

LPA (Layered Process Audit) Checklist

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Process Definition & Documentation

Focuses on the clarity, completeness, and accessibility of process documentation.

Is the process flow diagram (PFD) current and accessible?

- ☐ Yes
- ☐ No
- ☐ N/A

Briefly describe the process being audited.

Write something...



Are process inputs clearly defined and documented?

- ☐ Yes
- ☐ No
- ☐ N/A

Revision number of the process document being audited.

Enter a number...

Date of last process document revision.

Enter date...

Describe any discrepancies observed between documented process and actual practice.

Write something...

Is the process owner clearly identified and contact information available?

- ☐ Yes
- ☐ No
- ☐ N/A

Equipment & Tooling

Evaluates the condition, maintenance, and calibration of equipment and tooling used in the manufacturing process.

Equipment ID/Asset Tag Number

Last Calibration Date

Next Calibration Due Date

Calibration Result (within tolerance?)

Equipment Condition (Visual Inspection)

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

Any observed issues/deviations from expected operation?

Write something...

Maintenance Schedule Followed?

- ☐ Yes
- ☐ No
- ☐ N/A

Upload Calibration Certificate (if applicable)

 Upload File

Raw Materials & Components

Assesses the receiving, storage, and handling of raw materials and components to ensure quality and traceability.

Incoming Material Rejection Rate (Last 3 Months)

Enter a number...

Last Raw Material Supplier Audit Date

Enter date...

Raw Material Traceability System Used

- ☐ Lot Number Tracking
- ☐ Batch Number Tracking
- ☐ Serial Number Tracking
- ☐ No Traceability

Storage Conditions Verified (Select all that apply)

- ☐ Temperature Control
- ☐ Humidity Control
- ☐ Proper Ventilation
- ☐ Protection from Sunlight
- ☐ Pest Control

Describe any discrepancies found during raw material inspection.

Write something...

Attach recent Certificate of Analysis (CoA) for critical raw material.

 Upload File

Material Handling Equipment Inspection Frequency

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ Quarterly

Work Instructions & Procedures

Verifies that work instructions are accurate, up-to-date, and followed consistently by operators.

Are work instructions readily available at the point of use?

- ☐ Yes
- ☐ No
- ☐ Partially

Describe any instances where work instructions were unclear or inadequate. (If applicable)

Write something...

Are work instructions reviewed and updated periodically?

- ☐ Yes, annually
- ☐ Yes, as needed
- ☐ No

How often are work instructions reviewed (in months)?

Enter a number...

Which of the following methods are used to ensure adherence to work instructions?

- ☐ Visual aids (e.g., posters, diagrams)
- ☐ Operator training
- ☐ Supervisory oversight
- ☐ Regular audits
- ☐ Other: [Long Text Field]

Are changes to work instructions documented and communicated effectively?

- ☐ Yes
- ☐ No
- ☐ Partially

Upload an example of a recent work instruction revision (if applicable).

 Upload File

Operator Training & Competency

Confirms operators have the necessary training, skills, and authorization to perform their tasks.

Does the operator have documented training records?

- ☐ Yes
- ☐ No
- ☐ N/A

Which training modules have been completed by the operator (check all that apply)?

- ☐ Process Overview
- ☐ Equipment Operation
- ☐ Safety Procedures
- ☐ Quality Control
- ☐ Problem Solving

Last Training Completion Date

Enter date...

Number of training hours received on this process

Enter a number...

Describe any gaps in operator training identified.

Write something...

Was competency assessment performed?

- ☐ Yes
- ☐ No
- ☐ N/A

Upload copy of operator training certificate (if applicable)

 Upload File

Process Control & Monitoring

Evaluates the methods used to control and monitor the manufacturing process, including data collection and analysis.

Cycle Time Measurement Frequency

Statistical Process Control (SPC) Usage

- ☐ Implemented & Effective
- ☐ Implemented, Needs Improvement
- ☐ Not Implemented

Description of Key Process Parameters Monitored

Last Calibration Date of Monitoring Equipment (e.g., Gauges, Sensors)

Data Collection Methods Used

- ☐ Manual Data Entry
- ☐ Automated Data Logging
- ☐ Statistical Process Control (SPC) Software
- ☐ Operator Charts

Frequency of Data Collection for Critical Parameters

Enter time...

Summary of Trending Data & Analysis (attach data if available)

Write something...

Attach Example Monitoring Data Report

 Upload File

Non-Conforming Material Handling

Reviews the process for identifying, segregating, and correcting non-conforming materials or products.

Is there a defined procedure for handling non-conforming materials?

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Briefly describe the procedure for identifying and segregating non-conforming materials.

Write something...

Average number of non-conforming materials generated per shift.

Enter a number...

What actions are taken with non-conforming materials (select all that apply)?

- ☐ Rework
- ☐ Scrap
- ☐ Return to Supplier
- ☐ Quarantine for further evaluation
- ☐ Other (specify in long text)

If 'Other' was selected above, please specify the action taken.

Write something...

Is documentation readily available that tracks the disposition of non-conforming materials?

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Date of last review/update of the non-conforming material handling procedure.

Enter date...

Upload sample documentation of non-conforming material disposition records (e.g., MRB logs).

 Upload File

Quality Control & Inspection

Focuses on the effectiveness of quality control measures and inspection processes throughout the manufacturing cycle.

Sample Size for Incoming Material Inspection

Enter a number...

