NE→XT NPI
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New Product Introduction Manual

Supplemented with APQP/PPAP principles

New England Expert Technologies (NE-XT) utilizes a New Product Introduction (NPI) process that encompasses all the functions within an organization to define, develop and launch processes on a new or improved product. Our NPI process uses a phased approach incorporating APQP principles and with gated reviews performed by a cross functional board at the end of each phase to minimize risk and assure a robust production launch.

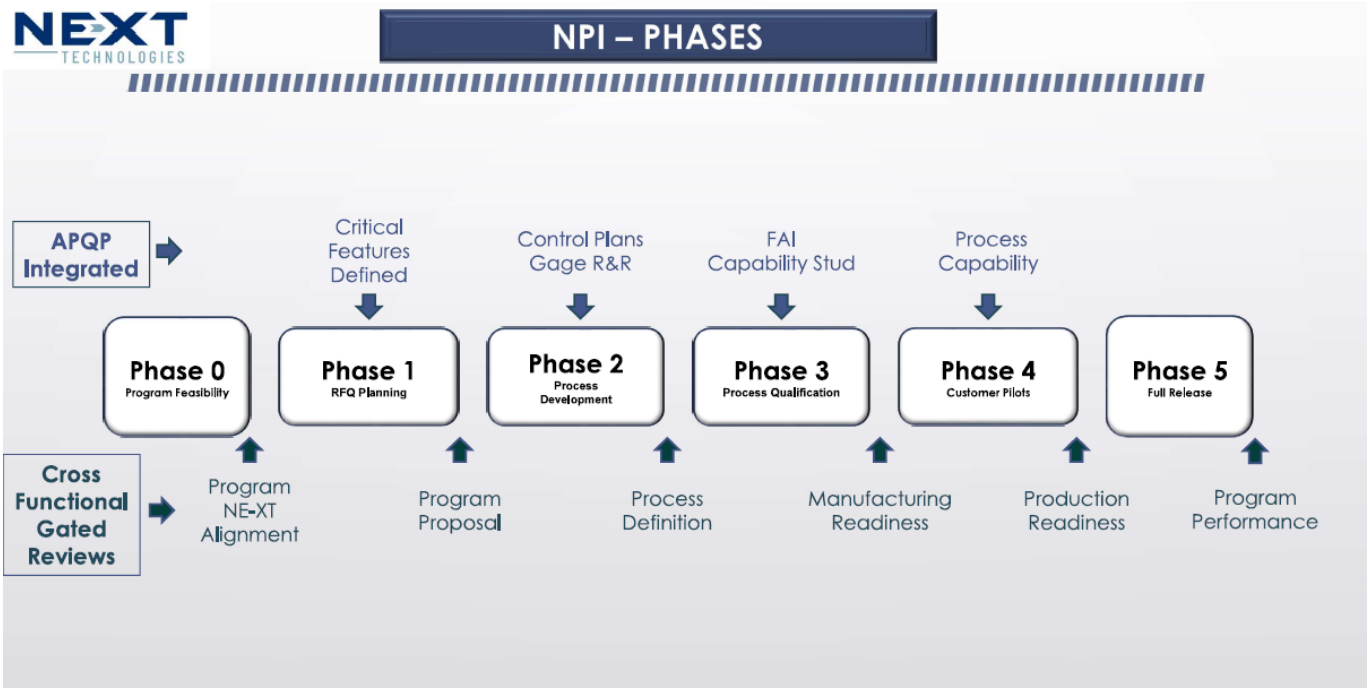

TABLE OF CONTENTS

1. NPI History

The NPI process is based on the fundamentals and principles of the APQP model with some refinements made, aligning with NE→XT Technologies. These include Phases with Gated reviews and Elements.

1.1 The 6 Phases of NPI, aligned with NE→XT Technologies, are defined as follows:

- **Phase 0 – Program Feasibility**

Collect project inputs, review cost, capacity, and business opportunity.

- **Phase 1 – RFQ Planning**

Set the project frame (product and process requirements, key actors, key tasks, and timing plan).

- **Phase 2 - Process Development**

Design the process considering all identified requirements and risks.

- **Phase 3 - Process Qualification**

Design the manufacturing and assembly processes considering all identified requirements and risks.

- **Phase 4 – Customer Pilots**

Validate that the process is producing the specified product at the required rate.

- **Phase 5 – Full Release**

Reduce variation, manage any non-conformity, continuous improvement, and feed lessons learned back into NPI development projects and APQP.

1.2 APQP Elements

APQP elements are the activities and deliverables completed during each phase. Effective project management ensures timely completion of activities and deliverables, and when necessary, escalation and removal of roadblocks. Effective implementation of the APQP plan results in on-time and on-quality products delivered to the customer.

Not all elements will apply to every project. Each new project should include an evaluation of applicability for each element. The elements for each phase are as follows:

Phase 0 Program Feasibility

1.02 Feasibility Assessment & Project Inputs

1.03 SOW (Statement of Work) Review (if provided)

Phase 1 RFQ Planning

1.01.1 Product Specification/Standards & Process Requirements

1.02 Preliminary Listing of Critical Items (CIs) and Key Characteristics (KCs)

1.04 Project targets – schedule, and cost (minimum)

1.05 Preliminary Bill of material (BOM)

1.06 Preliminary sourcing plan

1.07 Preliminary process flow diagram

Phase 2 Process Development

2.01 Contract Review

2.02.1 Project Plan

2.02.2 Process Risk Analysis (Risk Cube)

2.02.3 Bill of Material (BOM)

2.02.4 Process for Manufacturing and Assembly (PFMA)

2.03 Special requirements, including product Key Characteristics (KCs) and Critical Items (CIs) listings

2.04 Preliminary risk analysis of sourcing plan

2.05 Packaging specification/Labelling/Part Marking

2.06 Production Process Review

2.07 Development product build plan

2.08 Production Preparation Planning

Phase 3 Process Qualification

3.01 Process flow diagram (finalized).

3.02 Floor plan layout (Production).

Note: Additional details are provided in the Element Card. *Click on any element in the list to go directly to the Element Card.*

1.3 Element deliverables

Deliverables are the specific outputs defined for each element. The documents are linked at the bottom of each element card for easy, quick access.

2. NPI Management Process

NPI is applicable to all type of products (no matter their complexity). It requires an increased planning and monitoring effort. The organization should define where these responsibilities lie within the organization.

The scope of the NPI project should be based on a risk evaluation of the product and its sub-systems. Typically, risk categories will cover technology, manufacturing processes, supply chain performance, product criticality, and complexity.

Formally identify all project team members. Their nomination should specify their role within the team. Main roles include business development, NPI director, and the board members that will delegate responsibilities and deliverables to the kickoff team.

APQP element applicability is formed based on customer requests & requirements.

When tasks, responsibilities and timing are defined and agreed to by all parties, the NPI Director creates the Project plan. The plan is the basis for determining the requirements and its deliverables in each phase.

During the phased reviews each member from the cross-functional team will present the deliverables required for that phase to the board. These will be reviewed to ensure their completion is on-time and on-quality.

Phase 0: Program Feasibility	**Introduction**

Phase Definition:
The goal of phase 0 is to have new opportunities presented to the NPI team. Attendees include Business Development, Finance, Quality, Engineering and NPI director at a minimum.

Here the team will review the framework of the potential project(s).

- Risks
- Revenue opportunity
- Overall feasibility assessment
- Staffing (resources)

Completion of phase 0 is indicated by the majority vote. Once vote is completed, Phase 1 is scheduled, and the team is chosen to complete the framework of phase 1 that is then reviewed by members of the board.

Phase 0 Program Feasibility

Element 0.01	**Feasibility Assessment, Project Inputs & Review of SOW**

Element Owner: NPI Director

Element Definition:

The feasibility assessment and project inputs consist of scheduling a meeting, reviewing the design records and customer requirements for manufacturing feasibility, confirming the product can be made to the defined requirements and specifications, qualified, packaged and delivered in the desired quantities and within the budget and timing targets.

The outcome of the review is a commitment to move forward to phase 1 based on the consensus of a team typically consisting of business development, NPI director and the NPI board members. Following phase 1 there will be a gated review held by the board members that will determine whether the organization will move forward with the project.

The SOW is a formal document provided by the customer that defines the entire scope of the work involved for a producer, clarifies deliverables, and gives a timeline.

The statement of work should include:

- Deliverables
- project start-up date
- Project Volume
- Customer Requirements
- Critical Items/Key Characteristics

The details in the SOW are reviewed by both parties to ensure all customer requirements are understood and the suppliers selected have the capability to comply. Identified exceptions if applicable are resolved between both parties and SOW is revised accordingly.

Deliverables: Meeting Minutes

Necessary Inputs:	**Source of inputs:**
Manufacturing Engineering Lessons learned NPI Board Customer Regulatory Requirements	Manufacturing Engineering Quality Engineering Customer

Resources:
Business Development, NPI Director, Manufacturing Engineer, Customer

1.0 Phase 1: RFQ - Planning	**Introduction**

Phase Definition:

The goal of phase 1 is to develop a proposal satisfying customer requirements as well as fulfilling NE-XT business needs. To better compose a satisfying proposal for both the customer and NE-XT organization, inputs from multiple sources are desired. This includes but is not limited to the NPI team, kickoff team, the customer, regulatory requirements, benchmark data, lessons learned, company knowledge and strategy.

