

Internal Audits

Fighting for Resources

Presented October 14th, 2008



ASQ
AMERICAN SOCIETY
FOR QUALITY




Orange Empire Section 0701

Presented by
Diane Kulisek






www.capatrak.com
805-522-5005 O
805-320-7879 C
dkulisek@capatrak.com
2493 Pinewood Place
Simi Valley, CA 93065



Internal Audits – Fighting for Resources

by Scott Adams

Dilbert




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2



Internal Audits – Fighting for Resources


TOPICS

What will be addressed:

- What constitutes an internal audit?
- Do internal quality audits have value?
- Can resources required to perform internal audits avoid negatively impacting other business priorities?
- Audit Basics
- Links to some helpful on-line resources and tools for audit performance

October 14, 2008 3

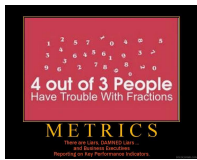
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You know you're an internal auditor when:

You check the release date and rev level before you ready your daily newspaper.



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What constitutes an internal audit?

- **Terms and Definitions**
- **How often should internal audits be performed?**
- **What should be audited? Why? How?**

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What constitutes an internal audit?


Terms and Definitions (Compliance-driven)

- ISO/CD2 19011: 2001 Guidelines on Quality and Environmental Management Systems Auditing
 - The Committee Draft of ISO 19011 doesn't define "quality audit" nor "internal audit".
- "Audit":
 - "systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled."
- Audit criteria:
 - "set of policies, procedures or other requirements against which collected audit evidence is compared." Audit evidence consists of "records, statements of fact or other information, relevant to the audit and which are verified."

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Terms and Definitions (Business-driven)

“Internal auditing is:

- An independent, objective assurance and consulting activity designed to add value and improve an organization’s operations.
- It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.”


-Institute of Internal Auditors

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What constitutes an internal audit?



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Terms and Definitions

Business-driven Internal Audit:


- independent activity
- objective activity
- assurance activity
- consulting activity
- designed to add value
- designed to improve an organization's operations.
- helps an organization accomplish its objectives
- a systematic approach
- a disciplined approach
- evaluates/improves effectiveness
- evaluates/improves risk management
- evaluates/improves control processes
- evaluates/improves governance processes

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What constitutes an internal audit?


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■ You know you're an internal auditor when:

You ask to see a material cert following the birth of you child.



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 **Internal Audits – Fighting for Resources**

■ **How often should internal audits be performed?**

- Annual plan
- Risk-based
- Input from management
- Includes all internal audit activities
- Adequate resources
- Flexibility
- Changes during the year

What constitutes an internal audit?

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What constitutes an internal audit?

■ **What should be audited? Why? How?**

- Documentation and testing of internal controls
- Efficiency, effectiveness, and economy of operations
- Review major projects and new computer systems
- Consulting services
- Fraud investigation
- Compliance with legislation
- Risk management

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What constitutes an internal audit?

■ **What should be audited? Why? How?**

- *Financial Auditing*
focus on balance sheet and income statement
- *Operational Auditing*
focus on resource utilization, accomplishment of operational goals
- *Compliance Auditing*
focus on adherence to laws and regulations
- *IT Auditing*
focus on integrity and security of computer systems
- *Performance Auditing*
focus on effectiveness, economy, and efficient use of resources
- *Program Auditing*
focus on achieving program goals

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- You know you're an internal auditor when:
You have the family org chart posted on the refrigerator



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Do internal quality audits have value?

- Do internal audits make good business sense?
- How do internal audits support compliance with quality management system standards or regulatory requirements?
- Can an economic case for internal quality audits be made?
- Can Internal Audits be Cost Effective?
- Internal Audit Metrics and ROI Analysis

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Do internal quality audits have value?

- **Do internal audits make good business sense?**
- **Risk management in \$\$\$\$**
 - **Liability \$ Considerations**
 - **Self-discipline – Efficiency**
 - **Expense/Cost (\$)**
Reduction/Elimination
 - **Profitability (\$)**
Improvement/Increase

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Do internal quality audits have value?

