Built In Zero Defects
General Requirements

August 2019
Supplier Development Engineering

THE SDE TEAM MISSION IS TO SUPPORT THE LITTLEFUSE 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

<table>
<thead>
<tr>
<th>CORPORATE VALUES</th>
<th>OPERATIONS VALUES</th>
<th>QUALITY VISION</th>
<th>CONTINUOUS IMPROVEMENT CULTURE</th>
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</table>

<table>
<thead>
<tr>
<th>STRATEGIC OBJECTIVES</th>
<th>PRINCIPAL OPERATIONAL CAPABILITIES</th>
<th>RESULTS</th>
</tr>
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<tr>
<td>• Customer Satisfaction</td>
<td>• Talent Management</td>
<td>• Safety Incidents &lt;</td>
</tr>
<tr>
<td>• Flawless Product Introduction</td>
<td>• 5-Phase Product Development</td>
<td>• Customer Complaints &lt;</td>
</tr>
<tr>
<td>• Acquisition Integration</td>
<td>• Quality Management System</td>
<td>• On Time Delivery &lt;</td>
</tr>
<tr>
<td>• Order to Cash Acceleration</td>
<td>• Centers of Excellence</td>
<td>• Cash Conversion Cycle &lt;</td>
</tr>
<tr>
<td>• Sustainable Pipeline of Best Talent</td>
<td>• Corporate Social Responsibility</td>
<td>• Productivity &lt;</td>
</tr>
</tbody>
</table>

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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

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<th>13. ALARM &amp; ESCALATION</th>
</tr>
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<td>2. NON CONFORMING MATERIAL &amp; IDENTIFICATION</td>
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<td>16. QUALITY FOCUSED CHECKS</td>
</tr>
<tr>
<td>5. STANDARDIZED WORK</td>
<td>17. BYPASS / DEVIATION MANAGEMENT</td>
</tr>
<tr>
<td>6. PROCESS CHANGE CONTROL &amp; VALIDATION</td>
<td>18. VERIFICATION STATION (FINAL INSPECTION / GP12)</td>
</tr>
<tr>
<td>7. VISUAL CONTROLS / VISUAL STANDARDS</td>
<td>19. ANDON SYSTEM IMPLEMENTATION</td>
</tr>
<tr>
<td>8. MAINTENANCE</td>
<td>20. REWORK / REPAR CONFIRMATION</td>
</tr>
<tr>
<td>9. SUPPLY CHAIN MANAGEMENT</td>
<td>21. SHIPPING / APPROVED PACKAGING</td>
</tr>
<tr>
<td>10. LAYERED PROCESS AUDIT</td>
<td>22. FEEDBACK AND FEEDFORWARD</td>
</tr>
<tr>
<td>11. PFMEAs / RISK REDUCTION &amp; ANNUAL REVIEW</td>
<td>23. CONTAMINATION CONTROL</td>
</tr>
<tr>
<td>12. GAGE CALIBRATION / MSA</td>
<td>24. TRAINING</td>
</tr>
</tbody>
</table>
Built In Zero Defects

The Elements
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
Fast Response Problem Solving System/Team Problem Solving Process

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

Flow Diagram
- Show Process Flow
- Picture the process
- This is your foundation to create the PFMEA, CP, Layouts, etc.

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

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

Job Descriptions
- Enlist your job/WI descriptions
List potential modes

PFMEA Example

List any actions as needed and/or applicable
Process Control & Process Control Plan Implemented

Control Plan Example

<table>
<thead>
<tr>
<th>Part Certification</th>
<th>Control Plan Category</th>
<th>Control Plan Number</th>
<th>Control Plan Description</th>
<th>Date (Org)</th>
<th>Date (Rev)</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CP 423-005 C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Control Plan Example

- **Frequency of control:**
  - Check sheet used to register the records
  - **Control Method:**
    - F423-002
    - Correct process if parts contain material from the test inspection, reject material according to P13-01
    - F423-005
    - Correct process if parts contain material from the test
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