During this phase, the product and process concept becomes available, a project team is established, stakeholders understand what tasks need to be completed along with the timing for their completion. Establishing a robust project plan during the Planning phase is critical for the success of the project.

Completion of phase 1 is indicated by the finalization of the product specifications, project targets, availability of the preliminary BOM, and completion of other applicable activities and deliverables listed below.

Phase 1 RFQ - Planning

0.01 Product Specifications/Standards & Process requirements
0.02 Preliminary Listing of Critical Items (CIs) and Key Characteristics (KCs)
1.02 Project targets – schedule and cost (Minimum)
1.01.3 Preliminary Bill of Materials (BOM)
1.03 Preliminary Sourcing Plan
1.04 Preliminary Process Flow Chart (PFD)

Element 1.01.1	**Product specifications/Standards & Process Requirements**

Element Owner: Manufacturing Engineering

Element Definition:

The team will review the customer prints and SOW (if provided) to determine scope of work. The product specifications & process requirements are created by a cross functional team taking customer requirements, as well as regulatory requirements and converting them into clearly defined process objectives. Product process requirements may include but are not limited to items such as:

- Functional performance
- Architecture constraints (e.g. space, interfaces, external envelop, etc.)
- Type of material
- Special processing constraints
- Weight & Size
- Regulatory requirements (safety environment and trade compliance, etc.)
- In-house best practices & lessons learned

The product process requirements are intended to define and prioritize the constraints and expectations of the product. These requirements are reviewed and mutually agreed upon with the customer. As the result of the prioritization, a preliminary listing of CIs and KCs is defined.

Deliverables:

Product & Process Specification Document

Inputs:	**Source of input**
Lessons learned (from previous similar projects) Customer, regulatory & internal requirements	Customer Manufacturing Engineering Quality Engineering Procurement Health & Safety (if necessary)

Resources:

Customer, Manufacturing Engineering, Quality Engineering

Element 1.03	**Preliminary Listing of Critical Items (CIs) and Key Characteristics (KCs)**

Element Owner: Manufacturing Engineering & Quality Engineering

Element Definition:

CIs are the items which will have a significant impact on product realization and subsequently its use. KCs are attributes or features whose variation has a significant impact on the CI and/or product. The impact includes safety, performance, fit, form, function, manufacturability, service life, etc. These items require specific actions to ensure they are adequately managed through the manufacturing processes.

Customer and supplier knowledge of the product and the manufacturing processes will help determine the preliminary product and process CIs and KCs.

The determination of preliminary product and process CI/KC is done by a cross-functional team Manufacturing Engineering and supported by Quality.

Deliverables:
A preliminary listing of CIs and KCs agreed upon between supplier and customer

Inputs:	**Source of Inputs**
Lessons Learned	Quality Engineering
Design Standards (Product knowledge)	Project Leader
PFMEA on similar products	Manufacturing Engineering
Program Requirements	Producer
Technical (design and process) Requirements	

Resources:

Quality, Program Management, Manufacturing Engineering

Methodology:

1. Each involved function (Quality, Program Management and Manufacturing Engineering) should review the technical requirements and data inputs and create their CIs/KCs proposal.
2. The team meets and agrees on the preliminary CIs/KCs.
3. Flow preliminary CIs/KCs to product and process design and to supply chain when necessary.

Element 1.02	**Project Targets – schedule and cost**
Element Owner: Manufacturing Engineering	
Element Definition: Project targets include preliminary schedule and cost. These targets should be based on customer expectations for time, cost, and quantity. These targets can be described as follows: • Product schedule are milestones defined by the organization to execute the activities to be performed according during the development process • Product and Project cost shall include total cost of ownership (development, production, procurement, logistics, overhead cost etc.)	
Deliverables: Project Targets Document	
Necessary Inputs: Manufacturing Engineering Quality Engineering	**Source of inputs** Project team (Quality Engineering, Manufacturing Engineering, Procurement)

Element 1.04	**Preliminary Bill of Material (BOM)**
Element Owner: Manufacturing engineering	
Element Definition: Complex products are best managed by breaking the product into manageable sub-systems (Product Breakdown Structure (PBS)). These sub-systems are the basis for the Preliminary BOM and drive the early make-buy decisions. The team should establish a preliminary BOM/Make-Buy Document using PBS and considering the early product/process assumptions. The preliminary BOM will be the starting point for subsequent process design as well as supplier selection activities.	
Deliverables: • Preliminary BOM	
Necessary Inputs: Producer Product Specification Design Standards (Product knowledge) Lessons Learned Producer benchmarking and capability evaluation Industrial strategy Purchasing strategy	**Source of input** Cross-functional team Manufacturing Engineering Manager Procurement Manager Supplier Performance Management
Resources: Manufacturing Process Engineering, Procurement/Contract, Suppliers and Quality Organization	

Element 1.07	**Preliminary Sourcing Plan**

Element Owner: Procurement

Element Definition:

Once the preliminary BOM is developed, the organization will begin making the initial make/buy decisions, i.e. identify items that will be produced in-house and those that will be outsourced. This should be done as soon as possible so that supplier is engaged early in the planning process.

A sourcing plan is developed for the identification and selection of supplier that will be supporting the development and production of outsourced items. The sourcing plan should consider the overall program timing and ensure synchronization with program commitments.

Requirements for flow down to supplier should be identified from the SOW and provided to the supplier as early as possible.

Deliverables:

- Make/buy decisions
- Sourcing plan
- Identified requirement to be flowed down to supplier

Necessary Inputs:	**Source of inputs:**
Project targets	Procurement
Preliminary BOM	Manufacturing Engineering
Supplier product specification	Program Manager
Preliminary PFD	Quality Engineer
Timing requirements	Customer
SOW	
List of approved suppliers and their capabilities	

Resources:

Procurement, Quality, Manufacturing Engineering, Program Management

Methodology:

1. The team performs an analysis for make/buy decisions.
2. Procurement is advised of items to be purchased and is provided the necessary information regarding product and quality requirement that will be flowed down to suppliers.
3. Procurement determines supplier's capability based on supplier's performance history and similarity with previously provided products and/or services.
4. Procurement gathers key information (program timing, preliminary BOM) and develops a sourcing plan considering the above and identifying potential risks.
5. The team agrees to the sourcing plan and the associated risks identified.
6. Mitigation plans are developed as appropriate to the level of risk.
7. Procurement implements and monitors the plan.

Element 1.05	**Preliminary Process Flow Diagram**
Element Owner: Manufacturing Engineering & Quality Engineering	
Element Definition: The preliminary Process Flow Diagram (PFD) provides an anticipated overview of the sequence of manufacturing activities, from receiving to shipment to the customer. It should also take into account the transfer operations from step to step. A well-defined preliminary PFD supports early process planning, e.g. logistics, supplier selection and engagement, facilities, equipment, etc. The preliminary PFD should highlight the most critical activities, such as those requiring longer lead times or additional qualification(s). Development of the preliminary PFD should start once the preliminary BOM is complete. Representatives from potential manufacturing sources should be included, as appropriate.	
Deliverables: Preliminary PFD signed off by manufacturing engineering, production, procurement, and quality.	
Necessary Inputs:	**Source of input:**
Technical requirements	
Preliminary BOM	Quality Engineering
Quality requirements	Manufacturing Engineering
Manufacturing process expertise	Procurement
Key Characteristics and Critical Items	
Design Standards (product knowledge)	
Producer performance and capability	
Resources: Manufacturing Engineering, Quality Engineer, Procurement,	

2.0 Phase 2 Process Development	**Introduction**

Phase 2 discusses the translation of the project requirements, as determined in phase 1, into a controlled, verified, and validated process design. During this phase the product key characteristics, the intended production processes, and potential suppliers used to realize the product, are identified. In addition, the feasibility of the process proposed is assessed by the team created.

Phase 2 Process Development

Element 2.02.1	**Contract Review**
Element Owner: Manufacturing Engineering & Quality Engineer	
Element Definition: Contract Review is the process of reviewing the design records and all associated documents of the contract. These can be based on the Product Design Requirements, Drawings and the SOW provided. They can include: • Physical or electronic/digital drawings • Electronic/digital models • Software • Special process specifications • Material specifications • Supplementary specifications • Customer specifications • Product Function (Input / Output) • Product Envelope (Size & Weight) • Appearance specifications (if any) • Product KCs.	
Deliverables: Complete contract review checklist with action plan as applicable. NEXT PPR Document	
Necessary Inputs: Statement of Work (SOW) Lessons learned Purchase orders Flow downs	**Source of Input:** Customer Program Manager Manufacturing Engineering Quality Engineer
Resources: Customer, Quality Engineer, Manufacturing Engineer	
Methodology: 1. Review contract details 2. Review the Design Records and SOW. 3. Complete contract checklist ensuring all requirements have been covered and planned appropriately.	

