Built In Zero Defects General Requirements

August 2019

Littelfuse®

Expertise Applied | Answers Delivered

Supplier Development Engineering

THE SDE TEAM MISSION IS TO SUPPORT THE LITTELFUSE GLOBAL BUSINESS BY DEVELOPING QUALIFIED, COMPETITIVE AND RELIABLE SUPPLIERS AND MAINTAIN AN OVERALL PERFORMANCE TO COMPLY WITH CUSTOMERS' NEEDS

LITTELFUSE – Company Profile

Littelfuse Inc. designs, manufactures, and sells circuit protection, sensor and control devices for use in the automotive, electronics, and industrial markets worldwide. It operates through three segments: Electronics, Automotive, and Industrial

Our **Purpose**: To improve the safety, reliability, and performance of our customers' products that use electrical energy

Our **Mission**: Drive double-digit growth by accelerating organic growth and investing in strategic acquisitions

The Littelfuse corporate values are:

- Customer Focus
- Results Driven
- Teamwork
- Integrity
- Innovation

BIZD Strategy In Relation To LFOS

Littelfuse Operating System

OPERATIONAL EXCELLENCE: EVERYONE, EVERY DAY, EVERY WHERE

LITTELFUSE Quality Policy

LITTELFUSE **commits to exceptional customer value through our relentless pursuit of operational excellence and zero defects, driving continuous improvement in everything we do.**

In support of this commitment *LITTELFUSE* will:

- Engage with our customers to deliver best in class service and support;
- Leverage our applications expertise to understand our Customers' needs and emerging opportunities;
- Deliver technology and products that provide innovative and reliable solutions to the market;
- Empower our people to create a data driven and socially responsible culture that they are proud to be part of;
- Celebrate our individual and team successes

Our Expectations to Suppliers:

We set high standards that apply to Littelfuse and to our suppliers. Our suppliers are responsible for ensuring the quality of their products, meeting our DPPM & quality incidents requirements established in our procedure of supplier rating system or QMP. With an ultimate goal of zero defects, meeting delivery commitments, and keeping costs competitive

All suppliers are also expected to deliver high quality service, maintain appropriate inventory, demonstrate technical knowledge and make continuous improvements. We look for suppliers who are flexible, committed to growing the relationship and focused on the end user. In return, we provide the support, information and resources needed to help our suppliers meet these expectations, and to jointly achieve our goal of total customer satisfaction

What we expect from you:

- Quality products that fully meet specification
- Environmental compliance
- On-time delivery
- Competitive costs
- Adequate inventory
- Technical knowledge
- High quality service
- Continuous improvement
- Shared goals, and
- Commitment to the business relationship

Built In Zero Defects Elements

- **BUILT IN ZERO DEFECTS** tools provide a basic guideline for those quality management system requirements that our supplier base is expected to implement in alignment with Littelfuse ***ZERO DEFECTS - ZERO EXCUSES*** philosophy

- By implementing the **BIZD elements**, our supplier base will benefit from an overall improvement in performance which we can measure through our supplier Scorecard (SC), Critical Risk Supplier (CRS) and even on-site QMS audits

- The material included in this presentation is just a **quick reference**. We encourage you to look for additional information, training courses and literature for a thorough implementation of each element

LITTELFUSE BIZD Core Elements

1. FAST RESPONSE PROBLEM SOLVING SYSTEM
2. NON CONFORMING MATERIAL & IDENTIFICATION
3. PROCESS CONTROL PLAN
4. PROCESS CAPABILITY REVIEW
5. STANDARDIZED WORK
6. PROCESS CHANGE CONTROL & VALIDATION
7. VISUAL CONTROLS / VISUAL STANDARDS
8. MAINTENANCE
9. SUPPLY CHAIN MANAGEMENT
10. LAYERED PROCESS AUDIT
11. PFMEAs / RISK REDUCTION & ANNUAL REVIEW
12. GAGE CALIBRATION / MSA
13. ALARM & ESCALATION
14. FIFO / MATERIAL HANDLING PROCESS
15. ERROR PROOFING VERIFICATION
16. QUALITY FOCUSED CHECKS
17. BYPASS / DEVIATION MANAGEMENT
18. VERIFICATION STATION (FINAL INSPECTION / GP12)
19. ANDON SYSTEM IMPLEMENTATION
20. REWORK / REPAR CONFIRMATION
21. SHIPPING / APPROVED PACKAGING
22. FEEDBACK AND FEEDFORWARD
23. CONTAMINATION CONTROL
24. TRAINING

Built In Zero Defects

The Elements

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BIZD 1

Fast Response Problem Solving System

Team Problem Solving Process

Fast Response Problem Solving System/Team Problem Solving Process

Fast Response:

- The disciplined execution of quality and production milestones that must be targeted for completion within a 24 hour (D1 – D3), 3 calendar days (D4) and 14 calendar days (D5 – D6) to prevent reoccurrence of a problem
  - D1: Establish Team
  - D2: Problem Description
  - D3: Interim Containment Actions
  - D4: Identify root cause(s)
  - D5: Identify the permanent corrective action
  - D6: Validate the corrective action
- Ensures that quality issues are immediately addressed and closed using standardized approach and avoid reoccurrence

Fast Response Problem Solving System/Team Problem Solving Process

Problem Solving:

- Littelfuse seeks to create a proactive culture of problem solving, where projects are aligned to corporate, business unit, department and personal goals. We aim to create a culture of quality through engagement
- Understanding prior to the end of the shift/day/week/month if achieving the target is in jeopardy allows us to take prioritize efforts and take steps to resolve the roadblocks
- The purpose of tiered meetings is to facilitate daily and rapid communication at all levels and solicit input to ultimately improve
  - Safety
  - Quality
  - Delivery
  - Cost (Productivity)

Fast Response Problem Solving System/Team Problem Solving Process

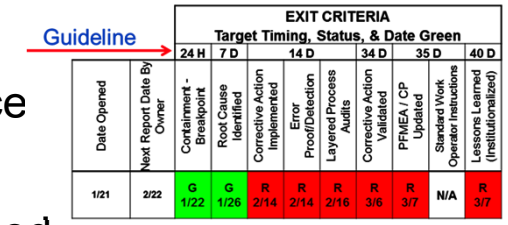
FR Tracking Board Example:

The Plant Manager or designated manufacturing lead shall:

- Ensure that Fast Response process is maintained and effective
- Designate a champion & co-champion as the facilitator

At the Fast response meeting, site leadership shall:

- Designate a leader (natural owner) for each concern / issue if one has not been already assigned
- Ensure proper support from all disciplines through attendance
- Identify action required and owner for items statused in RED
- Establish the next report out date for the issue if it is not closed



		EXIT CRITERIA Target Timing, Status, & Date Green									
Guideline →		24 H	7 D	14 D			34 D	35 D		40 D	
Date Opened	Next Report Date By Owner	Containment - Breakpoint	Root Cause Identified	Corrective Action Implemented	Error Proof/Detection	Layered Process Audits	Corrective Action Validated	PFMEA / CP Updated	Standard Work Operator Instructions	Lessons Learned (Institutionalized)
1/21	2/22	G 1/22	G 1/26	R 2/14	R 2/14	R 2/16	R 3/6	R 3/7	N/A	R 3/7

What is not a Fast Response meeting?

- Fast Response Meeting was started but stopped, because:
  - It became a problem solving meeting (too long)
  - No daily issues reported (-> weekly -> wind up)
  - Issues remained open too long because of no regular feedback
- Practical Problem Solving Form or equivalent is not used
- No clear definition of what is a “significant issue”
- Problem solving in office not at Point of Cause
- Missing why’s (Drill Deep) to find main root cause
- Read across (Drill Wide) is not completed
- Lessons Learned database available, but not in use

BIZD 2

Non – Conforming Material

Material Identification

Non-Conforming Material / Material Identification

Purpose:

- Ensure there is a system in place to avoid non-conforming material from reaching the customer (Littelfuse)

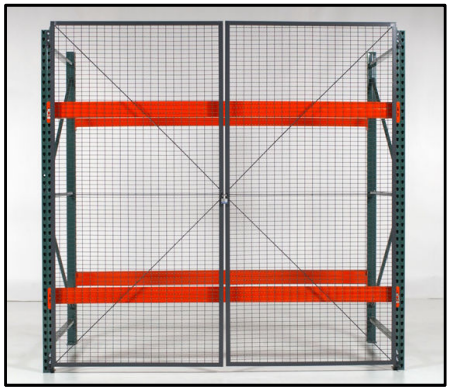
When to use:

- To identify non-conforming and/or suspect material detected on-site
- To account for and identify any non-confirming and/or suspect material after a customer notification about a quality incident. Ensure that the entire pipe-line is considered: on-site, in-transit, at the customer, at final customer/user

Non-Conforming Material / Material Identification

Elements:

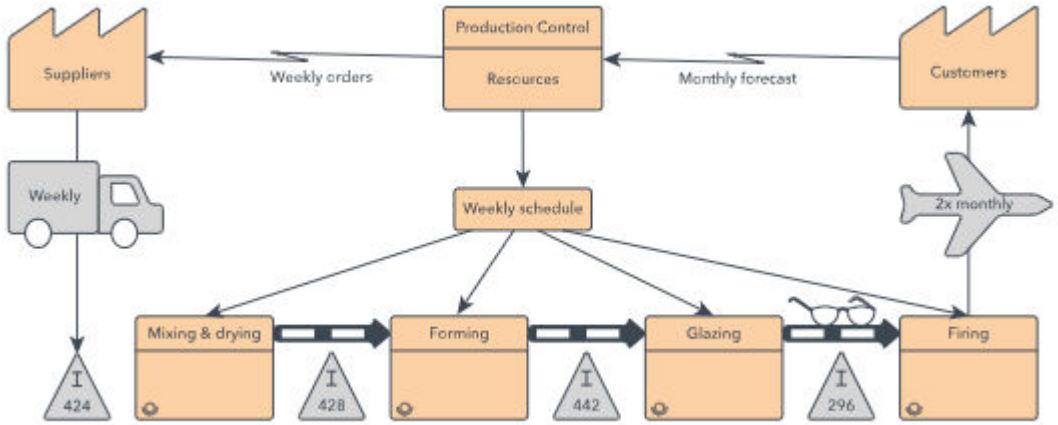
- Procedure or Instruction. Clear responsibilities
- Material identification methods
  - Tags
  - Labels
  - Containers
  - Locations: Racks, quarantine areas, “cages”



Non-Conforming Material / Material Identification

Elements (continued):

- Defined communication: Internal and External (Carriers, customers, …)
  - Open/Honest communication with customer is expected
- Consider the entire value stream: suppliers, inventory, WIP, in-transit, at customers



Non-Conforming Material / Material Identification

- Importance of traceability
  - Quick identification of suspect inventories
- Non-conforming material identification is the result of containment activities
- Definition for the reintroduction of material into the value stream is also critical:
  - Who is responsible?
  - What process is followed to define material is no longer “non-conforming”?
  - How is material identified? Maintain traceability

Non-Conforming Material / Material Identification

- Implement an inventory process where there are steps clearly defined to give disposition for non-conforming material:
  - Responsibility
  - Time frame or lead times for required actions
  - Costs associated with keeping inventory
- Material that is the result of any containment activity (inspection, sorting, rework, …) needs to have the proper identification (customer approval may be required) and traceability

BIZD 3

Process Control

Process Control Plan Implemented

Process Control & Process Control Plan Implemented

Purpose:

- A Process Control Plan (PCP) is a "summary description" of the methods used in the manufacturing environment to minimize variation and control product and process characteristics in order to ensure capability and stability of the manufacturing process. It is a structured approach for the design, selection and implementation of control methods, and reactions to problems with the manufacturing and assembly operations when they do occur

What is the relationship between Process FMEA and PCP?

- Process FMEA is an input to the Process Control Plan. Typically, the causes from the Process FMEA become process characteristics in the PCP and the Process Controls from the Process FMEA become control methods in the PCP. There are other inputs to the PCP, including Process Flow Diagram

Process Control & Process Control Plan Implemented

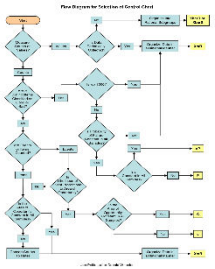
How do Process FMEAs improve PCPs?

- The Process FMEA is a key contributor to the effectiveness of the Process Control Plan. This linkage between the PFMEA and the PCP goes two ways:
  - The Process FMEA team includes representation from the manufacturing controls area, in order to ensure that the team considers all needed input from process controls as part of the analysis
  - When the Process FMEA team identifies failure modes and associated causes that are not currently detected or controlled in PCPs or associated procedures, the PCP and procedures can be updated and improved, so all failure modes of concern are detected and controlled during manufacturing or assembly. Any changes to PCPs or procedures should be included in the Process FMEA recommended actions

Process Control & Process Control Plan Implemented

PCP relation with PFMEA & WI

Flow Diagram



- Show Process Flow
- Picture the process
- This is you foundation to create the PMEA, CP, Layouts, etc.

PFMEA

- List/Document each operation
- Specify current controls
- Enhanced control with recommended actions
- List KPC's/KCC's

Document:
- Inspection frequency
- Checking/Gage devices
- Reaction plans in case of non-conforming product

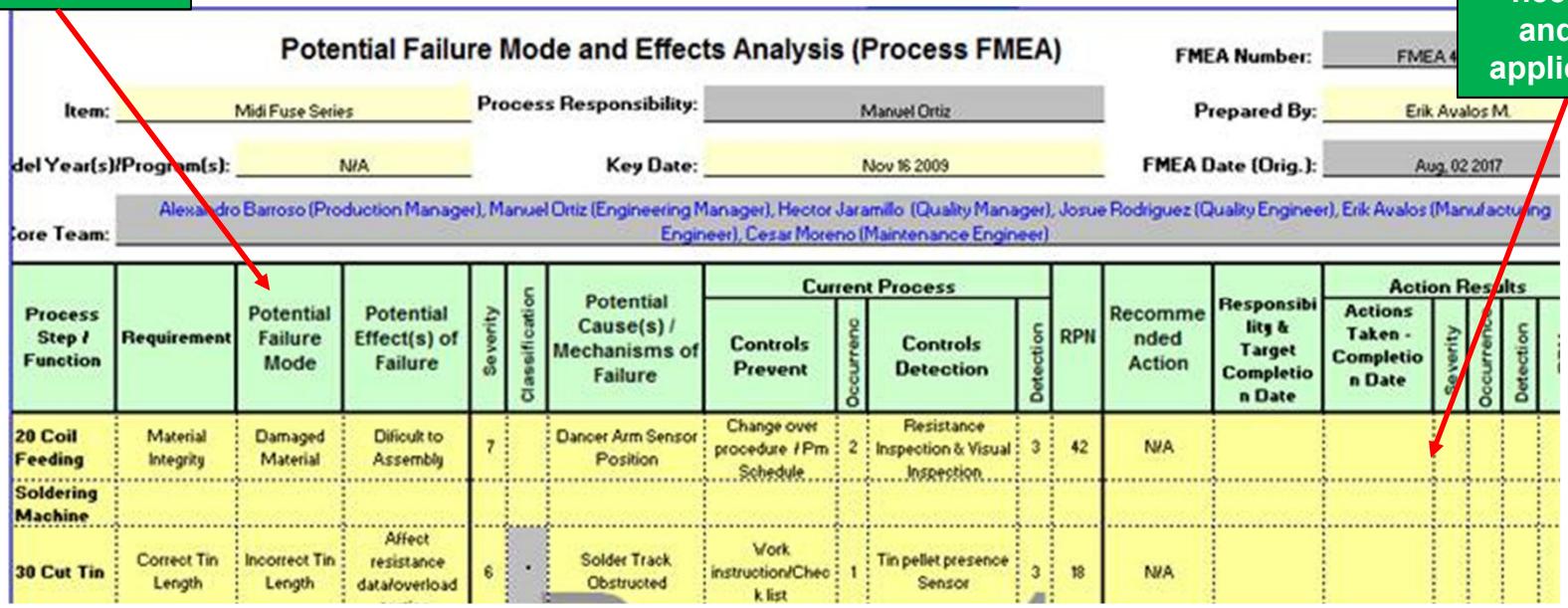
- Enlist your job/WI descriptions

Process Control & Process Control Plan Implemented

List potential modes

PFMEA Example

List any actions as needed and/or applicable



Potential Failure Mode and Effects Analysis (Process FMEA)

FMEA Number: FMEA 4

Item: Midi Fuse Series | Process Responsibility: Manuel Ortiz | Prepared By: Erik Avalos M.