<table>
<thead>
<tr>
<th>Process control plans are developed as an output of the Risk Analysis Process</th>
<th>Method of implementing the required process controls are documented</th>
<th>Data is analyzed to ensure process output remains capable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Plans</td>
<td><strong>Process Control Methods</strong>&lt;br&gt;• Trend Charting&lt;br&gt;• Statistical Process Control&lt;br&gt;• Capability Studies&lt;br&gt;• Layered Audits&lt;br&gt;• Process Monitoring</td>
<td><strong>Countermeasures</strong>&lt;br&gt;• Reaction Plans&lt;br&gt;• Alarm &amp; Escalation Process&lt;br&gt;• Problem Solving</td>
</tr>
<tr>
<td>Dictated by engineering requirements</td>
<td>Implemented to comply with engineering requirements</td>
<td>Process output measured against engineering requirements</td>
</tr>
</tbody>
</table>

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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

**Tool/Method**
- QCOS
- Control Plans
- Tool & Equipment Bulletins
- Process Monitoring

**Control Variation**
- (USL) (UCL)
- (LCL) (LSL)
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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

<table>
<thead>
<tr>
<th>Cp</th>
<th>Cpk</th>
<th>Pp</th>
<th>Ppk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-term estimate of process capability, is a measure of variation relative to specification limits</td>
<td>Short-term estimate of process capability, this is a measure of average and variation relative to specification limits</td>
<td>Long-term estimate of process capability is a measure of variation relative to specification limits</td>
<td>Long-term estimate of the process capability, is a measure of average and variation relative to specification limits</td>
</tr>
</tbody>
</table>

- \( P_p \) is a long term it will most likely be less the \( C_p \). For \( P_{pk} \) will most likely be less than \( C_{pk} \).
- \( C_{pk} \) 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

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

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

### SECTION 3: Product Variables

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Process Number</th>
<th>Variables</th>
<th>Sample size</th>
<th>Specifications</th>
<th>Actual values</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>059525.PHP</td>
<td>Resistance 1</td>
<td>730</td>
<td>4.700</td>
<td>5.471</td>
<td>A5/Total</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 4: Process Functionality

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Process Number</th>
<th>Variables</th>
<th>Validation Method</th>
<th>Criteria</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td></td>
<td></td>
<td>Push the button (3)drop</td>
<td>Machine should stop, alarm and do not start</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D2</td>
<td></td>
<td></td>
<td>Push the button (3)drop</td>
<td>Machine should stop, alarm and don't start</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D3</td>
<td></td>
<td></td>
<td>Push the button (3)drop</td>
<td>Machine should stop, alarm and do not start</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D4</td>
<td></td>
<td></td>
<td>Push the button (3)drop</td>
<td>Machine should stop, alarm and do not start</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D5</td>
<td></td>
<td></td>
<td>Open the door and try to start the machine</td>
<td>Machine should stop and show alarm and do not start</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D6</td>
<td></td>
<td></td>
<td>Open the door and try to start the machine</td>
<td>Machine should stop and show alarm and do not start</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D7</td>
<td></td>
<td></td>
<td>Open the door and try to start the machine</td>
<td>Machine should stop and show alarm and do not start</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D8</td>
<td></td>
<td></td>
<td>Interrupt the guard crossing the hand</td>
<td>Machine should stop and do not start</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D9</td>
<td></td>
<td></td>
<td>Move the anti-off bermoral and activate the sensor.</td>
<td>Machine should stop and show alarm</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D10</td>
<td></td>
<td></td>
<td>Remove strip and try to start the machine</td>
<td>Machine should stop and show alarm</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D11</td>
<td></td>
<td></td>
<td>Remove strip and try to start the machine</td>
<td>Machine should stop and show alarm</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D12</td>
<td></td>
<td></td>
<td>Remove strip and try to start the machine</td>
<td>Machine should stop and show alarm</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D13</td>
<td></td>
<td></td>
<td>Remove strip and try to start the machine</td>
<td>Machine should stop and show alarm</td>
<td>A5/Total</td>
</tr>
<tr>
<td>D14</td>
<td></td>
<td></td>
<td>Remove strip and try to start the machine</td>
<td>Machine should stop and show alarm</td>
<td>A5/Total</td>
</tr>
</tbody>
</table>