Element 1.08	**Project Plan**

Element Owner: Program Manager

Element Definition

The project plan defines the scope, activities, and deliverables for Advanced Product Quality Planning (APQP). APQP activities and deliverables may vary based on product complexity, associated risk, and customer requirements. The planning team should consider all deliverables included herein for applicability to the project (reference: Aerospace International Standard 9145 Appendix B).

The plan includes scheduled start and completion dates for APQP deliverables aligned with customer requirements. At a minimum, the plan should include key customer driven dates (e.g. first delivery, FAI, Production, certification). Each activity identified in the plan should have a designated responsible person.

Adherence to the project plan ensures that each activity is completed on time and the necessary resources are available. Progress against the plan should be monitored regularly, frequency of reviews should be defined in the plan.

The plan is created at the start of Phase 2 and is agreed upon by and communicated to stakeholders, including customers and suppliers (as appropriate). It will only be modified if the overall project timing changes. Monitoring the APQP process and adherence to the timeline is a key to successful implementation. Project Plan is the basis for the team's commitment and ensures success of program timing.

Deliverables:

Agreed upon timing plan that includes activities, due dates, and responsible parties

Necessary Inputs:	**Source of input**
Applicable task lists	Cross-functional Team
Project timing requirements	Program Manager
	Customer

Resources:

Program Management, Manufacturing Engineering, Procurement, Quality, Customer, Production Manager

Methodology:

1. Program Manager provides the key dates that may affect the project timing requirements to the team.
2. The cross-functional team determines which elements are applicable.
3. Task owners propose their preliminary timing plan to the Program Manager.
4. Program Manager collates all timing proposals.
5. The team reviews conflicts and agrees to an acceptable timing plan that will support program targets.
6. Program Manager communicates project plan to all stakeholders.

Element 2.01	**Process Risk Analysis (Risk Cube)**

Element Owner: Manufacture Engineering

Element Definition:

A Process Risk Analysis/Risk Cube is used to identify potential failure modes related to process performance, reliability, and repeatability. The Process Risk Analysis/Risk Cube is performed by the assigned cross functional team and should be done early in the process phase to ensure that identified risks are mitigated before the process is finalized.

A Process Risk Analysis is a summary of the team's inputs including an analysis of all the steps in the process identifying those that could go wrong based on experience, past or current concerns.

This includes process repair and/or overhaul that may need to take place over time.

Process Failure Modes and Effects Analysis (PFMEA) methodology can be used as a record of this activity.

A Process Risk Analysis/Risk Cube is a live document that is updated throughout the product life cycle based on latest performance, reliability, repeatability, and design changes (revisions).

Deliverables:

- Process Risk Analysis/Risk Cube
- Recommended actions for risk mitigation
- Identification of CIs and product KCs

Necessary Inputs:	**Source of Input:**
Past process performance (work holding, layout, etc)	MFG Engineering
Lessons learned	Quality Engineer
	Cross Functional
	Team

Resources:

Customer, Quality Engineer, Manufacturing Engineering

Element 2.02.2	**Bill of Material (BOM)**
Element Owner: Manufacturing Engineering	
Element Definition: The Bill of Material (BOM) is the list of all components and materials contained in the Design Records required to produce a finished product. The preliminary BOM, defined in phase 1, continues to mature through the design synthesis of phase 2. In this phase, the BOM is fully defined and released for production. All future revisions are controlled through the configuration management process.	
Deliverables: Released BOM	
Necessary Inputs: Preliminary BOM PFMEA	**Source of Input:** Manufacturing Engineering
Resources: Manufacturing Engineering, Quality, Procurement	
Methodology: 1. Update the preliminary BOM.	

Element 3.04	**Preliminary Process Failure Mode and Effects Analysis (PFMEA)**

Element Owner: Manufacturing Engineering

Element Definition:

A PFMEA is a structured method for analyzing process risk by ranking and documenting potential failure modes within a process. The analysis includes:

- identification of potential failures and their effects,
- ranking of factors (e.g., severity, frequency of occurrence, detectability of the potential failures), and
- identification and results of actions taken to reduce or eliminate risk.

The producing organization performs a preliminary risk analysis of the manufacturing process and comes up with mitigation plans for high risks using the PFMEA. The PFMEA assists in the identification of process KCs, helps prioritize action plans for mitigating risk, and serves as a basis for continuous improvement, and a repository for lessons learned.

The Preliminary PFMEA is developed by a cross-functional team and is finalized in phase 3 after the process has been developed.

Deliverables:

Preliminary PFMEA with potential mitigation plans for high risks.

Necessary Inputs:	**Source of inputs:**
Preliminary Process Flow Diagram	Manufacturing Engineering Quality Engineering

Resources:

Manufacturing Engineering, Quality Engineering, Operations representative, Facilities Management, Health, Safety & Environment (HS&E) Representative

Methodology:

1. Form a cross functional team that identifies and documents the potential failures for each operation and associated process steps contained in the PFD.
2. For each failure mode, the team will come up with mitigation plans.

Element 2.03	**Special requirements, including product Key Characteristics (KCs) and Critical items (CIs) listings**

Element Owner: Manufacturing/Quality Engineering

Element Definition:

Special requirements have a high risk of not being achieved. Examples include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity.

Preliminary critical items (CIs) and key characteristics (KCs) are identified in phase 1. During the design processes and the Design Risk Analysis of phase 2, the preliminary list of CIs and KCs should be reviewed. Additions to the list will be made when new risks, which cannot be eliminated by design, need to be controlled by key characteristics. The CIs and KCs are indicated in the design records. The finalization of critical items and key characteristics is an output of the Design Risk Analysis and PFMEA.

Deliverables:

List of the CIs and KCs.

Necessary Inputs:	**Source of Input:**
Product design	Customer
Customer specifications	Past Experience
Risk Analysis/PFMEA	Manufacturing Engineering
Preliminary CIs and KCs list	Quality Engineering

Resources:

Manufacturing Engineering, Quality Engineering

Methodology:

1. Consult the list of CIs and KCs determined in 1.03 Preliminary listing of Critical Items (CIs) and Key Characteristics (KCs)
2. Conduct the Risk Analysis & PFMEA identifying high risk areas.
3. During steps 1 and 2, identify CIs and KCs that, when in control, reduces the risks to an acceptable level.
4. Update the preliminary CIs and KCs list with the new information.

Element 2.04	**Preliminary Risk Analysis of Sourcing Plan**
Element Owner: Manufacturing Engineering, Procurement, Program Management	

Element Definition:

Risk associated with supplier selection should be identified and mitigated as appropriate and as early as possible. These risks may be associated with technology, logistics, lead-time, authenticity (counterfeit parts prevention), sole source, etc. Judicious supplier selection is the first step towards minimizing supplier risk.

The sourcing risk evaluation should include:

- Capacity
- Capability
- Performance (quality and delivery history of existing suppliers)
- Financial stability
- Certifications, as required, 9100, 9110, 9120, Nadcap, etc.
- Regulatory requirements e.g. DOD, ITAR and other requirements
- Logistics/Location
- Total cost
- New site/source qualification
- Customer specific requirements.

Selected and/or potential suppliers should provide input to this risk analysis and its mitigation plan.

NOTE: The risk analysis of the sourcing plan is initiated in this phase and will continue through all subsequent phases.

Deliverables:

A sourcing plan with identified risks, aligned by each proposed supplier, and the mitigation plans

Necessary Inputs:	**Source of Input:** Regulatory
Technical Design requirements including:	Agencies Customer
Product technology requirements	Manufacturing Engineering
Manufacturing technology requirements	Procurement
PFMEA requirements	Suppliers
Approved supplier list	
Supplier data/performance history (see list above)	
Regulatory requirements	

Resources:

Supplier Quality Engineer, Suppliers, Manufacturing Engineering, Procurement, Quality

Methodology:

1. Select suppliers that are likely to be capable of supporting all customer requirements.
2. Review and identify all customer requirements and any risk associated with.
3. Propose appropriate risk mitigation actions and document them in the plan.
4. If applicable, provide input into the process and document it.

Element 2.05	**Packaging specification, Labelling, Part Marking**

Element Owner: Manufacturing Engineering

Element Definition:

To support a successful product launch it is essential that there is proper definition and planning for all new packaging required to handle and ship the product to subcontractors or to the customer.

Establishing proper material handling methods ensure that products are adequately protected from damage, corrosion, or contamination during manufacturing processes, movement between operations, transit to external operations, and during storage.

Planned packaging ensures that the product or material is not physically damaged, nor will the packaging degrade in performance through the normal course of transportation, delivery, and storage. Packaging materials and methods are designed to conform to the internal and/or customer-defined requirements, satisfy standards for environmental safety, and pose no hazards to operators.

This planning should also consider the refurbishment or modification of any existing packaging.

Labeling and part marking are typically specified by the customer via drawings and specifications. During this phase, the producer should confirm that labeling and part marking requirements are understood and can be executed as planned. Customer approval is obtained when required.

Deliverables:

- Packaging specification agreed with the customers, where appropriate.
- Material Handling methods defined and documented
- Packaging, labelling, and part marking requirements is defined, understood, and approved as required.

