonconforming product escapes to the customer and where the organization is required to conduct a problem investigation by the customer, then the default problem solving methodology shall be the AESQ 8D problem solving process approach (steps D0 to D8); refer to RM13000. Alternative approaches may be acceptable to the customer with prior approval provided they meet the same intent.
- 10.2.3.2 Where suspected nonconformance is observed at any point in the product lifecycle (including design) and there is customer impact, the organization shall take immediate containment action to protect the customer.
- 10.2.3.3 Immediate response actions (refer to RM13000, step D0) in 8D shall be completed within 48 hours of the problem being identified unless otherwise agreed with the customer.
- 10.2.3.4 It is the organization's responsibility to fully contain the escape (refer to RM13000, step D3) implementing interim containment actions (ICA) by identifying all parts affected across the value chain. The organization shall work with key stakeholders, including the customer(s) and suppliers (if relevant), to ensure that containment is effective. The timescale for full containment being appropriate to the risk impact of the problem.
- 10.2.3.5 The organization shall communicate the status of the containment activity to the customer at regular intervals.
- 10.2.3.6 The organization, having initiated containment action, shall identify and complete root cause analysis, (refer to RM13000, D4) and corrective action(s) (refer to RM13000, D5) in a reasonable timescale to meet customer requirements.
- 10.2.3.7 The organization shall define an implementation plan for the corrective and preventive actions required and monitor progress.

NOTE: Corrective actions are taken to eliminate the cause of a nonconformity and to prevent recurrence. Preventive actions are taken to eliminate the cause of a potential nonconformity or other potential undesirable situation.

- 10.2.3.8 The organization shall take systemic action to prevent recurrence of this problem and other similar problems and capture the lessons learned.
- 10.2.3.9 The organization shall update all related DTDP(s) relative to the root cause generation and escape points.
- 10.2.3.10 The organization shall update the process flow diagram (PFD), process FMEA, and control plan with any lessons learned from the investigation, e.g., process FMEA occurrence and detection scores, control plan activities.
- 10.2.3.11 When the customer requires an investigation report from the organization as evidence of the problem-solving activity for a product nonconformance, it shall be provided using the AESQ 8D summary report, or one with an equivalent content (refer to RM13000).
- 10.2.3.12 The organization shall analyze the causes of each type of nonconformity and determine risk based prioritized improvement plans to continually improve performance (see [10.3.1](#)).
- 10.2.3.13 The organization shall ensure that it has problem solving practitioners that are trained and competent in the use of AESQ 8D problem solving methodology.

NOTE: For details of recommended training syllabus for problem solving specialists, refer to RM13000.

- 10.2.3.14 The organization shall have a criteria and approach defined for recognizing and addressing human factors causes in investigations, e.g., maintenance event decision aid; refer to RM13010.

10.2.4 Customer Complaints and In-Service Failures - Supplemental Requirements

- 10.2.4.1 The organization shall perform analysis on customer complaints and initiate problem solving and corrective action to prevent reoccurrence.
- 10.2.4.2 To the extent contractually agreed between the organization and the customer, the organization shall:
- Perform analysis on in-service failures of products that the organization has designed and initiate problem solving and corrective action to prevent reoccurrence.
 - Include analysis of any interaction of embedded software of the organization's product within the system of the customer's product.
 - Communicate the results of analysis to the customer and within the organization.

10.3 Continual Improvement

10.3.1 Continual Improvement - Supplemental Requirements

- 10.3.1.1 The organization shall have a systematic approach to continual improvement, including:
- Identification of the appropriate methodology used, objectives, measurement, effectiveness, and documented information.
 - A manufacturing process improvement action plan with emphasis on the reduction of process variation and waste; refer to RM13006.
 - Use of risk evaluation processes to identify potential areas of concern. This may be derived from such tools as FMEA and business continuity risk registers.

NOTE: Improvement methodologies can include approaches such as LEAN, 6 Sigma, 5S, etc. The organization should have a defined improvement process and have trained practitioners.

AS13100 - Chapter B
9145 - Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP) -
AESQ Supplemental Requirements

NOTE: The numbers in parentheses, preceding the paragraph text, relate to the paragraph numbering sequence applied in 9145.

13. (1. - 9145) SCOPE

13.3 Scope (APQP) - Supplemental Requirements

13.3.1 All or some phases of APQP are applicable to a:

- a. New product design or change to design.
- b. New or change to production location or source producing the product.
- c. New process or process change unless process change is negligible.

NOTE: Examples of negligible process change include:

- Change that does not have the potential to impact the performance of the process (quality, cycle time).
- Change of tooling that is not specific to process and an equivalent.
- Change that does not impact process stages that control or monitor KCs.
- Change that does not require a change to inspection/test methods.
- Change that does not introduce additional or alternative processing.

