Tucson-Old Pueblo Section

The Global Voice of Quality™

Internal QMS Auditing

Why is it so difficult?

Presented February 9, 2016
by R.Gryniewicz
ASQ Tucson Education Chair

Questions

- **Who here tonight performs Internal QMS Audits?**
- **Who believes Internal QMS Auditing is difficult?**
- **How does this difficulty make you feel?**
- **What are some of the reasons that makes them difficult?**

Questions

How do you conduct your Internal QMS Audits?

- **All at one time? Scheduled through year?**
- **Use checklists? (Yes or No)**
- **If checklists, pre-created/pre-approved? Or create as needed?**

Why do we conduct IQAudits?

Audits are not to be used as a part of a disciplinary action

ISO9001 and AS9100 Requirements

(some of them)

Tucson-Old Pueblo Section
ASQ The Global Voice of Quality™

ISO-9000 and AS9100 Requirements for Auditing

Conducted to determine if the QMS...

- **…conforms to planned arrangements,**
- **…conforms to customer contractual requirements (AS9100)**
- **…conforms to the QMS standard (ISO9001:2008, AS9000, etc.),**
- **…conforms to the organization's QMS requirements, and**
- **…is effectively implemented and maintained**

ISO-9000 and AS9100 Requirements for Auditing

- **An audit program shall be planned.**
- **Program shall take into consideration:**
  - **Status and importance of the processes and areas**
  - **results of previous audits**
- **Audit program shall define:**
  - **audit criteria**
  - **audit scope**
  - **audit frequency**
  - **audit methods.**

ISO-9000 and AS9100 Requirements for Auditing

- **When noncompliant conditions are found, management shall:**
  - **ensure any necessary corrections and corrective actions are taken**
  - **without undue delay**
  - **to eliminate detected nonconformities**
  - **to eliminate the causes of nonconormities.**

ISO-9000 and AS9100 Requirements for Auditing

- **Input to Management Review shall include:**
  - **results of audits**
  - **status of corrective actions**
  - **status of preventive actions**

Understanding Processes

Understanding Processes

A QMS implemented per ISO9001:2008/AS9100C is based on

managing processes

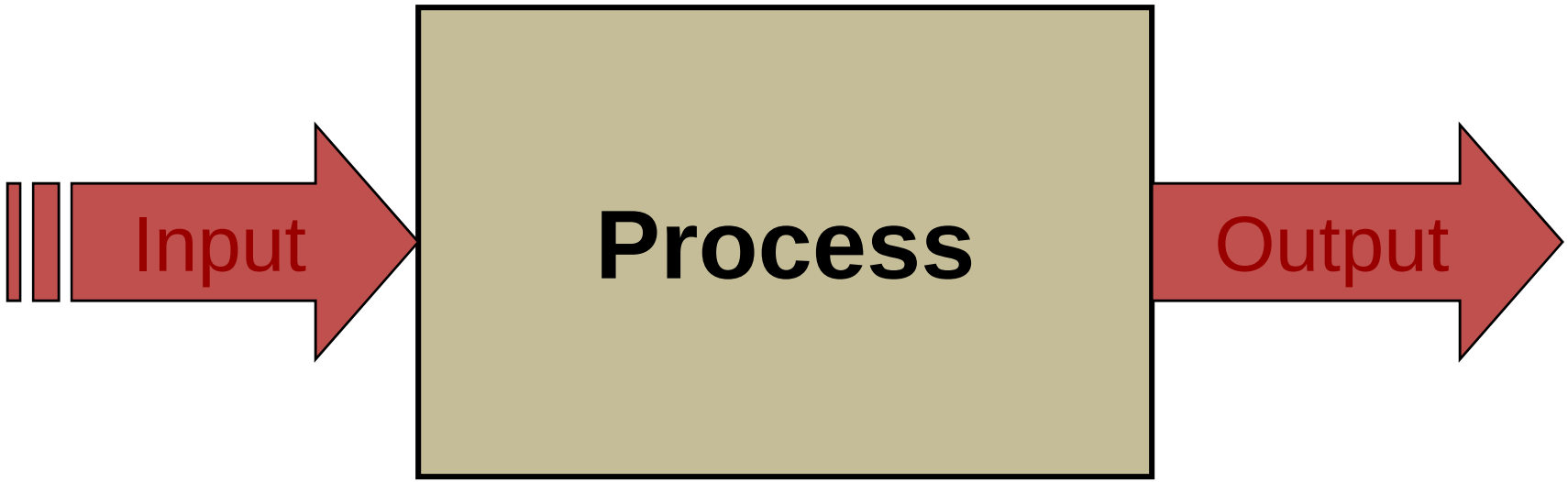
in order to satisfy the customer's needs with products/services.

Process

Definition:

A process is a set of interrelated or interacting activities which transforms input into outputs.

