

# PROCESS-BASED INTERNAL AUDITS

*that are compliant with ISO requirements*

by Mickey Jawa, CEO, SatiStar Management Consulting

*The ISO standards require that organizations conduct periodic process-based internal audits. Many companies have yet to truly implement this requirement. Many of the companies that claim that they're doing process audits are actually system audits – explaining that since the ISO9001:2000 standard was written as a process-based standard, their system audits become, by default, process-based.*

When the ISO9001 standard evolved to the ISO9000:2000 version, one of the biggest changes was the introduction of the concept of process management as an integral part of the overall Quality Management System (QMS).

Over the past few years, this has forced many quality practitioners to re-think how they plan and conduct internal quality audits. It has also compelled external auditors from registration bodies to learn a new way of auditing your QMS. To help, several guidelines have been issued. Unfortunately the actual rate of implementation of process-based auditing within companies is still far behind expectations. In fact, a recent survey by has found that over 75% of companies in North America have not yet implemented process-based internal audits.

## Types of Internal Audits

There are 3 main types of internal audits:

**System Audit:** An assessment to determine whether or not the company's QMS meets the requirements of the ISO9001 standard.

**Compliance Audit:** An assessment to determine whether or not you are following your policies, procedures and work instructions as documented.

**Process Audit:** An assessment to determine whether or not your QMS processes have been implemented effectively.

Most companies that are pursuing ISO9001 registration typically start out conducting System Audits – mainly because they need to know whether or not they're meeting the requirements of the standard.

Many registrars will also perform this type of audit when they review your submitted QMS manual.

## ISO Standard Requirements

Section 8.2.2 of ISO9001:2000 stipulates the need to conduct and document periodic internal audits for all relevant processes. It does not explicitly state that these audits need to be process-based. The same is true for ISO19011:2002 (Guidelines for Quality and/or Environmental Management Systems Auditing).

So, why the need to even consider process audits?

When ISO9001:2000 was issued it was a major revision compared to the previous version (ISO9001:1994). The standard became completely focused on business processes, and required organizations to use a process approach to their quality management systems.

With previous versions, the approach concentrated on compliance to specific and individual requirements, independently of how the system really contributed to achieving the organization's objectives. Auditors are now required to establish that the systems they are auditing have been based on these principles, one of which is the process approach.

To clarify things further, within the automotive world in December 2004 the International Automotive Task Force (IATF) released a set of process audit requirements that had the following stipulations:

- Registrars must adopt a process approach to their audits
- Companies seeking registration must use a process approach to internal audits
- Corrective actions need to include root cause analysis as well as define systemic corrective actions.
- Internal auditor competence and performance evaluation

In 2006, the International Organisation for Standardization in Geneva, Switzerland issued a global interpretation for all registrars that insisted that external and internal audits use a process-based approach with the same set of requirements.

So, even though process audits are not explicitly called for in the standard, they are implicit and are required.

Internal auditors are expected to go beyond auditing merely for "compliance" by focusing on risk, status and importance. This means they are expected to make more judgments on what is effective, rather than merely adhering to what is formally prescribed. The difference from the previous standard can be explained:

Under the 1994 version, the question was broadly "Are you doing what the manual says you should be doing?", whereas under the 2000 version, the question is more "Will this process help you achieve your stated objectives? Is it a good process or is there a way to do it better?"

## **A Step-by-Step Approach**

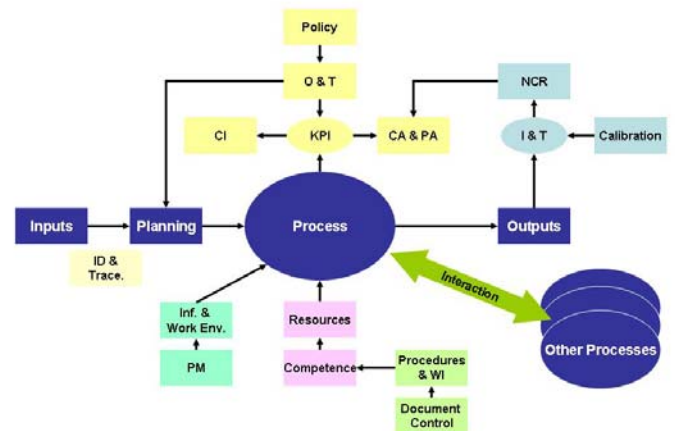
1. Identify all of your organization's processes
2. Understand those processes by creating process maps of how they work
3. Analyze the interaction between the various processes (by creating a high-level map of how the individual processes relate to each other)
4. Create a prioritized list of processes that must be audited in your internal audit. These will include each of the main value-adding processes you need in order to serve your

customers, as well as all of the supporting processes required by your QMS.