Necessary Inputs:	**Source of inputs:**
Process flow diagram(PFD)/PFMEA	Manufacturing Engineer
Internal packaging standards	Environmental, Health & Safety
Definition of packaging requirements & standard from customer (where defined)	Customer
Import/export regulations	Logistics
Environmental and Safety requirements	

Resources:
Manufacturing Engineering, Procurement (for outsourced processes), Production, Quality

Element 2.06	**Production Process Review**
Element Owner: Process Design Engineering	

Element Definition:

A Process review is a systematic and cross-functional review of engineering drawings, specifications, functional requirements, material specifications and approach to process design, ie; work holding and datum Structure. The purpose of a Process design review is to identify potential problems, propose corrective actions, review proposed process designs and authorize progression to the next stage of the development process. Each review should demonstrate how the Process design requirements are fulfilled. In addition, the design requirements of PFMEA should be incorporated without compromising conformance to product specification.

Deliverables:

Process Design review reports highlighting process design and risk mitigating actions.

Necessary Inputs:	**Source of Input:**
Customer drawings	Manufacturing Engineering
Customer specs, functional requirements	Quality Organization
Material specifications	Customer
Outputs of PFMEA	

Resources:

Engineering, Quality.

Methodology:

1. Receive required inputs from appropriate stakeholders.
2. Systematically evaluate inputs against the plan, including test plans and quality plans.
3. Identify areas of concern.
4. Review and propose appropriate actions to mitigate risks, delays, and other concerns.
5. Inform stakeholders of progress, planned actions to mitigate identified risks and the need for additional resources.
6. Obtain concurrence from stakeholders to proceed to the next stage of the design process.
7. Evaluate changes to the design process as they are proposed.
8. Provide input into the design change process.

Element 2.07	**Development Process Build Plan**
Element Owner: Process Development Team	
Element Definition: A Development Process Build Plan establishes the product manufacturing requirements, gaging, inspections, CMM programming, 3-D printed part if necessary and assembly sequences as applicable to be performed to build pre-production products for product and process evaluations. The plan should define: • Sources of material, components and assemblies • Minimum technology and manufacturing maturity levels for each product/part • Manufacturing processes to be used • Quantity of parts required • Detailed schedule for the manufacturing, inspection and reporting activities. Lessons learned during the manufacture/build process may signal the need for process improvements.	
Deliverables: • A Development Product Build Plan that defines the items as detailed above. • Formal reports documenting the outcome of the manufacture/build process including a record of the discrepancies that arise along with their proposed solutions.	
Necessary Inputs: Customer specifications Design record requirements PO Requirements Preliminary Statement of Work	**Source of Input:** Manufacture Engineer Quality Engineers Procurement SQE
Resources: Quality Engineers, Manufacturing Engineers	

Element 3.03	**Production Preparation Planning**

Element Owner: Manufacturing Engineer

Element Definition:

The producer should identify and plan for equipment, tooling, fixtures, and jigs required to produce and qualify product. This activity includes the following:

- Analyzing the capacity of existing equipment and facilities,
- Assessing the need for refurbishment or modification of any existing equipment, tooling, jigs, or fixtures and testing equipment and/or Determining the need for new equipment, tooling, and facilities for new processes
- Identifying skills, training, and manpower required, including external certifications

The producer should develop a Production Preparation Plan and track progress on a regular basis to promptly identify and react to delays or problems. Status of the plan is communicated to the customer as required.

Deliverables:

- A Production Preparation Plan covering all aspects of obtaining and qualifying human resources, tooling, facilities, and equipment
- An Agreed progress reporting schedule

Necessary Inputs:	**Source of inputs:**
Process Flow Diagram	Manufacturing Engineering
Current and Future Plant layout	Production Planner
Capacity analysis	Human Resources
Specifications for all tooling and equipment	Quality Engineering
Skills assessment and Manpower assessment	

Resources:

Manufacturing Engineering, Quality Engineering, Procurement, Program Manager, Operations, Facility Engineering, Human Resource Manager, Health Safety & Environment Representative

Methodology:

1. Determine facility/equipment/tooling/personnel necessary to meet the customer demand rate and analyze the existing capacity.
2. Identify the need for new equipment, tooling, and facilities for new processes or expansion of capacity.
3. Define skills, training, and manpower required, including external certifications
4. Develop a plan to include all aspects of obtaining and qualifying human resources, tooling, facilities, and equipment.
5. Obtain cross-functional agreement on the production preparation plan and establish a schedule for regular reviews to monitor progress.

3.0 Phase 3 Process Qualification	**Introduction**

Phase Definition:

During phase 3 the processes and methods for producing the product are designed and developed. Phases 1 & 2 constitute necessary inputs to ensure that the teams developing the manufacturing processes clearly understand the customer's requirements, the design requirements, and the manufacturing organization's requirements. Planning for the manufacturing processes is started as soon as sufficient product information is available. The Production Readiness Review (PRR) at the end of this phase, provides the team with confidence that the process is capable of producing product consistently and in compliance with customer and producer requirements.

Phase 3 Process Design & Development

- 3.01 Process flow diagram (Finalized)
- 3.02 Floor plan layout (Production)
- 3.03 Process Failure Mode & Effect Analysis (PFMEA) (Finalize)
- 3.04 Process Key Characteristics (KCs)
- 3.05 Control plan
- 3.06 Preliminary capacity assessment
- 3.07 Work station documentation
- 3.08 Measurement Systems Analysis (MSA) Plan
- 3.10 Supply Chain Risk Management Plan
- 3.11 Production Readiness Review (PRR) results

Element 3.01	**Process Flow Diagram**

Element Owner: Manufacturing Engineering

Element Definition:

The Process Flow Diagram (PFD) is a representation of the sequence of operations required to manufacture the product from receipt goods to shipment of finished product to the customer. This encompasses the movement of product internally from one-step to the next, as well as movement to and from external operations. It also includes alternate processes, i.e. different processes used to achieve the same output (e.g. backup equipment, secondary sources, d sequence change). The PFD requires sufficient detail for each step to clearly and completely describe the process required to make the product.

This activity should start once the preliminary design is released and should build upon the preliminary process flow diagram created in phase 1.

The Process Flow Diagram is updated as changes to the process sequence are made.

Once this document is released, changes should be revision controlled.

Deliverables:

Process Flow Diagram approved by Engineering, Operations and Quality.

Necessary Inputs:	**Source of inputs:**
Preliminary Process Flow Diagram	Quality Engineering
Design Records	Manufacturing Engineering
Bill of Material	Procurement
Key Characteristics	
Tooling and Equipment	
Outsourced Processes	
Packaging Specification	

Resources:

Manufacturing Engineering, Quality Engineering

Methodology:

1. The Preliminary PFD is updated to reflect the latest design, BOM, and process details.
2. The team reviews PFD to ensure that:
   - all process steps are included and completely describe the process required to receive, make, inspect, test, protect, store, and ship product,
   - alternate processes are included, and
   - movement to internal and external operations are included.
3. The proposed PFD is reviewed by Engineering, Operations, and Quality, and approved or amended as appropriate.
4. Update PFD as changes are incorporated into the process

Element 3.02	**Floor Plan Layout**
Element Owner: Manufacturing Engineer	
Element Definition: The floor plan layout will clearly show the final position and layout for all processes used to manufacture and inspect the product.	
Deliverables: Plant layout plan approved by the management team.	
Necessary Inputs: Process flow chart Equipment list Existing plant layout plan Building Layout	**Source of inputs:** Manufacturing Engineering Facility Management

Resources:

Manufacturing Engineering, Operations Manager, Quality Engineering, Quality Manager, Facility Engineering, Lean Experts, Health Safety & Environment Representative

Methodology:

1. Manufacturing Engineer develops a draft layout plan to map a physical flow which is appropriate to produce the product.
2. Cross-functional review with Production, Quality, Facilities, and Maintenance to optimize the draft plan using relevant experience, lessons learned, and best practice benchmarking.
3. Equipment relocated/placed (when it becomes available) as planned.
4. Manufacturing Engineer updates the layout plan in accordance with the inputs, and obtains formal agreement from Operations and Quality Managers.

Element 3.04	**Process Failure Mode and Effects Analysis (PFMEA)**

Element Owner: Manufacturing Engineering

Element Definition:

A PFMEA is a structured method for analyzing process risk by ranking and documenting potential failure modes within a process. The analysis includes:

- identification of potential failures and their effects,
- ranking of factors (e.g., severity, frequency of occurrence, detectability of the potential failures), and
- identification and results of actions taken to reduce or eliminate risk.

The producing organization performs a risk analysis of the manufacturing process and identifies mitigation plans for high risks using the PFMEA methodology. The PFMEA assists in the identification of process KCs, helps prioritize action plans for mitigating risk, and serves as a basis for continuous improvement, and a repository for lessons learned.

The PFMEA is developed by a cross-functional team during the design and development of the manufacturing process.

CIs and KCs, identified in the design records are documented and evaluated in the PFMEA.

