Today’s consumer has more options than they’ve ever had before, and their expectations are higher because of it. Products and services that exceed those expectations quickly become the go-to choice. Those that fail to measure up in terms of cost, quality, or ease of access risk being sold out by those that can deliver. As such, companies are finding it necessary to implement complex processes and procedures, including corrective and preventative actions, and internal audits.

Unfortunately, these highly beneficial processes and procedures often result in a need for extra time and resources. Paperwork necessary to complete the processes must be filled out and organized, often manually, which can lead to waste as well as lost, duplicated, or erroneous data. Corrective actions must then be taken in order to handle the influx of adverse events caused by errors and mismanagement of time, resources, or data.

In short, massive loss potential exists for companies attempting to improve quality standards. Thankfully there are some tools, resources, processes, and procedures that can help. Layered Process Audits, and software that can ensure those internal audits are carried out effectively, are just one example.

**What are Layered Process Audits**

Layered Process Audits (LPAs) are a processed-based approach to conducting internal audits. The goal is to ensure that quality management standards are continuously adhered to. In turn, company stability and first-time through capabilities are improved. The need for repeated audits to address issues within the Quality Management System, Manufacturing Process, and Product audits are also reduced.

Though LPAs themselves are an added responsibility, requiring both time and commitment from all levels of the organization, they have been shown to produce real dividends to companies that utilize them. Early phases find problems within the systems they are assigned to, offering an opportunity to
correct issues closer to the triggering of an event. Later audits help to find improvement opportunities so that issues can be resolved before they become a problem. The end result is a large list of benefits, including:

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- Improved communication
- Improved discipline throughout the company
- Continuous improvement
- Standardization
- Improved efficiency in processes
- Improved effectiveness of QMS
- Prevention of errors and mistakes in operations
- Reduction of wasted time and resources
- Measurable reduction in cost and company loss

**When to Expect Results from LPA**

Though there are many measurable and notable benefits that result from the LPA process, you can’t expect to see results overnight. In fact, the most successful companies take a strategic, step-by-step approach that moves from one department or process to another when first implementing an LPA process.¹

This process, known as the phasing process, ensures that the company reaps the most benefits in the long-term. As such, the goal should not be to see results quickly, but to see improvements during each step of the LPA implementation process.

**Starting Your LPA Process the Right Way**

Before you conduct a single audit, there are some steps that you should take to ensure the overall success of your LPA. The first step is to develop a team of LPA auditors that will be responsible for the entire implementation process. The responsibilities of the team include:

1. Development of the LPA procedure
2. Development of an audit checklist
3. Determining which processes/departments/products/procedures will be audited
4. Determining the frequency of audits
5. Developing measurements of the LPA process

¹ *Layered Process Audit (LPA), A Process Based Approach to Internal Audits* by Karl Door
6. Monitoring and collecting data on LPA audits  
7. Reporting to management at agreed upon intervals  
8. Presenting audit results to management to gain approval

**Understanding the Phase Approach**

As mentioned previously, the phase approach is one of the most commonly used (and most successful) methods for implementing LPA processes and procedures. Though the audit team is responsible for executing the phases, management should oversee the LPA activity. They should also be prepared to analyze the results to determine if the end LPA plan will provide long-term benefits to the company.

It should also be noted that, once the entire phase cycle is applied to a process, it is complete. Each new process audited in the future will restart the entire cycle, starting with Phase I.

- **Phase I - The Planning Phase**

  During Phase I, the LPA team will determine which processes, products, or areas will be audited first. These should be the processes, products, or areas at highest risk or that have the potential to see the most improvement. The following are some important tips to completing the first phase of the LPA implementation process:

  - Evaluate complaints. When deciding which processes/products/departments to audit first, consider the number and nature of customer complaints, first-time through capabilities, number and complexity of inspections, high RPN values on FMEA, and input from departments and/or supervisors.

  - Develop an Audit Plan. The plan should take into account the size of the organization, scope of processes, complexity of products/processes, and competency level of auditors. If necessary, use a formal checklist structure. Also consider other tools (Control Plans, flow charts, etc.) that could help improve the audit process.

  - Start a “Lessons Learned” record to ensure that information and data on each LPA expansion is documented. This will help to ensure that improvements made during each phase and cycle of the audit process are carried through to the next phase or
cycle.

- Set a goal to ensure that all other processes/departments/products are worked into the LPA audit schedule. Most organizations work with a goal of all departments/processes/products being included in the LPA about six months from the first audit.

- **Phase II - The Approval Phase**

  During this phase of the LPA, the audit team will attempt to gain approval from Top Management for their Audit Plan. In most instances, a presentation on the outputs from Phase I should be given. Be sure to also clearly communicate the resources that will be needed to implement the LPA (i.e. manpower, time, checklists, tools, etc.).

  Once Top Management approval is received, the LPA team should organize a meeting to inform those affected by the LPA auditing process of the impending audit. This is known as a “rollout.”

  **Success Tips for Your Team/Organization Meeting:**
  
  - Include Top Management if possible
  - Clearly outline timing, plans, and methods to be used in the LPA process
  - Provide reasons and benefits for the new auditing process
  - Offer an opportunity for questions to address concerns
  - Understand that resistance to change is normal. It should be addressed early on to improve morale and employee compliance

- **Phase III - The Initial Audit Phase**

  It is during Phase III that the LPA team will record any and all issues and problems identified during the initial audit. When an error or problem is found, management should be notified. The LPA team should also ensure that a corrective action (supported by documentation and detailed procedure) is in place to remedy the issue(s). Auditors should then review the results of that corrective action with the departments/personnel that developed or carried out the corrective action, ensuring that:
The immediate issue/problem has been resolved
A root cause evaluation has been conducted
The CAPA addressed the root cause by establishing a systematic correction

- Phase IV - The Review Phase

Once the initial audit is complete, the LPA team should review all results of the completed cycle to look for areas in which the Audit Plan and process can be improved upon for future cycles. To conduct a thorough review, the LPA team should:
  - Review the lessons learned log
  - Consider the efficacy of all completed corrective actions
  - Look at the validity of final findings
  - Reach out to personnel of department audited for feedback
  - Seek feedback from auditors that carried out initial audit

Once the team has fully reviewed the first cycle, adjustments should be made to the audit plan. All changes should be discussed, reviewed, and agreed upon by the LPA team prior to adding it to the Audit Plan. Once a change has been added, it should be utilized in the LPA process of future cycles.

Effectively Managing Your Company’s LPA

As you can see, the LPA process is quite complex with several tedious steps and mounds of paperwork to be completed. This can result in a number of issues for most companies such as:

- Ineffective/inconsistent tracking of corrective action and improvement initiatives
- Lost, duplicated, misplaced documents skewing audit results
- Wasted time spent creating, completing, and managing paperwork
- Reports, documents, and tools needed to carry out audits or gain approvals may be difficult to locate within the system
- Confusion and inconsistency can lead to compliance and conformity issues among personnel and auditing staff

The CEBOS LPA Software Suite can reduce the risk of these (and many other) common core issues associated with managing an LPA. Time spent managing,
completing, tracking, and reporting are reduced during any and all audits. Point and click creation makes it easy to copy or modify templates for different departments or procedures, and outputs can be reviewed in a variety of formats. Our automated system can even be integrated into other software programs to create a better quality management system overall.

To learn more about our LPA software and how it can help your company stay organized during the audit process, call us at (810) 534-2222 or email info@cebos.com for additional information.