5. Create and issue an audit plan for each of these processes
6. Conduct the audits using qualified auditors who have been trained on process audits.

## **Process Audit Methodology**

The diagram shown below provides a roadmap for planning and conducting process-based internal audits for all of your identified processes.



For any single process:

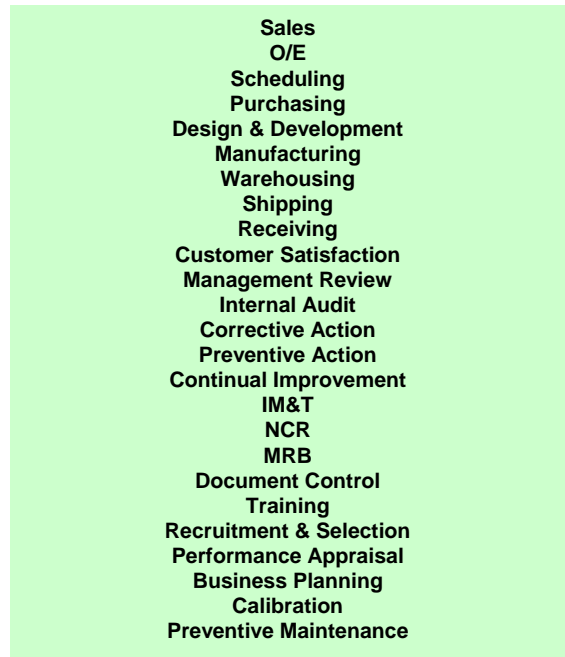
1. Dark blue:
  - o First, understand how this process interacts with other business processes.
  - o Define all of the inputs, such as customer orders, raw materials, etc.
  - o Define all of the process outputs, including finished goods or services, information, designs and drawings, etc.
  - o Understand how the organization plans and schedules all of the activities involved with the process. Ensure that they're taking the overall Objectives and Targets into account.
2. Pale blue:
  - o Determine how the organization knows if their process output is meeting defined customer requirements.
  - o Ensure that this monitoring is using inspection, measuring and test devices that have been calibrated.

- o See how they identify and handle any non-conformity, and that this is used to trigger Corrective & Preventive Action.
3. Yellow:
- o Now, starting with the company's stated Quality Policy, develop an understanding of what is most important to the organization and how this process relates to the policy.
  - o Examine the Objectives and Targets and understand how the process supports them.
  - o Determine which Key Performance Indicators (KPIs) are used to monitor the performance of the process, and show how these KPIs relate to the Objectives and Targets.
  - o Wherever the targets are not being met, are there clear action plans to address the deficiencies? These action plans can trigger Continual Improvement or Corrective & Preventive Actions.
4. Aqua:
- o Determine what infrastructure is important for the ongoing operation of the process. See if this has been documented.
  - o Is the Preventive Maintenance program ensuring that the required infrastructure is always available when needed?
  - o Examine the Work Environment to ensure that workers' health, safety and security are protected. Also determine their other infrastructure needs such as sufficient lighting, computers, etc.
5. Pink:
- o Determine resources needed to operate the processes.
  - o Resources need to be qualified on the basis of their education, experience, knowledge, skills and their training. This should be documented for every position on the organizational diagram.
6. Pale green:
- o Determine what kind of training (on Procedures and Work Instructions) is required in order to meet the qualification needs.

- o Finally, see how all of the relevant documents (policies, procedures, work instructions, forms, checklists, etc.) are controlled.

### **Typical Processes**

Process-based audits are considerably more complex than system audits. It's important for your internal auditors to be well trained in process auditing. You will especially want to select auditors who have a profound understanding of how processes work.



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