Understanding Processes



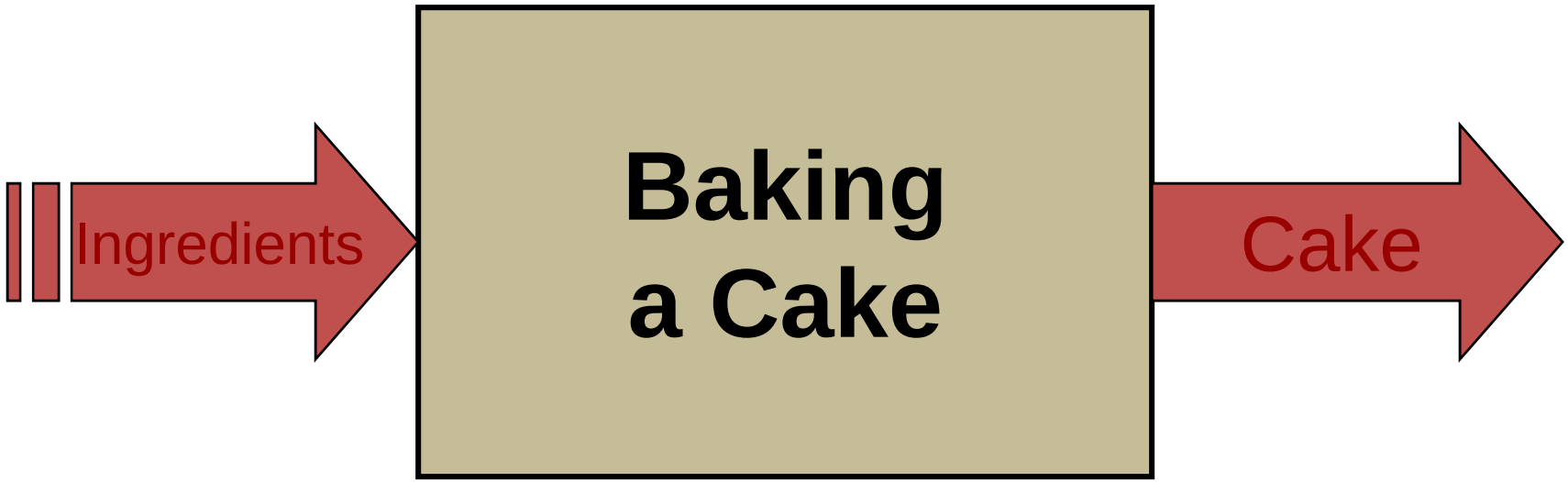
Understanding Processes

...managing processes...

- **Determine (or identify)**
- **Provide**
- **Communicate**
- **Ensure**
- **Maintain**
- **Monitor**
- **Measure**
- **Analyze**
- **Improve**

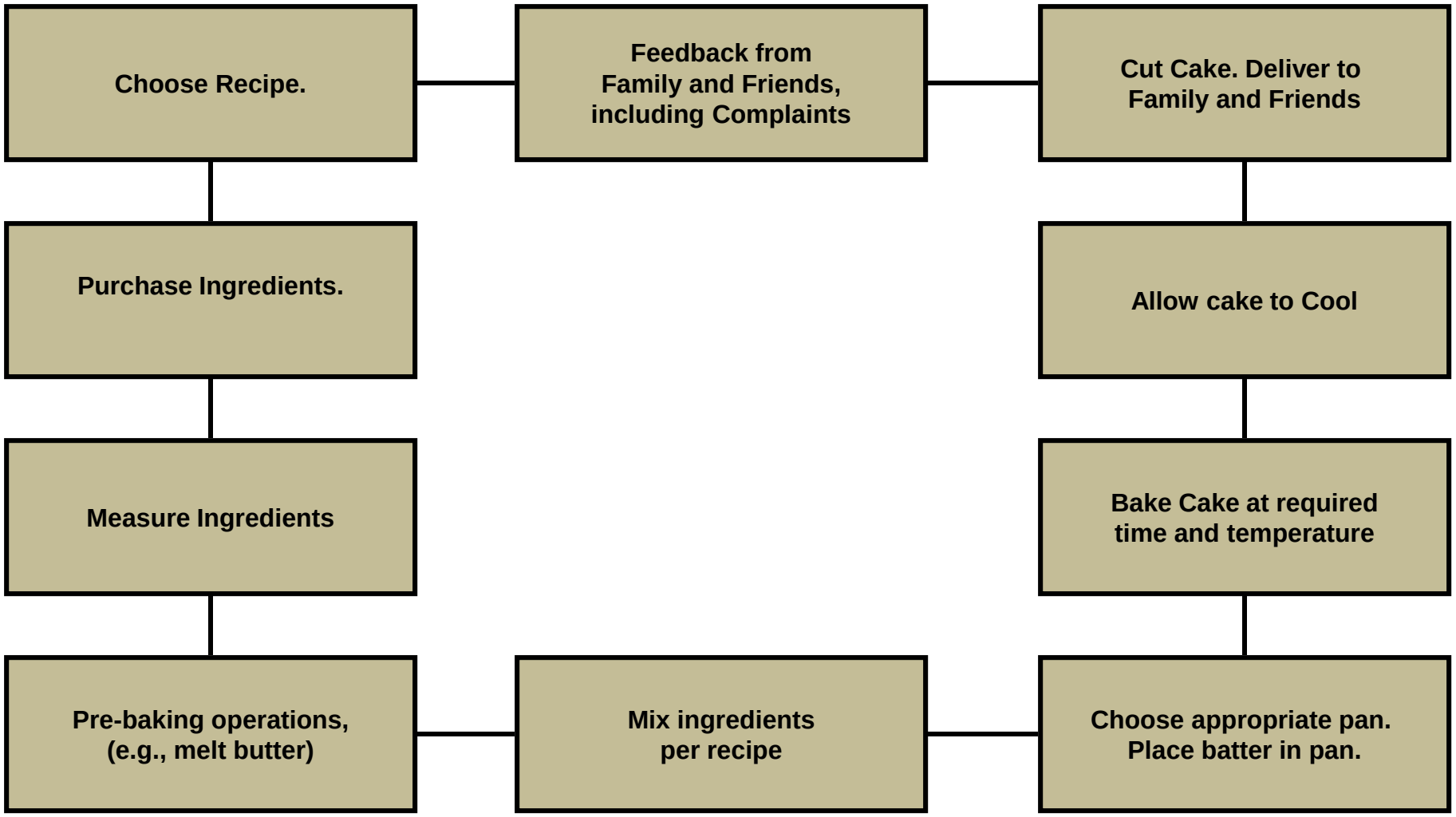
These words are repeated throughout ISO9001:2008