del Year(s)/Program(s): N/A | Key Date: Nov 16 2009 | FMEA Date (Orig.): Aug. 02 2017

ore Team: Alexandro Barroso (Production Manager), Manuel Ortiz (Engineering Manager), Hector Jaramillo (Quality Manager), Josue Rodriguez (Quality Engineer), Erik Avalos (Manufacturing Engineer), Cesar Moreno (Maintenance Engineer)

Process Step / Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) / Mechanisms of Failure	Current Process: Controls Prevent	Occurrence	Current Process: Controls Detection	Detection	RPN	Recommended Action	Responsibility & Target Completion Date	Action Results: Actions Taken - Completion Date	Severity	Occurrence	Detection
20 Coil Feeding	Material Integrity	Damaged Material	Dificult to Assembly	7		Dancer Arm Sensor Position	Change over procedure / Pm Schedule	2	Resistance Inspection & Visual Inspection	3	42	N/A					
Soldering Machine																	
30 Cut Tin	Correct Tin Length	Incorrect Tin Length	Affect resistance data/overload	6		Solder Track Obstructed	Work instruction/Check list	1	Tin pellet presence Sensor	3	18	N/A					

Process Control & Process Control Plan Implemented

Control Plan Example

Part Certification

Control Plan Category: ○ Prototype ○ Pre-Launch ◉ Production			Key Contact Name: Hector Jaramillo(Quality Manager)	Date (Orig): 2/18/2013	Date (Rev): 6/9/2016 / Page
Control Plan Number: CP 423-005 C			Key Contact Phone: (52) 878 782 6222	Customer Engineering Approval and Date (If Req'd): N/A	Date (If Req'd): N/A
Part Number: 0498060.MX1M5, 0498080.MX1M5	Customer drawing rev: N/A	ECL: N/A	Supplier / Plant Approval / Date: N/A	Customer Quality Approval and Date (If Req'd): N/A	Date (If Req'd): N/A
Part Name / Description: Midi Fuse One Hole			Other supplier approval by (If Req'd): N/A	Other Approval and Date (If Req'd): N/A	Date (If req'd): N/A
Supplier / Plant: Littelfuse, S.a. de C.V. / P. Negras, Mex.	Supplier Code: N/A		Other Approval Date (If Req'd): N/A	Other Approval Date (If Req'd): N/A	
Core team Members: Hector Jaramillo (Quality Manager), Juan Castilla (Manufacturing Engineer), Elvia Ferrer (Quality Engineer), Luis Monroy (Engineering Services Manager), Alberto Espino (Production Manager)					

			Characteristics				Methods					
Part / Proc #	Process Name / Operation description	Machine, Device, Jig, Tools For Mfg.	No.	Product	Process	Special Characteristics	Product / Process Specification / Tolerance	Evaluation / Measurement Technique	Sample Size	Sample Freq.	Control Method	Reaction Plan
10	Load Pre stamped element coil			Element with one hole			According to H423-09-007	Visual	Once	Every setup/Change Over	F423-002	Correct process, inspect production parts, contain material from the last inspection, reject material according to P13-01
				Element with one hole orientation			According to H423-09-026	Visual	Once	Every setup/Change Over	F423-005	Correct process, inspect production parts, contain material from the last

Check sheet used to register the records

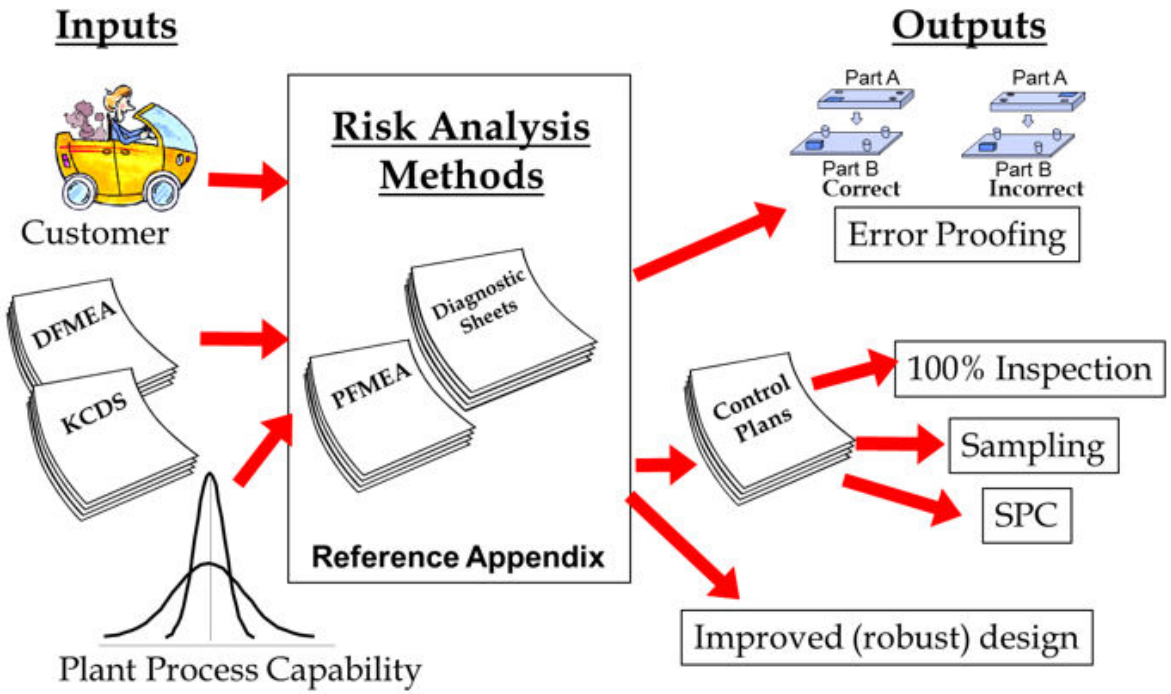
Frequency of control

Process Control & Process Control Plan Implemented

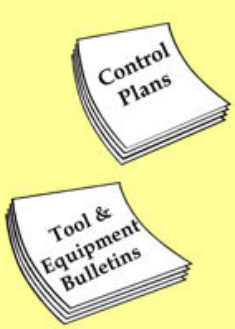
What to Look For When a PCP is implemented?

- Sample process control plans and ensure checks are performed at the correct frequency and sample size
  - Confirm that checks are documented using the proper control method (i.e. control charts, check sheets)
  - Check that reaction plans from the process control plan are present, followed and effective
  - Check how sample size is determined and how it is linked with occurrence number
  - Check that sample size is reviewed on a regular basis
  - Check that testing sample size is according to customer requirement/testing standard as minimum
  - Check that process specific requirements are met, audit records are kept, and action plans in case of gaps are followed
  - Check that sample size and frequency adequately protects the customer so that product does not ship to the customer before the completion and results of the inspection/test are known

Process Control Plan Implemented



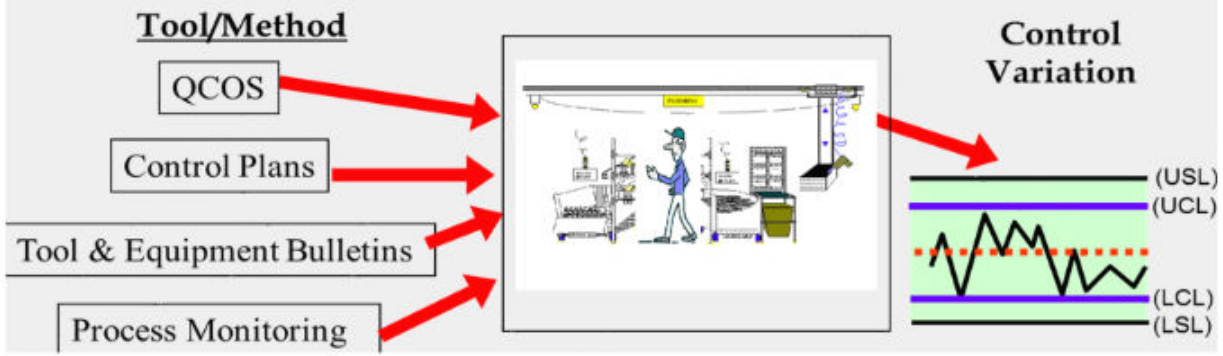
Process Control Plan Implemented

Process control plans are developed as an output of the Risk Analysis Process	Method of implementing the required process controls are documented	Data is analyzed to ensure process output remains capable
	**Process Control Methods** • Trend Charting • Statistical Process Control • Capability Studies • Layered Audits • Process Monitoring	**Countermeasures** • Reaction Plans • Alarm & Escalation Process • Problem Solving
Dictated by engineering requirements	Implemented to comply with engineering requirements	Process output measured against engineering requirements

Process Control Plan Implemented

Process controls are developed to drive daily checks that are conducted at the team level to control variation within the process.

- Processes are identified through a risk analysis method
- Determine the appropriate tool/method to use for each process
- Document results and follow up with corrective actions
- Control process output variation within quality standard limits



BIZD 4

Process Capability Review

Process Capability Analysis

Purpose:

- Evaluate the process and the ability to meet customer requirements

When to use:

- To prove that the process meets customer requirements
- To verify that supplied part meet design requirements
- To determine short and long term performance

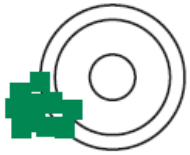
Cp, Cpk, Pp and Ppk

- Are statistical measures of process quality capability

C_p	C_{pk}	P_p	P_{pk}
Short-term estimate of process capability, is a measure of variation relative to specification limits	Short- term estimate of process capability, this is a measure of average and variation relative to specification limits	Long-term estimate of process capability is a measure of variation relative to specification limits	Long-term estimate of the process capability, is a measure of average and variation relative to specification limits

- P_p is a long term it will most likely be less the C_p. For P_{pk} will most likely be less than Cpk.
- C_{pk} involves average and variation it will either be equal or less than C_p, Likewise P_{pk} will either be equal to or less than P_p

Process spread versus centering

High C_p High C_{pk} ($C_{pk} \sim C_p$)		Centered Low spread (High C_p)
High C_p Low C_{pk} ($C_{pk} < C_p$)		Not centered (Low C_{pk}) Low spread (High C_p)
Low C_p Low C_{pk} ($C_{pk} \sim C_p$)		Centered High Spread (Low C_p)

Low C_p Low C_{pk} ($C_{pk} < C_p$)		Not centered (Low C_{pk}) High Spread (Low C_p)
Low C_p High C_{pk} ($C_p < C_{pk}$)	N/A	N/A

Note: The combination of Low C_p and High C_{pk} is not possible.

Control and capability are not the same, High Cpk does not necessarily mean that process is in control

Values expected for Cpk

Automotive industry ≥1.67

and for Non Automotive ≥ 1.33

Process spread versus centering

- When capability is not met, two choices are available:
  - Reduce Variation
  - Increase the specification limits
- Reducing variation allows the process to shift and still produce defect-free parts

BIZD 5

Standard Work

Standard Work

Purpose:

- Standard work is one of the most important building blocks of Lean Manufacturing. Written standard work procedures, such as Standard Operation Sheets (SOS) and Standard Work Combination Tables (SWCT), are the result of organizing tasks in the best sequence of steps for people, equipment, tooling and materials. This standardized way is the “one best way” known today to do the task with regard to safety, quality and efficiency

- Standard work is the foundation of daily improvement. A process must be standardized and stabilized before continuous improvement can be made. Including standard work as an integral part of operating our business will enable us to drive continuous improvement. When an opportunity to improve the process is identified and proven by the team, the standard work is changed, all associates are trained and all team members complete the task in the new standardized way

Standard Work Benefits

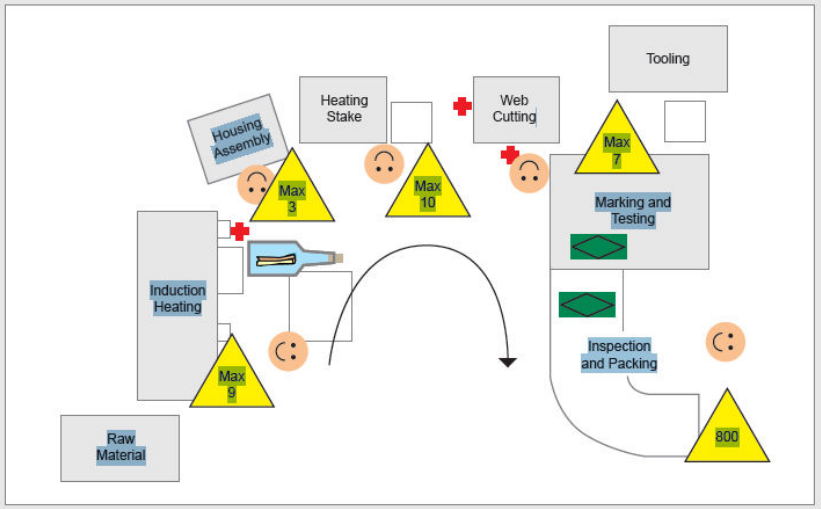
- Best, easiest and safest way to do a job
- Best way to preserve know-how and expertise
- A way to measure performance
- A way to show the relationship between cause and effect
- Basis for both maintaining and improving the process
- Means to provide objectives and indicate training goals
- Basis for training
- Basis for audit or diagnosis
- Means for preventing errors and minimizing variability
- Method to maintain internal and external compliance

Steps To Creating Standard Work

- Grasp the facts
- Identify job elements
- Measure time for all the elements
- Establish job element breakdown sheet
- Create Standard Operation Sheets (SOS)
- Create Standard Work Combination Tables (SWCT) as needed

An example of a Standard Operation Sheet is shown below.

Work Flow	From:	First Process: Induction Heating	Masterfuse PQ 34 SOS	Prod Family/VSM/Cell: Masterfuse line 1
	To:	Last Process: Inspection & Packing:		PQ34



Quality Inspection	Safety Prevention	Bottle Neck	Standard WIP Point	WIP Quantity	Takt Time (Seconds/unit)	Lead Time (Hours)	Walk Path With Part	Walk Path Without Part
				829	16	4.0		

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BIZD 6

Process Change Control

Process Change Validation

Process Change Control

Element Concept Definition:

- To ensure that no unnecessary changes are made, that all changes are documented, that services are not unnecessarily disrupted and that resources are used efficiently

- Suppliers shall establish and utilize a defined process to standardized communication and documentation, build readiness reviews utilizing a cross functional team and quality reviews before and after the change

- All internal/external process change MUST be documented
  - A formal procedure/process is available
  - Forms shall be controlled through a document control process/procedure

- These are some examples where a PCN is required:
  - Change in Process parameters, out of the processes letter or established in the initial validation
  - Movement of equipment (Change Layout) within the plant
  - Add new devices, tools, controls to the current process/change in tools, fixtures, devices
  - Change in the process Flow and/or add new process to the current process
  - Sub-suppliers changes

An example of a “ procedure of process change control ” is shown below

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INTERNAL PROCEDURE

TITLE: PROCESS CHANGE NOTIFICACION (PCN)	NUMBER: P05-03-PCP	REVISION: 4
	DATE: AUGUST 04th, 2017	PAGE: 1 DE 15
THIS DOCUMENT CANCELS AND SUPERSEDES	NUMBER: P05-03-ABU	REVISION: 3

Verificar si el procedimiento se usa 24 hrs. después del 14/09/2018 11:45

1.0 INDEX

2.0 PURPUSE

The purpose of this procedure is to define and implement the steps that need to be followed to generate and apply a process change notice.

3.0 SCOPE

This procedure will apply in all the processes of the automotive (PCP) plant.

Prepared by: Itzeel Perez.		**Title:** Quality Systems Coordinator.	
Signature:		**Date:**	
Reviewed by:	**Title:**	**Signature:**	**Date:**
Hector Jaramillo	Quality Manager.		
Sergio Fernández	Assembly Operations Manager.		
Juan Campos	Assembly Operations Manager.		
Juan A. Castro	Molding Operations Manager.		
Arnoldo Fuentes.	Plating Operations Manager.		
Manuel Azuela	Maintenance Manager		
Francisco Hernandez	Product Engineering Manager.		
Jesus A. Garcia	Supply Chain Manager		
Approved by: Manuel Ortiz		**Title:** Engineering Services Manager	
Signature:		**Date:**	

Form # E400-002 Rev. 1 Emission 11/07

Littelfuse

INTERNAL PROCEDURE

TITLE: PROCESS CHANGE NOTIFICACION (PCN)	NUMBER: P05-03-PCP	REVISION: 4
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Verificar si el procedimiento se usa 24 hrs. después del 14/09/2018 11:45

4.0 POLICY

Is Littelfuse's policy to give an adequate follow-up to the process change notice before implementing it.