(Refer to RM13145)

16. (4. - 9145) ADVANCED PRODUCT QUALITY PLANNING (APQP) REQUIREMENTS

16.1 (4.1 - 9145) General Requirements

16.1.4 Refer to 9145:11/2016 - 4.1.4 requirements.

NOTE: RM13145 Applicability Matrix tables are considered when defining application of APQP.

16.1.6 APQP - Supplemental Requirements

16.1.6.1 The organization shall:

- a. Establish a documented procedure, to comply with AESQ APQP and PPAP requirements (see [16.1](#)).

NOTE: AESQ APQP and PPAP Flow (see [Figure 2](#)) provides a model for an organization's procedure.

- b. Apply supply chain risk management process (see [Section 18](#)) and provide result, unless otherwise specified by the customer.

APQP and PPAP Process Flow

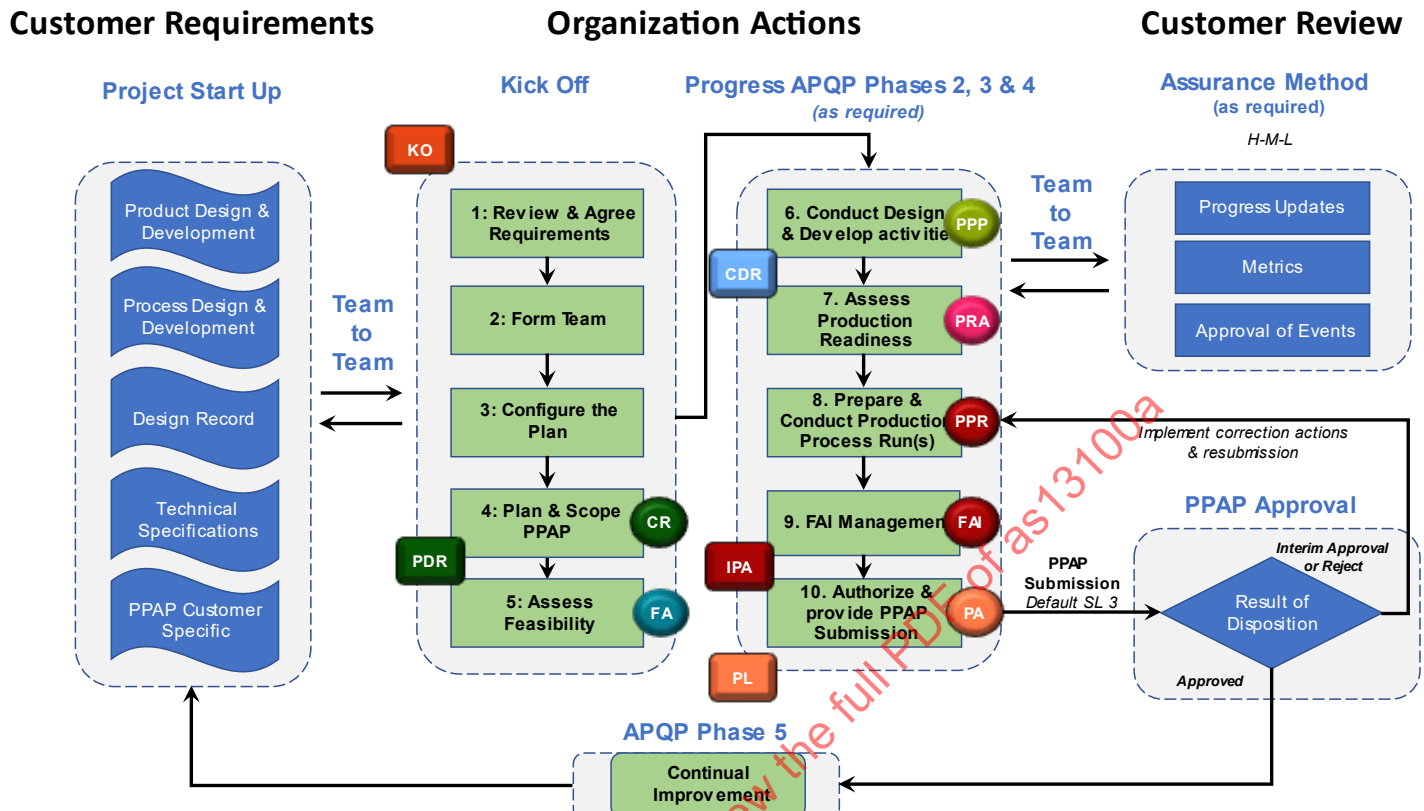


Figure 2 - APQP and PPAP flow plan diagram

16.1.7 APQP and PPAP Flow and APQP and PPAP Timing Plan Illustrations - Supplemental Requirements

16.1.7.1 The APQP and PPAP flow (see [Figure 2](#)) describes a customer/supplier management process for any product APQP and PPAP. This is harmonized with 9145, using AESQ APQP and PPAP events, (a development of those found within 9145) and APQP and PPAP timing (see [Figure 3](#)) which develops the conceptual illustration found within 9145.