Understanding Processes

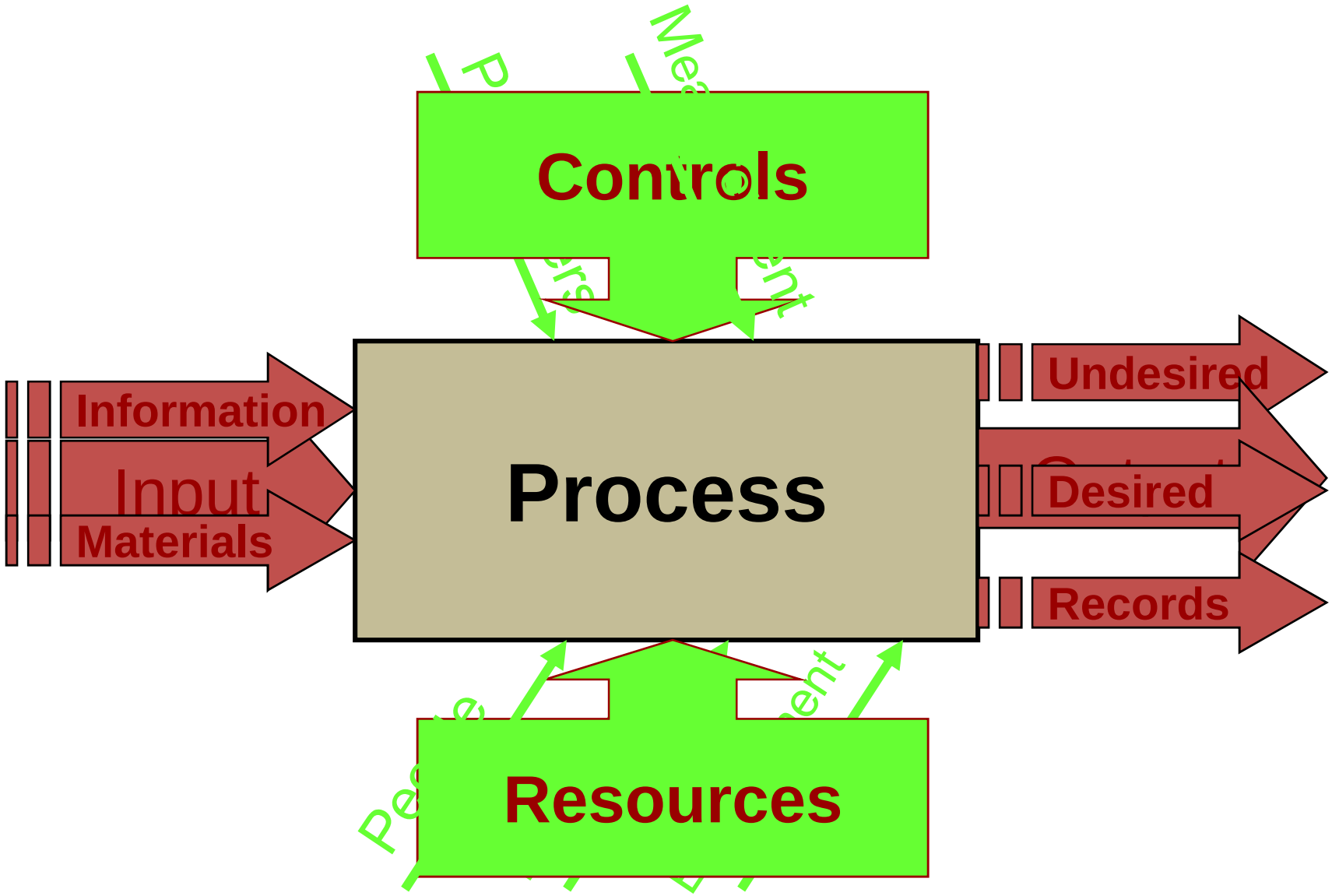


Tucson-Old Pueblo Section
ASQ The Global Voice of Quality™

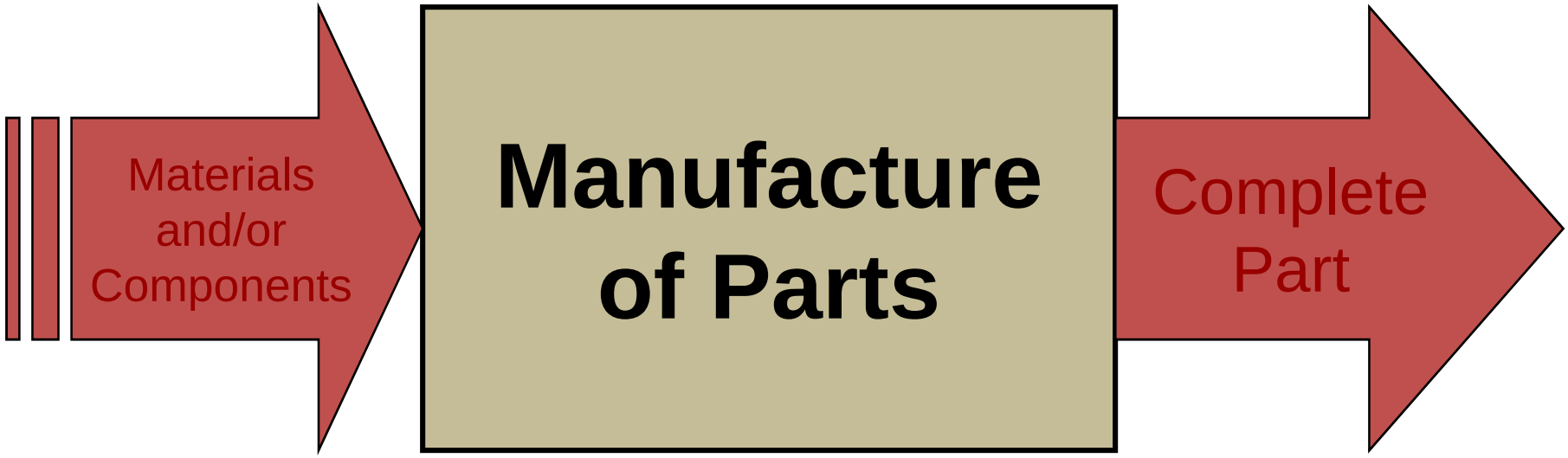
Process: Baking a Cake



Process Activity Diagram

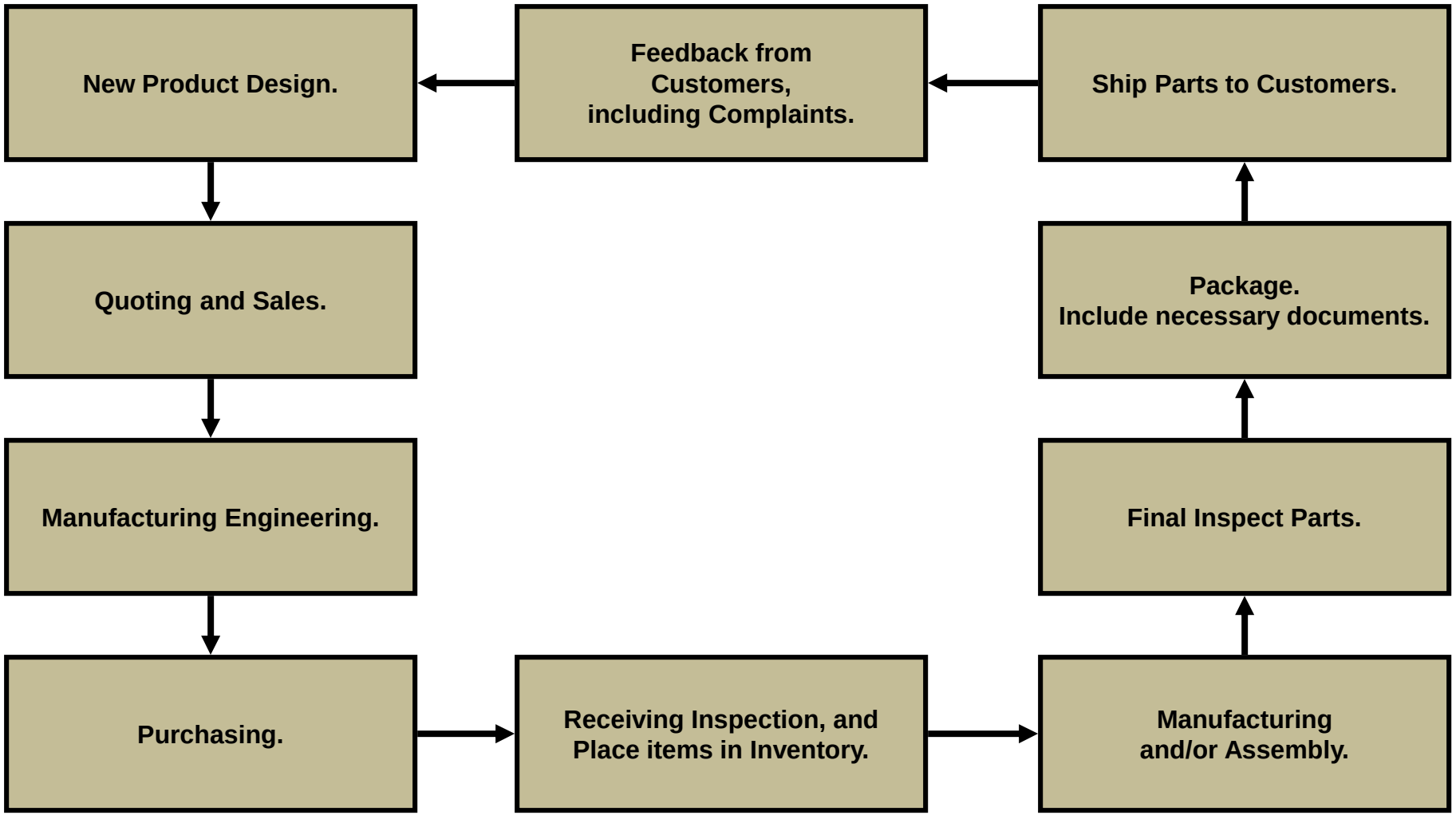


Understanding Processes



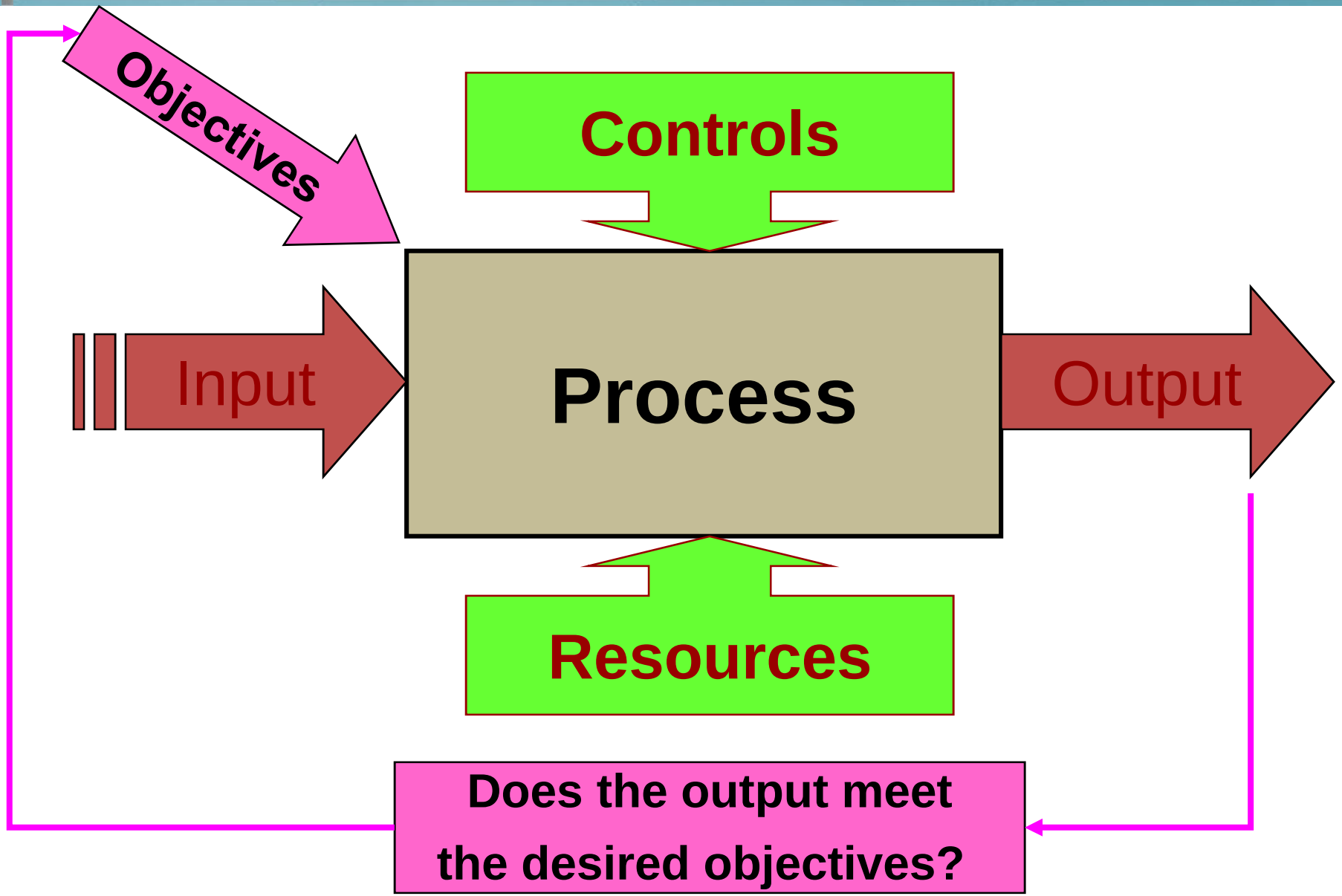
Tucson-Old Pueblo Section
ASQ The Global Voice of Quality™

Basic QMS Processes



Process Identification

Process Identification



Why are we auditing processes?

To ensure that...

- …we meet the QMS Standard Requirements
- ...documented procedures/WI's are available to fulfill the requirement *(complete and controlled?)*
- …necessary resources are provided
- …personnel are assigned to the function *(trained? qualified?)*
- …controls are implemented to measure process parameters and performance
- …the function is being performed *(per procedure?)*
- …records provide evidence *(controlled?)*
- ***...the process as implemented is effective (i.e., we find evidence that the process is capable of consistently producing the desired results)***

