The Initial Internal Audit of an ISO 9001:2015 QMS

Michael Prior, CQA
Quality Institute of America
9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:
   a) conforms to:
      1) the organization’s own requirements for its quality management system;
      2) the requirements of this International Standard;
   b) is effectively implemented and maintained.
9.2.2 The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
d) ensure that the results of the audits are reported to relevant management;
e) take appropriate correction and corrective actions without undue delay;
f) retain documented information as evidence of the implementation of the audit programme and the audit results.
The net additions to ISO 2015-what are they and how do they affect an audit?

4 Context of the organization

- 4.1 Understanding the organization and its context
- The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.
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• The organization shall monitor and review information about these external and internal issues.

• NOTE 1 Issues can include positive and negative factors or conditions for consideration.

• NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.
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• **NOTE 3** Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

• **4.2 Understanding the needs and expectations of interested parties**
• Due to their effect or potential effect on the organization’s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

a) the interested parties that are relevant to the quality management system;

b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.
6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.
6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;
b) how to:
1) integrate and implement the actions into its quality management system processes (see 4.4);
2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.
NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization’s or its customers’ needs.
6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall:

a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;
g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.
6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a) what will be done;
b) what resources will be required;
c) who will be responsible;
d) when it will be completed;
e) how the results will be evaluated.

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).
The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the integrity of the quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.
7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.
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This knowledge shall be maintained and be made available to the extent necessary.
When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization’s objectives.

NOTE 2 Organizational knowledge can be based on:
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a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).
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• Clauses are less prescriptive
• New thinking on “how” to audit
  • Less prescriptive demands new discipline
  • More emphasis on process approach
• Use of checklists is diminished?
• “Interview” style of auditing is now in?
Interview style

– Open discussion of:
  • Processes
  • Documentation
  • Inspection
  • Risk Analysis
  • Overall QMS
Checklists

- ISO 2015 seems less interested in checklist forms than in techniques using interviewing or meeting style formats.

- A greater emphasis is placed on analysis of risk and determining if the company has properly addressed risks in its TOTAL QMS.

- Has risk been identified and analyzed to determine whether the company will receive its expected outputs?
What is “shall” and what does it mean?

- Legally, it is a **must**…
- ISO 2015 contains over 70 shall’s…
- Easiest way for an organization to adhere to the shall’s is a written document or procedure, work instruction, etc.
- ISO 2015 **is** less prescriptive (no “big 6”) but it still requires adherence to mandatory acts of conduct and compliance.
What is my style?

- ISO 2008 style: Show me your processes/procedures, etc.
- ISO 2015 style: Why do you have these processes/procedures?
  - A company should be able to justify its reasons for the processes/procedures it utilizes in its QMS and production outputs
- Previous checklist style would be inefficient and “miss the mark” of the intended results of the new standard
- A new way of thinking and presentation is now required for auditing
- Observation of what a company deems it needs for its QMS and justify what is observed with the new requirements
• Are checklists to be banned? Not required?
  
  • No - just a new way to use them and their objective isn’t strict compliance – I.E does the company have this or that?
  • What does the company have and why? Is risk accounted for and analyzed? How is risk identified and documented? How does a company adhere to the shall’s present in the new standard?
  • Checklists should be a “tool” for the auditor to gain perspective into the reasoning of the company’s documentation and processes - why does the company need this over that or justifications for exemption of certain standard requirements
• Remember: There is more than ONE approach to risk management
  • The auditee should be able to describe and justify what there approach to risk is…
  • This could prove to be difficult the first time the audit is undertaken…why?

• For the Auditor:
  • What do YOU know about risk/risk management?
  • What are YOUR sources of knowledge/experience?
  • Remember – this is YOUR first ISO 2015 audit too…
• **Auditor competency vs. audit competence**
  – **Auditor**: An auditor’s knowledge of processes and output expectations
    • Derived from training, certification and experience
    • Traditional expectation from client and registrars
  – **Audit competence**: How the audit is conducted and what results are expected
    • The expected “process” of auditing
  – **Justifications of findings**: A non-conformance IS a non-conformance – ISO 2015 doesn’t change this…
    – Don’t be intimidated by the new wordings – proof is still proof…without it, a finding exists…
Conclusion

• Remember the shall’s…
• Look for documentation, if it is not present or sparse, then…
• Observe what the company deems is needed and necessary and seek its “proof”
• Look for reasoning from the company into its QMS and how it is documented or presented
• Understand risk and how it is identified, properly analyzed and how does the company document its’ risks