---

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

### SECTION 7: Safety Inspection for New and Modified Equipment

<table>
<thead>
<tr>
<th>Machine Name &amp; ID</th>
<th>Machine Location</th>
<th>Date of Inspection</th>
<th>Conducted by</th>
<th>Department #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>10/02/2017</td>
<td>Noel Paredes</td>
<td>621</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Equipment Status</th>
<th>New</th>
<th>X</th>
<th>Modified</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment Inspected</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Are all Machine Guards in place and adequate?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have all Machine Hazards been identified and warning signs posted?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all Operating procedures posted?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all Controls accessible and labeled?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do all Machine Indicating lights work?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the Emergency STOP in appropriate location and does it work?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have chemical hazards been identified?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have operator training been completed?</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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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
Built In Zero Defects

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
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.

    \[
    \text{OEE} = \text{AVAILABILITY} \times \text{PERFORMANCE} \times \text{QUALITY}
    \]

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

- Although OEE is simple to calculate (there are several online 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).
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.)
Built In Zero Defects

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

### Suppliers Evaluation

### Problem Solving & Communication

### System Audit

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

- **Level 1: Line supervisor**
  - Daily Audit

- **Level 2: Engineers**
  - Weekly Audit

- **Level 3: Area managers and Plant Manager**
  - Monthly 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

1. Modify and schedule the audits per month.
2. Share LPA checklist to the corresponding persons by levels.
3. Audit the area and verify checklist items and share results.
4. Level 3 is responsible to audit open actions from level 1 and 2 according to checklist for level 3.
5. Open actions will be listed, and assigned to the responsible
6. 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**

<table>
<thead>
<tr>
<th>AUDITORIA ESCALADA DE PROCESO</th>
<th>NIVEL 1 - DIARIAMENTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nombre del Auditor:</td>
<td>Turno:</td>
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**ENTRENAMIENTO**

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<tbody>
<tr>
<td>1.1 ¿Se cuenta con las bitácoras de rastreabilidad?</td>
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<td>1.2 ¿Cuentas con el proceso de acuerdos de áreas marcado?</td>
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<td>1.3 ¿Están presentes los equipos de medición con sus identificaciones y calibraciones actualizadas?</td>
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<td>1.4 ¿Están presentes los equipos de limpieza con sus identificaciones y calibraciones actualizadas?</td>
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<td>1.5 ¿Están presentes los equipos de seguridad con sus identificaciones y calibraciones actualizadas?</td>
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<tr>
<td>3.1 ¿Se realiza la liberación del proceso / producto / cambios de modelo y se registran los datos?</td>
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**EQUIPO DE MEDICIÓN**

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<tbody>
<tr>
<td>4.1 ¿Se encuentra limpia el área de trabajo?</td>
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**MANTENIMIENTO**

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<tbody>
<tr>
<td>5.1 ¿Los equipos de producción no cuentan con fajas de aire, aceite, agua, etc.?</td>
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<tbody>
<tr>
<td>7.1 ¿Las guardas de seguridad funcionan correctamente?</td>
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**ENTRENAMIENTO**

1.1 ¿El personal cuenta con el entrenamiento necesario para realizar la operación en la que está? | Verificar que los asociados estén entrenados en la operación que están realizando. Pedir al supervisor matriz de entrenamiento como evidencia de entrenamiento en el área de trabajo.
1.2 ¿El personal cuenta con el entrenamiento necesario para realizar la operación en la que está? | Verificar que si existe operación tipo A el operador tenga calificación >= 75% (4 cuadrantes) y operaciones no críticas mínimo 25%

**ENTRENAMIENTO**

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1.2 ¿El personal cuenta con el entrenamiento necesario para realizar la operación en la que está? | Verificar que si existe operación tipo A el operador tenga calificación >= 75% (4 cuadrantes) y operaciones no críticas mínimo 25%
# LPA Checklist level 2 example