- **How do internal audits support compliance with quality management system standards or regulatory requirements?**
 - **Every ISO 9001:2000 based QMS requires internal audits.**

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Do internal quality audits have value?

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- Can an economic case for internal quality audits be made?
- YES.
 - Begin every Paragraph with a sentence that has a monetary value in it somewhere that relates to cost reduction or profit increase.
 - Cite past findings with said outcomes in chart or table format to back-up claim(s)... preferably directly from your Accounting Department.
 - Use the Lean Sigma fadish buzz phrase: “value-added” somewhere in the paragraph.

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Do internal quality audits have value?

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- Can Internal Audits be Cost Effective?
- Internal Audit Metrics and ROI Analysis
 - Do a simple cost-benefit comparison using the past year, 3 years or 5 years of data.
 - Cost in Manhours per year to perform audits in plan as a ratio to (Dollars of Cost or Expenses avoided + Dollars of Profit gained).

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Do internal quality audits have value?

- Can Internal Audits be Cost Effective?
- Internal Audit Metrics and ROI Analysis
 - Example:
 - 10 audits * 4 manhours = 400 manhours per year x 40./hour = \$16,000./year for audit plan
 - Scrap avoided as a direct result of internal audits: \$32,000./year.
 - Value of Increased Units Shipped as a direct result of internal audits: \$320,000./year.
 - $\$16K/(\$32K + \$320K) = 1/(2+20) = 1/22$.
 - Translation:
 - You add \$22 to your company's bottom line for every \$1 spent on internal audits.


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- You know you're an internal auditor when:
You ask to see the Gage R&R before you allow your blood pressure to be checked



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Can resources required to perform internal audits avoid negatively impacting other business priorities?

Can resources required to perform internal audits avoid negatively impacting other business priorities?

Can resources required to perform internal audits avoid negatively impacting other business priorities?

- **How do internal quality audits relate to an organization's lean sigma philosophy?**
- **Tips, Tricks and Techniques for Securing Adequate Internal Audit Resources**

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Can resources required to perform internal audits avoid negatively impacting other business priorities?

Can resources required to perform internal audits avoid negatively impacting other business priorities?

- **How do internal quality audits relate to an organization's lean sigma philosophy?**
 - **They Don't.**

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■ **Tips, Tricks and Techniques for Securing Adequate Internal Audit Resources**

- Make the Internal Audit Program a Lean Sigma Project
- Use cost-benefit analysis and ROI
- Write it into the Strategic Plan for the Company
- Write it into the Department Budget
 - Call it something obscure like: "Value-added productivity improvement assessments"
 - Use only an acronym when you can get away with it ("VA-10-IA" for Value-added 10 Internal Audits)
- Draft Company Accountants as Internal Auditors
- Use laid-off personnel as Contract Auditors (via Temp Agency)
- Use retired employees as Contract Auditors
- Use local ASQ members out of work as Contract Auditors
- Use local ASQ consultants as Contract Auditors
- Point out that Sales agreed to a Customer Contract that contains provisions requiring Internal Audits (i.e. via ISO 9001:2000 compliance) without fully realizing it.

Can resources required to perform internal audits avoid negatively impacting other business priorities?

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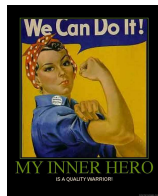
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■ **You know you're an internal auditor when:**

Anything worth fighting for is worth fighting dirty for.



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Audit Basics

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Audit Basics

- **Quality Management System (QMS) and Regulatory Requirements for Internal Audits**
- **Recommended Internal Audit Practices**
 - Organization roles
 - Auditor selection
 - Audit methods
 - Audit outcomes
- **How to Assure Long Term Internal Audit Effectiveness**

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Audit Basics

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- **Quality Management System (QMS) and Regulatory Requirements for Internal Audits**
 - As noted previously, ALL ISO 9001:2000-based Quality Management Systems Require Internal Audits
 - In Canada, ISO 13485:2003 became a regulatory requirement equivalent to the US FDA-based Federal Regulations (21-CFR-820) as of July 2006.

