



Selecting Internal Auditors For ISO 9001:2000

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to

Orange Empire ASQ Section 0701



Tonight's Agenda

- What does the standard require of internal audits?
- What do the guidance documents say about internal audits?
- What do the guidance documents say about internal auditors?
- Selecting internal auditors
- Questions

What's The Same

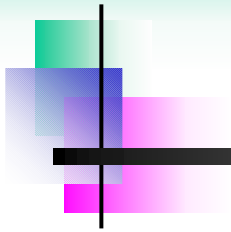
Internal Audits: 1994 vs 2000

- Must have a documented procedure
- Must schedule audits based on status and importance of the activity being audited
- Must use competent and impartial auditors
- Must determine conformance to requirements of the standard **and** the QMS
- Must determine if implementation/maintenance of the QMS is effective
- Requires timely corrective action

What's Different

Internal Audits: 1994 vs 2000

- Process approach required
- Use of objectives for continuous improvement
- Reduced documentation requirements (focus is now on processes, not documents)



What Does the Standard Require?

A look at ISO 9001:2000

Requirements for Internal Audits

ISO 9001:2000

8.2.2 Internal audit

The organization must conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to

- 1) the planned arrangements (see 7.1),
- 2) the requirements of this International Standard and
- 3) the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

Source: ISO 9001:2000, para 8.2.2

ISO 9001:2000

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

- a) quality objectives and requirements of the product;
- b) the need to establish processes, documents, and provide resources specific to the product;
- c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

Source: ISO 9001:2000, para 7.1

ISO 9001:2000

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

- a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyze these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

Source: ISO 9001:2000, para 4.1

ISO 9004:2000

Section 8.2.1.3 Internal Audits

Subjects for consideration by internal audits include:

- Effective and efficient implementation of processes
- opportunities for continuous improvement
- capability of processes
- effective/efficient use of statistical techniques
- use of information technology
- analysis of quality cost data
- effective/efficient use of resources
- process/product performance results and expectations
- adequacy/accuracy of performance measurements
- improvement activities



The internal audit process must, at a minimum cover four requirements:

- 1) does the QMS conform to the planned arrangements (see 7.1)?,
- 2) does the QMS conform to the requirements of ISO 9001:2000?
- 3) does the QMS conform to the quality management system requirements established by the organization?
- 4) is the QMS effectively implemented and maintained?

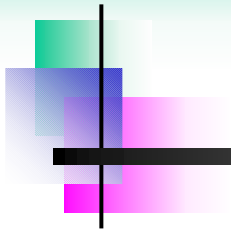
Three requirements deal with conformance. The fourth deals with a judgement about effectiveness.



Typical Approaches to Internal Audits

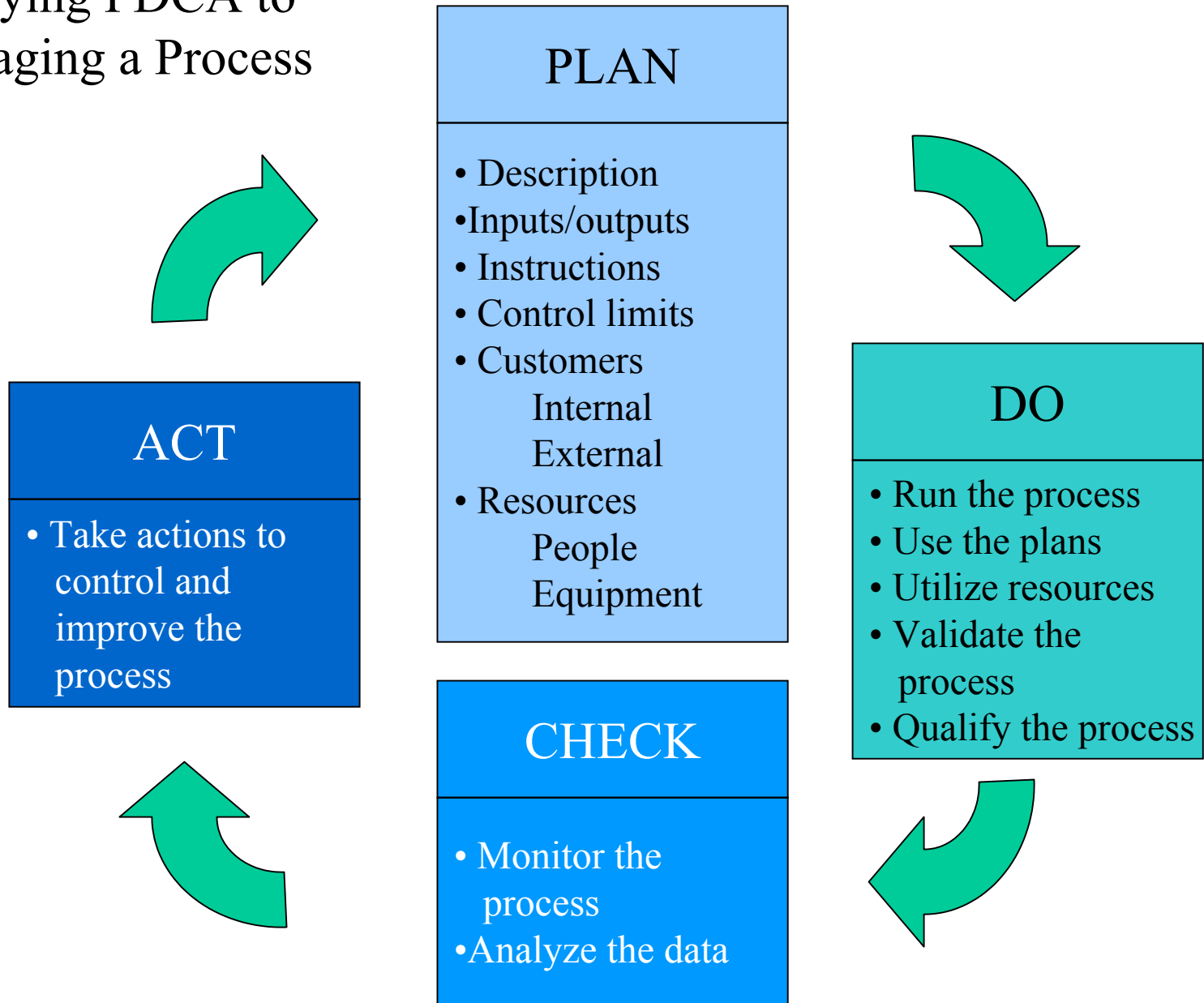
- The checklist audit - use a checklist that covers the requirements of the standard
- The procedure audit - question employees to see if they are following QMS procedures
- The functional audit - audit all applicable requirements (QMS and ISO) in a functional area