5.0 REFERENCES

5.1 Global system of PCN
5.2 VDA 6.3

6.0 DEFINITIONS

6.1 PCN: Process Change Notice.
6.2 Form F466-003 Array of activities and validation of ECO, GCF & PCN's of PCP

7.0 AUTHORITY

The plant manager or his designee will have the final authority of generating a process change notice and be responsible for implementing this procedure.

8.0 PROCEDURE

8.1 Any Staff of the management or designees can generate a process change notice, using the PCN global system

These are some examples that apply generating a PCN for a change of process:

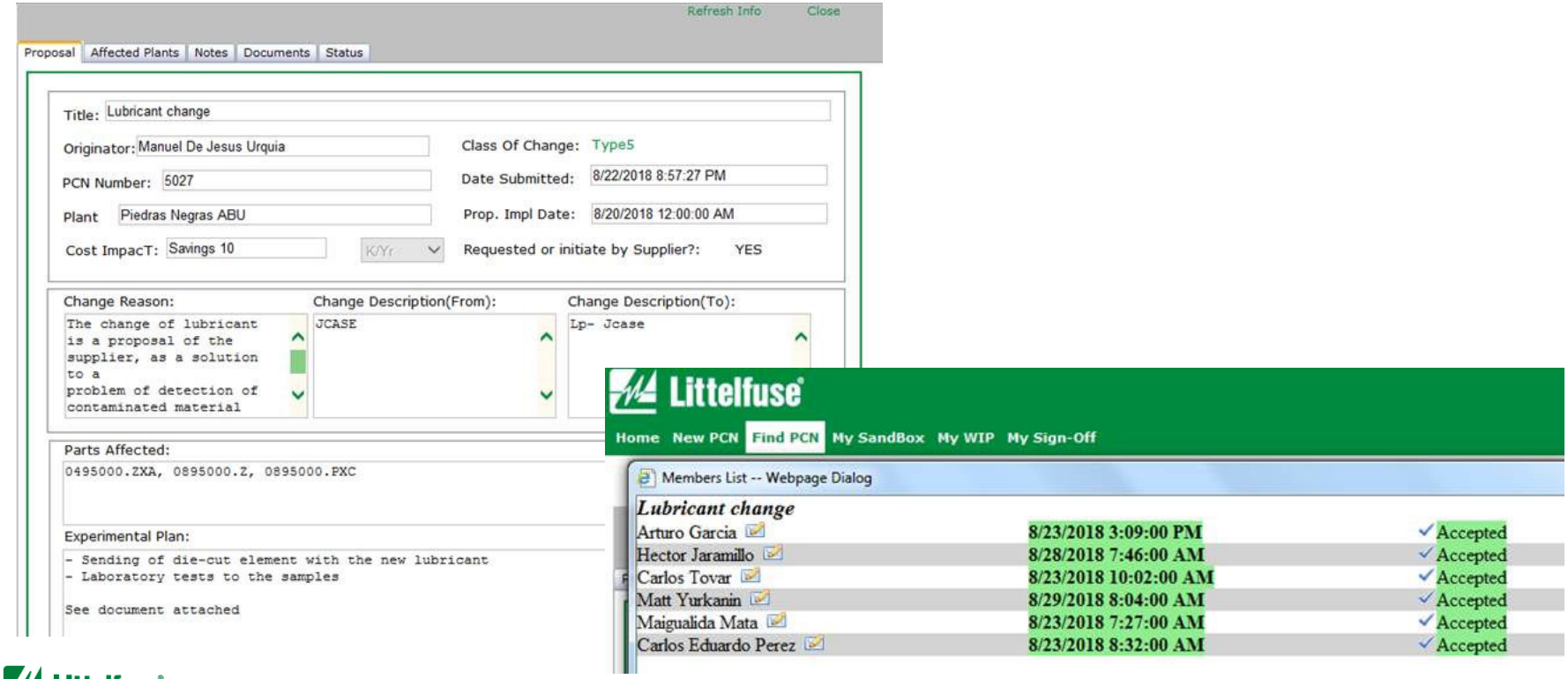
1. Change in the logic of the PLC programs, view, etc.
2. Change in Process parameters, out of the processes letter or established in the initial validation.
3. Movement of equipment (Change Layout) within the plant.
4. Add new devices, tools, controls the current process.
5. Change in tools, fixtures, devices.
6. Change any technology equipment within the production line.
7. Change on the process flow.
8. Add new process to the current process
9. Change some consumables in the process that is in contact with the product (Example, lubricants).

8.2 Any staff of the management or designee has to generate an evaluation study to verify that the change and/or modification of the process or machinery can be feasible.

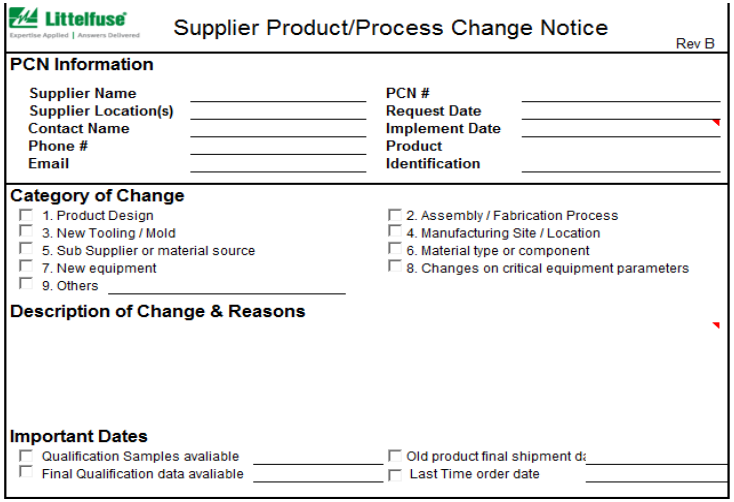
8.2.1 If the functionality of the product gets affected or the team considers that the change is not feasible the PCN gets rejected from the system.

8.2.2 If the functionality of the product does not get affected and the change of process is feasible, this is when it has to be authorized for able to process it by the means of the PNC system.

An example of a “process change control form” is shown below



An example of a “process change control form” is shown below



Littelfuse
Expertise Applied | Answers Delivered

Supplier Product/Process Change Notice

Rev B

PCN Information

Supplier Name		PCN #	
Supplier Location(s)		Request Date	
Contact Name		Implement Date	
Phone #		Product Identification	
Email			

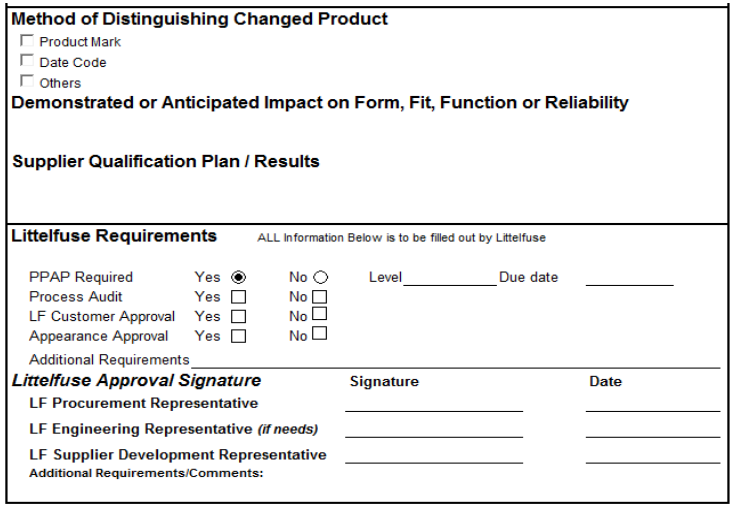
Category of Change

- ☐ 1. Product Design
- ☐ 2. Assembly / Fabrication Process
- ☐ 3. New Tooling / Mold
- ☐ 4. Manufacturing Site / Location
- ☐ 5. Sub Supplier or material source
- ☐ 6. Material type or component
- ☐ 7. New equipment
- ☐ 8. Changes on critical equipment parameters
- ☐ 9. Others _____

Description of Change & Reasons

Important Dates

- ☐ Qualification Samples avaliable _____ ☐ Old product final shipment da _____
- ☐ Final Qualification data avaliable _____ ☐ Last Time order date _____



Method of Distinguishing Changed Product

- ☐ Product Mark
- ☐ Date Code
- ☐ Others

Demonstrated or Anticipated Impact on Form, Fit, Function or Reliability

Supplier Qualification Plan / Results

Littelfuse Requirements ALL Information Below is to be filled out by Littelfuse

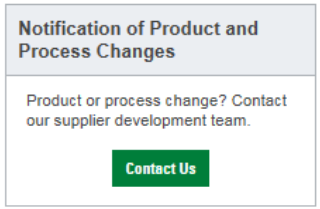
PPAP Required	Yes ◉	No ○	Level _____	Due date	_____
Process Audit	Yes ☐	No ☐			
LF Customer Approval	Yes ☐	No ☐			
Appearance Approval	Yes ☐	No ☐			

Additional Requirements _____

Littelfuse Approval Signature	**Signature**	**Date**
LF Procurement Representative		
LF Engineering Representative *(if needs)*		
LF Supplier Development Representative		

Additional Requirements/Comments:

https://www.littelfuse.com/about-us/supplier-quality.aspx



Process Change Validation

Element Concept Definition:

- This validation applies to any new process (launch or transference) or for bigger changes in process and / or modifications to the process already in existence (new machine, machinery updating, etc.)

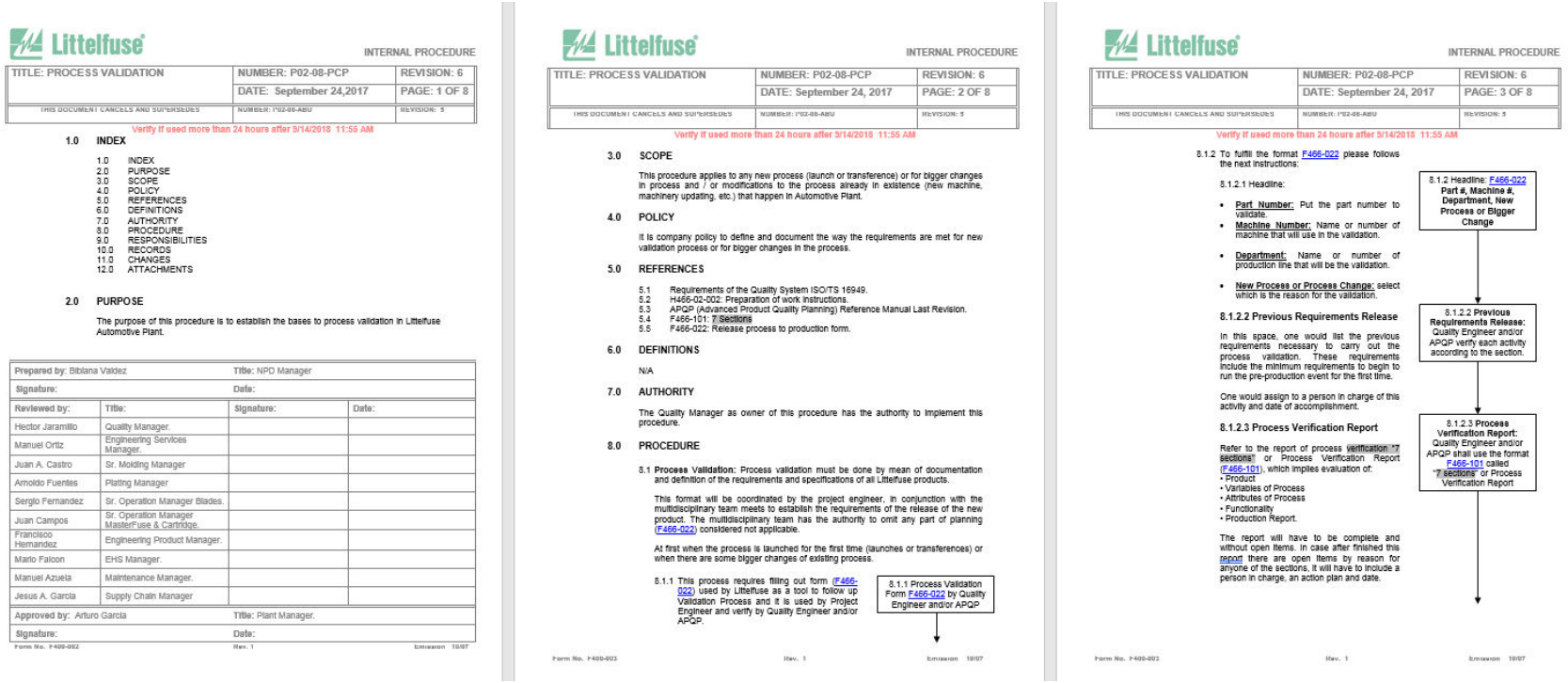
- Organization shall establish a process to ensure a successful “Process change validation” , it must include, but not limited to:

  – Standardized procedure & forms define the requirements for process change validation
  – Run and rate conducted under the same conditions of planned mass production. (changeovers, operators, control plan, floor plan, production materials, appropriate volume, etc.)

  [The process change validation confirms the manufacturability of a change within the normal production environment]

  – Quality reviews before and after the change

An example of a “procedure of process change validation” is shown below



Littelfuse

INTERNAL PROCEDURE

TITLE: PROCESS VALIDATION	NUMBER: P02-08-PCP	REVISION: 6
	DATE: September 24,2017	PAGE: 1 OF 8
THIS DOCUMENT CANCELS AND SUPERSEDES	NUMBER: P02-08-ABU	REVISION: 5

Verify if used more than 24 hours after 9/14/2018 11:55 AM

1.0 INDEX

2.0 PURPOSE

The purpose of this procedure is to establish the bases to process validation in Littelfuse Automotive Plant.

Prepared by: Bibiana Valdez		**Title:** NPD Manager	
Signature:		**Date:**	
Reviewed by:	**Title:**	**Signature:**	**Date:**
Hector Jaramillo	Quality Manager.		
Manuel Ortiz	Engineering Services Manager.		
Juan A. Castro	Sr. Molding Manager		
Arnoldo Fuentes	Plating Manager		
Sergio Fernandez	Sr. Operation Manager Blades.		
Juan Campos	Sr. Operation Manager MasterFuse & Cartridge.		
Francisco Hernandez	Engineering Product Manager.		
Mario Falcon	EHS Manager.		
Manuel Azuela	Maintenance Manager.		
Jesus A. Garcia	Supply Chain Manager		
Approved by: Arturo Garcia		**Title:** Plant Manager.	
Signature:		**Date:**	

Form No. F-400-002 Rev. 1 Emission 10/07

Littelfuse

INTERNAL PROCEDURE

TITLE: PROCESS VALIDATION	NUMBER: P02-08-PCP	REVISION: 6
	DATE: September 24, 2017	PAGE: 2 OF 8
THIS DOCUMENT CANCELS AND SUPERSEDES	NUMBER: P02-08-ABU	REVISION: 5

Verify if used more than 24 hours after 9/14/2018 11:55 AM

3.0 SCOPE

This procedure applies to any new process (launch or transference) or for bigger changes in process and / or modifications to the process already in existence (new machine, machinery updating, etc.) that happen in Automotive Plant.

4.0 POLICY

It is company policy to define and document the way the requirements are met for new validation process or for bigger changes in the process.

5.0 REFERENCES

5.1 Requirements of the Quality System ISO/TS 16949.
5.2 H466-02-002: Preparation of work instructions.
5.3 APQP (Advanced Product Quality Planning) Reference Manual Last Revision.
5.4 F466-101: 7 Sections
5.5 F466-022: Release process to production form.

6.0 DEFINITIONS

N/A

7.0 AUTHORITY

The Quality Manager as owner of this procedure has the authority to implement this procedure.

8.0 PROCEDURE

8.1 **Process Validation:** Process validation must be done by mean of documentation and definition of the requirements and specifications of all Littelfuse products.

This format will be coordinated by the project engineer, in conjunction with the multidisciplinary team meets to establish the requirements of the release of the new product. The multidisciplinary team has the authority to omit any part of planning (F466-022) considered not applicable.

At first when the process is launched for the first time (launches or transferences) or when there are some bigger changes of existing process.

8.1.1 This process requires filling out form (F466-022) used by Littelfuse as a tool to follow up Validation Process and it is used by Project Engineer and verify by Quality Engineer and/or APQP.