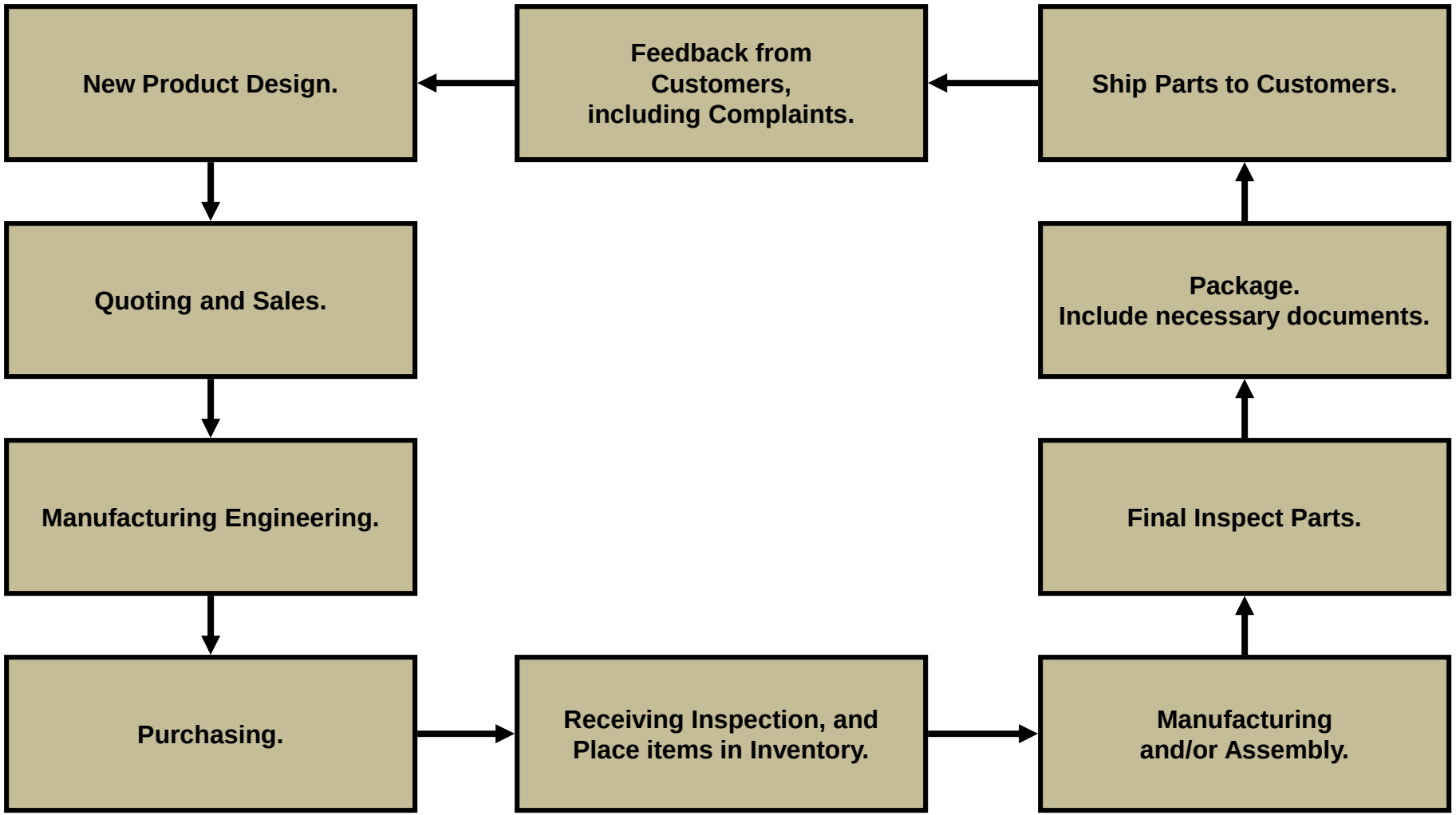
Status and Importance

Status and Importance

- **COPs – Customer Oriented Processes *(core processes, typically are the product realization processes)***
- **SOPs – Support Oriented Processes *(support to one or more COPs)***
- **MOPs – Management Oriented Processes *(apply to all COPs, SOPs, and other MOPs)***

Tucson-Old Pueblo Section
ASQ The Global Voice of Quality™

Core Processes



Support Oriented Processes

- Receiving Inspection
- In-Process Inspection
- Non-Destructive Testing
- Process Documentation
- Calibration
- Preventive Maintenance
- Tooling Management *(Design, Purchase, Manufacture, Storage)*

Management Oriented Processes

- Management Review
- Internal QMS Audits
- Document Control
- Records Control
- Nonconforming Product
- Corrective Action
- Preventive Action
- Continuous Improvement

Audit Paths

Two Recognized QMS Audit Paths

- Trace Forward.
- Trace Backward.

Tucson-Old Pueblo Section
ASQ The Global Voice of Quality™

QMS Audit Path: Trace Forward

- **Begin by learning or knowing the applicable requirements.**
- **Reviewing the policies to verify they are covered.**
- **Review the procedures to identify how the policies are implemented.**
- **Review any work instructions to learn about any specific activities performed in completing the task.**
- **Fill out a Process Activity Diagram.**
- **Document your audit plan in appropriate detail.**
- **Conduct an audit of the process/area against the specifics required actions.**
- **Use the activity diagram to record the process.**

Tucson-Old Pueblo Section
ASQ The Global Voice of Quality™

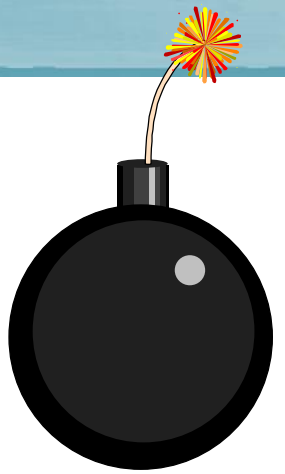
QMS Audit Path: Trace Backward

- **Begin by identifying a result (output) of the activity/process.**
- **Ask the auditee(s) how the job is performed to get the result. Allow auditee to explain fully, only asking questions when necessary.**
- **Record notes as applicable. Fill out the activity diagram.**
- **Ask for any applicable documented work instructions or procedures.**
- **Review the documents comparing them to what auditee explained. Compare to the activity diagram.**
- **Ask questions as appropriate.**
- **Document any findings.**

Trace Forward

Benefits

- In depth understanding of the process.
- Verifies that the system is complete.
- Permits a true audit plan to be developed.
- Activity diagram is completed based on the documented plan.



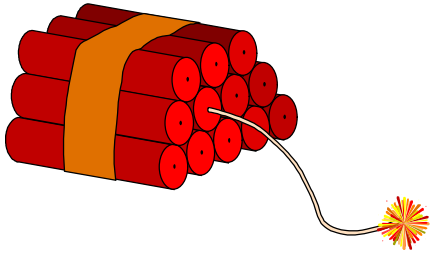
Drawbacks

- Preparation of the audit plan may be time-consuming.
- Because of time spent reviewing documents, it may not permit an appropriate review of the actual function.