16.1.7.2 A description of PPAP events are defined in [Table 10](#) (refer to RM13145) which provides detail on both the APQP and PPAP flow as well as APQP and PPAP timing plan.

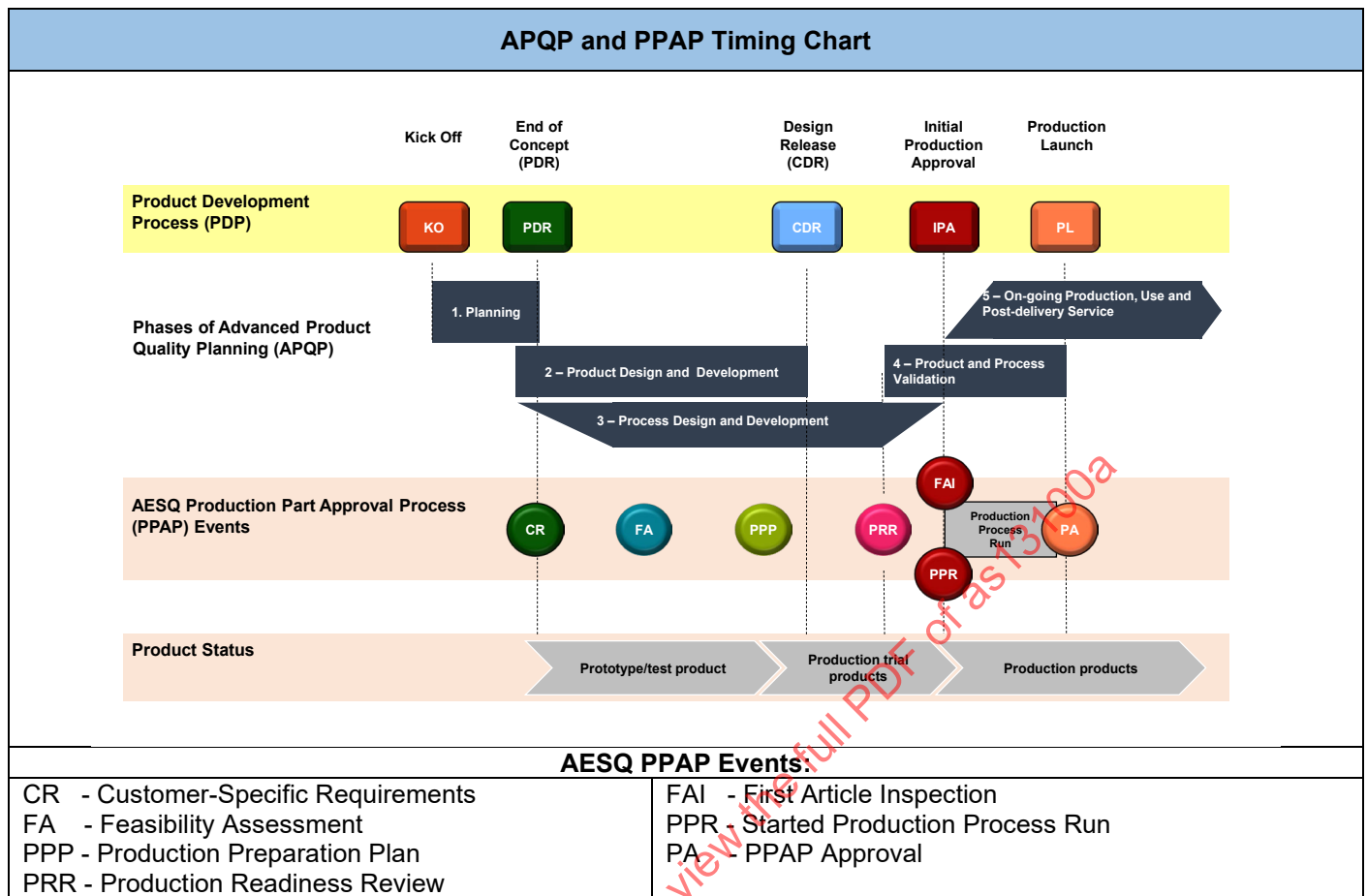


Figure 3 - APQP and PPAP timing chart illustrations

Table 10 - AESQ PPAP events

Ref	Event	Description
	Customer-Specific Requirements	The purpose of this event is to be confident that early agreement has taken place for any additional PPAP requirements for the product specified by the customer and/or the organization. Refer to RM13145. Customer-specific requirements for PPAP are explained more within Tables 13 and 14.
	Feasibility Assessment	The purpose of this event is to be confident at an early stage of the project in the potential to produce the product design during production. This confidence is established through the involved production supply organization(s) assessment of feasibility. i.e., the facility or facilities intended for producing the product are satisfied and agreed that the proposed design can be manufactured, assembled, tested, packaged, and delivered in enough quantity, on schedule and at an acceptable cost to the customer. The scope of feasibility agreed in this context can be for a new engineering design, modification, or an existing product that is new to the facility such as a transfer from one facility to another.
	Production Preparation Plan	The purpose of this event is to be confident that the preparation planning is suitable for the level of complexity being managed and resources needed by the production supply organization. i.e., the facility or facilities intended for producing the product have identified and planned all resources (e.g., production and test/inspection equipment, tooling, jigs, fixtures, computing processes, materials, supply chain, trained work force, facilities) required to produce a product in enough quantity to satisfy the customer demand rate.
	Production Readiness Review	The purpose of this event is to be confident that the production processes are appropriately defined, documented, and ready for production by the production supply organization. i.e., the facility or facilities intended for producing the product have assessed and are satisfied with the process design and development activities (e.g., operator training, manufacturing documentation, control plan, associated measurement tools, specification of equipment, tools and fixtures, maturity of developed processes and their evaluations such as manufacturing readiness level).
	Production Process Run start	The purpose of this event is to be confident that the production validation activities are progressing, and physical demonstration is underway. i.e., the facility or facilities involved have started to produce product from the processes intended for on-going serial production (processes evaluated in the PRR).