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Audit Basics

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- **Recommended Internal Audit Practices**
 - Organization roles
 - Auditor selection
 - Audit methods
 - Audit outcomes

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Audit Basics


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- **Recommended Internal Audit Practices**
 - Organization roles

Management:

- Define [internal] auditing policy
- Assign responsibility of internal audit program
 - Quality Manager
- Must be advised of internal audit outcomes
 - discussed at management review

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Audit Basics


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- Recommended Internal Audit Practices
 - Organization roles

Quality Manager:

- Establish & maintain internal audit system
- Develop schedule
- Coordinate audits
- Manage corrective action system
- Advise management audit outcomes

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Audit Basics

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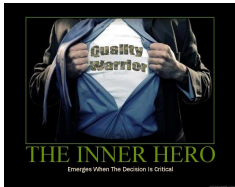
- Recommended Internal Audit Practices
 - Auditor selection
 - Shouldn't inspect their own work.... but can inspect work in their own department (as long as it's not theirs)
 - Certification is nice, but not required
 - Formal training is nice, but not required

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- You know you're an internal auditor when:
you can cite the ISO 9001 standard and the QS-9000 requirements, right down to the sub-clause, but not your own shirt size



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- Recommended Internal Audit Practices
 - Audit methods

Audit Basics



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32



Audit Basics

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- Recommended Internal Audit Practices
 - Audit methods – Audit Plan

2007 INTERNAL STRATEGIC AUDIT PLAN
ISO 13845, 21 CFR 820 CMDCAS and MDD 93/42/EEC

Month	Standard	Estimated Completion Date	Actual Completion Date	Departments Effectcd	NCO (Y/N) If Yes #/If No N/A
N/A	ISO 13485:2003 21 CFR 820 (GMP, FDA GMP) CMDCAS, MDD 93/42/EEC (details below)	TBD	TBD	All (GM-001)	N/A
Feb-07	ISO 13485:2003 Sections 1.0, 2.0, 3.0 (Preface, General, Purpose, Scope, Normative Reference, Terms and Definitions)	TBD	TBD	Regulatory Affairs (GM-001)	N/A
Feb-07	ISO 13485:2003 Sections 4.0, 4.1, 5.0, 6.1 and 6.1 (Management, General, Management Responsibility, Management Commitment, Customer Focus, Quality Policy, Responsibility, Authority and Communication, Management Representative, Internal Communication, Management Review, Resource Management and Provision of Resources)	TBD	TBD	Executive Management Team (GM-001, GP-003, GP-016, GP-009, GP-004, GP-006)	
Oct-07	ISO 13485:2003 Section 4.2 (Document Control)	TBD	TBD	Regulatory Affairs (GP-005, DC-001)	N/A
Sep-07	ISO 13485:2003 Section 6.2 (Human Resources)	TBD	TBD	Human Resources (GP-006, GP-002)	N/A
Aug-07	ISO 13485:2003 Sections 6.3 and 6.4 (Infrastructure and Work Environment)	TBD	TBD	Facilities and Maintenance (GP-006, GP-007)	N/A
Jan-07	ISO 13485:2003 Section 7.0 and 7.1 (Product Realization and Planning)	TBD	TBD	Operations (GP-008)	N/A
Dec-07	ISO 13485:2003 Sections 7.2 and 8.2.1 (Customer Related Processes, Feedback including Customer Complaints)	TBD	TBD	Marketing (GP-020)	N/A

Form-090 Revision 01
Page 1 of 3

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33



Audit Basics

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- Recommended Internal Audit Practices
 - Audit methods - Checklists