Trace Backward

Benefits

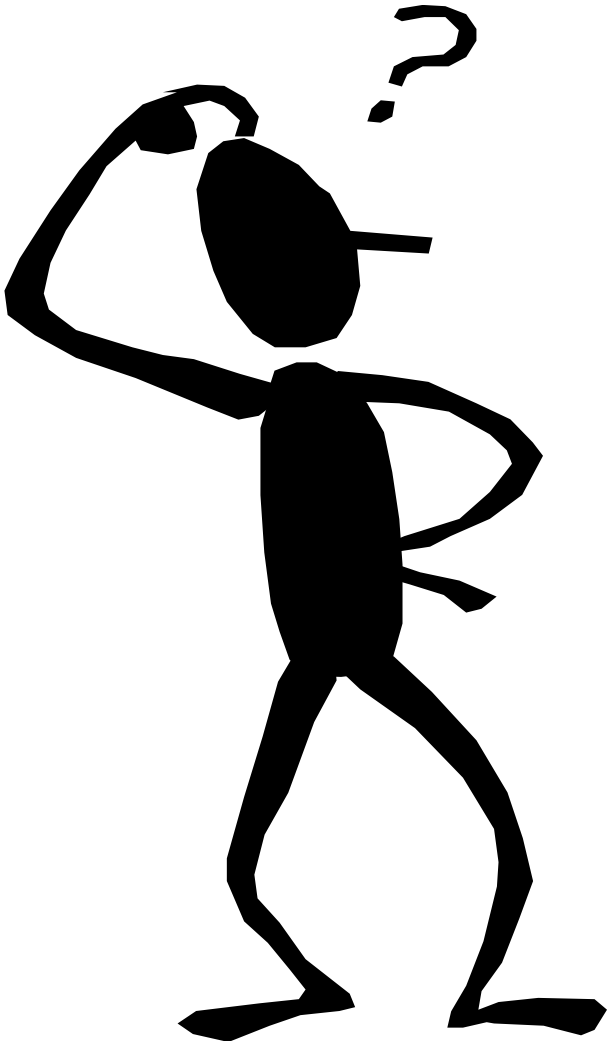
- Audits can be completed relatively quickly.
- A good auditor has the freedom to review requirements in a broader sense.



Drawbacks

- Auditor needs to be familiar with the process before the audit.
- Without checklists, required pieces of the process can be missed, thereby missing potential noncompliances.

The Debate on Audit Checklists

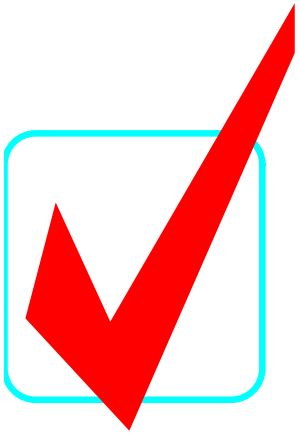


HOW

...do you write an audit plan?

The Audit Plan can be documented in a variety of ways appropriate to the situation:

- Generic definition of audit plan; details to be determined by the auditor during the audit.
- Detailed list of questions with blocks to be filled in during the audit.
- A specific checklist as referenced in procedure or by the generic audit plan.



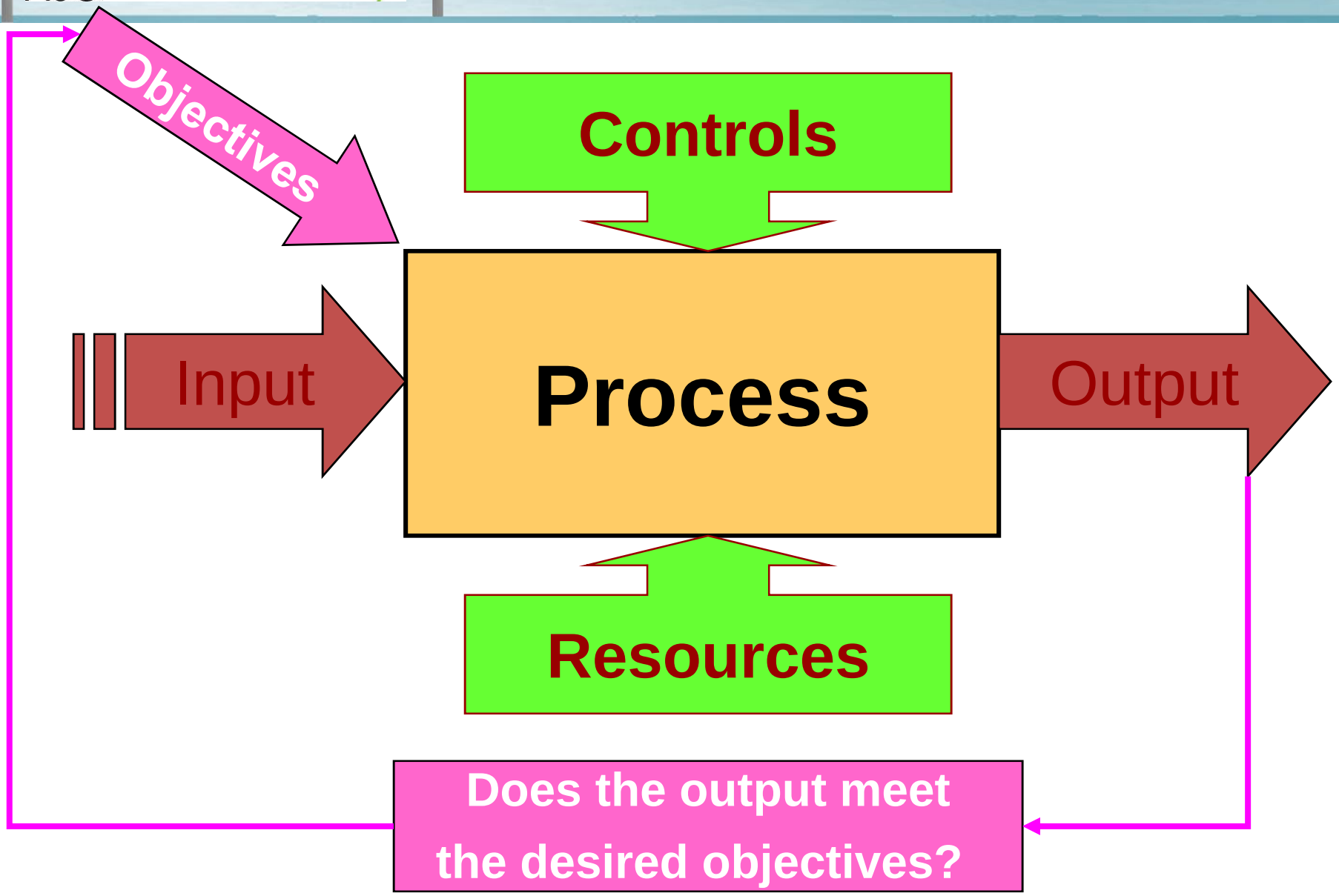
Checklists provide...