The PFMEA is continually updated as process changes occur, non-conformances arise, and risks are identified and addressed.

Deliverables:

Completed approved PFMEA and a plan to reduce high priority risks.

Necessary Inputs:	**Source of inputs:**
Process Flow Diagram	Manufacturing Engineering
Quality performance data (similar parts & processes)	Quality Engineering
PFMEA (similar parts & processes)	
Key Characteristics	
Control Plan (similar parts & processes)	

Resources:

Manufacturing Engineering, Quality Engineering, Operations representative, Facilities Management, Health, Safety & Environment (HS&E) Representative

Methodology:

3. Form a cross functional team that identifies and documents the potential failures for each operation and associated process steps contained in the PFD.
4. For each failure mode, the team will list the failure, rank severity, list causes and list preventative methods taken to eliminate the cause.

Element 3.05	**Process Key Characteristics (Process KCs)**

Element Owner: Manufacturing Engineer

Element Definition:

Process KCs can be inputs to, or outputs from the manufacturing process. Key process inputs are the process parameters which, if measured and controlled within prescribed limits, will guarantee the capability of the production process. Key process outputs are the product or process attributes which, when measured and compared to prescribed limits, validate the capability of the process. In other words, these are the key parameters which when controlled, will minimize process variation that could impact product quality. Most process KCs are derived from the PFMEA, however; they can come from customer requirements and/or best practices.

Control of process key characteristics via Statistical Process Control (SPC) charts or other means, enables a preventive approach to quality. Process drift can be recognized and addressed before it leads to nonconformance.

Deliverables:

List of Process KCs

Necessary Inputs:	**Source for inputs:**
Key product Characteristics	Customer
PFMEA	Manufacturing Engineering
Lessons Learned	Quality Engineer
Company knowledge (best practices)	

Resources:

Manufacturing Engineering, Quality Engineering, Operations

Methodology:

1. Identify high-risk items from PFMEA.
2. Identify potential process KCs by reviewing the process steps related to the high-risk items identified in step 1.

   NOTE: Typically Process KCs are assigned to those process inputs that drive variability of the output.
3. Finalize the list of process KCs and insure their inclusion in the manufacturing operating instructions and control plan.

   NOTE: The process KCs are typically reviewed by the Quality Engineer and operations personnel.

   NOTE: Process KCs should be monitored as designated through the control plan by either 100% checking or SPC.

Element 3.06	**Control Plan**

Element Owner: Manufacturing Engineer and Quality Engineer

Element Definition:

The Control Plan is a written description which links manufacturing process steps to key inspection and control activities. The intent of a control plan is to control the design characteristics in accordance to the print requirements and the process variables to ensure product quality.

The purpose of the control plan is to document control methods imposed on the product and process including identification of product features and process control settings to be monitored, the measurement methods to be used, and sampling sizes and frequencies along with associated control limits to assure reduced variation and maintain the desired quality level.

The control plan details how product quality is controlled and confirmed at each stage of the manufacturing process, including defining the actions to be taken when the process becomes unstable and/or nonconforming product is detected (i.e., reaction plans). The control plan should be sufficiently detailed to clearly define who is responsible for completing the specified quality control tasks/activities at each stage of the process. The control plan is agreed to by the supplier's quality and production departments, and by the customer (when required).

1. Phases of the Control Plan

The control plan is developed in phase 3 as a preliminary control plan to express to the customer our method of controlling the given product through all its operations. The control plan is finalized in phase 4 once a definitive process has been created and ran through reviewing and eliminating possible risks.

2. Content of the Control Plan

At a minimum, the control plan contains the following information:

- Organization's name/site designation,
- Part number(s),
- Part name/description.
- Engineering change level (i.e., revision level),
- Process name/operation description,
- Operation/process step number,
- Product or process related Key Characteristics (KCs) and Critical Items (CIs),
- Product or process specification/tolerance,
- Evaluation/measurement technique,
- Sample size and frequency,
- Control method, including error-proofing, and Reaction plan

The control plan is revised and updated throughout the life of the product in response to new quality issues and/or product/process changes.

Deliverables:	
Control plan signed and approved by: Quality and production.	
Necessary Inputs:	**Source of inputs:**
PFMEA & Process Risk Analysis Product KCs/Process KCs Process flow chart Inspection Quality performance data Process capabilities (similar parts & processes) Process Change (to update the control plan)	Manufacturing Engineering Quality Engineering Operations
Resources:	
Manufacturing Engineering, Quality Engineering, Operations, Facilities Management	

Element 3.07	**Preliminary Capacity Assessment**

Element Owner: Manufacturing Engineer / Industrial Engineer

Element Definition:

A Preliminary Capacity Assessment is performed early in the process planning and development phase to determine resources (e.g., people, equipment, facilities) necessary to produce product at the customer's demand rate. The assessment should include a review of the capability and capacity of existing tooling/equipment, inspection /test equipment, trained/qualified personnel and facilities to determine if they are adequate to meet the customer's demand profile. If additional equipment/resources are needed, a detailed plan should be developed to ensure capacity needs are achieved to support project timing (see Production Preparation Planning). The plan should be continually monitored to drive on-time completion of tasks. Delays and roadblocks should be escalated as necessary.

Deliverables:

- Capacity analysis
- A capacity plan to close any identified gaps

Necessary Inputs:	**Source of Input:**
Customer demand rate	Customer
Capacity data for existing tooling/equipment, Inspection/test equipment	Manufacturing Engineering Quality Engineering
Existing facilities and personnel	Facilities Management
Process Flow Diagram	Logistics/Production Planner
Process capability data with respect to design requirements	Project Manager
Functional Test requirements	
Project schedule	

Resources:

Manufacturing Engineering, Logistics/Production Planner, Operations Personnel, Facilities Management, Supply Chain (for purchased items)

Methodology:

1. Determine facility/equipment/tooling needs required to meet the customer demand rate.
2. Analyze the capacity of existing equipment and facilities.
3. Determine if additional capacity on existing equipment and/or the refurbishment or modification of any existing equipment, tooling, jigs or fixtures and testing equipment is needed.
4. Identify the need for new equipment, tooling and facilities for new processes.
5. Include the details for obtaining additional tooling, facilities and equipment in the Production Preparation Plan.
6. Obtain cross-functional agreement on the plan and establish a schedule for regular reviews to monitor progress.
7. Obtain Escalate issues as needed.

Element: 3.08	**Work Station Documentation**

Element Owner: Manufacturing Engineer

Element Definition:

Appropriate workstation documentation is needed for all products and all phases of production, i.e. prototype, production trials and serial production.

Process documentation should contain all controls specified in the control plan to ensure product and process compliance.

Work Station Documentation includes:

- Travelers and Routers – documents containing sequential activities needed to produce the product.
- Work instructions: Detailed instructions for the process step, including tools, materials and methods needed, quality criteria may also be included.
- Inspection instructions: Detailed instructions for inspecting product, including gages, tools, fixtures and record keeping requirements.
- Maintenance schedules and instructions: Instructions for maintenance activities that are performed at the workstation by operators, including tools and materials needed to perform the tasks as well as the record keeping requirements to confirm that the maintenance has been performed as required.
- Data collection check sheets and SPC charts: Worksheets and SPC charts designed to collect process and/or product data to confirm that requirements have been fulfilled. These documents should include a record of dates and times the task was performed and operator identification.
- Visual displays for collecting “real –time” process status, safety information, etc.

All work stations documents are controlled documents, which are maintained to reflect the current process and design information at all times.

Deliverables:

All applicable workstation documentation accessible at the work stations

Necessary Inputs:	**Source of inputs:**
Process Flow Chart	Manufacturing Engineer
Control Plan	Quality Engineer
Maintenance Plan	Facility Maintenance
Operator Experience	Operators

Resources:

Manufacturing Engineering, Quality Engineering, Facility Maintenance, Operators

Methodology:

Review process flow chart and define detailed product routing, Configure Manufacturing Execution System (Epicor) to reflect the defined product routing. Determine all process steps that require detailed Workstation documentation. Create required detailed Workstation documentation. Validate Workstation documentation with operators and quality engineer. Issue documentation and make available at workstation. Manage any changes through configuration control.

NOTE: Workstation documentation contains highly detailed information that is subject to error in its preparation. Therefore, they should be reviewed and approved by Lead Quality Engineer.

Element 3.09	**Measurements Systems Analysis (MSA) Plan**
Element Owner: Manufacturing or Quality Engineer	

Element Definition:

Measurement systems specified in the Control Plan must be capable of evaluating product and process conformity. In phase 3, gages and other measurement methods are selected and a MSA Plan is established to ensure that they will be appropriately validated in phase 4 when the actual MSA is performed. The MSA plan should include at a minimum: responsibility to ensure gage linearity, accuracy, repeatability, reproducibility, and correlation of duplicate gages.

Measurement systems exhibiting excessive variation used in the evaluation of product/process may result in erroneous decisions about product and process conformity. MSA evaluates variation from the Inspector, Inspection Method, Component, Measuring Equipment, and Environmental conditions. The purpose of MSA is to identify the nature of variation and create corrective actions to reduce variation to the acceptable level.