	First Article Inspection	The purpose of this event is to be confident that product verification needs have been satisfied. i.e., the facility or facilities involved have applied First Article Inspection.
	PPAP Approval	The purpose of this event is to be confident that process validation results have been understood and needs have been satisfied. i.e., the facility or facilities involved have evaluated and provided the PPAP submission for disposition.

16.2 (4.2 - 9145) Advanced Product Quality Planning Project Management

16.2.1 Advanced Product Quality Planning Project Management - Supplemental Requirements

16.2.1.1 The organization shall:

- a. Account for supply chain risk management process (see [Section 18](#)) when developing and managing the plan.
- b. Develop metrics that monitor progress and satisfaction of APQP and PPAP events.
- c. The organization shall account for APQP and PPAP elements when planning APQP deliverables for APQP Phases 2, 3, and 4. Refer to RM13145 Applicability Matrix tables.

16.3 (4.3 - 9145) Phase 1 Requirements - Planning

16.3.5 Phase 1 - Planning - Supplemental Requirements

- 16.3.5.1 The organization shall account for supply chain risk management process (see [Section 18](#)) when developing project plan.

16.4 (4.4 - 9145) Phase 2 Requirements - Product Design and Development

16.4.7 Phase 2 - Product Design and Development - Supplemental Requirements

- 16.4.7.1 The organization shall use design FMEA to satisfy design risk analysis; refer to RM13004.

NOTE: Further risk analysis may be needed to assess safety and criticality.

16.5 (4.5 - 9145) Phase 3 Requirements - Process Design and Development

16.5.10 Phase 3 - Process Design and Development - Supplemental Requirements

16.5.10.1 The organization shall:

- a. Conduct process flow diagrams (PFDs), process FMEA, and control plans (see NOTE 1); refer to RM13004. These shall be completed for a specific part number. A family or group of parts approach is not allowed unless approved by the customer.
- b. Account for supply chain risk management process (see [Section 18](#)), when developing production preparation plan.
- c. Include all requirements of the design record when developing the inspection/test plan (workstation documentation).
- d. Have developed a prelaunch control plan (see [Section 19](#)) when product verification, process validation, and/or data capture activities are to take place.
- e. Develop the associated MSA plan to satisfy MSA requirements for the product as defined in [Tables 3](#) and [4](#) (see NOTE 2). For additional guidance on planning, refer to RM13003 and RM13145.
- f. Include the requirements of this paragraph when conducting a production readiness review (PRR).

NOTE 1: This is an element of the PPAP file and may be required for the submission (submission levels).

NOTE 2: MSA plan documents the planned activities that are to be carried out during APQP Phase 4 (product and production validation) to satisfy MSA requirements for the product.