QUALITY MANAGEMENT SYSTEM (QMS)					
General					
	Y	N	N/A		COMMENT
• Do you have a documented quality management system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
• Are outsourced processes addressed by the QMS?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Quality Management System Manual					
• Do you have a Quality Management System Manual	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		QMS MANUAL PROVIDED WITH SURVEY
• Does the QM reference the procedures in the QMS and describe their interaction?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Control of Documents					
• Do you have a document control system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
• Are documents approved for adequacy prior to use and reviewed and updated when necessary?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
• Are current revisions of documents available for those who need to use them?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
• Are revisions removed or identified to prevent unintended use of superseded instructions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Control of Records					
• Do you have a process to control quality records?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
• Have you defined quality records within your QMS?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
• Are records of inspections and tests maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
• Are all records used to document the QMS legible, readily identifiable and retrievable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
• Are there defined controls to identify, store, protect, retrieve, and disposition quality records?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
• Are quality records retained for a specified period of time?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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34




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- You know you're an internal auditor when:

You have a checklist for EVERYthing



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Audit Basics

- Recommended Internal Audit Practices
- Audit outcomes


Corrective Action Status Report - Internal Audit (Refer to Internal Audit Report file for details)

CAR Item # for Type*	Type*	CAR #	Audited Procedure and Date of Audit	Description	Actionee(s)	Notes
1	MIF	507	OP-4.09.4 Preventive Maintenance 07/18/03	Printed Maintenance Log Sheet indicates invalid locate due to data entry error	[Process Owner Name]	The invalid location was corrected in the MainStar database and any future PM work orders will reflect the valid location.
2	MIF	507	OP-4.09.4 Preventive Maintenance 07/18/03	Machine Description does not match description in MainStar	[Process Owner Name]	3 New Machine Maintenance Log was placed at the Machine with the proper description to match the machine.
1	MAF	494	OP-4.06.0 Rev C Material Organization 06/13/03	No formal procedure in place for evaluation and reevaluation of suppliers	[Process Owner Name]	In work with [Employee name] ECD \$29 per [Mgr's name]
1	MAF	513	OP-4.15.2 Rev C Storage Handling Pack, Presser, & Delivery 07/17/03	Referenced storage requirements (Par 6.4.3) not found.	[Process Owner Name]	In work – ECD \$/S per [Mgr's name]
1	MIF	494	OP-4.06.0 Rev C Material Organization 06/13/03	Request for quote form has no form number	[Process Owner Name]	Buyers are no longer using a "Request for Quote" Form.

*Type Key: MAF = Major Finding (nonconformity, correction required); MIF = Minor Finding (nonconformity, correction recommended); O = Observation (opportunity for improvement); OF = Other Finding (finding or observation made during audit of an unrelated Operating Procedure)

Page 1 of 43

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Audit Basics

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- **How to Assure Long Term Internal Audit Effectiveness**
 - Keep emphasizing the value-added
 - Continue to notice the fads, er.... trends, and make sure you hook the audit program up to whatever flavor it is that year
 - Keep utilizing resources other people forgot were available

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Links to helpful on-line resources and tools for audit performance

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- **Links to some helpful on-line resources and tools for audit performance**
 - <http://www.internal-auditor.com>
 - <http://www.9000resource.com>
 - The Institute of Internal Auditors: <http://www.theiia.com>
 - Quality Progress Article by Greg Hutchins: "The State of Quality Auditing" http://www.asq.org/pub/qualityprogress/past/0301/25_state_of_qual.html
 - Ethics and Enron Script by Dennis Arter and J.P. Russell: <http://www.jp-russell.com/pdfs/Ethics-and-Enron-script.pdf>
 - <http://www.capatrak.com>

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**THANK YOU!
May I answer Your
Questions?**

**Presented by
Diane Kulisek, President**



www.capatrak.com
805-522-5005 O
805-320-7879 C
dkulisek@capatrak.com
2493 Pinewood Place
Simi Valley, CA 93065