<table>
<thead>
<tr>
<th>Pregunta</th>
<th>Respuesta</th>
</tr>
</thead>
<tbody>
<tr>
<td>¿El personal cuenta con su entrenamiento necesario para realizar la operación en la que está?</td>
<td>Verificar que los asociados estén entrenados en la operación que están realizando. Pedir al supervisor realizar de entrenamiento como evidencia de entrenamiento en el área de trabajo. Verificar que si existe operación tipo A el operador tenga calificación &gt;= 75% (4 cuadrantes) y responsable y fecha.</td>
</tr>
<tr>
<td>¿Se realiza la liberación del proceso / producto / cambios de modelo y se registran los datos?</td>
<td>Verificar con el auditor de calidad / operador que la Primera Pieza de la corrida haya sido auditada, esté colocada en el lugar asignado y que se mantenga el registro de la liberación.</td>
</tr>
<tr>
<td>¿Se encuentran dentro de fecha de calibración los equipos de medición?</td>
<td>Verificar con el auditor de calidad / operador que la Máquina/Celda: máquina esté dentro de los ciclos de datos de estampado están registrados en bitacoras y que se tenga a la mano la evidencia que muestre que se realizó la verificación de sensores o poka yokes (según aplique).</td>
</tr>
<tr>
<td>¿Se realizó la Verificación de Sensores o Poka Yokes?</td>
<td>Verificar que el equipo de producción no cuenta con fugas de aire, aceite, agua, etc. Según aplique.</td>
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<tr>
<td>¿Se está llevando a cabo el Kan-Ban de Datos/moldes?</td>
<td>Verificar que el Kan-Ban de Datos está corriendo. Llevar controles de hoja viaje datos/datos/identificación del estado de uso.</td>
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<tr>
<td>¿Se encuentra limpia el área de trabajo?</td>
<td>Verificar que la limpieza general. No fusibles en piso, ni sobre la maquinaria, no objetos personales, aceite en la maquinaria, no objetos personales, aceite en la maquinaria, no objetos personales, aceite en la maquinaria.</td>
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<tr>
<td>¿Se revisan los metricos en el área.?</td>
<td>Verificar que las guardas de seguridad cumplan con su función. Llevar registros de mantenimiento.</td>
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<td>¿Se revisan los metricos en el área.?</td>
<td>Verificar que el plan de control se encuentre accesible para su uso y cuenta con los datos necesarios para que el proceso funcione.</td>
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<tr>
<td>¿Se realizó la Verificación de Sensores o Poka Yokes?</td>
<td>Verificar con el auditor u operador (según aplique) que se tengas una evidencia que muestre que se realizó la verificación de sensores o poka yokes (según aplique). En caso de los poka yokes, estos deben estar identificados (según aplique).</td>
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<tr>
<td>Pregunta</td>
<td>OK</td>
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<tr>
<td>1.1 ¿Se cuenta con las Bitácoras de Rastreabilidad?</td>
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<tr>
<td>1.2 ¿Están las piezas rechazadas identificadas y separadas del proceso?</td>
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<tr>
<td>1.3 ¿Se tienen en el área material diferente al número de parte al cual está corriendo, al número de parte que está corriendo que pudiera ocasionar mezcla de material?</td>
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</tr>
<tr>
<td>1.4 ¿Están las guardas de seguridad funcionando correctamente?</td>
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<tr>
<td>1.5 ¿Se tiene en el área material diferente al número de parte al cual está corriendo, al número de parte que está corriendo que pudiera ocasionar mezcla de material?</td>
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<tr>
<td>1.6 ¿Las guardas de seguridad funcionan correctamente?</td>
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<tr>
<td>1.7 ¿Los ciclos de datos corte, moles y datos de estampado están registrados en bitácoras?</td>
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<tr>
<td>1.8 ¿Se está llevando a cabo el Kan-Ban de Datos/ molde?</td>
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<tr>
<td>1.9 ¿Se encontró limpieza en el área de trabajo?</td>
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<tr>
<td>1.10 ¿Caweb / Fast response - Caweb: Verificación de acciones implementadas correctamente?</td>
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<tr>
<td>2.1 ¿El personal cuenta con su entrenamiento y matriz de entrenamiento como evidencia de entrenamiento en el área de trabajo?</td>
<td></td>
</tr>
<tr>
<td>2.2 ¿Se realiza la liberación del proceso / producto con cambios de modelo y se registran los datos?</td>
<td></td>
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<tr>
<td>2.3 ¿Los ciclos de datos corte, moles y datos de estampado están registrados en bitácoras?</td>
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<tr>
<td>2.4 ¿Se está llevando a cabo el Kan-Ban de Datos?</td>
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<tr>
<td>2.5 ¿Tiene efectividad la operación tipo A?</td>
<td></td>
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<tr>
<td>2.6 ¿Se realiza la liberación del proceso / producto con cambios de modelo y se registran los datos?</td>
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<tr>
<td>2.7 ¿Los ciclos de datos corte, moles y datos de estampado están registrados en bitácoras?</td>
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<tr>
<td>2.8 ¿Se está llevando a cabo el Kan-Ban de Datos?</td>
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<tr>
<td>2.9 ¿Tiene efectividad la operación tipo A?</td>
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<tr>
<td>2.10 ¿Se realiza la liberación del proceso / producto con cambios de modelo y se registran los datos?</td>
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<tr>
<td>2.11 ¿Los ciclos de datos corte, moles y datos de estampado están registrados en bitácoras?</td>
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<tr>
<td>2.12 ¿Se está llevando a cabo el Kan-Ban de Datos?</td>
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<tr>
<td>2.13 ¿Tiene efectividad la operación tipo A?</td>
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</tbody>
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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