16.6 (4.6 - 9145) Phase 4 Requirements - Product and Process Validation

16.6.9 Phase 4 - Product and Process Validation - Supplemental Requirements

16.6.9.1 The organization shall:

- a. Conduct MSA per [16.5.10.1.e](#) and MSA plan.
- b. Use product from the production process run (see [Table 13](#)) to conduct Initial manufacturing performance studies as part of the capacity verification. Refer to RM13145 (see NOTE).
- c. Determine the process stability and capability for KCs; see [9.1.1](#). When conducting initial process capability studies (see [Table 13](#)), refer to RM13145 (see NOTE).
- d. Use product from the production process run (see [Table 13](#)) to determine the dimensional/nondimensional results; refer to RM13145.
- e. Review and revise, if necessary, the developed control plan to ensure it represents the approved production process. (see [Section 19](#)) (see NOTE).
- f. Conduct FAI in accordance with 9102 (see NOTE).
- g. Complete the PPAP submission in accordance with the AESQ PPAP requirements (see [Table 13](#)).

NOTE: This is an element of the PPAP file and may be required for the submission (submission levels).

17. (5. - 9145) PRODUCTION PART APPROVAL PROCESS REQUIREMENTS

17.1 (5.1 - 9145) Process Requirements for Production Part Approval Process

17.1.1 Process Requirements for Production Part Approval Process - Supplemental Requirements

17.1.1.1 The organization shall:

- a. Define the person(s) responsible for PPAP approval (PPAP Coordinators) and their qualification, including provided customer qualifications and the use of customer authorized representatives when specified by the customer.

NOTE: Regarding details of the role profile and recommended qualification requirements for the organization's PPAP coordinators and customer authorized representatives; refer to RM13145.

- b. Develop the PPAP file and PPAP submission for the product(s) in accordance with submission/retention levels (see [Table 11](#)), AESQ PPAP elements requirement (see [Table 13](#)), and customer-specific requirements (see [Table 14](#)).
- c. Provide the PPAP submission in accordance with Submission Level 3 (see [Table 11](#)) as the default, unless otherwise specified by the customer.

- 17.1.1.2 For submission/retention levels (see [Table 11](#)), this defines submission, witness, and retention requirements associated to each submission level. In all instances, supporting data for the PPAP elements shall be gathered regardless of the submission level and held within the PPAP file. Applicability is mandated through this AESQ APQP and PPAP standard and/or customer requirements. For typical use of PPAP elements for various types of situations, see [Table 12](#).

Table 11 - Submission/retention levels

PPAP Element Number	AESQ PPAP Element	Submission Level				
		SL 1	SL 2	SL 3	SL 4	SL 5
P1	Design record	S R	S R	S R	C R	S R W
P2	Design FMEA	R ⁽¹⁾	R ⁽¹⁾	S R ⁽¹⁾	C R ⁽¹⁾	S R W ⁽¹⁾
P3	Process flow diagram	R	R	S R	C R	S R W
P4	Process FMEA	R	R	S R	C R	S R W
P5	Control plan	R	S R	S R	C R	S R W
P6	Measurement system analysis verification	R ⁽²⁾	R ⁽²⁾	S R ⁽²⁾	C R ⁽²⁾	S R W ⁽²⁾
P7	Initial process capability studies	R	S R	S R	C R	S R W
P8	Packaging, labeling standard, and documentation	R	R	S R	C R	S R W
P9	First article inspection	R ⁽³⁾	S R ⁽³⁾	S R ⁽³⁾	C R ⁽³⁾	S R W ⁽³⁾
P10	Customer-specific requirements	R	S R	S R	C R	S R W
P10.1	Dimensional/nondimensional results	R	S R	S R	C R	S R W
P10.2	Initial manufacturing performance studies	R	R	S R	C R	S R W
P11	PPAP approval form (or equivalent)	S R	S R	S R	C R	S R

Key/Legend	
S	Submit to customer (or nominated representative).
R	Retain a record as part of the PPAP file and make available to the customer upon request.
C	Consult customer - submission (S) and/or witness (W) may be required.
W	Witness by customer (or nominated representative) through a supporting data/information review at manufacturing location.

⁽¹⁾ Design and manufacture organization only.

⁽²⁾ When specified by the related MSA Plan (Phase 3 of APQP).

⁽³⁾ In accordance with 9102.