8.1.1 Process Validation Form F466-022 by Quality Engineer and/or APQP

Form No. F-400-002 Rev. 1 Emission 10/07

Littelfuse

INTERNAL PROCEDURE

TITLE: PROCESS VALIDATION	NUMBER: P02-08-PCP	REVISION: 6
	DATE: September 24, 2017	PAGE: 3 OF 8
THIS DOCUMENT CANCELS AND SUPERSEDES	NUMBER: P02-08-ABU	REVISION: 5

Verify if used more than 24 hours after 9/14/2018 11:55 AM

8.1.2 To fulfill the format F466-022 please follows the next instructions:

8.1.2.1 Headline:

- **Part Number:** Put the part number to validate.
- **Machine Number:** Name or number of machine that will use in the validation.
- **Department:** Name or number of production line that will be the validation.
- **New Process or Process Change:** select which is the reason for the validation.

8.1.2.2 Previous Requirements Release

In this space, one would list the previous requirements necessary to carry out the process validation. These requirements include the minimum requirements to begin to run the pre-production event for the first time.

One would assign to a person in charge of this activity and date of accomplishment.

8.1.2.3 Process Verification Report

Refer to the report of process verification "7 sections" or Process Verification Report (F466-101), which implies evaluation of:
• Product
• Variables of Process
• Attributes of Process
• Functionality
• Production Report.

The report will have to be complete and without open items. In case after finished this report there are open items by reason for anyone of the sections, it will have to include a person in charge, an action plan and date.

8.1.2 Headline: F466-022 **Part #, Machine #, Department, New Process or Bigger Change**

8.1.2.2 **Previous Requirements Release:** Quality Engineer and/or APQP verify each activity according to the section.

8.1.2.3 **Process Verification Report:** Quality Engineer and/or APQP shall use the format F466-101 called "7 sections" or Process Verification Report

Form No. F-400-002 Rev. 1 Emission 10/07

An example of a “process change validation” is shown below (7 section report)

PROCESS VERIFICATION REPORT

10-27-17

Date of build:

Validation Porpouse: ECO☐ New Product Introductio☑

Department Number: 621

Quality Engineer Resposible: Claudia Torres

UNSLOTTED MCASE

0695000.PXP

INDEX

SECTION 1: Product Validation Plan

Overload Test Quality lab

Item No.	Part Number	Test	Sample size	Specification			Actual values			Evaluation
				MIN	MAX	Units	MIN	AVG	MAX	
1A	0695015.PXP	Overload test 135%	8	60	1800	Sec				
2A	0695020.PXP	Overload test 135%	8	60	1800	Sec				
3A	0695025.PXP	Overload test 135%	8	60	1800	Sec				
4A	0695030.PXP	Overload test 135%	8	60	1800	Sec				
5A	0695040.PXP	Overload test 135%	8	60	1800	Sec				

Force Test Quality lab

Item No.	Part Number	Test	Sample size	Specification			Actual values			Evaluation
				MIN	MAX	Units	MIN	AVG	MAX	
10A	0695015.PXP	Insertion	6	≤ 44.1		N	24.1	28.15	32.2	PASS
		Extraction	6	≥ 4.9		N	13.1	17.9	22.7	PASS
		Push Out A	6	≥ 47.75		N	62.2	66.7	71.2	PASS
		Push Out B	6	≥ 47.75		N	54.9	67.25	79.6	PASS

SECTION 2: Product Attributes

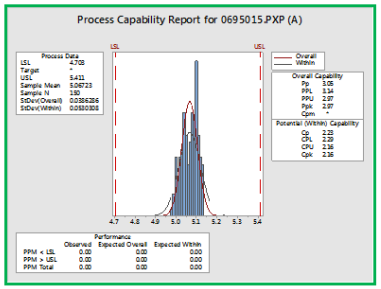
Item No.	Part number	Attributes	Sample size	Defects	Evaluation	%
1B		Cold solder	2,000	0	PASS	0.00
2B		Contaminated solder	2,000	0	PASS	0.00
3B		Incomplete solder	2,000	0	PASS	0.00
4B		Missing solder in one hole	2,000	0	PASS	0.00
5B		Missing solder in both holes	2,000	0	PASS	0.00
6B		Partial stamp	2,000	0	PASS	0.00
7B		Excess stamp	2,000	0	PASS	0.00
8B		Burn element	2,000	0	PASS	0.00
9B		Bent element	2,000	0	PASS	0.00
10B	0695015.PXP	Short shot housing	2,000	0	PASS	0.00
11B		Contaminated housing	2,000	0	PASS	0.00

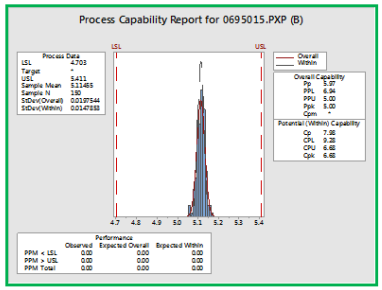
An example of a “process change validation” is shown below (7 section report)

SECTION 3: Product Variables

Resistance

Item No.	Part Number	Variables	Sample size	Specification			Actual values					Evaluation
				MIN	MAX	Units	Min	Max	Cpk	CP	PPK	
1C	0695015.PXP	Resistance_1	150	4.703	5.411	mOhms	4.9800	5.1320	2.16	2.23	2.97	PASS
		Resistance_2					5.0580	5.1690	6.68	7.98	5.00	





Item No.	Part Number	Variables	Sample size	Specification			Actual values					Evaluation
				MIN	MAX	Units	Min	Max	Cpk	CP	PPK	
2C	0695020.PXP	Resistance_1	150	3.185	3.665	mOhms						PASS
		Resistance_2										

SECTION 4: Process Functionality

Item N	Process	Test	Validation Method	Criteria	Evaluation (OK/NO O
D1	Induction Machine	Emergency Stop active HMI Box	Push the button (E-Stop)	Machine should stop, show alarm and do not start	OK
D2		Emergency Stop active base rear right side	Push the button (E-Stop)	Machine should stop, show alarm and do not start	OK
D3		Emergency Stop active base rear left side	Push the button (E-Stop)	Machine should stop, show alarm and do not start	OK
D4		Emergency Stop active base front rright side	Push the button (E-Stop)	Machine should stop, show alarm and do not start	OK
D5		Safety Guard 801 LS. Door rear left side	Open the door and try to start the machine	Machine should stop and show alarm and do not start	OK
D6		Safety Guard 802 LS. Door rear center	Open the door and try to start the machine	Machine should stop and show alarm and do not start	OK
D7		Safety Guard 803 LS. Door rear right side	Open the door and try to start the machine	Machine should stop and show alarm and do not start	OK
D8		Light Curtain Block	Interrumpt the guard crossing the hand	Machine should stop and show alarm and do not start	OK
D9	Dereeler	008/09 Limit Sensor dereeler	Move the amr of the derreler and activate the sensor.	Machine shouldn't start and show alarm.	OK
D10	Induction Machine Station 1	001/03PE Feed strip in, strip present	Remove strip and try to start the machine	Machine shouldn't start and show alarm.	OK
D11		001/04PE Feed strip in, strip position	Move the strip and try to start the machine	Machine shouldn't start and show alarm.	OK
D12	Induction Machine Station 2	001/07PRS Element detection.	Cut one element and start the machine	The machine shouldn't stop and it shouldn't feed solder.	OK
D13		001/08PRS Element detection	Cut one element and start the machine	The machine shouldn't stop and it shouldn't feed solder.	OK
D14		001/09PRS Element detection	Cut one element and start the machine	The machine shouldn't stop and it shouldn't feed solder.	OK

An example of a “process change validation” is shown below (7 section report)

SECTION 5: Production Line Performance Index

Machine number: Mcase + 3
Shift: 2da
Supervisor Name: Eduardo Pizarro
Sample Request Number: N/A
Part Number: 06952030.PXPS

Item No.	Indicator	Result	Target	Evaluation	Comments
1E	Cycle Time	97.52	85.00	PASS	100 pcs per minute Target = 100% 85 pcs per minute Target = 85%
2E	Good Parts	19651	21760	FAIL	25,600 pcs Targer = 100% 21,760 pcs Targer = 85%
3E	Rejected Parts	536	869	PASS	536 parts rejected
4E	Available Time (Minutes)	207.0	256	FAIL	PASS if Availability % is ≥ Target
5E	Downtime (Minutes)	49.0	12.8	FAIL	49 minutes (Process issues)
6E	Performance	97.52%	85%	PASS	
7E	First Pass Yield (FPY) - Yield at End of Line (EOL)	97.34%	96%	PASS	
	New Product Yield (NPY) - Cumulative				
8E	Availability	80.86%	95%	FAIL	
9E	OEE	76.76%	77%	FAIL	

SECTION 6: Packaging Validation

Item No.	Attributes	Method	Sample size	Defects	Evaluation	%
1B	Packaging strenght to hits	Drop test by free fall	1	1	FAIL	100.00
		Total	1	1		100.00

An example of a “process change validation” is shown below (7 section report)

SECTION 7: Safety Inspection for New and Modified Equipment					
Machine Name & ID:	Maquina ensambladora Mcase plus # 3 y Maquina Inductora Mcase Plus # 3		**Department #**		621
Date of Inspection:	10/28/2017		**Conducted by:**		Fidel Paredes
Equipment Status	**New**	X	**Modified**		

Equipment Inspection	YES	NO	Equipment Inspection	YES	NO
Are all the Machine Guards in place and adequate?	X		Do all the Safety Interlocks work?	X	
Have all the Machine Hazards been identified and Warning signs posted?	X		Are there any exposed pinch points?		X
Are all Operating procedures posted?	X		Are there any sharp edges exposed?		X
Are all Controls accessible and labeled?	X		Are all the pipe and hose fittings tight?	X	
Do all Machine Indicating lights work?	X		Is the Equipment secured to the floor or does it have appropriate matting?		X
Is the Emergency STOP in appropriate location and does it work?	X		Have LOTO procedures been developed?	X	
Have all chemical hazards been identified?	X		Has operator training been completed?	X	

BIZD 7

Visual Controls / Visual Standards Communicated and Understood

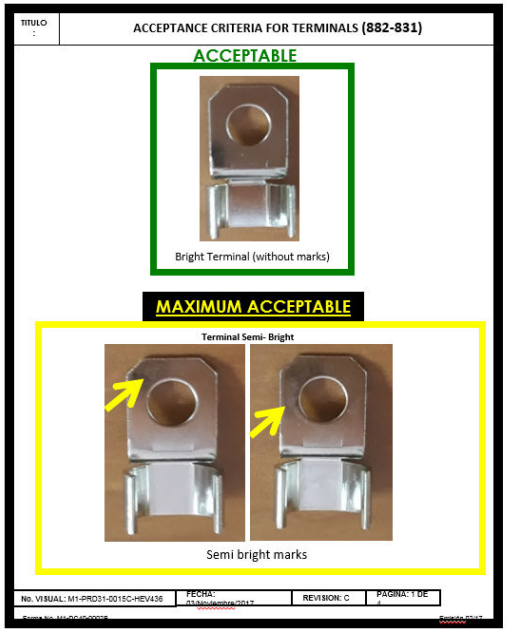
Visual Controls / Visual Standards Communicated And Understood

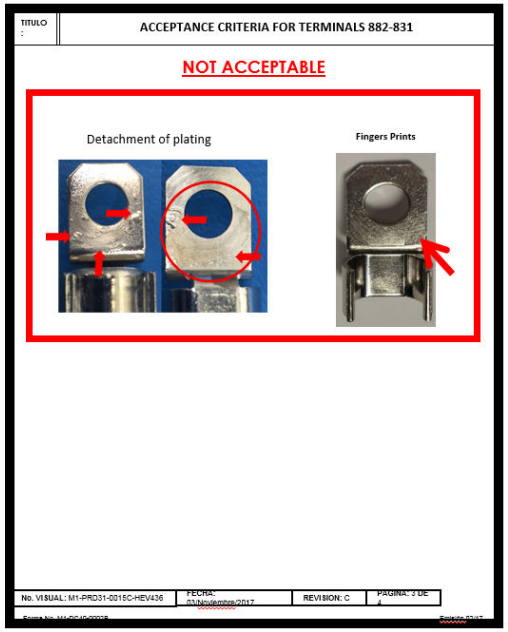
Visual Controls:

- Using visual means to track performance to expectations, identify nonstandard conditions, and generally manage the process
- Visual standards should be standardized , controlled , and updated regularly based on new issues and new risks
- Visual Standards such as Boundary samples , Quality alerts , master parts should be communicated to all team
- Visual Standard documents should be controlled
- Visual standards should be updated based on Fast Response and customer feedback

Visual Controls / Visual Standards Communicated And Understood

Examples: Product Quality Standard





BIZD 8

Maintenance

Maintenance

Purpose:

- Defines the necessary routines to maximize the productivity of equipment and tooling for its entire life cycle

When to use:

- To implement a system for Corrective, Preventive and Predictive maintenance
- To implement a TPM system → Total Productive Maintenance
- To have a maintenance system that not only focuses on equipment but also on tools and the control for critical spare parts

Maintenance

Elements:

- KPI (Key Process Indicator): Overall Equipment Efficiency (OEE), downtime, “mean time to repair”, others
- Defined schedule for Preventive Maintenance (PM)
- Written routines for Preventive and Predictive Maintenance
- Tracking methods for PM performed according to schedule
- Trained technicians
- “Lock-out and Tag-out” as a standard practice

Maintenance

- Corrective Maintenance:
  - Performed after a breakdown detection
  - Objective: Ensure the **restart of the equipment** as soon as possible
- Preventive Maintenance:
  - Performed according to predefined frequencies or on the basis of predefined criteria
  - Objective: Reduce the probability of **breakdowns or equipment wear**
- Predictive Maintenance:
  - Based on the measurement of key parameters on the equipment.
    - Examples: Vibration Analysis and thermography on electrical equipment

Maintenance

- TPM – Total Productive Maintenance:
  - The ultimate goal is to pursue perfection: **zero defects and zero unplanned equipment stops**
  - TPM is a set of techniques to help ensure that every machine in a production process is always able to effectively perform its required tasks

Maintenance

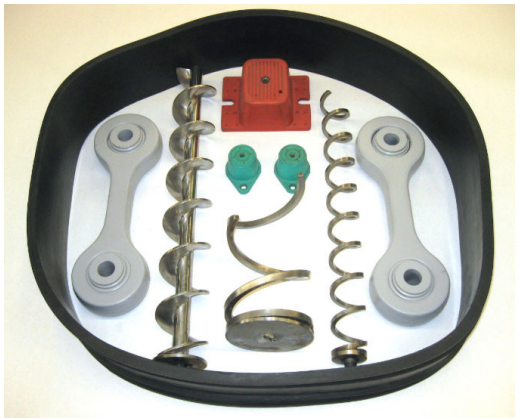
- Measuring:
  - **Overall Equipment Efficiency (OEE):** is frequently used as a key metric in TPM and Lean Manufacturing programs and gives you a consistent way to measure the **effectiveness** of TPM and other initiatives by providing an overall framework for measuring production **efficiency**
    - **OEE = AVAILABILITY x PERFORMANCE x QUALITY**

AVAILABILITY	PERFORMANCE	QUALITY
When or how often do you lose total availability of your equipment? How long are your setups? Does your equipment break down frequently?	Does your equipment start and stop frequently? Does your equipment run at 100% of its designed speed?	Do you manufacture quality products? Are your processes repeatable?

- Although OEE is simple to calculate (there are several on line references and guidelines), OEE data is only meaningful in the contest of your situation and your efforts to **improve** it. Within OEE, you should look for the losses or bottleneck that can be eliminated for a cost/benefit that makes sense. Also, OEE objectives vary from one industry to another (based on type of equipment)

Maintenance

- Another key element of a **complete Maintenance system** is to have an implemented control for Critical Spare Parts:
  - **Critical spare parts** identified for bottleneck equipment
  - Inventory management system (maximums and minimums) for spare parts
  - Spare parts inventory linked to key equipment (quick access to location, components identified, etc.)



