

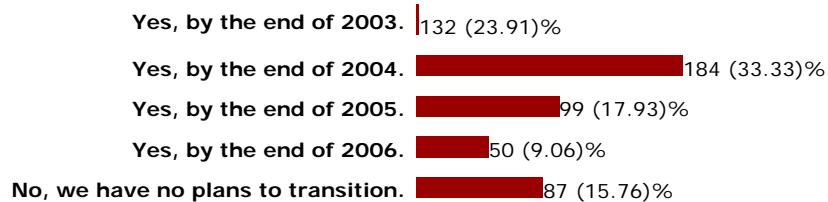
***In this Issue:***

***Identifying and Documenting a Nonconformity***

**Problems breed problems, and the lack of a disciplined method of openly attacking them breeds more problems." - Philip Crosby**

*Looking for a disciplined problem solving approach for your organization, contact us today.*

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Still time to submit ideas and suggestions for our [www.QualityGuru.com](http://www.QualityGuru.com) website. We are launching a contest for the month of May 2005 for Anyone that submits ideas and suggestions for website content. Put your creative hats on and tell us what you would like to see, read, and be involved with that would benefit you and your organization!

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**Lean Certification Standard Underway**

The Society of Manufacturing Engineers, the Association for Manufacturing Excellence and The Shingo Prize for Excellence in Manufacturing are working together to develop a new standard for lean certification.

In a survey with more than 1,100 industry respondents, 77 percent indicated a likelihood of pursuing lean certification, while 83 percent stated that the collaborative development of a lean standard is critical, very important, or important. Additionally, 60 percent of those surveyed thought lean leaders at their organization should be certified.

## Identifying and Documenting a Nonconformity

The primary focus of any management system audit is to identify and determine if the current system is developed as stated, is effectively implemented, and is being maintained. An organization that is registered to ISO 9001:2000 has effectively implemented a management system that conforms to the requirements of the standard and its business practices. Therefore, audit emphasis should then be on verifying process conformity, not on documenting nonconformities.

Internal auditing requires auditors to obtain a good understanding of the management system and the nature of the business they work within. An auditor's role is to perform an assessment of whether an auditee's defined processes are adequate enough to meet its objectives and customer requirements. This includes assessing the extent of the auditee's availability of supporting procedures, documents, and process descriptions. Effective audits result from auditors maintaining a comprehensive approach and looking for facts, not the faults. However, when the audit evidence determines that there is a nonconformity, the nonconformity must be documented correctly.

What is a nonconformity? According to the definition in ISO 9001:2000 (3.6.2), a nonconformity is "non-fulfillment of a requirement." There are three basic parts to a well-documented nonconformity:

- The audit evidence to support auditor findings
- A record of the requirement against which the nonconformity is detected
- The statement of the nonconformity

While all of these need to be addressed, it is the audit evidence that is the first part to be identified and documented. When a competent auditor first observes audit evidence, he or she may feel a potential nonconformity does exist. At this point, an auditor may not possess a 100 percent certainty that a nonconformity exists. The competent auditor will then document the audit evidence for the potential nonconformity in their notes, before pursuing additional audit trails. In many instances, to confirm a potential nonconformity requires the auditor to investigate either upstream and/or downstream a process to verify evidence that a nonconformity exists.

If there is no audit evidence – there is no nonconformity. If there is evidence – it must be documented as a nonconformity. Be Careful of nonconformity classification – for example, ("observations," "opportunities for improvement," "recommendations"). In the long term, this

softer classification can be a detriment to the organization and its customers. The risk is that this classification may be given a lower priority for corrective action, or worse case, be ignored as insignificant. The evidence must enable the organization to find and confirm the auditor finding.

The next step for the auditor is to record the specific requirement that is not being met. If the auditor can't identify a requirement, then the auditor can't raise a nonconformity. Requirements can come from many sources, for example, ISO 9001:2000, the organizations management system, internal and external requirements, regulatory/statutory, or the organization's customers. It is important that the auditor identifies and records the specific requirements. Write-out the exact text of the requirement no matter what the source when available. This will ensure auditor bias is not visible, and will enhance the auditor's credibility within the organization.

The final and very important part of documenting a nonconformance is the writing of a statement of nonconformity. This statement directs the root cause analysis, correction and corrective action by the organization, it must be specific. The statement of nonconformity should:

- Be self-explanatory and be related to the process/system issue.
- Be unambiguous, language correct (use your organization's language/terms, etc.), and as concise as possible.
- Not be a restatement of the audit evidence, or be used in lieu of audit evidence.

If all three parts (1) The audit evidence, (2) The requirement, and (3) The statement of nonconformity are well documented, everyone in the organization can read and understand the nonconformity. It is essential that all nonconformities are recorded and documented in a systematic manner.

A well conceived Nonconformity Report including formalized Root Cause analysis, Corrective and Preventive Action processes, and Process Based Internal Auditor Training, will provide the organization a system that will deliver documented tangible results and improved operational performance.

*Are you and your organization getting the results you expect from your Internal Audit System?*

*Sustaining Edge Solutions delivers training that covers these areas and much more.*

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