None of these approaches provides a challenging audit which leads to improvement



- Internal audits are about processes and systems
 - are they effective?
 - are they meeting requirements?
 - could they be improved?
- Internal auditors must make judgements

Applying PDCA to Managing a Process



Using Internal Audits to Test the Process Approach

PLAN

- Are process inputs and outputs defined?
- Have controls been defined?
- Have responsibilities for the process been defined?

DO

- Are process instruction being followed?
- Does the process need to be qualified?
- Does the data indicate the process is capable?

ACT

- Are actions taken if the process goes out of control?
- Are actions taken if output does not meet the plan?
- Is process data analyzed for possible preventive action or improvement?
- Has the process been identified as one needing improvement?

CHECK

- Is the process being monitored?
- Does the data get to the person who is responsible for the process?
- Is the process achieving planned results?

Using Internal Audits to Audit the QMS Objectives

PLAN

- How are QMS objectives established at relevant functions and levels?
- How are objectives documented and communicated?

DO

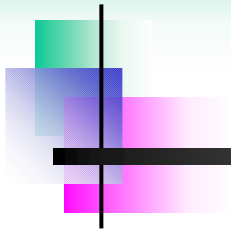
- Has responsibility been assigned to achieve objectives?
- Have action plans been established for achieving objectives?
- Have dates for completion been established ?
- Have resources been provided?

ACT

- When progress towards objectives does not occur, what action is taken?
- If the objective does not achieve the desired results, what action is taken?

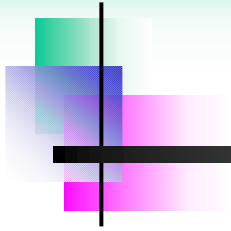
CHECK

- How is progress towards the objective measured?
- How will achieving the objective lead to improvement?
- Is progress (or lack of) towards the objective reported to management?



“The purpose of internal audits should be to gather and analyze the information needed to make informed judgements about the organization’s systems and feed those judgements to the managers responsible for those systems. Although they should be rooted in specific facts and observations, they must not be limited to them.”

Source: DeWitt Beeler



Selecting Internal Auditors

ISO 10011-2 part 7.0

Personal Attributes

- open minded and mature
- possess sound judgement
- analytical skills
- tenacity
- ability to perceive situations in a realistic way
- ability to understand the role of individual units within the overall organization

ISO 19011:2002 (CD3)

Personal Attributes

- Open minded - willing to consider alternate ideas or points of view
- diplomatic - tactful in dealing with people
- observant - constantly and actively aware of physical surroundings and activities
- perceptive - instinctively aware and able to understand and adapt to situations

ISO 19011:2002 (CD3)

Personal Attributes

- tenacious - persistent, focused on achieving objectives
- decisive - reaching timely conclusion based on logical reasoning and analysis
- self-reliant - acts and functions independently while interacting effectively with others
- ethical - fair, truthful, sincere, honest, discrete



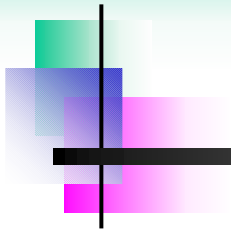
Selecting Internal Auditors

- Internal auditors can be a key part of process and performance improvement
- Internal auditors should be intelligent, inventive, persistent, tenacious, with a strong desire to make things better
- Avoid the temptation to use least busy, least useful employees



Selecting Internal Auditors

The question we have ask ourselves, are the people we select to be our internal auditors, capable of performing internal audits as required by ISO 9001:2000?



QUESTIONS?