BIZD 9

Supply Chain Management

Supply Chain Management

Definition:

- Supply chain management (SCM) is the broad range of activities required to plan, control and execute a product's flow, from acquiring raw materials and production through distribution to the final customer, in the most streamlined and cost-effective way possible

- SCM encompasses the integrated planning and execution of processes required to optimize the flow of materials:
  - Demand, planning, inventory, management and logistics

Supply Chain Management

Scope:

- Tiered supply base

Purpose:

- To reduce the risk of the sub-tier supply base to customer activities and make sure that they are controlled

Supply Chain Management

Supply Management Requirements	What To Look For:
Tier Supplier targets are defined and their performance are tracked.	Is there a process at all tiered suppliers for tracking internal and external issues? and/or do they mandate a Fast Response process used?
Annual Audits are performed, issues found are tracked until closed	Are annual Tiered Audit performed?
Quality Data is used in the sourcing decision process	Is there a process for a selection and qualification of the sub-suppliers?

BIZD 10

Layered Process Audit

Layered Process Audits

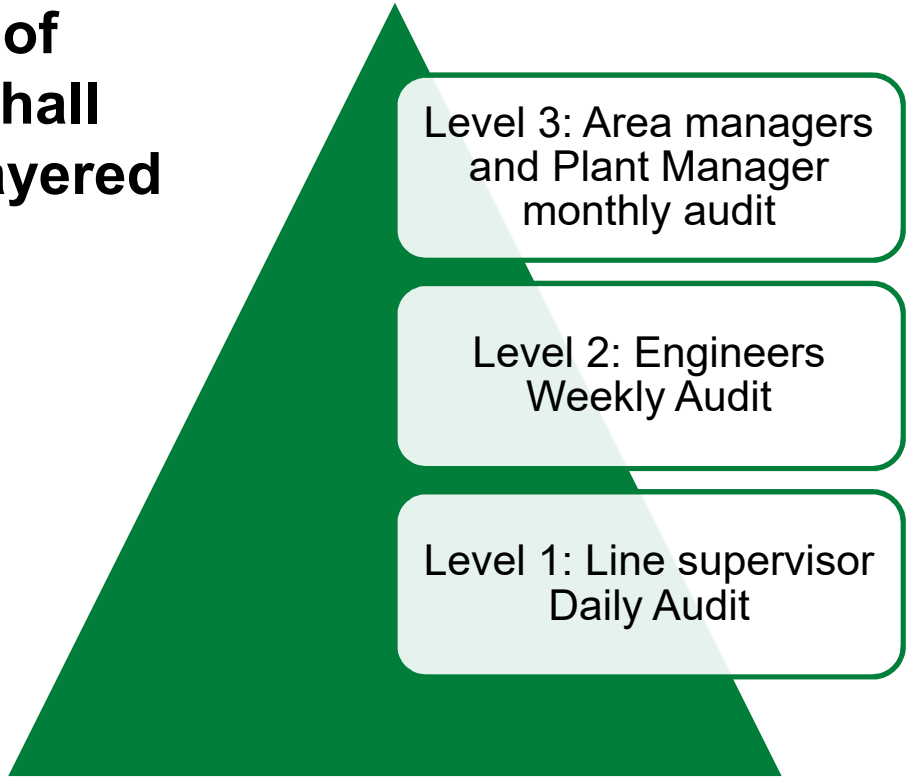
Layered process audits (LPAs) is a quality technique that focuses on observing and validating how products are made, rather than inspecting finished products

Purpose:

Is to verify that the documented processes are met to ensure a production system working in optimal conditions, involve different levels of management in the process audits and eliminate potential problems identified during the audits, as well as standardize work practices

Layered Process Audits

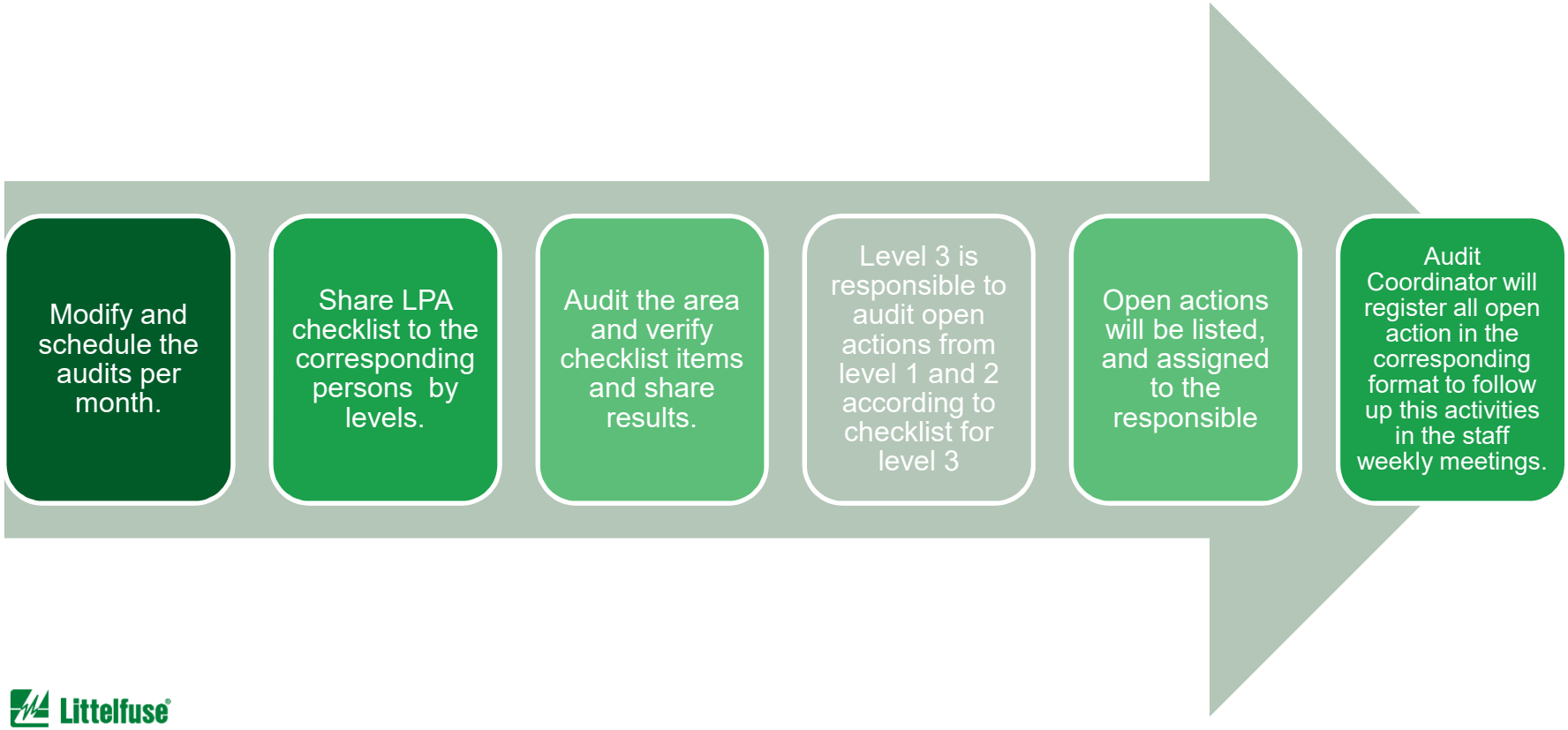
Various layers of management shall conduct the Layered Audit:



LPA in summary

- Assesses the supplier's compliance to standardized processes
- Assigns management the responsibility for assuring the effective implementation and adherence to scheduled audits
- Identifies opportunities for continuous improvement
- Provides coaching opportunities
- Requires management to actively participate in the audit process on the shop floor on a frequent basis
- Includes customer-specific and quality-focused checks reviewed by all layers including management
- Assigns management the responsibility of ensuring that effective corrective actions and counter measures are in place

LPA Process


Modify and schedule the audits per month.
Share LPA checklist to the corresponding persons by levels.
Audit the area and verify checklist items and share results.
Level 3 is responsible to audit open actions from level 1 and 2 according to checklist for level 3
Open actions will be listed, and assigned to the responsible
Audit Coordinator will register all open action in the corresponding format to follow up this activities in the staff weekly meetings.

LPA Checklist level 1 example

AUDITORIA ESCALONADA DE PROCESO — **NIVEL 1 - DIARIAMENTE**

Nombre del Auditor: _____ **Turno:** _____

Instrucciones:
1) Realizar auditoria sólo durante el turno asignado. 2) Marcar en la columna "OK" si se esta en cumplimiento el requerimiento de cada punto y en la columna "NOK" si no se esta cumpliendo con el requerimiento. Marcar en la columna "N/A" cuando no aplique. 3) El auditor deberá documentar al reverso de esta hoja las inconformidades encontradas , asignando responsable y fecha.

			Area			Area			Area			Area			Area		
		Fecha:	/ /			/ /			/ /			/ /			/ /		
		Máquina/Celda:															
	Pregunta:	Que buscar:	Lun			Mar			Mie			Jue			Vie		
			OK	NOK	N/A	OK	NOK	N/A	OK	NOK	N/A	OK	NOK	N/A	OK	NOK	N/A
CALIDAD																	
1.1	¿Se cuenta con las Bitácoras de Rastreabilidad?	Verificar que las Bitácoras de Rastreabilidad esten colocadas en el lugar asignado, llenadas correctamente (sin espacios en blanco), con letra legible y disponibles para futura consultas.															
1.2	¿Se realizó la Verificación de Sensores o Poka Yokes?	Verificar con el auditor u operador (según aplique) que se tenga a la mano la evidencia que muestre que se realizó la verificación de sensores o poka yokes (según aplique). En caso de los poka yokes, estos deberán estar identificados (según aplique).															
1.3	¿Está corriendo el proceso de acuerdo a los parámetros establecidos?	Verificar con el operador o supervisor que los parámetros establecidos en las hojas de instrucción por operación, se esten siguiendo correctamente. De lo contrario, se deberá tener un plan de acción documentado. No deberán tener acordiones con especificaciones fuera del Sistema de Control de Documentos.															
1.4	¿Estan las piezas rechazadas identificadas y separadas del producto bueno?	Verificar con el auditor piezas no conformes o piezas con caracteristicas defecturas deben ser separadas con su identificacion y alejarlas del flujo de produccion. Contenedores identificados y no saturados de material no conforme.															
1.5	¿Se tiene en el area material diferente al numero de parte que esta corriendo que pudiera ocasionar mezcla de material?	Verificar no haya partes de corrida anteriores o de diferente numero de parte al cual esta corriendo, al igual no se permiten sobrantes en la linea de produccion Hojas de trabajo sobre material que se pudiera perder la visibiliad Piezas retiradas del proceso en caso de una falla y se encuentra en mantenimiento															
1.6	El plan de control se encuentra accesible para su uso y cuenta con los datos necesarios para que el proceso funcione	Plan de Control debe de estar disponible en el lugar de trabajo. Debe de contener y definir metodos de prueba, parametros del proceso.															
ENTRENAMIENTO																	
2.1	¿El personal cuenta con su entrenamiento necesario para realizar la operación en la que esta?	Verificar que los asociados esten entrenados en la operación que estan realizando. Pedir al supervisor matriz de entrenamiento como evidencia de entrenamiento en el área de trabajo. Verificar que si existe operacion tipo A el operador tenga calificación >= 75% (4 cuadrantes) y operaciones no criticas minimo 25%															
VALIDACION																	
3.1	¿Se realiza la liberacion del proceso / producto / cambios de modelo y se registran los datos?	Verificar con el auditor de calidad / operador que la Primera Pieza de la corrida haya sido auditada, este colocada en el lugar asignado y que se mantenga los registros de la liberacion.															
EQUIPO DE MEDICION																	
4.1	¿Se encuentran dentro de fecha de calibración los equipos de medición?	Verificar que los equipos de medición se encuentren en buen estado y que su etiqueta este dentro de fecha.															
MANTENIMIENTO																	
5.1	¿Los ciclos de dados corte, moldes y dados de estampado están registrados en bitacoras?	Verificar que las bitácoras de ciclos de dados estén llenadas correctamente (sin espacios en blanco), y que su acumulado no sobre pase lo estipulado en la bitácora.															
5.2	¿El equipo no tiene fugas de aire, aceite, agua, etc.?	Verificar que el equipo de producción no cuente con fugas de aire, aceite, agua, etc. según aplique.															
5.3	¿ Se esta llevando acabo el Kan-Ban de Dados/ moldes?	Verificar que se este respetando el Kan-Ban de Dados. Llenado correcto de hoja viajera dados/moldes Identificacion del status de uso															
ORDEN Y LIMPIEZA																	
6.1	¿Se encuentra limpia el área de trabajo?	Verificar en las áreas de trabajo que se tenga una limpieza general. No fusibles en piso, ni sobre la maquinaria, no objetos personales, aceite en la maquina o piso, equipo de limpieza sobre la maquina.															
SEGURIDAD																	
7.1	¿Las guardas de seguridad, funcionan correctamente?	Verificar que las guardas de seguridad cumplan con su función. Se realizará una prueba de funcionamiento.															

LPA Checklist level 2 example

AUDITORIA ESCALONADA DE PROCESO — **NIVEL 2 - SEMANAL**

Nombre del Auditor: _____ **Área Auditada:** _____ **Turno:** _____

Instrucciones:
1) Realizar auditoria sólo durante el turno asignado. 2) Marcar en la columna "OK" si se esta en cumplimiento el requerimiento de cada punto y en la columna "NOK" si no se esta cumpliendo con el requerimiento. Marcar en la columna "N/A" cuando no aplique. 3) El auditor deberá documentar al reverso de esta hoja las inconformidades encontradas , asignando responsable y fecha.

			SEM 1			SEM 2			SEM 3			SEM 4		
	Pregunta:	Que buscar:	OK	NOK	N/A	OK	NOK	N/A	OK	NOK	N/A	OK	NOK	N/A
	Fecha:		/ /			/ /			/ /			/ /		
	Máquina/Celda:													
CALIDAD														
1.1	¿Se cuenta con las Bitácoras de Rastreabilidad?	Verificar que las Bitácoras de Rastreabilidad esten colocadas en el lugar asignado, llenadas correctamente (sin espacios en blanco), con letra legible y disponibles para futura consultas.												
1.2	¿Se realizó la Verificación de Sensores o Poka Yokes?	Verificar con el auditor u operador (según aplique) que se tenga a la mano la evidencia que muestre que se realizó la verificación de sensores o poka yokes (según aplique). En caso de los poka yokes, estos deberán estar identificados (según aplique).												
1.3	¿Está corriendo el proceso de acuerdo a los parámetros establecidos?	Verificar con el operador o supervisor que los parámetros establecidos en las hojas de instrucción por operación, se esten siguiendo correctamente. De lo contrario, se deberá tener un												
1.4	¿Estan las piezas rechazadas identificadas y separadas del producto bueno?	Verificar con el auditor piezas no conformes o piezas con caracteristicas defecturas deben ser separadas con su identificacion y alejarlas del flujo de produccion. Contenedores identificados y no saturados de material no conforme.												
1.5	¿Se tiene en el area material diferente al numero de parte que esta corriendo que pudiera ocasionar mezcla de material?	Verificar no haya partes de corrida anteriores o de diferente numero de parte al cual esta corriendo, al igual no se permiten sobrantes en la linea de produccion Hojas de trabajo sobre material que se pudiera perder la visibiliad Piezas retiradas del proceso en caso de una falla y se encuentra en mantenimiento												
1.6	El plan de control se encuentra accesible para su uso y cuenta con los datos necesarios para que el proceso funcione	Plan de Control debe de estar disponible en el lugar de trabajo. Debe de contener y definir metodos de prueba, parametros del proceso.												
1.7	¿Se revisan los metricos en el area.?	Verificación del monitoreo de métricos en piso de producción, como también que los métricos sean compartidos y entendidos por los asociados. Como ejemplo: quejas, PPMs, Yield, Scrap, sin limitarse a estos.												
ENTRENAMIENTO														
2.1	¿El personal cuenta con su entrenamiento necesario para realizar la operación en la que esta?	Verificar que los asociados esten entrenados en la operación que estan realizando. Pedir al supervisor matriz de entrenamiento como evidencia de entrenamiento en el área de trabajo. Verificar que si existe operacion tipo A el operador												
VALIDACIÓN														
3.1	¿Se realiza la liberacion del proceso / producto / cambios de modelo y se registran los datos?	Verificar con el auditor de calidad / operador que la Primera Pieza de la corrida haya sido auditada, este colocada en el lugar asignado y que se mantenga los registros de la liberacion.												
EQUIPO DE MEDICION														
4.1	¿Se encuentran dentro de fecha de calibración los equipos de medición?	Verificar que los equipos de medición se encuentren en buen estado y que su etiqueta este dentro de fecha.												
MANTENIMIENTO														
5.1	¿Los ciclos de dados corte, moldes y dados de estampado están registrados en bitacoras?	Verificar que las bitácoras de ciclos de dados estén llenadas correctamente (sin espacios en blanco), y que su acumulado no sobre pase lo estipulado en la bitácora.												
5.2	¿El equipo no tiene fugas de aire, aceite, agua, etc.?	Verificar que el equipo de producción no cuente con fugas de aire, aceite, agua, etc. según aplique.												
5.3	¿ Se esta llevando acabo el Kan-Ban de Dados/ moldes?	Verificar que se este respetando el Kan-Ban de Dados. Llenado correcto de hoja viajera dados/moldes Identificacion del status de uso												
ORDEN Y LIMPIEZA														
6.1	¿Se encuentra limpia el área de trabajo?	Verificar en las áreas de trabajo que se tenga una limpieza general. No fusibles en piso, ni sobre la maquinaria, no objetos personales, aceite en la maquina o piso, equipo de limpieza sobre la maquina.												
SEGURIDAD														
7.1	¿Las guardas de seguridad, funcionan correctamente?	Verificar que las guardas de seguridad cumplan con su función. Se realizará una prueba de funcionamiento.												
8.1	Caweb / Fast response	- Caweb: Verificacion de acciones implementadas de ultima queja de cliente oficial del area. (Verificar con el Ing. de Calidad asignado) - Fast response: Revision de tableros Fast response, tableros actualizados y acciones en tiempo o completadas con su Minuta Correspondiente esto solo aplica para: lineas Mini Fuse y Mcase Plus .												

