After the Audit

What's Next??

Corrective Action

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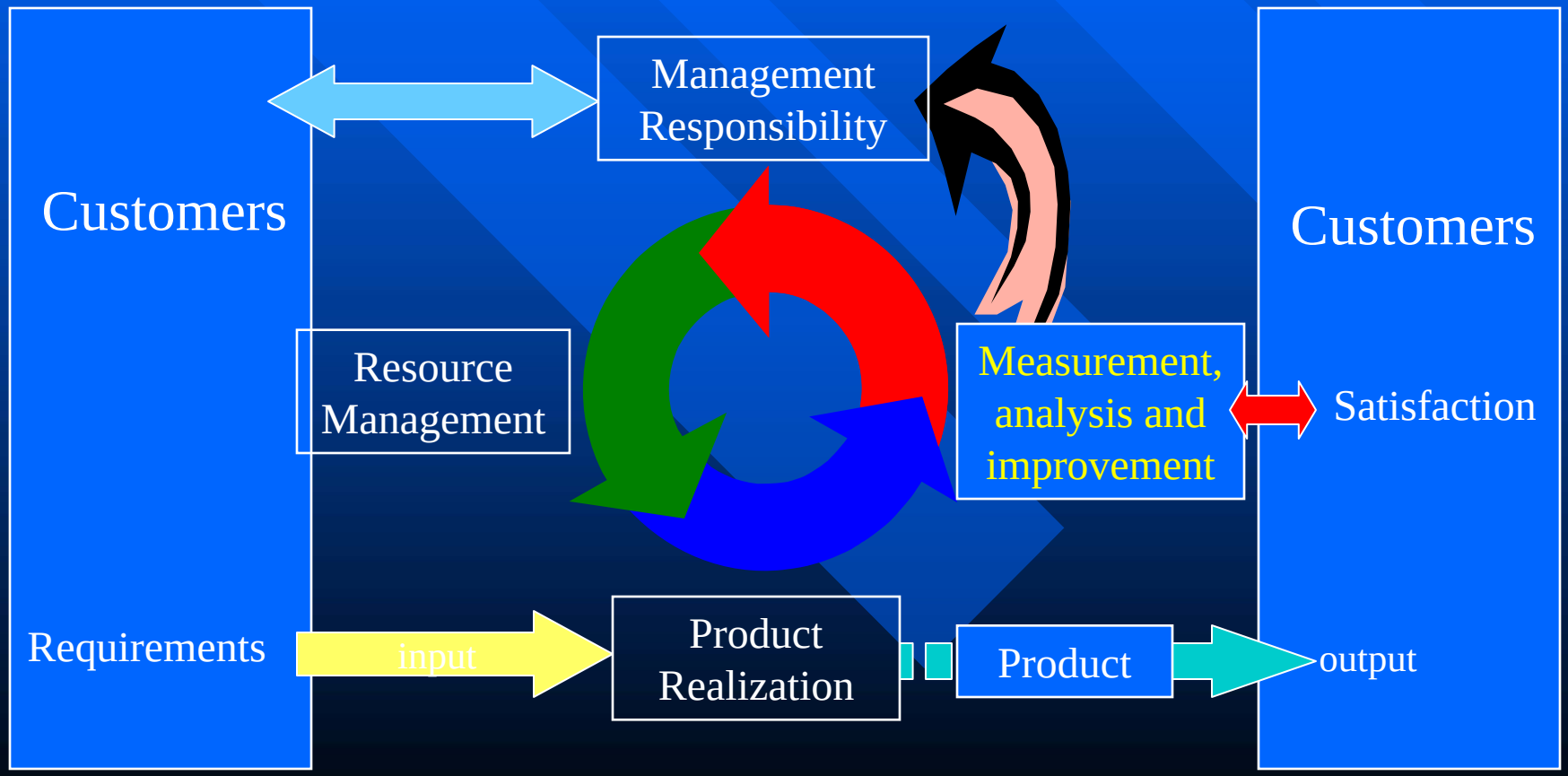
Agenda

- ISO19011:2002
- ISO 9001:2000
- Corrective Action Systems (IA input)
  - CAPA Plans
  - Follow Up
  - Effectiveness
- Consider other Requirements
  - ISO 13485:2002
  - AS9100B
  - TS16949:2002
  - ISO17025:2005
- External Audits

Quality Management System



Internal Audit

- ISO 19011:2002
  - The audit is completed when all activities described in the audit plan have been carried out and the approved audit report has been distributed.