The key areas to be assessed are:

- Precision
  - Repeatability – variation due to a single operator or piece of equipment
  - Reproducibility – variation between operators
- Accuracy
  - Resolution - ability to measure small changes based on defined tolerance
  - Bias - a consistent difference in the measurement versus known standard
  - Stability - bias over time
  - Linearity - bias throughout the measurement range

During this phase, the accuracy elements of the measurement system, i.e. resolution, bias, stability, and linearity can be assessed using the planned measuring equipment, existing calibration data, and prototype parts. Precision is assessed during the MSA activity in phase 4 when actual parts and final measuring equipment is available.

Deliverables:

Plan identifying all measurement systems to be evaluated, including persons responsible for evaluating them and the timing for accomplishing the tasks.

Necessary Inputs:	**Source of inputs:**
PFMEA	Customer
Key Product Characteristics	Quality Engineer
Key Process Characteristics	Manufacturing Engineer
Control Plan	
Inspection Plan	
Work Instructions	

Methodology:

1. Review Control plan and/or inspection plan to identify all product and process characteristics to be measured.
2. Review the measurements to be taken and the appropriateness of the selected measurement gages and methods.

   NOTE: Appropriateness of gages is determined through the accuracy elements of the MSA study (resolution, bias, stability and linearity).
3. Where the gages or methods are determined not appropriate, investigate and update control plan as needed.
4. Identify which measurements will need to undergo MSA. Criteria to consider include:
   - Criticality of the measurements (as a minimum anything linked to a Product and/or process KC)
   - Past experience of using the measurement system and evidence of its capability
5. Create a plan showing when each measurement will be validated. The plan should consider tooling, measurement equipment, and part availability as well as operator training and the overall program plans. The plan identified who is responsible for each activity and the due date.
6. As further controls are added to the control plan, the MSA Plan must be updated to reflect these changes.

Element 3.10	**Supply Chain Risk Management**

Element Owner: Procurement

Element Definition:

Risk within the supply chain is identified and managed to ensure on-going quality and delivery performance. Now that all producers involved in the manufacturing process are selected, a supply chain analysis should be performed to identify and evaluate risks. Producers that are high risk or provide high-risk components (complex, high severity failure ranking on features, material availability, etc.) should be included in the analysis. Special attention should be given to any producer whose design may be unique and/or difficult or outside their normal or typical operating limits.

The analysis should identify producers' names, locations and other information such as, capacity data (launch and peak), quality and delivery performance, lead time, stocking locations inventory levels, logistics methods, financial performance, necessary to evaluate risk.

Risks identified should be evaluated and prioritized. Action plans should be put in place to minimize the highest priority risks.

Deliverables:

- Risk analysis
- Risk mitigation plan

Necessary Inputs:	**Source of inputs:**
List of selected producers	Producer/Supplier
Bill of Material	Procurement
Supply Chain performance data	Manufacturing Engineering
Producer capability/capacity assessment	Supplier Quality
List of high-risk components	

Resources:

Procurement, Quality, Production Control & Planning, Finance

Methodology:

Establish the elements of the risk analysis, e.g. producers experience level, part complexity, part and/or supplier history, producer's location and/or capacity, etc.

1. Identify producers that are high-risk or provide high-risk component and document the producers' names, locations and risk data gathered for each producer.
2. From the analysis, identify the high-risk producers.
3. Develop a mitigation plan for the high-risk producers.
4. Where risks may not be fully mitigated, contingency plans are developed.

Element 3.12	**Production Readiness Review (PRR)**

Element Owner: Manufacturing Engineering

Element Definition:

The NPI director and the designated team conduct a PRR to verify that the manufacturing process is accurately documented and is ready to produce product that will meet customer requirements The cross functional team includes but is not limited to Quality engineering, Manufacturing engineering, procurement, and operations. The review should include both a desktop review of all workstation documentation as well as a physical review of the manufacturing facilities and equipment. The review should also include an assessment of supply chain readiness either in advance of or as part of the PRR. The review will cover all aspects of the manufacturing process including equipment, gages, tools, fixtures, software programs, material availability, supply chain readiness, operator training, workstation documentation, control plan, packaging/labelling, material handling, part marking and associated measurement tools.

The results of the review, including corrective action to resolve identified risks or issues, are recorded. Management should confirm that all outstanding actions are satisfactorily closed or mitigated before the significant production run can be started.

Deliverables:

- Finalized documented manufacturing process
- Action plan for resolution of identified risks or issues

Necessary Inputs:	**Source of inputs:**
Equipment, tooling and fixtures, gages, software programs	Manufacturing Engineering
Assessment of supply chain readiness	Procurement
Subcontracted material availability confirmed	Industrial Engineering
Workstation documentation	Facilities Management
Assessment of operator readiness, i.e. skills matrix, training, certifications, etc.	Quality Engineering
	Logistics/Production Planner
	Human Resources

Resources:
Manufacturing Engineering, Operations personnel, Quality Engineering

Methodology:

1. A cross-functional team reviews the status and confirms satisfactory completion of:
   - work station documentation,
   - equipment, tooling and fixtures, gages, software programs,
   - supply chain readiness, including material availability, and
   - operator readiness, i.e. skills matrix, training, certifications, etc.
2. Gaps are identified and documented
3. Develop action plan to close gaps
4. Conduct a formal review at the management level to confirm that all outstanding actions will be satisfactorily closed or mitigated before the significant production run is initiated.

4.0 Phase 4 Customer Pilots Product and Process Validation	**Introduction**

Phase Definition:

The goal of phase 4 is to demonstrate that the manufacturing processes can produce conforming product at the customer's demand rate. At this point, the product definition has been finalized and the process design has been verified through the PRR in the previous phases. Phase 4 starts with the initial production runs where product is produced at the planned production rate using production equipment and processes. This is done to gain knowledge of production capability as well as product conformity. Of particular interest are measurement systems, control plans, capacity verification and First Article Inspection (FAI).

PPAP (Production Part Approval Process) is the key element in phase 4 where product and process validation occurs. PPAP combines First Article Inspection and process qualification. Final product approval is established once the PPAP file is submitted and approved by the customer. The PPAP requirement extends through the life of the product. In other words, all applicable PPAP elements must be updated by the producer any time the process and/or the product is changed and, when required by the customer, a PPAP resubmission may be necessary.

Phase 4 Product and Process Validation

Element 4.01	**Production Process Run(s)**

Element Owner: Manufacturing Engineer

Element Definition:

Production Process Runs are conducted to validate that all production processes, intended for serial production, can achieve production quality and meet customer demand rate. In order to accomplish this, the producer should ensure that only final production processes are employed; specifically tooling, fixturing, gauging, and trained operators. Project team members should be available to support the production runs in order to identify and resolve all issues that may arise.

Attention should be placed on observing safety and ergonomic issues, as well as the potential for Foreign Object Damage (FOD). In addition to producing product, the production run(s) should also focus on verifying the manufacturing support system (e.g. component supply, preventative maintenance, FOD and handling damage prevention, tool and equipment changeover, the logistics system).

During the production run, processes should be closely observed. Data should be collected and problems recorded as they are identified.

Data collection may include:

- production performance (cycle time, equipment breakdowns, changeover time, actual run time, production line work balance, and capacity data),
- availability and accuracy of all production documentation at work station,
- adherence to work instruction,
- quality data as per control plan,
- risks or concerns observed,
- potential sources of FOD,
- safety and ergonomic issues, and
- effectiveness of fixtures, tools, equipment, gauges, etc.

Products produced from the Production Run(s) are used to provide data for PPAP submission, including data for determining initial process capability.

Problems identified during the significant production run should be used to correct/improve the production process and associated documentation in order to reduce risk and variation in series production.

Deliverables:

- Adequate quantity of products necessary to complete FAI and PPAP deliverables
- Confirmation that the manufacturing system will support production needs
- Identification of issues
- Action Plan to track issues to closure

Necessary Inputs:	**Source of Inputs:**
Production equipment, e.g. tooling, fixtures, gauging Work Station Documentation Trained Operators Control Plan Maintenance plan Design records Key Characteristics	Manufacturing Engineering Quality Engineering Facility Management Production management Training coordinator

Resources:

Manufacturing Engineering, Quality Engineering, Production Operators, Inspection Technicians, Production Supervision

Methodology:

1. Produce parts using approved tooling, fixturing, gauging, and work station documentation. The quantity of parts to be produced will be the quantity required by the customer or the quantity of parts required in order to satisfy FAI and PPAP requirements.
2. Collect data as planned.
3. Segregate any non-conforming (NC) product in accordance with NC product procedure.
   a. Identify the source and nature of defects.
   b. Take corrective action as necessary.
4. Immediately involve the appropriate support functions (Engineering, Quality, Production Control, etc.) to identify and document all issues.
5. Assign issues to appropriate support staff and track issues through to resolution.
6. Update all relevant documents (Manufacturing Process Documents, FMEA, Control Plan, etc.) after the issues are solved and/or the process changes implemented.
7. When the producer is unable to achieve targeted quality levels after applying corrective actions to the process, issues should be escalated to top management and the customer should be informed accordingly.