LPA Checklist level 3 example

AUDITORIA ESCALONADA DE PROCESO — **NIVEL 3 - MENSUAL**

Nombre del Auditor: _____ **Área Auditada:** **Turno:** _____

Instrucciones:
1) Realizar auditoria sólo durante el turno asignado. 2) Marcar en la columna "OK" si se esta en cumplimiento el requerimiento de cada punto y en la columna "NOK" si no se esta cumpliendo con el requerimiento. Marcar en la columna "N/A" cuando no aplique. 3) El auditor deberá documentar al reverso de esta hoja las inconformidades encontradas , asignando responsable y fecha.

Fecha: / /
Máquina/Celda:

	Pregunta:	Que buscar:	SEM OK	SEM NOK	SEM N/A
CALIDAD					
1.1	¿Se cuenta con las Bitácoras de Rastreabilidad?	Verificar que las Bitácoras de Rastreabilidad esten colocadas en el lugar asignado, llenadas correctamente (sin espacios en blanco), con letra legible y disponibles para futura consultas.			
1.2	¿Se realizó la Verificación de Sensores o Poka Yokes?	Verificar con el auditor u operador (según aplique) que se tenga a la mano la evidencia que muestre que se realizó la verificación de sensores o poka yokes (según aplique). En caso de los poka yokes, estos deberán estar identificados (según aplique).			
1.3	¿Está corriendo el proceso de acuerdo a los parámetros establecidos?	Verificar con el operador o supervisor que los parámetros establecidos en las hojas de instrucción por operación, se esten siguiendo correctamente. De lo contrario, se deberá tener un plan de acción documentado. No deberán tener acordiones con especificaciones fuera del Sistema de Control de Documentos.			
1.4	¿Estan las piezas rechazadas identificadas y separadas del producto bueno?	Verificar con el auditor piezas no conformes o piezas con caracteristicas defecturas deben ser separadas con su identificacion y alejarlas del flujo de produccion.			
1.5	¿Se tiene en el area material diferente al numero de parte que esta corriendo que pudiera ocasionar mezcla de material?	Verificar no haya partes de corrida anteriores o de diferente numero de parte al cual esta corriendo, al igual no se permiten sobrantes en la linea de produccion Hojas de trabajo sobre material que se pudiera perder la visibiliad Piezas retiradas del proceso en caso de una falla y se encuentra en mantenimiento			
1.6	El plan de control se encuentra accesible para su uso y cuenta con los datos necesarios para que el proceso funcione	Plan de Control debe de estar disponible en el lugar de trabajo. Debe de contener y definir metodos de prueba, parametros del proceso.			
ENTRENAMIENTO					
2.1	¿El personal cuenta con su entrenamiento necesario para realizar la operación en la que esta?	Verificar que los asociados esten entrenados en la operación que estan realizando. Pedir al supervisor matriz de entrenamiento como evidencia de entrenamiento en el área de trabajo. Verificar que si existe operacion tipo A el operador tenga calificación >= 75% (4 cuadrantes) y operaciones no criticas minimo 25%			
VALIDACIÓN					
3.1	¿Se realiza la liberacion del proceso / producto / cambios de modelo y se registran los datos?	Verificar con el auditor de calidad / operador que la Primera Pieza de la corrida haya sido auditada, este colocada en el lugar asignado y que se mantenga los registros de la liberacion.			
EQUIPO DE MEDICIÓN					
4.1	¿Se encuentran dentro de fecha de calibración los equipos de medición?	Verificar que los equipos de medición se encuentren en buen estado y que su etiqueta este dentro de fecha.			
MANTENIMIENTO					
5.1	¿Los ciclos de dados corte, moldes y dados de estampado están registrados en bitacoras?	Verificar que las bitácoras de ciclos de dados estén llenadas correctamente (sin espacios en blanco), y que su acumulado no sobre pase lo estipulado en la bitácora.			
5.2	¿El equipo no tiene fugas de aire, aceite, agua, etc.?	Verificar que el equipo de producción no cuente con fugas de aire, aceite, agua, etc. según aplique.			
5.3	¿ Se esta llevando acabo el Kan-Ban de Dados/ moldes?	Verificar que se este respetando el Kan-Ban de Dados. Llenado correcto de hoja viajera dados/moldes Identificacion del status de uso			
ORDEN Y LIMPIEZA					
6.1	¿Se encuentra limpia el área de trabajo?	Verificar en las áreas de trabajo que se tenga una limpieza general. No fusibles en piso, ni sobre la maquinaria, no objetos personales, aceite en la maquina o piso, equipo de limpieza sobre la maquina.			
SEGURIDAD					
7.1	¿Las guardas de seguridad, funcionan correctamente?	Verificar que las guardas de seguridad cumplan con su función. Se realizará una prueba de funcionamiento.			
8.1	Caw eb / Fast response	- Caw eb: Verificacion de acciones implementadas de ultima queja de cliente oficial del area. (Verificar con el Ing. de Calidad asignado) - Fast response: Revision de tableros Fast response, tableros actualizados y acciones en tiempo o completadas con su Minuta Correspondiente esto solo aplica para: lineas Mini Fuse y Mcase Plus .			

BIZD 11

Failure Mode and Effects Analysis (FMEA)

Failure Mode and Effects Analysis (FMEA)

Purpose:

- To assess and mitigate potential risks and failure modes associated with the product design and manufacturing process

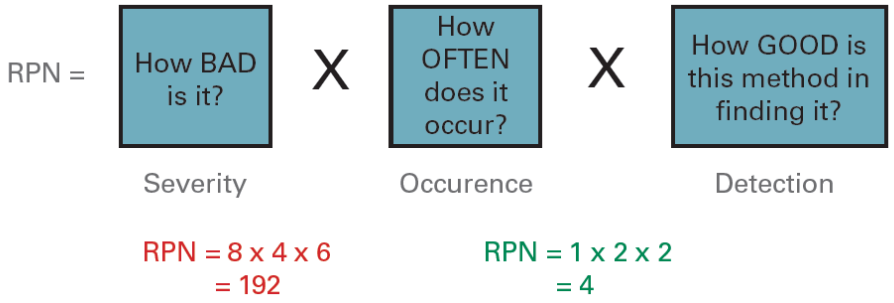
When to use:

- During the product design and development process
- During the process design and development process
- During and after release of product and processes

8 Steps to Creating a FMEA

- What are the functions?
- What can go wrong?
- What are the effects?
- How bad is it?
- What are the causes?
- How often does it happen?
- How can the cause be found?
- How good is the method of finding it?

A Risk Priority Number (RPN) is assigned to each risk



Numbers go from low to high for all three. For example, if something is unlikely to happen, it would get a low number. If something is likely to occur, it would get a high number

Establish action plans to “drive” RPN to low numbers

The priority is to address the highest RPN

LF requires that any severity ranking of 9 or 10 be addressed with a corrective action plan. Furthermore, potential failure items in the top 20% of the high RPN ranking items must have action items addressing the potential failure mode identified

Littelfuse's PFMEA template for reference only

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)

				FMEA Number:	FILE.XLS
				Prepared by:	
Item:		Process Responsibility	ORGANIZATION	FMEA Date (Orig.)	
Model Year(s)/Program(s)	APPLICATION	Key Date		FMEA Date (Rev.)	
Core Team:					

Process Step / Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Causes(s) of Failure	Occurrence	Current Process Controls Prevention	Current Process Controls Detection	Detection	RPN	Recommended Action	Responsibility	Target Completion Date	Action Results					
															Actions Taken	Effective Date	Severity	Occurrence	Detection	RPN

BIZD 12

Gage Calibration/Measurement System Analysis

Gage Calibration/Measurement System Analysis

Element Concept Definition:

- To determine if the measurement system is producing good/consistent measurements

- Measurement System Analysis (MSA) can be used when:
  - Implementing a new process and measurements are retrieved
  - Before any experiment is applied to processes
  - Continuously validate the measurement systems over time

- Measurement system
  - Gage: Any device used to take a measurement or set of measurements

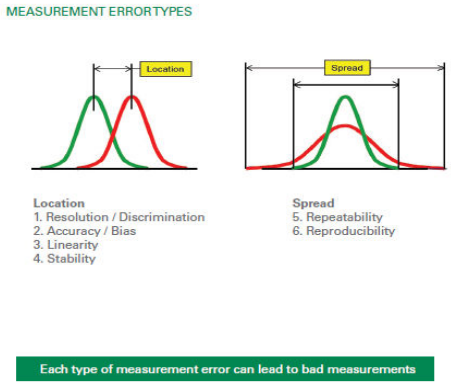
Gage Calibration/Measurement System Analysis

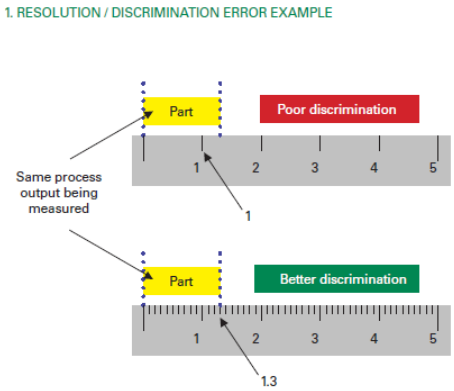
- Gage Calibration/Measurement System Analysis
  - Adjustment: A set of operations to bring a gage into a state of performance suitable to use
  - Calibration: A set of operations that compares and evaluates under specified conditions, the relationship between a gauge
  - Certification: A set of operations to document the results of a calibration, indicating conformance or non-conformance to specifications
  - Master: A device used to check and/or adjust a gage to a specified value
  - Mastering: A set of operations to verify that the gage results agree with the master
- A good/consistent measurement system will:
  - Have the measurements that are all "close" to the reference value
  - Have the variability of the gauge be smaller compared with the sample variation

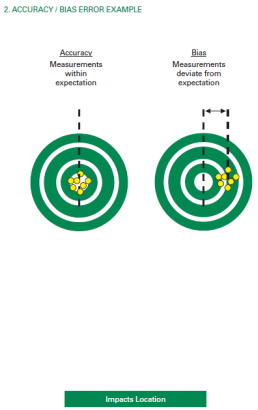
NOTE: For additional information refer to the latest version/edition of "Measurement System Analysis (MSA)" published by the AIAG

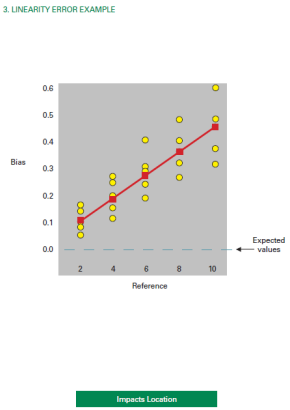
Gage Calibration/Measurement System Analysis

Typical measurement error types:

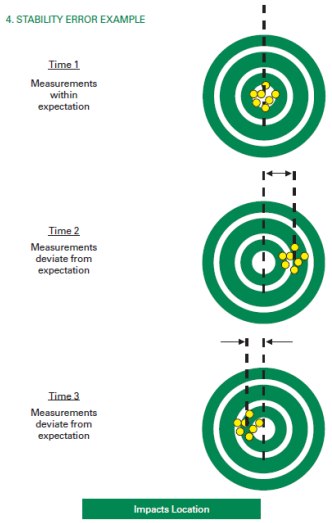


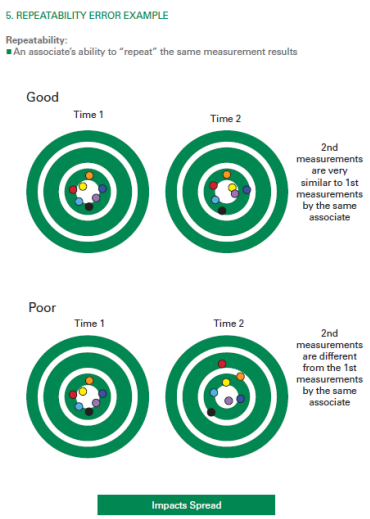


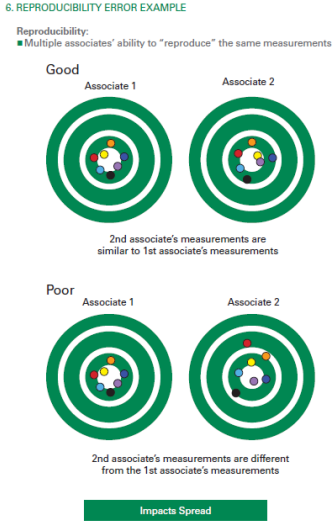


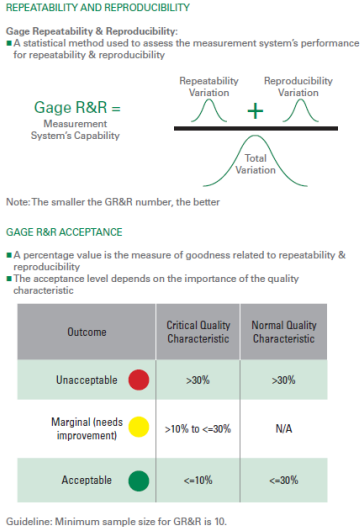


Gage Calibration/Measurement System Analysis









Gage Calibration/Measurement System Analysis

Measurement System Analysis (MSA) is an experimental and mathematical method of determining how much the variation within the measurement process contributes to overall process variability .

MSA is a requirement for qualification. For qualification, supplier must submit and follow the following:

- All measuring equipment and gauges are calibrated.
- **A GR&R must be submitted for devices measuring data on CTQs and for each measurement device mentioned on the control plan on all Level 3 submissions**
- The minimum requirement for Gage R&R is:
  - A Gage R&R study using Total Tolerance samples.
  - % R&R below 10% is acceptable.
  - % R&R between 10% and 30% is marginal acceptable, need an action plan to address and improve the method of measurement.
  - Gages with R&R at 30% or more cannot be used.
  - Number of distinct data categories (ndc) >= 5.
- The **ANOVA** analysis method is recommended to be used to calculate %R&R.
- For visual devices and Go/ No-Go measuring equipment, the Attribute Gage Study shall be performed. At least must be used one out of the following methods:
  - Attribute gage bias report (Analytical method)
  - Gage repeatability and reproducibility report (Attribute hypothesis test method)
- Any equipment or gauge that is not meeting the %R&R should not be used and must have a plan to fix it or replace it.

BIZD 13

Alarm and Escalation

Alarm and Escalation

Definition:

- When a defect is detected, feedback to the appropriate team or individual will be given by using a communication system
- The alarm is raised by using audio/visual signals (e.g. Andon)
- The alarm process directs the support functions to:
  - Go and See the problem
  - Apply containment to prevent further flow of defects
  - Initiate problem solving

Alarm and Escalation Flow Example

- The escalation plan is intended to give the sponsor and management visibility to provide assistance in completing a project

Schedule Slip	 Escalation Path	Required Action
None, due date approaching in 2 weeks	Friendly reminder to Owner & Project Team	None
1 week	Warning e-mail to project Owner & Project Team	Complete project
2 weeks	Warning e-mail to project Owner, Project Team and Sponsor	Formal local recovery plan
3 weeks	Warning e-mail to project Owner, Project Team, Sponsor, Corporate Lean Team and GM/Director	Conference call with e-mail list (resource review and recovery plan)
4 weeks	Warning e-mail to project Owner, Project Team, Sponsor, Corporate Lean Team, GM/Director, and Business Unit VP	Conference call with e-mail list (resource review and recovery plan)

BIZD 14

FIFO / First in – First Out

Material Handling Process

FIFO / First In – First Out. Material Handling Process

Purpose:

- Maintain an inventory management system where the First parts to come In are the First ones to go Out a storage location (inventory of raw materials, finished goods, in-process, good to be sold, etc.)

