



SUBJECT	Status and importance	REV	12-10
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During the early phases of implementing an ISO 9001 based quality management system, where the immediate goal is to achieve certification, internal audits should focus on ensuring that the system documentation and practices fully meet all the requirements of the standard. This typically involves a “desk audit” of the quality manual and procedures to verify that all the mandatory ISO “bases” have been covered followed by a complete compliance to practices audit.

Once the system’s compliance is established, future audits should no longer be scheduled in slavish conformance to an annual calendar. Far too many firms operate under the erroneous assumption that they must audit all processes to all requirements every year, when, in fact, the inverse is the rule. ISO9001:2008 (8.2.2) says *"An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits."*

The terms “status” and “importance” are not defined in the standards and so we are left with the task of deciding what they mean in each of our respective organizations. We view “status” as a reference both to changes that occurred relative to the process or activity and to the performance of the process or activity over time.

Status questions would include:

Since the last review or audit, have there been any changes to the process or factors influencing the process and what was the nature of those changes? For example:

- New or revised methods and/or documentation
- New Materials
- New Suppliers
- New Personnel
- New Work rules
- New/Modified Equipment, Location, Facilities, Environment
- New Requirement(s), Statutes, Rules, Regulations, Standards, etc.
- New Customer/Market

Since the last review or audit, what has been the performance history of the process, its inputs and outputs to Key Performance Indicators (KPIs) established by you to track system performance, as required by 5.4.1 of ISO9001:2008, et al. *"Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy."*

For example:

- Performance to process objectives
- Performance trends (quality and delivery)
- Customer complaints & Corrective Actions: frequency of recurrence and timeliness of clearance
- Nonconformances (internal and supplier)
- Returns, Repairs, Reworks, Yield
- Labor hour or material cost averages
- Improvement recommendations

Performance to such KPI’s is objective evidence of the system’s effectiveness at achieving its goals and fulfilling its purpose and can be used to focus less audit resources on processes that have proven to be stable and effective over time and more on those where problems have arisen in the past or where significant changes have been made.

We view “importance” as a reference of the potential impact the process or activity can have on achievement of critical objectives.



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Importance Questions would include

How critical is this process to your ability to realize your quality policy and achieve your objectives?

Consider for example,

- What is the probability that a breakdown could cause or reasonably lead to delivery of a nonconforming product or service to the external customer?
- dissatisfaction of the external customer?
- a violation of a statute or regulation?
- a product or personal safety problem?
- a failure to achieve a key measurable objective?

Internal Audit Planning Guide

Identify Process/ Activity	Metric/ Discernable	Performance History past 12 months	What Changed				
			Personnel	Methods	Facilities/ Equipment	Environment	Other
	<i>This identifies the information/ data you collect as indicators of compliance and effectiveness. "Metric" is numerically quantifiable. "Discernable" an attribute you can see but not necessarily metrify. (The evidence must be verifiable I.e not an opinion or "feeling")</i>	<i>The OBJECTIVE EVIDENCE that tells you whether or not process performance has been stable and is performing per plan.</i>					

EXAMPLE 1

Identify Process/ Activity	Metric/ Discernable	Performance History past 12 months	Personnel	What Changed	Facilities/ Equipment	Environment	Other
Doc Control (System)	Compliance with ISO	OK in 2008 system audit	Process Owner - None; Approver - None	Procedures and forms now controlled electronically vs original paper system. *	Controlled & distributed via software	None	None

* This would warrant a complete doc control system audit



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Example 2

Identify Process/ Activity	Metric/ Discernable	Performance History past 12 months	Personnel	What Methods	Changed Facilities/ Equipment	Environment	Other
Doc Control (Applied) I.e. results	<i>Instances of wrong docs in use as discovered from internal audits, NC's, CAPA's, complaints</i>	Only two minor, isolated NCs *	None	None	None	None	None

*** Here you would not do another system audit BECAUSE YOU HAVE EVIDENCE THAT THE SYSTEM WORKS but you would conduct collateral (I.e. "drive-by") doc control audits, namely, check for use of correct docs as you audit other processes. I call these "drive by" audits.**

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