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

How 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.
### POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Requirements</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity Classification</th>
<th>Potential Causes(s) of Failure</th>
<th>Occurrence</th>
<th>Current Process Controls Prevention</th>
<th>Current Process Controls Detection</th>
<th>Detection</th>
<th>RPN</th>
<th>Recommended Action</th>
<th>Responsibility</th>
<th>Target Completion Date</th>
<th>Action Results</th>
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</tr>
</tbody>
</table>

**Prepared by:**

**FMEA Number:**

**FILE.xls**

**FMEA Date (Orig.):**

**FMEA Date (Rev.):**

**Core Team:**

**APPLICATION**

**ORGANIZATION**

**Key Date**
Built In Zero Defects

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:

- Each type of measurement error can lead to bad measurements.
Gage Calibration/Measurement System Analysis

4. Stability Error Example
- Good: Measurements within expectation
- Poor: Measurements deviate from expectation

5. Reproducibility Error Example
- Good: Measurements are very similar in the same measurements by the same associate
- Poor: Measurements are different from the 1st associate's measurements

6. Reproducibility Error Example
- Good: 2nd associate's measurements are similar to 1st associate's measurements
- Poor: 2nd associate's measurements are different from the 1st associate's measurements

Repeatability and Reproducibility
- Gage Repeatability
- Gage Reproducibility

Gage R&R = Measurement System's Capability

Note: The smaller the GRR, the better

Gage R&R Acceptance
- A percentage value is the measure of goodness related to repeatability & reproducibility
- The acceptance level depends on the importance of the quality characteristics

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Critical/Desirable</th>
<th>Normal/Desirable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unacceptable</td>
<td>&lt;5%</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>Marginal (needs improvement)</td>
<td>&gt;5% to &lt;80%</td>
<td>80%</td>
</tr>
<tr>
<td>Acceptable</td>
<td>&lt;5% to &gt;80%</td>
<td>&lt;5%</td>
</tr>
</tbody>
</table>

Guideline: Minimum sample size for GRR is 10.
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