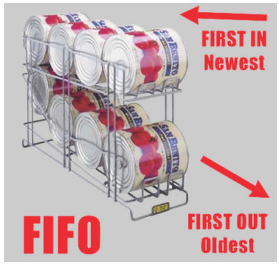
When to use:

- To keep lot traceability and avoid obsolescence and expired materials
- To track the cost of inventory that is sold or shipped to the customer
- Used also for customer service queues

FIFO / First In – First Out - Material Handling Process

Elements:

- FIFO system must be documented through an instruction or guideline
  - Process to follow → Standardized work
  - Material identification (as needed). Visual aids
  - Verification (audits and controls) that FIFO is in place and working
- FIFO must be used for all storage locations throughout the value stream (including repackaging areas, quality inspections, reworks, etc.)
- A FIFO system also follows the rules of proper material handling
  - Lot traceability
  - Proper handling to avoid damages
  - Clear material status and identification at all stages



BIZD 15

Error Proofing (Poka-Yoke) Verification

Error Proofing (Poka-Yoke) Verification

Error-proofing is the implementation of fail-safe mechanisms to prevent a process from producing defects. This activity is also known by the Japanese term poka-yoke, from poka (inadvertent errors) and yokeru (to avoid)

Purpose:

- A method to avoid mistakes

When to use:

- Designing a new process
- After making improvements to a process
- Implementing error-proofing solutions that prevent errors / defects

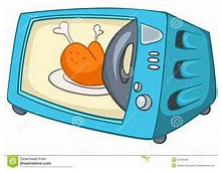
Error Proofing (Poka-Yoke) Verification

Examples:

- Lawn mowers have a safety bar on the handle that when released, switches off the machine

- Child-resistant tops for medicines and household chemicals make it difficult for children to consume the contents

- Microwave oven will not work unless the door is shut



Error Proofing (Poka-Yoke) Verification

Why is “Zero Defects” an important concept?

- There is always a cost associated with producing defects
- Maintain customer satisfaction and loyalty, leading to steady or increasing sales
- All processes have the potential for defects
  - Hence, all processes offer an opportunity for the elimination of defects and the resultant quality improvement

Error Proofing (Poka-Yoke) Verification

What causes defects? Process variation from…

- Poor procedures or standards
- Machines
- Non-conforming material
- Worn tooling
- Human mistakes

Except for human mistakes, these conditions can be predicted and corrective action can be implemented to eliminate the cause of defects.

BIZD 16

Quality Focus Checks

Quality Focus Checks

Identification of critical operations, and customer feedback which need to be reviewed each shift

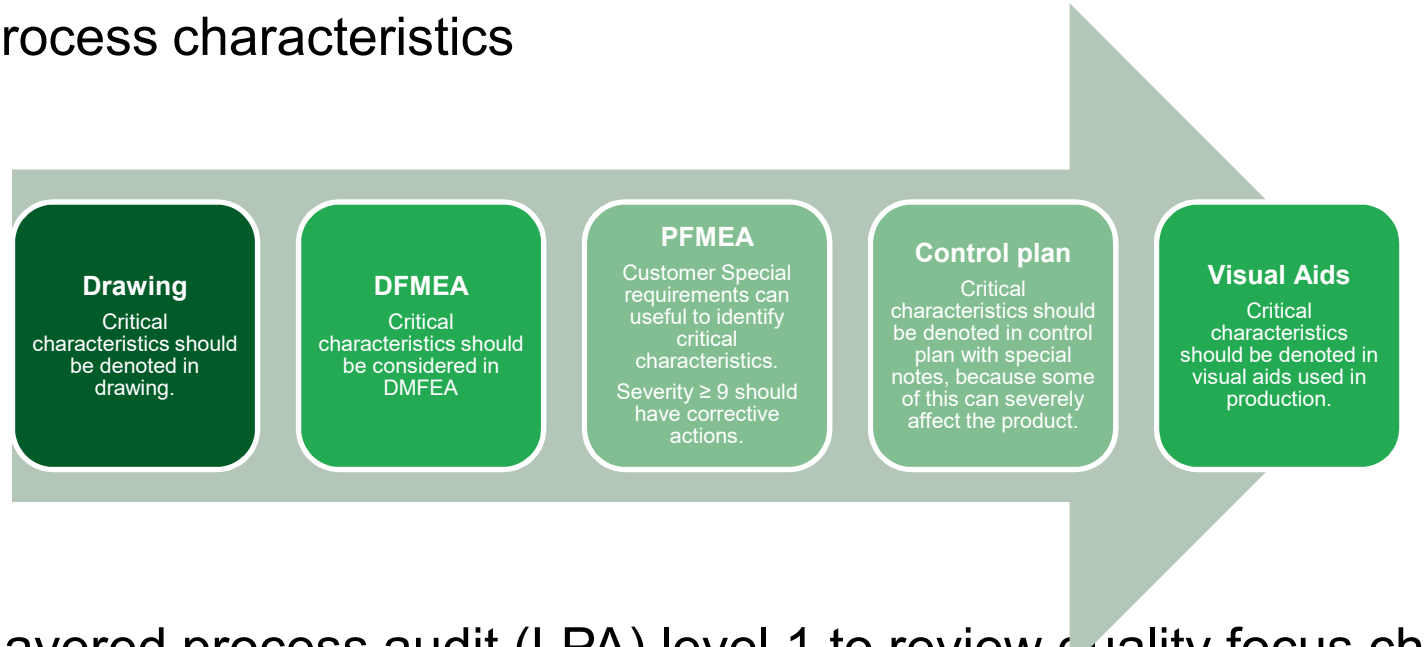
Purpose:

Reduce risk, define customer critical parameters, improve process to minimize defects, control processes to ensure continued and improve performance

Quality Focus Checks

Critical operations

Key process characteristics



Use Layered process audit (LPA) level 1 to review quality focus checks

Checklist for LPA

AUDITORIA ESCALONADA DE PROCESO — **NIVEL 1 - DIARIAMENTE**

Nombre del Auditor: _____ **Turno:** _____

Instrucciones:
1) Realizar auditoria sólo durante el turno asignado. 2) Marcar en la columna "OK" si se esta en cumplimiento el requerimiento de cada punto y en la columna "NOK" si no se esta cumpliendo con el requerimiento. Marcar en la columna "N/A" cuando no aplique. 3) El auditor deberá documentar al reverso de esta hoja las inconformidades encontradas , asignando responsable y fecha.

			Area			Area			Area			Area			Area		
		Fecha:	/ /			/ /			/ /			/ /			/ /		
		Máquina/Celda:															
	Pregunta:	Que buscar:	Lun			Mar			Mie			Jue			Vie		
			OK	NOK	N/A	OK	NOK	N/A	OK	NOK	N/A	OK	NOK	N/A	OK	NOK	N/A
CALIDAD																	
1.1	¿Se cuenta con las Bitácoras de Rastreabilidad?	Verificar que las Bitácoras de Rastreabilidad esten colocadas en el lugar asignado, llenadas correctamente (sin espacios en blanco), con letra legible y disponibles para futura consultas.															
1.2	¿Se realizó la Verificación de Sensores o Poka Yokes?	Verificar con el auditor u operador (según aplique) que se tenga a la mano la evidencia que muestre que se realizó la verificación de sensores o poka yokes (según aplique). En caso de los poka yokes, estos deberán estar identificados (según aplique).															
1.3	¿Está corriendo el proceso de acuerdo a los parámetros establecidos?	Verificar con el operador o supervisor que los parámetros establecidos en las hojas de instrucción por operación, se esten siguiendo correctamente. De lo contrario, se deberá tener un plan de acción documentado. No deberán tener acordiones con especificaciones fuera del Sistema de Control de Documentos.															
1.4	¿Estan las piezas rechazadas identificadas y separadas del producto bueno?	Verificar con el auditor piezas no conformes o piezas con caracteristicas defecturas deben ser separadas con su identificacion y alejarlas del flujo de produccion. Contenedores identificados y no saturados de material no conforme.															
1.5	¿Se tiene en el area material diferente al numero de parte que esta corriendo que pudiera ocasionar mezcla de material?	Verificar no haya partes de corrida anteriores o de diferente numero de parte al cual esta corriendo, al igual no se permiten sobrantes en la linea de produccion Hojas de trabajo sobre material que se pudiera perder la visibiliad Piezas retiradas del proceso en caso de una falla y se encuentra en mantenimiento															
1.6	El plan de control se encuentra accesible para su uso y cuenta con los datos necesarios para que el proceso funcione	Plan de Control debe de estar disponible en el lugar de trabajo. Debe de contener y definir metodos de prueba, parametros del proceso.															
ENTRENAMIENTO																	
2.1	¿El personal cuenta con su entrenamiento necesario para realizar la operación en la que esta?	Verificar que los asociados esten entrenados en la operación que estan realizando. Pedir al supervisor matriz de entrenamiento como evidencia de entrenamiento en el área de trabajo. Verificar que si existe operacion tipo A el operador tenga calificación >= 75% (4 cuadrantes) y operaciones no criticas minimo 25%															
VALIDACION																	
3.1	¿Se realiza la liberacion del proceso / producto / cambios de modelo y se registran los datos?	Verificar con el auditor de calidad / operador que la Primera Pieza de la corrida haya sido auditada, este colocada en el lugar asignado y que se mantenga los registros de la liberacion.															
EQUIPO DE MEDICIÓN																	
4.1	¿Se encuentran dentro de fecha de calibración los equipos de medición?	Verificar que los equipos de medición se encuentren en buen estado y que su etiqueta este dentro de fecha.															
MANTENIMIENTO																	
5.1	¿Los ciclos de dados corte, moldes y dados de estampado están registrados en bitacoras?	Verificar que las bitácoras de ciclos de dados estén llenadas correctamente (sin espacios en blanco), y que su acumulado no sobre pase lo estipulado en la bitácora.															
5.2	¿El equipo no tiene fugas de aire, aceite, agua, etc.?	Verificar que el equipo de producción no cuente con fugas de aire, aceite, agua, etc. según aplique.															
5.3	¿ Se esta llevando acabo el Kan-Ban de Dados/ moldes?	Verificar que se este respetando el Kan-Ban de Dados. Llenado correcto de hoja viajera dados/moldes Identificacion del status de uso															
ORDEN Y LIMPIEZA																	
6.1	¿Se encuentra limpia el área de trabajo?	Verificar en las áreas de trabajo que se tenga una limpieza general. No fusibles en piso, ni sobre la maquinaria, no objetos personales, aceite en la maquina o piso, equipo de limpieza sobre la maquina.															
SEGURIDAD																	
7.1	¿Las guardas de seguridad, funcionan correctamente?	Verificar que las guardas de seguridad cumplan con su función. Se realizará una prueba de funcionamiento.															

BIZD 17

Deviation Management

Deviation Management

Purpose:

- The purpose of this element is to define and establish the steps to follow when generating and implementing a Temporary Internal Deviation

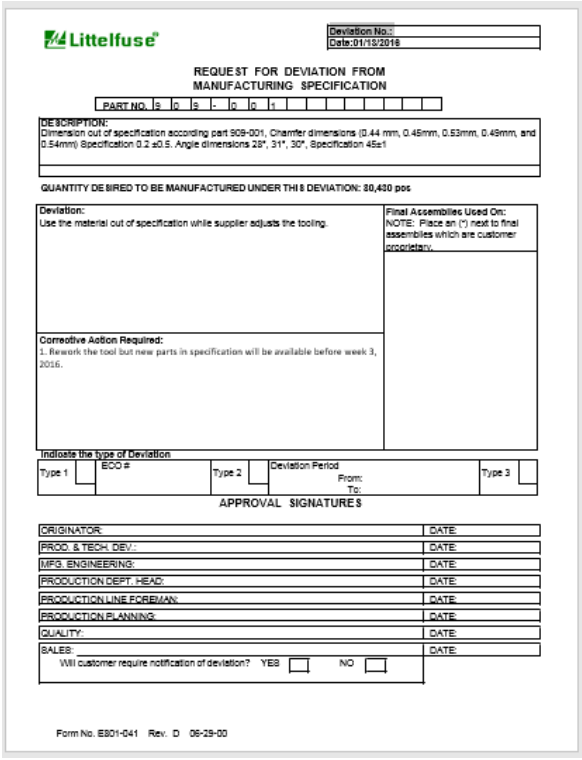
- A Temporary Internal Deviation is defined as:

  - A change in one or more product characteristics established in the Engineering Drawings and /or Bill of materials
  - A change in a process or product characteristic currently approved in the PPAP
  - Any time the process is altered outside the approved documented control plan

- It is Littelfuse requirement that suppliers communicate any temporary deviations identified and submit them for our approval before they are implemented

Make sure your suppliers use this same process…

Deviation Request Format Example



Littelfuse

Deviation No.:
Date:01/13/2016

REQUEST FOR DEVIATION FROM
MANUFACTURING SPECIFICATION

PART NO. 0 2 5 - 0 0 1

DESCRIPTION:
Dimension out of specification according part 909-001, Chamfer dimensions (0.44 mm, 0.46mm, 0.53mm, 0.49mm, and 0.54mm) Specification 0.2 ±0.5. Angle dimensions 28°, 31°, 30°, Specification 45±1

QUANTITY DESIRED TO BE MANUFACTURED UNDER THIS DEVIATION: 30,430 pcs

Deviation:
Use the material out of specification while supplier adjusts the tooling.

Final Assemblies Used On:
NOTE: Place an (*) next to final assemblies which are customer proprietary.

Corrective Action Required:
1. Rework the tool but new parts in specification will be available before week 3, 2016.

