Nexteer Global Supplier Quality
Early Production Containment Training

Supplier Early Production Containment Process Overview

- Purpose: Protect the customer by increasing confidence that all Early Production Containment(EPC) shipments will meet Nexteer's quality expectations and validate the production control plan
- Includes the utilization of a Pre-Launch Control Plan
- Covers production runs during the start-up and acceleration of a new/changed product, manufacturing process
- The default timeframe is 90 regular production days unless instructed otherwise by the Nexteer AQE. The last 30 days in that period must be with using the regular production control plan.
  - If no defects are found in that 30 day period then the supplier may request exit from EPC with the Nexteer AQE.
  - If a defect is found within this 30 day period, exit from EPC will not be granted.
- It is possible for a supplier to exit some EPC activity while keeping other portions in place as part of the production control plan
- Any defects found at a Nexteer plant or at a customer location require a 5-Why analysis and additional containment activities. Documents may need to be reviewed and updated or additional clarification of requirements may be required.

Supplier Early Production Containment Process Overview

- Agreement between the AQE and supplier on early production containment requirements and exit criteria are important. This activity should be documented and well understood by both parties. The AQE may want to conduct an audit of this activity as well as request and review data on a regular basis.

- Exiting will be based on the following:
  - The effectiveness of the EPC to meet Nexteer's expectations of Zero Defects
  - All problem cases related to this specific product closed, or a Nexteer approved plan to close
  - Production Control Plan validated. Gate charts reviewed.
  - Nexteer supplier quality engineer has verified all exit criteria has been met

Pre-Launch Control Plan

Early Production Containment – **Pre-Launch Control Plan** Overview

- Pre-Launch Control Plan contains all the EPC strategies
- Must contain the same controls that are documented in the regular production control plan
  - In addition, special efforts over and above regular controls should be implemented
- Should contain all known critical conditions/characteristics of a part, and any other other potential areas of concern
- In general, all special characteristics should be 100% checked
  - Process parameters, which are determined to have a direct effect on special characteristics should also be monitored and documented at an increased frequency.

Early Production Containment – **Pre-Launch Control Plan** Overview

- The control plan needs to be reviewed to ensure that it comprehends correct inspection frequencies as well as a lot control strategy. The PFD may need to be reviewed to comprehend setup and other hidden factory items (reject handling).
- Any defects found during pilot / prototype runs must be comprehended in the Pre-Launch Control Plan
  - A gate chart should be kept during all runs prior to PPAP. That gate chart should determine some of the items to be checked/controlled as additional verification during the EPC period.
  - This gate chart should be updated and reviewed prior to exiting the pre-launch activity. If corrective actions are implemented, you would expect to see no more of that type of defect if the corrective action was adequate. All suspect parts must be analyzed

Early Production Containment – **Pre-Launch Control Plan** Overview

- Quality control documentation should be reviewed based on data collected. The PFMEA and control plan should be updated to comprehend and control new failure modes as well as RPN values.
- Part variation within a product family should be comprehended (Reference slide 14 for more information)
- Labeling and incoming inspection should also be part of the control plan verification strategy. Variation of incoming material may yield information to internal variation. Labeling is a serious issue throughout many organizations.
- Living document, must be submitted for PPAP and each time there is a revision
- Certain EPC controls may remain as part of the standard production flow and should be documented in the Production Control Plan(PCP)

Supplier - Early Production Containment
Overall Strategy Summary

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Overall Strategy Summary

- Identification of person responsible
- Development of the Pre-launch Control Plan
- Establishment of a reaction plan for immediate containment and notification of Nexteer
- Identification of the measurement equipment and data collection devices/activities
- Establish a Supplier Reporting Frequency using the Nexteer F1075 EPC Workbook Template. The template is located on the Supplier Portal under Quality Processes in the APQP & Current Production Cycle Documents

Supplier Early Production Containment
Overall Strategy Summary

- Early production containment (EPC) activities (extra inspection) treated the same as regular production activities.
  - Work instructions, training, verification of gauges, data collection, reaction plans and management layered audits need to included
    - Without a standard method for measurement the values mean nothing. (consider touch point inspection)
    - Layered audits should verify standard work, part handling, reaction to abnormal activities as well as monitoring good quality practices.
    - Audit data (product and process) must be collected, plotted, and reviewed at a regular basis. If defects are found at the audit inspection points, the audits must remain in place.
    - The supplier's launch team should review all defects(minimum daily) and establish corrective action plans. New (unknown) defects need special attention to determine root cause quickly.