Table 12 - Typical use of PPAP elements

PPAP Element Number	AESQ PPAP Element	Situation						
		New Product Design	Product Design Change	Transfer From One Facility to Another (No Product Mod)	New Process (No Product Mod or New Product Design)	Processing Changes (No Product Mod)	Specific To Process Tooling Replace/Refurb.	Negligible Process Change ⁽⁴⁾
P1	Design record	X	X					
P2	Design FMEA	X ⁽¹⁾	X ⁽¹⁾					
P3	Process flow diagram	X	X	X	X	X		
P4	Process FMEA	X	X	X	X	X		
P5	Control plan	X	X	X	X	X		
P6	Measurement system analysis verification	X ⁽²⁾	X ⁽²⁾	X ⁽²⁾	X ⁽²⁾	X ⁽²⁾	X ⁽²⁾	
P7	Initial process capability studies	DR	DR	DR	DR	DR	DR	
P8	Packaging, labeling standard, and documentation	X	X	X	X	X		
P9	First article inspection	X ⁽³⁾	X ⁽³⁾	X ⁽³⁾	X ⁽³⁾	X ⁽³⁾	X ⁽³⁾	X ⁽³⁾
P10	Customer-specific requirements	X	X	X	X	X	X	
P10.1	Dimensional/nondimensional results	X	X	X	X	X	X	
P10.2	Initial manufacturing performance studies	X	X	X	X	X		
P11	PPAP approval form (or equivalent)	X	X	X	X	X	X	

Key/Legend	
X	Recommended (mandatory if customer and/or regulator require this) for the related situation with either: - Create new. - Update the existing. - Develop in part aligned to what has changed.
DR	Consideration is given to the requirements of the design record (e.g., identification of KCs).
Blank	Create, update, or develop task is unlikely. Apply, retain and submit requirements in accordance to Table 11 and the assigned submission level.

(1) Design and manufacture organization only.

(2) When specified by the related MSA plan (Phase 3 of APQP).

(3) In accordance with 9102.

(4) Examples of negligible process change include:

Change that does not have the potential to impact the performance of the process (quality, cycle time).

Change of tooling that is not specific to process and an equivalent.

Change that does not impact process stages that control or monitor KCs.

Change that does not require a change to inspection/test methods.

Change that does not introduce additional or alternative processing.

17.2 (5.2 - 9145) Production Part Approval Process File and Submission

17.2.3 Production Part Approval Process File and Submission - Supplemental Requirements

17.2.3.1 The organization shall:

- a. Meet all specific requirements of the AESQ PPAP elements requirements; see [Table 13](#).
- b. Ensure that the PPAP coordinator (see [17.1.1](#)) for the product has reviewed the PPAP submission and authorized the PPAP approval form (or equivalent) on behalf of their organization.

Table 13 - AESQ PPAP elements requirement

PPAP Element Number	AESQ PPAP Element	Section Reference
P1	Design record	Phase 2 Requirements - Product Design and Development (see 16.4).
P2	Design FMEA	- Phase 2 Requirements - Product Design and Development (see 16.4). - Refer to RM13004.
P3	Process flow diagram	- Phase 3 Requirements - Process Design and Development (see 16.5). - Refer to RM13004.
P4	Process FMEA	- Phase 3 Requirements - Process Design and Development (see 16.5). - Refer to RM13004.
P5	Control plan	- Phase 3 (if required) and 4 Requirements - Process Design and Development⁽¹⁾ (see 16.5 and Section 19) - Refer to RM13004 template or an equivalent. - Refer to RM13006 Process Control Methods.
P6	Measurement system analysis verification	- Phase 4 Requirements - Product and Process Validation (see 16.6). - Refer to RM13003.
P7	Initial process capability studies	- Phase 4 Requirements - Product and Process Validation (see 16.6). - Refer to RM13006.
P8	Packaging, labeling standard, and documentation	- Phase 3 Requirements - Process Design and Development (see 16.5). - Refer to RM13145.
P9	First Article Inspection	Phase 4 Requirements - Product and Process Validations (see 16.6).
P10	Customer-specific requirements	- Phase 4 Requirements - Product and Process Validations (see 16.6). - Refer to RM13145. These are additional requirements specified by the customer and/or the organization that apply during the application of PPAP, e.g., customer demand rate target, process quality targets, dates for PPAP events to be satisfied, number of products to be produced during the production process run or runs and additional PPAP elements.⁽²⁾

PPAP Element Number	AESQ PPAP Element	Section Reference
P10.1	Dimensional/ nondimensional results	- Have recorded dimensional, material, and/or performance test results defined by inspection/test plans (workstation documentation) from randomly selected products⁽³⁾ produced during the production process run. - Evaluate conformity⁽⁴⁾ and record the results.⁽⁵⁾ - Refer to RM13145.
P10.2	Initial manufacturing performance studies	The organization as part of their capacity verification shall: - Have determined target values for manufacturing process operations (process cycle time and yield) to achieve the customer demand rate. - Have conducted initial manufacturing studies during a production process run to measure manufacturing process operations (process cycle time and yield).⁽⁶⁾ - Evaluate the results to determine the achievement of target values and potential to satisfy customer demand rate. - Confirm results to customer. - Refer to RM13145.
P11	PPAP approval form (or equivalent)	- Phase 4 Requirements - Product and Process Validations (see 16.6). - PPAP - Approval Form (9145 - Appendix D).