Indicate the type of Deviation

Type 1	ECO #	Type 2	Deviation Period From: To:	Type 3

APPROVAL SIGNATURES

ORIGINATOR:	DATE:
PROD. & TECH. DEV.:	DATE:
MFG. ENGINEERING:	DATE:
PRODUCTION DEPT. HEAD:	DATE:
PRODUCTION LINE FOREMAN:	DATE:
PRODUCTION PLANNING:	DATE:
QUALITY:	DATE:
SALES:	DATE:

Will customer require notification of deviation? YES ☐ NO ☐

Form No. E801-041 Rev. D 06-29-00

BIZD 18

Verification Station

Verification Station

Element Concept Definition:

- Is a system in place to implement early containment practices during production ramp up and to monitor supplier efforts are in place to verify control of its processes during start-up and acceleration

- The organization should ensure that final inspections processes/instructions provide sufficient understanding and detail for all personnel who have direct responsibility for the operation of this process. The following items must be covered, but not limited to:

  - Procedure and forms for this process
  - Identification of the person responsible for the inspection process
  - Check list and work instructions shall be clear and must include each failure mode/quality defect
  - Inspection plan must be based on risk and part history
  - Identification of the measurement equipment and data collection devices/activities that will be used (as applicable)
  - Exit criteria is clear

Verification Station

Element Concept Definition (continued):

- Any finding must provide clear data to support alarm reactions and problem solving
- Verifications stations are not limited to product , process monitoring must be included as well as part of prevention

BIZD 19

Andon System Implementation

Andon System Implementation

In its basic form, “andon” is a signal

- An andon system is one of the main elements of the Jidoka quality control method pioneered by Toyota as part of the Toyota Production System and therefore now part of the lean approach
  - Andon System Could be by alarms , lighting or equivalent
  - Andon System help the team member to raise the flag when abnormality occurs
  - LPA might be used to check the effectiveness of Andon System

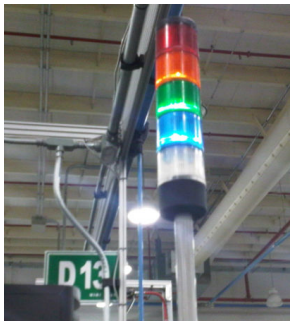
What andon does not do:

- Prevent defects
- Prevent defects from being passed forward
- Solve anomalies
- Replace good verbal communication between workers or teams
- Replace the need for containment actions to protect the customer when an issue is found

Andon System Implementation

It gives the worker the ability to stop production when a defect is found and immediately call for assistance

- Common reasons for manual activation of the andon are:
  - part shortage
  - defect created or found
  - tool malfunction
  - the existence of a safety problem



Leaders should use the Andon downtime tracking to analyze problem areas and identify waste in the current process

- **The focus should be on the pulls with the highest frequencies**. It means that the root cause of the problem has not been addressed. Also it absorbs a lot of the team leaders time and effort
- Downtime data should be analyzed after a predetermined period of time (weekly, bi-weekly, monthly) and problem solving process needs to be started
- During the problem solving we need to recognize the root cause of the problem, define and implement countermeasures to tackle the root cause, and then implement a follow-up process to make sure the root cause has been eliminated

BIZD 20

Rework & Repair

Confirmation Process

Rework & Repair - Confirmation Process

Purpose:

- Document the required methods for rework and repair, including: instructions for each rework or repair, re-inspection process, identification and traceability, inventory management and customer notification

When to use:

- To reduce waste by reworking or repairing materials
- To define the required inspections and testings necessary for reworked or repaired materials and parts
- To define the communication and notification channels for the approval and release of methods as well as materials/parts

Rework & Repair - Confirmation Process

Definitions:

- **Rework**: Reprocessing non-complying product to ensure compliance of the product to specifications
- **Repair**: Action on a nonconforming product to make it conform the specification. Repair could affect/change parts of a nonconforming product

Example (from "*The difference between touch-up, rework and repair*"):

- Fixing a flat tire by putting a plug on the tire or a patch is called a **Repair**, it doesn't look like it did when it was brand new
- But if the tire is low in pressure and air is added to the tire to bring it back to operational pressure, then, the act of putting air is called a **Rework**. There is no visible sign of any changes in physical appearance

Rework & Repair - Confirmation Process

Elements:

- A **Work Instruction** is required to perform any rework or repair
  - Personnel performing rework or repair activities need to receive all necessary training: Use of tools/equipment, use of Personal Protection Equipment (PPE), material handling and identification, verification of a correctly done rework or repair, use of Visual Aids
- Littelfuse approval is required for any **Rework** (use the deviation process)
- Product that is reintroduced into the value stream needs to:
  - Be identified
  - Keep traceability
  - Pass through the required quality inspections and verifications (per Control Plan)

CONFIRMATION PROCESS

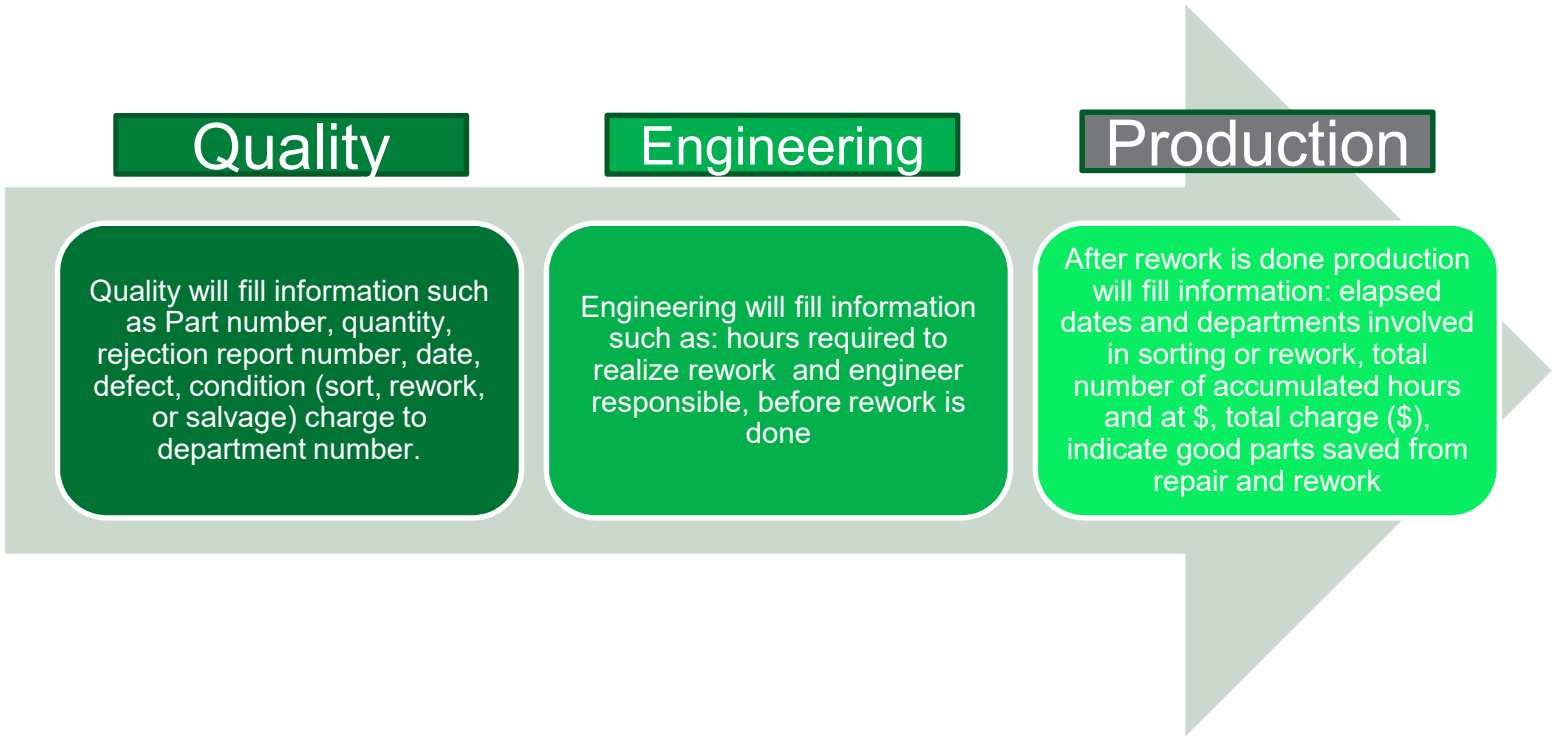
- Best practice would suggest that product is not run more than twice

Rework & Repair - Confirmation Process

Elements (continued):

- It is highly recommended to follow the PFMEA methodology when defining the flow for **Rework** and **Repair**
  - Are there any potential effects after reworking a part or product?
  - Are there any additional inspections/verifications needed on the product to assure conformance to specifications?
  - Are there actions in place to minimize the need for **Rework** and **Repair**?

Rework & Repair - Workflow



BIZD 21

Shipping Approved Packaging & Labeling

Shipping Approved Packaging

Purpose:

- All suppliers are responsible for the design and development of packaging, unless otherwise specified from LITTELFUSE Plant. The suppliers must ensure that all parts arrive at LITTELFUSE Plant in satisfactory quality condition. Any damages due to packaging will be the responsibility of the supplier
- Suppliers are responsible themselves for suggestion in the packaging or process improvements based on their knowledge and possibilities, unless otherwise specified from LITTELFUSE Plant
- The supplier is responsible for maintaining part quality standards within the LITTELFUSE Plant's determined container type. The supplier must provide packaging that can protect the parts through its methods of transportation as applicable (air, truck and/or sea) and types of handling planned for its final destination and intended point of use (end user)
- Due to the significant importance to our operations, the adherence to the supplier packaging requirements is mandatory and will be continuously monitored
- LITTELFUSE Plant's strives for continuous improvement from a packaging and supply chain perspective. Requests for changes of approved packaging may be made by the supplier, the receiving warehouse, the LITTELFUSE SDE and/or SQE. Suppliers are required to have a single packaging point of contact to respond quickly to any change requests

Shipping Approved Packaging

Purpose (continued):

- No change shall be allowed for handling, packing, packaging or storage without written permission of Littelfuse
- Goods shall be packaged in a method to preserve and protect from damage and/or degradation
- All goods are to be suitably prepared for shipment by Seller in accordance with acceptable commercial practices
- Seller shall cause the goods to be labeled and shipped to conform to all requirements of federal, state and local laws, including, without limitation, the marking of manufacture of the product, in a conspicuous place as legibly, indelibly and permanently as the nature of the article (or container) will permit
- Seller shall identify LITTELFUSE's purchase order number on Seller's invoice, packing list, bill of lading or any packages
- Seller shall attach an invoice to all shipments, in addition to forwarding a copy of such invoice to LITTELFUSE

Shelf Life

Shelf life is proper storage conditions and important to products as relates to chemical specification, environmental and temperature, etc. and all those involved in the handling process should be aware of this. Shelf life of product may be defined as the time between the production /packing of the product and point at which it becomes unacceptable under defined environmental condition

- The following requirements are to be fulfilled regardless of the choice of packaging type (returnable or non- returnable):

  - Damage-free delivery of parts (no product quality impacted)
  - Adequate damp and corrosion protection for packaged parts
  - Adequate transport safety
  - No unloading problems for industrial stacker trucks and conveyors
  - Ergonomic parts removal – easy handling
  - Maintaining of general safety
  - Snackability
  - Maintaining standard specified dimensions
  - Optimal container utilization, optimized load efficiency

Labeling

Purpose:

- The LITTELFUSE Global Container Label Requirements Standard provides written requirements for the printing and application of container labels
- LITTELFUSE provides specific data formats and barcode structure to our suppliers, and communicate the acceptable labeling standards expected from our trading partners
- Suppliers are mandatory to use the label formats when shipping to all LITTELFUSE facilities
- LITTELFUSE recommends the use of bar-coding software and hardware, which allow flexibility in label generation. Printers SHALL produce labels that meet AIAG specifications and tolerances if applicable. Thermal printers and laser printers are strongly recommended. Dot matrix printers SHALL NOT be used as bar-coded data can become skewed

Examples of mislabeling

- Wrong part number
- Partial container
- Wrong destination
- Wrong engineering level
- Unreadable bar code
- Missing label
- Wrong sequence
- Incorrect quantity
- Mixed containers on pallet

BIZD 22

Feedback and Feedforward

Improving Communication

Feedback and Feedforward

Definition:

- The standard way to communicate expectations and results between internal and external customers.

Scope:

- Make certain internal/external expectations are communicated and cascaded down through all levels within the organization.

Purpose:

- To ensure that information reaches those who need it on the right time.

Feedback and Feedforward

Quality Alert

- Quality Alert should be issued once concern is found at FR .
- Quality Alert is posted in inspection locations and point of cause

Communication

- Issues found in quality gates communicated to areas of cause

What to look for

- Look for fast feedback / feed forward flow between the Verification Station.

- Confirm quality alerts are posted at the operation for issues detected downstream e.g. Fast Response, Verification Station (Final Inspection/GP12).

Feedback and Feedforward

Benefits:

Improve Customer/Supplier relationship:

- Expectations are clearly understood (product quality standards).
- Correct and accurate information flows in a timely manner.
- Problem resolution is expedited.

Integrity of Data:

- Focus resources based on customer feedback.
- Data-driven problem solving.

Improved response time:

- Unresolved issues are escalated.
- Actions are implemented in a timely manner to prevent the flow of defects.

BIZD 23

Contamination Control

Contamination Control

Definition:

- A systematic control is in place to manage chemicals and residues.

Scope:

- To ensure chemical and residues are properly managed, storage and disposed within your facilities.

Purpose:

- Comply with environmental regulations.

Contamination Control

Sources of contamination:

- Original material/fluid from the tiered supplier
- Transfer from supplier to Littelfuse containers
- Material/Fluid handling at the station
  - Dirt/oil or foreign material on parts/fluids/sealers or dunnage
  - Incorrect PPE. e.g. cotton gloves instead of lint free
- System cleaning not completed correctly sediment still in the system such as metal from machining process
- Incorrect abrasive material, backing or particle size as well as forbidden materials being used (Silicon, lubricating oil)

Contamination Control

Requirements:

- Littelfuse needs clean material which is free from any source of contamination.
- Suppliers are expected to develop/implement standardized work to confirm material is shipped free from contamination.
- Some examples of items to check:
  - Material number
  - Lot number
  - Expiration Date
  - Seal not damaged e.g. containers, hoses and connections
- All components are protected from dirt and moisture
- Packaging design shall be reviewed and bought off by a cross functional team before is released.
- Littelfuse needs parts damaged or deformed free during transportation that meets original design intent.

BIZD 24

Training

Training

Definition:

- Training plan is identified:
  - Create training materials
  - Develop a training plan for the organization on the new process/system requirements
  - Train the organization per training plan
  - Measure the audience's understanding of the new process/system

Scope:

- To assist the organization in developing their associates in improving their skills, careers and competitiveness within the organization.

Purpose:

- Organize and facilitate learning and development. Expedite acquisition of the knowledge, skills, and abilities required for effective job performance.

How to develop a training plan:

- Perform a training needs assessment
- Develop learning objectives
- Create training materials
- Develop your training materials
- Conduct the training
- Evaluate the training
- Improve any training step when necessary

Training

What to look for

- The training effectiveness is essentially a measure that examines the degree to which training improves the associate's knowledge, skill, and behavioral pattern within the organization as a result of the training.

- There is an annual training plan developed for each associate based on the organization needs and supported by the leadership.

- Key steps to consider:
  - Benchmark against the competition
  - Survey your employees
  - Align training with management's operating goals
  - Run it like a business
  - Weave it into your company's culture
  - Keep innovating
  - Measure results

Training

Littelfuse
Expertise Applied | Answers Delivered

MATRIZ DE HABILIDADES

SUPERVISOR: JAVIER, CRISANTO, ALBERTO
LINEA: 644 MOLDEO MAXI
TURNO: 1,2,3,4
MES Y AÑO: ENERO 2019
PLANTA: PCP

#	No. Asociado	Nombre del Asociado	OPERACIONES													Multihabilidad
		TIPO DE OPERACIÓN	C	C	A	B	A	C	B	C	A	A				
		Tipo de operación puede ser: A - Crítica. Alta complejidad. B - Normal. Complejidad Media. C - Baja Complejidad, para asociados de nuevo ingreso.	EMPAQUE DE HOUSING MOLDEO MAXI	LLENADO DE BITACORAS DE REGISTRO A TIEMPO	ARRANQUE DE MAQUINA	LIMPIEZA DE MAQUINA MOLDEADORA	PURGADO DE MOLDES	PESADO EN BASCULA	SCRAP	CATALOGO DE DEFECTOS MOLDEO MAXI Y44 605	AJUSTE DE PROCESO	YELLOW BELT				
1	10907	ALEJANDRO ARTURO UÑATE LAVAREZ	◔	◔	◔	◔	◔	◔	◔	◔	◔	●	○	○	○	1
2	12603	CESAR IVAN DOMÍNGUEZ DÍAZ	●	●	●	●	●	●	●	●	◔	●	○	○	○	9
3	910002506	OTONIEL RAMIREZ SANCHEZ	●	●	●	●	●	◔	◔	●	◔	○	○	○	○	0
4	910005499	HECTOR ALONSO PRESAS GARCIA	●	●	●	●	●	●	●	●	○	○	○	○	○	0
5			○	○	○	○	○	○	○	○	○	○	○	○	○	0
6			○	○	○	○	○	○	○	○	○	○	○	○	○	0
7			○	○	○	○	○	○	○	○	○	○	○	○	○	0
8			○	○	○	○	○	○	○	○	○	○	○	○	○	0
9			○	○	○	○	○	○	○	○	○	○	○	○	○	0
10			○	○		○	○	○	○	○	○	○	○	○	○	0
11			○	○	○	○	○	○	○	○	○	○	○	○	○	0
12													○	○	○	0
13													○	○	○	0
14			○	○	○	○	○	○	○	○	○	○	○	○	○	0
15			○	○	○	○	○	○	○	○	○	○	○	○	○	0
		TOTAL CERTIFICACIONES:														9

Flexibility Chart

Supervisor de Área

RH/DO

BIZD Implementation Assessment / Questionnaire

Additional Information/references

- GM BIQS (GM 1927-36 BIQS Element Presentation)
  - https://www.iatfglobaloversight.org/wp/wp-content/uploads/2016/12/GM-Customer-Specifics-Requirements-ISO-TS-16949-26Oct2016-1.pdf
- AIAG Manual
  - https://www.aiag.org/quality/automotive-core-tools
- LITTELFUSE Enterprise Lean Six Sigma Guide
  - https://www.littelfuse.com/about-us/lean.aspx

Revision History

Revision	Date	Originator	Remarks
A	NOV 2018	Ruben Lozano (SDE)	First compilation of material and release
B	Aug 2019	Alfredo Heredia	Updated LF Quality Policy