Conducting Audit Follow Up

- ISO 19011:2002
  - The conclusions of the audit may indicate the need for corrective, preventive or improvement actions, as applicable.
  - The completion and effectiveness of corrective action should be verified.
    - » Part subsequent audit

ISO9001:2008

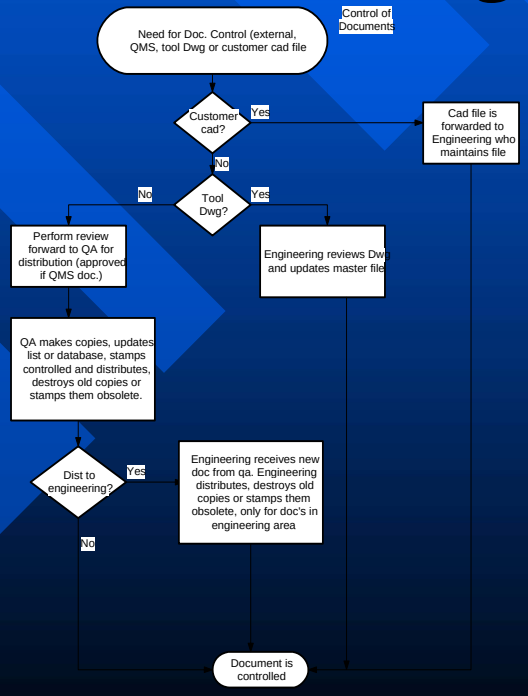
- Updated to emphasize the need for a documented procedure
  - A documented procedure shall be established…
  - "Establishing records" was moved ahead of "reporting results" in the list of topics in the procedure.
  - Created new sentence for "Records of audits and their results shall be maintained."

Audit Process

- ISO 9001:2000 – 8.2.2 Internal Audit
  - Management responsible for area shall
    - » Ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes
  - Follow-up activities shall include verification of the actions taken and the reporting of verification results.

After the Audit

- Do you use the Corrective Action System?
- Do you have another commitment tracking mechanism?



Findings

- Internal Audits
  - Who categorizes
    - » Major
    - » Minor
  - Do auditees respond differently?

Informing the Auditee

- Closing Meeting
- Discuss Corrective Action Plan
- Follow Up?????

Corrective Action Plan

- How long do you get to respond?
  - Two weeks?
    - » Is that for the Draft or Final CAPA plan?
    - » Are people late delivering their plan?
    - » Anyone ever disagree with the need to take corrective action?
    - » How do you handle the Repeat finding?
      - Not again……

Corrective Action Plan

- How long….does it take to **approve** the corrective action plan?
  - » Hours, days
    - – It Depends on..
  - » How many levels of management sign off??

Corrective Action Plan

- What do you do if **more than one** department is affected?
- What if your finding is not the part of the core process and is a **supporting process**?
  - Where do you conduct follow up?
  - Who prepares capa plan?

Resources

- ISO 9001:2000 6.1 Provision of Resources
  - Determine and provide resources to implement and **maintain** the qms and continually improve the effectiveness.
    - » Do you have adequate resources to manage the CAPA plan and **follow up?**

Follow Up Activities

- When do you do this?
  - It depends……
- Time Interval???
- Severity
- Next Audit

Follow Up Activities

- Is this a checkbox on the CAR?

Correction:
Root Cause: Corrective Action: Preventive Action: Effectiveness Check Yes ☐ No ☐

Form use: (4.14 CA -INTERNAL), (VENDOR CAR), (PREVENTIVE ACTION), (4.17 INTERAL AUDITING CA) (CIRCLE ONE)Action Number: (4.17) Audit Report Number: (4.17)

Minor or Major: **CONCERN AND EXTENT:** Auditor: _____ Assigned to: _____ Date: _____

2.0 CONTAINMENT AND SHORT TERM CORRECTIVE ACTION:

Due Date;_____ Date Implemented: _____

Person Responsible: _____

3.0 DEFINE AND VERIFY ROOT CAUSE:

4.0 PERMANENT CORRECTIVE ACTION TAKEN (must indicate a planned implementation date) :

Due Date;_____ Date Implemented:_____

Person Responsible:_____

5.0 VALIDATION OF CORRECTIVE ACTION: (BOTH IMPLEMENTATION AND EFFECTIVENESS)

Auditor Sign Off:_____ Date:_____

Quality Manager Sign Off::_____ Date:_____

Is training required? Documents require updating

Read Only
No

Read and Document Yes _____

Follow Up Activities

- Is this a general statement in next years report?
  - Verification of status of previous completed commitments was performed concluding that corrective actions implemented are in place and appear to be effective.

Is there detailed analysis?

CAPA#	**ISO 13485:2003**	Observation and Action	Effective
1113	5.6.2	Mgt Review Minutes do not include specific reference to continued compliance to CMDR.	Yes Verified Minutes from 17 March 2008.

Effectiveness

- How do you know?

Effectiveness

- **Who** decides if a corrective action is effective – Same auditor?
- What if you approved the plan and one year later??
  - **You** ask who approved this?
- What else do you look for?
  - Effectiveness……

Effectiveness
Is KPI related to Quality Objectives?