⁽¹⁾ Customer approval of the control plan applies unless otherwise specified by the customer (see [Section 18](#)).

⁽²⁾ See [Table 14](#) for common AESQ customer-specific requirements; it provides descriptions and meaning for additional PPAP Elements that may be occasionally required by customers using this standard.

⁽³⁾ The quality of products used should be suitable for the type of evaluation and customer-specific requirements.

⁽⁴⁾ Conformity evaluation includes achievement of process quality targets (process quality performance) specified by the organization and customer.

⁽⁵⁾ Results can be used to support confirmation or customer approval of meeting process quality targets, approval of Alternate Strategies to 100% Inspection (see [9.1.1.2](#)), data associated to sample products.

⁽⁶⁾ Initial manufacturing studies demonstrate the achievement of target process cycle time and yields; therefore, this indicates a potential (not an assurance) to satisfy customer demand rate and support production quantities at a consistent quality level.

17.2.3.2 The common specific customer requirements, AESQ PPAP Element 10 (see [Table 13](#)), can be expanded (see [Table 14](#)) with additional PPAP elements descriptions that may be occasionally required by customers.

17.2.3.3 These additional elements may be individually specified by a customer on occasion when determined as beneficial to the validation of the related product and/or process. This provides a common understanding to users of this standard.

Table 14 - Common AESQ customer-specific requirements

PPAP Element Number	AESQ PPAP Element	Meaning
P10.A	Customer engineering approvals	This is any engineering approval called on by customer's processes that requires the organization to have gained approval. Refer to RM13145.
P10.B	Process control surveillance	This is an assessment conducted during the production process run to confirm that effective manufacturing process control techniques were implemented in the applied production process. Refer to RM13145. The aim is to assure aspects such as: ▪ The developed workstation resources are implemented and fit for purpose. ▪ The manpower working on the product (production line, warehouse, handling, control) knows what to do on the product and when and how. ▪ The purchased material, parts and components are under control. ▪ The production and control machines and equipment are validated and maintained. ▪ The documentation relative to the product is implemented. ▪ The people in charge are trained. ▪ The environment has no negative impact on the product.
P10.C	Workstation inspection/test planning	This provides confidence that all product characteristics defined by the design record have tests and/or inspections specified during production to verify conformance against requirements of the design record (dimensional, material, and performance). Refer to RM13145. This is 100% inspection, unless approval was given for Alternate Strategies to 100% Inspection (see 9.1.1.2). Typically, confidence can be provided using a characteristics matrix; refer to RM13004.

18. AESQ SUPPLY CHAIN RISK MANAGEMENT PROCESS - SUPPLEMENTAL REQUIREMENTS

18.1 This provides a standardized approach to project-based APQP assurance in association with AESQ APQP and PPAP. AESQ supply chain risk management process (refer to RM13145) is a risk-based assurance method that operates top down with respect to the level of application in the supply chain and during the APQP project, e.g., more assurance on those organizations and/or products that are high risk or provide high-risk products (complex, high severity failure ranking on characteristics, material availability, unique and/or difficult, etc.).

18.2 The assurance practices deployed for supply chain risk management process shall include:

- a. APQP assurance actions aligned to ratings (e.g., H-M-L rating), that scopes what is expected between the organization and their suppliers and customers (AESQ APQP assurance framework); see [Table 15](#).
- b. Special attention during the project to the following for high-risk products and/or organizations:
 1. Sourcing strategy and plan, e.g., additional sources.
 2. Stocking policy, e.g., pull forward inventory, increase levels for periods of time.
 3. Supplier development strategy, e.g., technology development, capability improvements of suppliers.
 4. Special actions, e.g., financial, third-party inspection.

18.3 [Table 15](#) provides a minimum standard APQP assurance framework in association with supply chain risk management.