Supplier Early Production Containment
Overall Strategy Summary

- Processes should be monitored at a regular frequency based on validation and verification of stability over time.
  - If there is not sufficient data to validate the frequency established in the production control plan, the early production containment plan should include gathering the process data at an increased frequency (at least twice as often as recommended) and looking at stability over time to justify the monitoring frequency on the production control plan.
- There should also be Special reaction to the produced product if the processes are found to be unstable.
- If issues are discovered at the additional inspection area, extra inspection (reactive containment)prior to that step may be required. The extra inspection (reactive containment) can focus on the specific problem and not detract from the complete inspection that is already in place

Supplier Early Production Containment
Overall Strategy Summary

- If instructed by Nexteer, supplier will implement an EPC utilizing all or elements of the formal Controlled Shipping Level II process
- If the defect rate is abnormal (FTQ), extra containment should be in place until a root cause has been identified and corrective actions are in place. The additional audit activity should remain until sufficient data has been gathered to justify removal of that activity. If processes are scheduled to be added later for improvements in quality or capacity, they should also be placed into an early production containment process to verify their controls are adequate.
- Handling of parts should also be observed. Defects generated as a result of handling need to be reviewed for possible changes in packaging or standard work practices.

Supplier Early Production Containment
Overall Strategy Summary

- Based on historical production process indicators, additional controls may include:
  - Increased frequency/sample size at value stream inspection points
  - Mandated sub-supplier containment and/or supplier audits
  - Addition of inspection/control items and functional testing
  - Increased verification of label accuracy
  - Statistical evaluations
  - Enhancement of process controls
  - Increased verification of error proofing
  - Increased involvement and visibility of top management
  - Increased audits, verifying key manufacturing quality fundamentals such as standard work, part handling and adherence to established quality practices

Overall Strategy Summary

- Families of variation must be comprehended in the control strategy. Data must be collected and reviewed based on the variation expected. This makes setting a required time or quantity difficult.

- In general the strategy must capture a sufficient amount of data to demonstrate process stability throughout the known families of variation and a significant production quantity (e.g. 10% of the first year's volume) Some examples may include:
  - Multiple setups
  - Multiple molds or presses
  - Multiple batches
  - Multiple incoming batches
  - Multiple operators
  - Multiple process settings
  - Multiple flow paths
  - Variation within a batch

Early Production Containment Examples

Low Volume Example

For a bulk material produced in large quantities on an infrequent basis, the AQE may want to see multiple samples from the same batch and samples from multiple batches as well as documenting of certain process settings for each batch.

If there is some knowledge that the material is sensitive to operator setup, the AQE may request that each batch be prepared by a separate operator.

If there is some knowledge that the material varies with temperature extremes, the AQE may request that batches be sampled at various intervals throughout the entire year.

If the material will be produced by multiple processes each process should be validated through the early production containment requirements.

High Volume Example

For a high volume press operation producing thousands of parts per hour the AQE may ask the supplier to measure some quantity of parts at a set time sequence to look at wear or heat up issues.

The AQE may ask for measurements to be taken at each tool setup to look for setup variation. The AQE may also want additional sampling after any tool maintenance. Since so many parts are produced so quickly it would not make sense to base exit criteria on number of pieces.

If the setup could be operator dependent then the AQE would want to ask for multiple setups by multiple operators with multiple incoming lots to try to capture many of the known areas of variation. Again, it may take some time to complete a run sequence to collect data from all the areas of possible variation so a set time would probably not be applicable either.

Nexteer Standard Link

- Nexteer Standard – Early Production Containment