Inspection Method Used (e.g., Visual, Dimensional, Functional)

- ☐ Visual Inspection
- ☐ Dimensional Measurement
- ☐ Functional Testing
- ☐ Automated Optical Inspection (AOI)

Record of Key Inspection Results (Summary)

Write something...

Representative Inspection Record Example (PDF/Image)

 Upload File

Number of Rejected Units (Last Shift/Period)

Enter a number...

Disposition of Rejected Units

- ☐ Rework
- ☐ Scrap
- ☐ Return to Supplier

Last Calibration Date of Measuring Equipment

Enter date...

Inspection Criteria Used (Select all that apply)

- ☐ Blueprint Specifications
- ☐ Customer Requirements
- ☐ Internal Standards
- ☐ Industry Standards (e.g., ISO)

Environmental, Health & Safety (EHS)

Assesses adherence to EHS regulations and procedures within the manufacturing area.

Noise Level Measurement (dB)

Enter a number...

SDS Availability for Hazardous Materials

- ☐ SDS Present and Accessible
- ☐ SDS Present but Not Easily Accessible
- ☐ SDS Missing

PPE Usage - Check all that apply

- ☐ Safety Glasses
- ☐ Hearing Protection
- ☐ Gloves
- ☐ Respirator
- ☐ Safety Shoes
- ☐ High Visibility Vest
- ☐ None Observed

Last Safety Training Date

Enter date...

Observations Regarding Housekeeping (Spills, Waste Disposal)

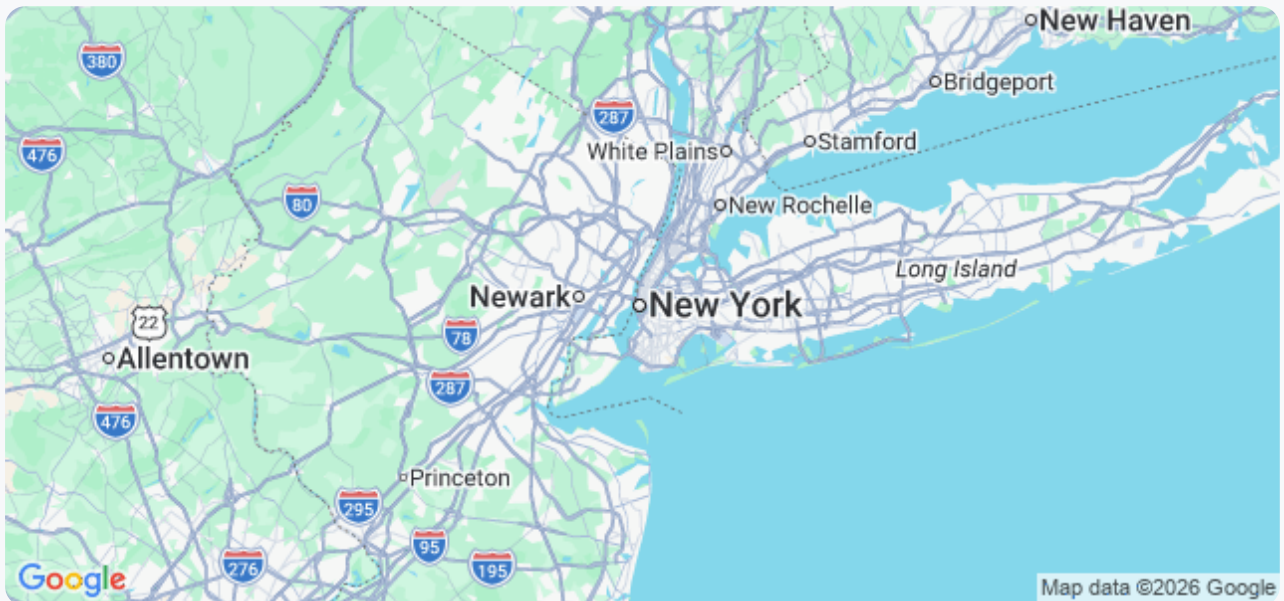
Write something...

Fire Extinguisher Inspection Status

- ☐ Up to Date
- ☐ Expiring Soon
- ☐ Expired

Location of Spill Kit

 [Set My Current Location](#)



Photographic Evidence of EHS Issues (if applicable)

 [Upload File](#)

Continuous Improvement & Corrective Actions

Examines the system for identifying, implementing, and tracking corrective actions and improvement initiatives.

Describe the process for identifying potential areas for improvement within the manufacturing process.

Write something...

Which tools or methodologies are used for continuous improvement (e.g., 8D, Kaizen, 5S)?

- ☐ 8D Problem Solving
- ☐ Kaizen Events
- ☐ 5S Methodology
- ☐ Value Stream Mapping
- ☐ Root Cause Analysis
- ☐ PDCA Cycle (Plan-Do-Check-Act)

What is the average time taken to implement a corrective action?

Enter a number...

Date of last formal review of improvement initiatives.

Enter date...

Describe how employee feedback is solicited and incorporated into improvement activities.

Write something...

Attach documentation related to recent improvement projects (e.g., project plans, reports).

 Upload File

How are completed corrective actions verified for effectiveness?

- ☐ Statistical Process Control (SPC)
- ☐ Process Audits
- ☐ Customer Feedback
- ☐ Visual Inspection
- ☐ Functional Testing

Describe the process for tracking the effectiveness of corrective actions over time. How are they closed out?

Write something...