Table 15 - AESQ APQP assurance framework

APQP Assurance Actions				
Risk Level	Assurance Methods			PPAP Approval
	Progress Updates ⁽¹⁾	Metrics ⁽¹⁾	Approval of Events ⁽¹⁾	PPAP Submission ⁽¹⁾
H	Y (maximum customer frequency)	Y	Y (all)	Y (based on SL)
M	Y (minimum customer frequency)	Y	Y (configured)	Y (based on SL)
L		Y		Y (based on SL)

Descriptions:

- Progress updates:⁽¹⁾ Periodic updates on progress relating to project and production preparation plans.
- Metrics:⁽¹⁾ Sharing of key metrics agreed with the customer and the achievement of targets.
- Approval of events:⁽¹⁾ Points during the products APQP cycle where the organization confirms the achievement of AESQ APQP and PPAP events.
- PPAP submission:⁽¹⁾ Providing PPAP submission for the product in accordance with its submission level.

⁽¹⁾ These are referenced as customer review items within [Figure 2](#).

19. CONTROL PLAN - SUPPLEMENTAL REQUIREMENTS

19.1 Control plans are written descriptions of the systems for controlling parts and processes (as described within 9145 - Appendix C). Two distinct phases of the control plan can be applied (9145 - Appendix C, C1 Phases of the control plan):

- Prelaunch: A description of the dimensional and nondimensional measurements, the timing of this is illustrated in [Figure 4](#).
- Production: A comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems that can occur during postproduction launch.

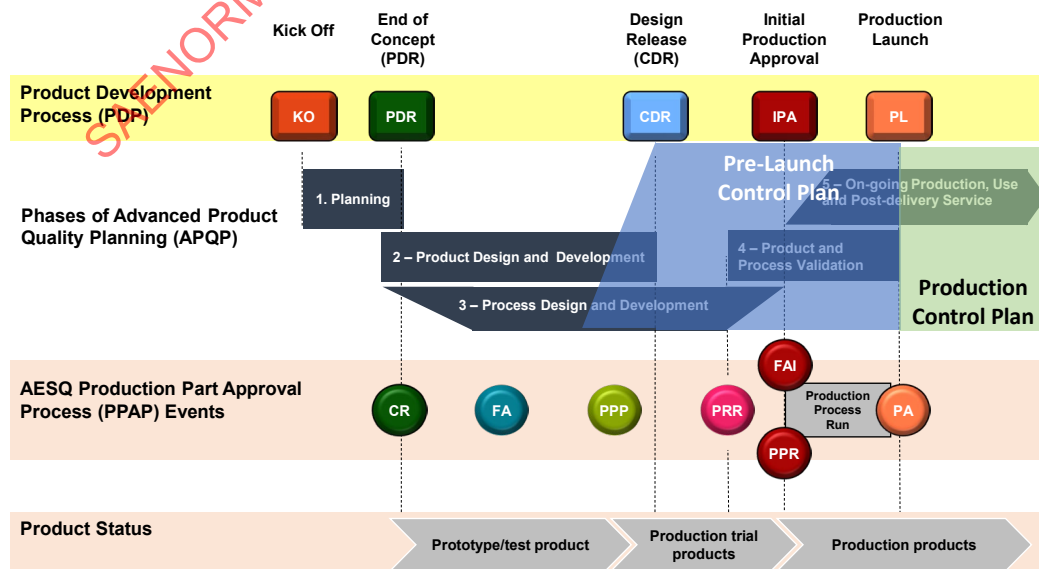


Figure 4 - AESQ timing of application

19.2 The organization shall:

Have a process for reviewing and updating the control plan (see NOTE 1) throughout the APQP phases of application and when changes occur (e.g., affecting product, production process, measurement, logistics, supply sources, process FMEA). Unless otherwise specified by the customer, this includes the approval of the control plan (see NOTE 2), as part of the PPAP submission.

NOTE 1: The control plan is not equivalent to the process control document defined in 9103.

NOTE 2: When prelaunch control plan(s) is in use, the pre-launch and production control plan(s) are used for PPAP submission.

19.3 Prelaunch Control Plan - Supplemental Requirements

a. When developing the prelaunch control plan, the organization shall include all dimensional and nondimensional measurements that are required. This includes enhancements that limit the potential for nonconformances and the validation of the production process. Examples of enhancements are:

1. Additional process controls (refer to RM13006) to those intended for regular/ongoing production which have been determined from knowledge (lessons learned, identified within standards, etc.), or through studies of the process such as design of experiments (DOE).
2. More occurrence of 100% test/inspection, i.e., in-process and final check points.
3. Evaluations to support reduce/sample inspection approval (refer to RM13002), determining capability of KCs (initial process capability studies).
4. Data collection to support evaluation of process quality performance such as defects per unit (DPU); refer to RM13145 for guidance.
5. Audits such as process control surveillance; see [Table 14](#). Refer to RM13145.
6. Identification of error-proofing device(s) for confirmation of effectiveness; refer to RM13006.
7. Product verification such as FAI (refer to RM13102).