Element: 4.02	**Measurement Systems Analysis (MSA)**

Element Owner: Manufacturing Engineer

Element Definition:

The purpose of the Measurement Systems Analysis is to implement the MSA Plan, as defined in phase 3, and assess variation introduced by the measurement systems. The sources of variation include measurement device, fixtures, operators and shop floor environmental conditions.

The organization should demonstrate that all measurement methods and checking aids included in the control plan are suitable, capable, and supports the customer demand rate. At a minimum, measurement analysis should be performed for each of the measurements that require validation as established in the MSA plan.(KC's).

Where the minimum acceptable level of error due to the measurement system (as defined in the MSA Plan) is not achieved, action should be taken to reduce the variation/error. For acceptable measurement system analysis results refer to AS13003, Table 2.

Deliverables:

- MSA results per MSA plan
- Action plan for those measurement systems not meeting acceptance criteria

Necessary Inputs:	**Source of Inputs:**
MSA Plan	Manufacturing Engineering
Key Characteristics (KCs)	Quality Engineering
Control Plan	Training Management
Inspection Instructions	Facilities Management
Measurement devices, e.g. gauges, fixtures	Metrology Specialist
Trained Inspector/Operator	

Resources:

Quality Engineering, Manufacturing Engineering, Production Operators, Inspection Technicians

Measurement System Methodology:

1. Review the MSA Plan.
2. Collect the appropriate number of parts from the Production Process Run(s).
3. Perform the required measurements and record data in accordance with the MSA Plan.
4. Analyze data and compute measurement variation/error (e.g. Bias, linearity, stability, precision to tolerance and/or precision to total variation).
5. Take actions as necessary to reduce the variation/error below the targeted value.

Element 4.03	**Initial Process Capability Studies**

Element Owner: Manufacturing Engineer

Element Definition:

Initial process capability studies demonstrate that the combination of people, machine, methods, material, and measurements have the potential to produce product that will consistently meet the design requirements. Initial process capability studies should be performed on product and process Key Characteristics identified in the control plan.

For initial process capability, data is collected on product and process KCs during the early Production Process Run(s) and will continue until sufficient data is collected to allow the calculation of process capability using Cpk (or Ppk as appropriate) indices. The minimum number of samples considered for a capability study should be determined between the Customer and the producer. A typical quantity for establishing process capability is 25, but may be lower as long as the acceptance criterion is statistically valid.

Where the target Cpk (or Ppk as appropriate) indices are not achieved, action should be taken to reduce the variation to below the targeted value.

Deliverables:

- Calculated Cpk (or Ppk as appropriate) indices from production products
- Action plan for variation reduction where Cpk indices are below the established acceptance value

Necessary Inputs:	**Source of Inputs:**
Product from Production Run(s)	Manufacturing Engineer,
Key Characteristics (KCs)	Quality Engineer
MSA results & Control Plan	Operations
Inspection Instructions	
Measurement devices, e.g. gauges, fixtures Trained Inspector/Operator	

Resources:

Manufacturing Engineering, Quality Engineering, Production Operator, Inspection Technician

Methodology:

1. Collect sufficient product samples from production process runs and Collect data on Key Characteristics as indicated in the control plan.
2. Determine if the process is statically stable.

   Note: Process capability indices (Cpk or Ppk as appropriate) can only be calculated after the process is determined to be stable. A process is not stable over time if special causes of variations are present. Those causes must be identified and removed.
3. Calculate the Cpk (or Ppk as appropriate) indices.
   - If capability studies do not meet ≥1.33, then 100% inspection is expected until 1.33 is achieved.

   Note: Capability studies can be affected by Engineering Changes, Process Change Requests, Design Change Requests, or part tolerance changes, and therefore must be re-submitted for characteristics affected by change.

Element 4.04	**Control Plan**

Element Owner: Manufacturing Engineer and Quality Engineer

Element Definition:

The Control Plan details how quality is controlled and confirmed at each stage of the manufacturing process, including as necessary the actions taken when deviations are found (reaction plans). All controlled characteristics must be listed on the Control Plan. The Control Plan should consider the process dominant variables (e.g. set-up, tooling, operator) and determine the appropriate level of control.

The development of the control plan is initiated in phase 3 (typically with the pre-production Control Plan) forming the basis for the Production Control Plan. The early Production Process Run(s) provide opportunity to evaluate the process output, review the control plan, and make appropriate changes to the process and control plan. The production control plan should be completed and approved as required, during to the early production runs.

The Control Plan is updated throughout the life of the program to reflect the current controls in place in the production process.

Deliverables:

Completed approved production Control Plan

Necessary Inputs:	**Source of Input:**
PFMEA	Manufacturing Engineering
Process Flow Diagram	Quality Engineering
Pre-production control plan	

Resources:

Quality Engineering, Manufacturing Engineering, Operations personnel

Methodology:

1. Review all inputs and incorporate all appropriate information into the Control Plan including results from PFMEA for identification of Key Characteristics and Process Key Characteristics.
2. Observe the process during the Significant Production Run(s) using the Control Plan to validate implementation and effectiveness of the planned controls.
3. When irregularities (e.g. unplanned variation, non-conformance, measurement issue, etc.) are observed and the process is modified during the run, the Control Plan and other affected workstation documentation is updated.
4. Publish the Production Control Plan when all issues are resolved and accepted by the customer as required.

Element 4.05	**Capacity Verification**
Element Owner: Manufacturing Engineer and Operations Management	
Element Definition: Capacity Verification is performed to demonstrate the ability of the producer to meet the demand profile of the customer as established in the production forecast. When verifying capacity, the producer will evaluate, equipment uptime, planned downtime (e.g. changeover, equipment maintenance), cycle time, yield, and defect rate, to verify that the available capacity satisfies the production demand forecast. Consideration should also be given to overall plant capacity, testing capacity, and any capacity shared with other customers (e.g. parts run on the same tooling and/or equipment). Capacity verification extends to all tiers of the supply chain.	
Deliverables: Verified capacity to satisfy the customer demand profile	
Necessary Inputs: Cycle time, changeover time, production losses, Planned and unplanned downtime history Operating configuration (shifts, operators, machines) Testing capacity Supply chain capacity Customer demand	**Source of Input:** Manufacturing Engineering Facilities Management Procurement Operations Management
Resources: Manufacturing Engineering, Operations personnel, Procurement, Facilities personnel	
Methodology: 1. Obtain demand profile for all customers using the same equipment/processes/testing facilities. 2. Determine needed capacity based on the demonstrated cycle time, change overtime, yield, etc. 3. Determine the available capacity based on calendar working days, shifts/day, hours/shift, expected downtime, etc. 4. If the needed capacity is below available capacity, create an action plan to resolve shortfall.	

Element 4.06	**Product Validation Results**

Element Owner: Manufacturing

Element Definition:

Validation Testing is the functional testing performed for the product/material to ensure customer-engineering requirements are satisfied. This testing should be performed using product/material produced from production tooling and processes wherever practical.

Deliverables:

- Results of all tests performed per the design validation plan
- Test results demonstrating conformance to requirements

Necessary Inputs:	**Source of Input:**
Process validation plan	
Product Specifications	Operations personnel
Parts from "Production Run(s)" and/or parts made via processes intended for serial production	Manufacturing Engineering

Resources:

Manufacturing Engineering, Operations personnel, Quality Engineering

Methodology:

1. Test product produced from the initial production run(s) as specified in the design validation plan.
2. Compile test results into a test summary report.

   NOTE: The validation test report should include the test(s) performed, date, test parameters, specification limits, test results, and outcome (pass/fail). Applicable material certifications should also be included as required.
3. Evaluate results to determine if all requirements have been achieved.
4. Take corrective action where requirements are not achieved.

Element 4.07	**First Article Inspection (FAI)**

Element Owner: Quality Engineering

Element Definition:

The purpose of the FAI is to provide objective evidence, based on an assessment of the first production article produced during the initial production run, that all engineering, design, and specification requirements are correctly understood, accounted for, recorded, verified, and fulfilled.

First Article Inspection is a complete, independent, and documented physical and functional inspection process to verify that prescribed production processes have produced an acceptable item as specified by engineering drawings, purchase order, engineering specifications, and/or other applicable design documents. This element must comply with the requirements of Aerospace Standard 9102 when contractually required by the customer.

Deliverables:

Approved First Article Inspection Report

Necessary Inputs:	**Source of Input:**
Design Characteristics	
First Production Run Parts	Manufacturing Engineer
Control plan	Quality Engineering
Inspection results	Supplier Quality Engineering
Functional Test Results	Operations personnel
Material Certifications	
Lab Certifications	
Design Record	
Manufacturing Process Documentation	
Non-conformance Documentation, as applicable	
FAI report for all sub components	

Resources:

Manufacturing Engineering, Quality Engineering, Supplier Quality Engineering, Operations/Inspection personnel

Element 4.08	**Production Part Approval Process (PPAP) file and form**

Element Owner: Quality Engineer

Element Definition:

The purpose of PPAP is to demonstrate that the planned production process has the potential to produce product consistently meeting design and specification requirements, as demonstrated during initial production runs at the production rate required to meet customer demand.