<table>
<thead>
<tr>
<th>Schedule Slip</th>
<th>Escalation Path</th>
<th>Required Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>None, due date</td>
<td>Friendly reminder to Owner &amp; Project Team</td>
<td>None</td>
</tr>
<tr>
<td>approaching in 2 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 week</td>
<td>Warning e-mail to project Owner &amp; Project Team</td>
<td>Complete project</td>
</tr>
<tr>
<td>2 weeks</td>
<td>Warning e-mail to project Owner, Project Team and Sponsor</td>
<td>Formal local recovery plan</td>
</tr>
<tr>
<td>3 weeks</td>
<td>Warning e-mail to project Owner, Project Team, Sponsor, Corporate Lean Team and GM/Director</td>
<td>Conference call with e-mail list (resource review and recovery plan)</td>
</tr>
<tr>
<td>4 weeks</td>
<td>Warning e-mail to project Owner, Project Team, Sponsor, Corporate Lean Team, GM/Director, and Business Unit VP</td>
<td>Conference call with e-mail list (resource review and recovery plan)</td>
</tr>
</tbody>
</table>
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
<table>
<thead>
<tr>
<th>NIVEL 1</th>
<th>DIARIAMENTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nombre del Auditor:</td>
<td>Turno: _________________________</td>
</tr>
<tr>
<td><strong>INSTRUCCIONES:</strong></td>
<td></td>
</tr>
<tr>
<td>1. Realizar auditoría sólo durante el turno asignado. 2. Marcar en la columna &quot;OK&quot; si se está cumpliendo el requerimiento de cada punto y en la columna &quot;NOK&quot; si no se está cumpliendo con el requerimiento. Marcar en la columna &quot;N/A&quot; cuando no aplica. 3. El auditor deberá documentar el reverso de esta hoja las incoformidades encontradas, asignando responsable y fecha.</td>
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<tr>
<td><strong>ENTRENAEMIENTO</strong></td>
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<tr>
<td>2.1 ¿El personal cuenta con su entrenamiento necesario para realizar la operación en la que está?</td>
<td>Verificar que los asociados estén entrenados en la operación que estén realizando. Pidir al supervisor su matriz de entrenamiento como evidencia de entrenamiento en el área de trabajo. Verificar si existe operación tipo A o el operador tenga calificación &gt; 75% (cualquiera) y operaciones no críticas mínimo 25%</td>
</tr>
<tr>
<td><strong>VALIDACIÓN</strong></td>
<td></td>
</tr>
<tr>
<td>3.1 ¿Se realiza la liberación del proceso, producto y cumbres de modelo y se registran los datos?</td>
<td>Verificar con el auditor de calidad / operador que la primera pieza de la corrida haya sido auditada, esta colocada en el lugar asignado y que se mantengan los registros de la liberación.</td>
</tr>
<tr>
<td><strong>EQUIPO DE MEDICION</strong></td>
<td></td>
</tr>
<tr>
<td>4.1 ¿Se encuentran dentro de fecha de calibración los equipos de medición?</td>
<td>Verificar que los equipos de medición se encuentran en buen estado y que su etiqueta esté dentro de fecha. Fecha: / / /</td>
</tr>
<tr>
<td><strong>MANTENIMIENTO</strong></td>
<td></td>
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<tr>
<td>5.1 ¿Los ciclos de dados corte, molde y dados de estampado están registrados en bitácoras?</td>
<td>Verificar que los ciclos de datos estén registrados en bitácoras. Llenado correcto de hoja viajera dados/moldes. Identificación del status de uso.</td>
</tr>
<tr>
<td><strong>LIMPIEZA</strong></td>
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<tr>
<td>6.1 ¿Se encuentra limpio el área de trabajo?</td>
<td>Verificar en las áreas de trabajo que se tenga una limpieza general. No faldas ni piso, no se observe la impureza, no objetos personales, aceite en la máquina o piso, equipo de limpieza sobre la máquina.</td>
</tr>
<tr>
<td><strong>SEGURIDAD</strong></td>
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<tr>
<td>7.1 ¿Son los medios de seguridad, funcionan correctamente?</td>
<td>Verificar que los medios de seguridad cumplan con su función. Se realizará una prueba de funcionamiento.</td>
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</table>
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
Built In Zero Defects

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
Built In Zero Defects

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
Built In Zero Defects

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)

- 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

**Quality**

Quality will fill information such as Part number, quantity, rejection report number, date, defect, condition (sort, rework, or salvage) charge to department number.

**Engineering**

Engineering will fill information such as: hours required to realize rework and engineer responsible, before rework is done.

**Production**

After rework is done production will fill information: elapsed dates and departments involved in sorting or rework, total number of accumulated hours and at $, total charge ($), indicate good parts saved from repair and rework.
Built In Zero Defects

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 conditions.

- 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

<table>
<thead>
<tr>
<th>Quality Alert</th>
<th>Communication</th>
</tr>
</thead>
<tbody>
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<td>• Quality Alert should be issued once concern is</td>
<td>• Issues found in quality gates</td>
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<td>found at FR.</td>
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<td>• Quality Alert is posted in inspection locations</td>
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<td>and point of cause</td>
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Feedback and Feedforward

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.
Built In Zero 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.
Training

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
## Flexibility Chart

### MATRIZ DE HABILIDADES

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### Supervisor de Área

R.H.E.D.O.
BIZD Implementation Assessment / Questionnaire
Additional Information/references

- GM BIQS (GM 1927-36 BIQS Element Presentation)

- AIAG Manual
  - https://www.aiag.org/quality/automotive-core-tools

- LITTELFUSE Enterprise Lean Six Sigma Guide
# Revision History

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<tr>
<td>A</td>
<td>NOV 2018</td>
<td>Ruben Lozano (SDE)</td>
<td>First compilation of material and release</td>
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<td>B</td>
<td>Aug 2019</td>
<td>Alfredo Heredia</td>
<td>Updated LF Quality Policy</td>
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