	Quality Objectives	
	Process Efficiency	Product Effectiveness
Strategic	▸ New product investment and capital efficiency ▸ Engineering, research & development spending ▸ Engineering productivity ▸ Resource utilization	▸ Sales growth ▸ Market share ▸ ROI ▸ Product lifecycle throughput ▸ Product profitability
Tactical	▸ Total development cost ▸ Applied time ▸ Elapsed time (cycle time)	▸ Price realization ▸ Product value/cost ▸ Warranty cost
Operational	▸ Design cost ▸ Budget performance ▸ Schedule performance	▸ Design-to-cost ▸ Quality ▸ Functional performance

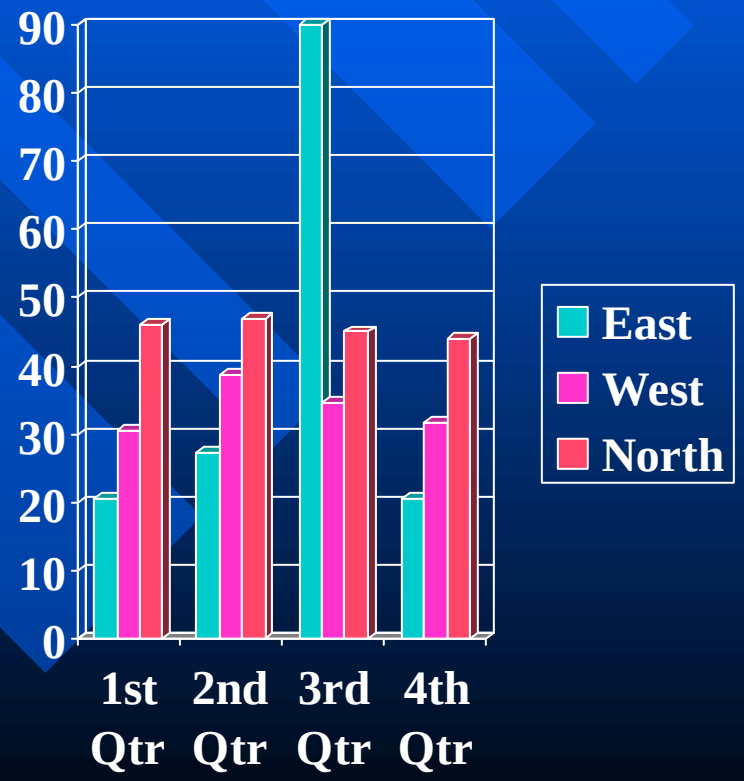
Monitoring for Effectiveness

- How do you monitor effectiveness?
  - Time based – Closed on time
  - Anyone use $$$$$$$
  - Is it QA or shared responsibility??

- How do you use results of audit findings to continually improve effectiveness of qms.
  - Is this data important?

Analysis of Data

- At Management Review
  - How or Do you analyze activity of Internal Audit System?
  - Process
  - Requirement
  - Time Intervals
  - Severity



Requirements to Consider

- AS9100B
- ISO13485:2003
- ISO17025:2005
- TS16949:2002

Does your procedure allow for an extension?

- AS9100B – Corrective Action 8.5.2 h.
  - Specific actions where timely and/or effective corrective actions are not achieved.
- Do you have this built into your procedure?
  - Extensions
  - How many??

ISO13485:2003

- Determining and implementing action needed, including, if appropriate, **updating documentation**
- Recording of the results of any **investigations** and of action taken
- Reviewing the corrective action taken and its **effectiveness**

ISO 17025: 2005

- The procedure for corrective action shall start with an investigation to determine..
- The laboratory shall monitor the results to ensure the corrective actions have been effective
- Additional Audits 4.11.15
  - When doubt on labs compliance the lab shall ensure that area are audited as soon as possible.

TS16949:2002

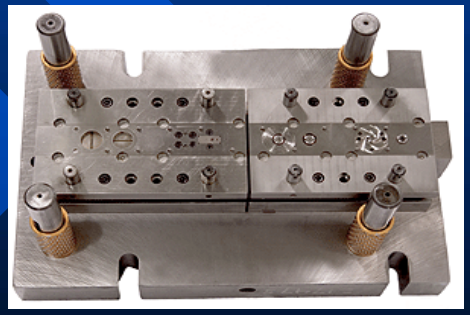
- 8.5.2 Corrective Action
- Problem Solving
- Error Proofing
- **Corrective Action Impact**
- Rejected Product Test Analysis

Internal versus External

- How do you handle audits of your suppliers?
- Do they get more time to respond?
- What if they do not respond?
  - Change status?
    - » Conditionally qualified
    - » Disqualify

Customer Audits

- What do your customer's expect in a corrective action response?
- What if you do not agree with your customer's finding?
- Any customer's require you to comply with their requirements
  - 21 CFR 210, 211
  - TS16949



Corporate Audits

- Who is audited by Corporate Office?
- Is the audit response procedure different
  - than your internal procedure?
- Do they use the same classification
  - Major?
  - Minor?

Summary
Quality Management System

Management Review

Corrective and Preventive Action

Internal Audit

Thank You

- For attending ASQ-Granite State Section.
- Meetings are posted on the web site.
- Third Wednesday of the Month

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