The process requires the producer to submit a PPAP file containing evidence that a specified set of requirements are fulfilled. To realize the benefits of the APQP, it is essential that PPAP artifacts be produced within the appropriate APQP phase as defined in this manual (reference: International Aerospace Standard 9145).

The PPAP submission is dispositioned by the customer as:

- approved; i.e. all PPAP requirements have been fulfilled,
- interim approved; i.e. partial fulfillment of PPAP requirements with applied restrictions, or
- rejected; minimum PPAP requirements not fulfilled.

The PPAP submission should be dispositioned as approved or interim approved by the customer before the producer can release product for shipment. The completed PPAP Approval form is a record of the PPAP disposition.

Changes to the product design and/or manufacturing process may require PPAP resubmission depending on the nature of the change (reference: International Aerospace Standard 9102) and customer requirements.

Deliverables:

PPAP approval

Necessary Inputs:	**Source of inputs:**
Parts from initial Production Runs	Customer
Design Records	Operations personnel
Design Risk Analysis (e.g., DFMEA); Process Flow Diagram	Design Engineering
FMEA	Manufacturing Engineering
Control Plan	Quality Engineering
MSA	
Initial Process Capability Studies	
Packaging, Preservation, and Labelling Approvals	
FAIR	
Customer PPAP Requirements	
PPAP Approval Form (or equivalent)	

Resources: Quality Engineering, Manufacturing Engineering, Operations Personnel, Customer.

Methodology:

1. Customer and producer agree on the content required for PPAP submission, the schedule for submission, and the timescales for customer approval.
2. Producer collects data and prepares documentation.
3. Producer submits PPAP package per customer PPAP requirements including the required artifacts (evidence of completion).
4. Customer reviews and dispositions the PPAP submission using the PPAP Approval form (International Aerospace Standard 9145, Appendix D) or equivalent document.
5. Customer notifies the producer of PPAP disposition.
6. Producer is authorized to release product in accordance with the PPAP disposition,
7. Producer resubmits PPAP as required (e.g. for rejected, interim approval, changes to product, and/or process).

Element 4.09	**Customer Specific Requirements**
Element Owner: Quality Engineer	
Element Definition: The Customer may specify activities and/or artifacts that exceed those required in the International Aerospace Standard 9145. These items are referred to as Customer Specific (PPAP) Requirements in the PPAP submission. Customer Specific Requirements may specify additional requirements or provide clarification of requirements, deliverables, and/or data submittals. These requirements should be identified during the phase 1 & 2, and with timing established and assigned to the appropriate functional organization.	
Deliverables: Identification and fulfillment of Customer Specific Requirements	
Necessary Inputs: Customer Specific Requirements	**Source of inputs:** Customer
Resources: Quality Engineering, Manufacturing Engineering	
Methodology: 1. The producer reviews the customer requirements to determine if there are any unique requirements (i.e. those requirements not included in 9145) 2. Customer unique requirements are included in the project plan with timing and responsibilities assigned. 3. Evidence of completion is included PPAP submission as required.	

Phase 5 Full Release	**Introduction**

Phase Definition:

This phase describes the activities that are to be performed post PPAP. Activities include defect reduction, improved cycle time, product improvements and cost reductions. As issues/opportunities arise, the established process and controls will be evaluated and updated as necessary.

A “Lessons Learned” activity should also be conducted. The organization should periodically review and evaluate the effectiveness of the product quality planning effort and tools used.
Appropriate actions should be identified and initiated as necessary to improve the APQP process.

Phase 5 On-going Production, Use, and Post-delivery Service

Element 5.01.1	**Measuring Performance**
Element Owner: Project Manager	

Element Definition:

It is important to ensure that product produced continues to meet all requirements. NE-XT should establish a means for monitoring performance in the manufacturing environment as well as in the customer environment and act on this information as it becomes available.

Key Performance Indicators (KPIs) are used to gage various functions and processes important to achieve organizational goals. Typical KPIs include program cost targets, customer satisfaction ratings (Quality, On-time delivery (OTD), Responsiveness), customer escapes, supplier performance, cost of poor quality, warranty costs, product field performance (mean-time-to-failure), etc.

Quality indices provide a quantitative measure of the ability to maintain and improve the consistency of product within specification and to meet performance targets. Typical quality indices include e.g. Cpk, Parts Per Million (PPM), rejection rates, Defects Per Million Opportunities (DPMO), First Pass Yield (FPY), etc.

On-time delivery of product must be maintained at or above the level desired by the customer throughout the life of the program. The capacity analysis should demonstrate the ability of the producer to meet the demand profile of the customer over the foreseeable time horizon. Changes is in the demand profile should be identified and addressed as soon as they are communicated by the customer.

At a minimum, when the project targets are not achieved and/or product is not performing to the customers' desired levels, actions should be taken to determine root cause and implement corrective actions.

Deliverables:

- Metrics that clearly demonstrate actual performance against targets and requirements
- Action plan to implement corrective actions as needed

Necessary Inputs:	**Source of Input:**
Customer satisfaction ratings	Customer, Quality Organization Procurement Customer Service

Resources:

Customer, Customer Support, Manufacturing, Quality

Methodology:

Quality and KPI

1. Identify quality indices and KPIs.
2. Collect and analyze performance data.
3. Communicate results to responsible organizations.
4. Develop and initiate corrective actions as necessary.

Capacity model

1. Obtain forecast from customer(s).
2. Determine capacity needed to meet customer demand.
3. Determine available capacity.
4. Calculate difference between available and required capacity.
5. Develop an action plan to meet demand profile where required.

Element 5.02	**Continuous Improvement Actions**

Element Owner: Quality Engineer, Manufacturing Engineering

Element Definition:

An effective customer/producer partnership is essential to improve product performance, quality, cost, delivery and overall customer satisfaction. The producer should investigate, evaluate and incorporate improvements to cost, delivery and lead time as well as opportunities to enhance product performance and overall customer satisfaction during its service life.

At a minimum, when the product is not performing to the customers' desired levels, actions should be taken to determine root cause and implement corrective actions. Product deficiencies may be related to design and/or production deficiency. In either case, the responsible organization should lead the root cause investigation and required corrective actions (reference (Aerospace Recommended Practice – 9136 Root Cause Analysis and Problem Solving (9S) Methodology)

Identification of sources of variation and its subsequent reduction is a key aspect of enhanced product performance, and a driver of continuous improvement initiatives focused on product quality. Variation reduction consists of monitoring of the production processes, with special attention given to Key Characteristics (KCs). Data analysis using statistical techniques (Cp and Cpk) is the preferred method for identifying variation reduction opportunities.

Improvement opportunities are prioritized; action plans are developed and implemented. Actions that result in changes to the product and processes may require customer notification and updates to product and process documentation (i.e. Design records, design risk analysis, Process Flow diagram, PFMEA, Control Plan, etc.). An updated PPAP submission is typically required.

Deliverables:

On-going data analysis and planned improvement actions

Necessary Inputs:	**Source of Inputs:**
Production data	Customer
Field data	Quality Engineer
Financial data	Manufacturing Engineering
Cost of poor quality	Finance
Customer complaints (escapes)	Program Office

Resources:

Quality Engineer, Design Engineer, Manufacturing Engineer, Operations, Finance, Program Manager

Methodology:

1. Review quality indices and KPIs to identify improvement opportunities.
2. Prioritize improvement opportunities based on cost, timing, customer impact, etc.
3. Communicate opportunities and make recommendations to stakeholders.
4. Develop and implement action plan (obtain customer approval as required)
5. Validate improvement(s).
6. Update documents as necessary (i.e. Design records, design risk analysis, Process Flow Chart, PFMEA, Control Plan, etc.).

Element 5.03	**Lessons Learned**

Element Owner: Project Manager

Element Definition:

The purpose of a Lessons Learned is to prevent the reoccurrence of problems previously experienced as well as build on those activities that went well. The organization should have a process for capturing and including lessons learned to improve the product realization process (APQP) and future products. Input should be requested as phases are completed and can originate from any functional group. Inputs may include; cost to budget, adherence to schedule (APQP plan, delivery), design changes, early field failures, corrective action plans, initial quality data, customer satisfaction, cost of poor quality, etc.

Lessons Learned reviews are intended to provide a forum by which candid discussions can take place regarding past issues. Action should be taken where opportunities for improvement are identified. Operating and design standards should be updated where needed.

The APQP project is closed when necessary, actions are taken to achieve targets and Lessons Learned are documented.

Deliverables:

- Record of lessons learned
- Successful activities captured and standardized for future programs
- Action plan(s) for improvement activities

Necessary Inputs:	**Source of Input:**
Project team feedback	Project Team
Customer feedback	Customer
Management feedback	Management
Data from performance metrics (cost, schedule adherence, quality, etc.)	

Resources: All members of NPI team

Methodology:

1. Gather and analyze appropriate data.
2. Develop and implement improvement action as needed:
   - Transfer knowledge to similar projects and products,
   - Record Lessons Learned in appropriate documents,
   - Update APQP process as needed.