- ...Structure
- ...Discipline

Checklists can...

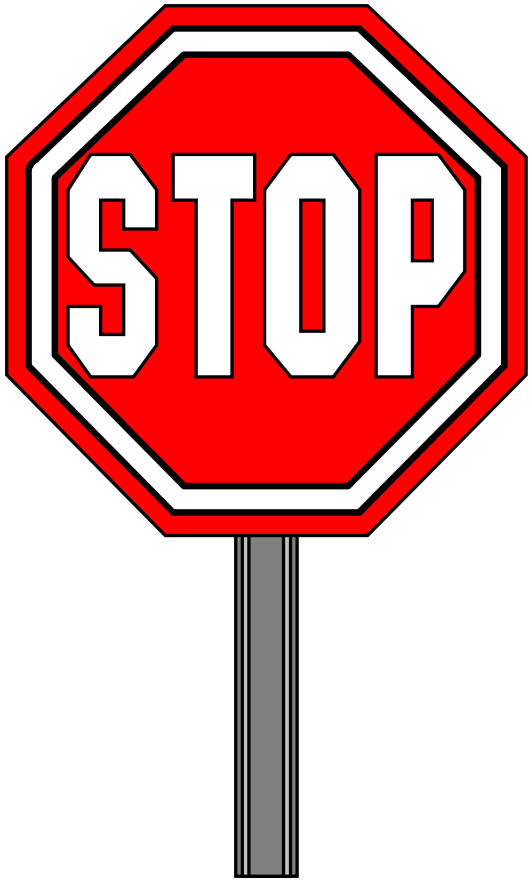
- save time for the auditor
- act as a memory jogger
- follow a logically defined order
- ensure that important requirements are not missed

Identify the Process



Personal Attributes

An Audit of the PROCESS!



It is an audit
of the **process!!**

It is NOT an audit
of the people

Communication Skills Required for Good QMS Auditors

- Listen attentively
- Put people at ease
- Put yourself in their position
- Don’t judge or argue
- Make eye contact
- Don’t interrupt

Tucson-Old Pueblo Section
ASQ The Global Voice of Quality™

Traits of a QMS Auditor

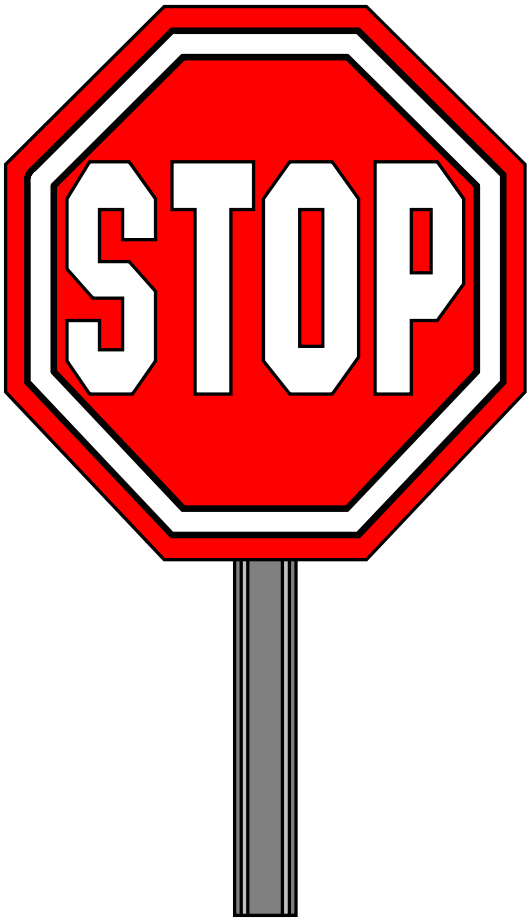
Good Traits

- Professional
- Punctual
- Smile
- Clear and concise
- Respectful of others time and situation
- Confident
- Develops trust with auditee
- Asks open ended questions

Bad Traits

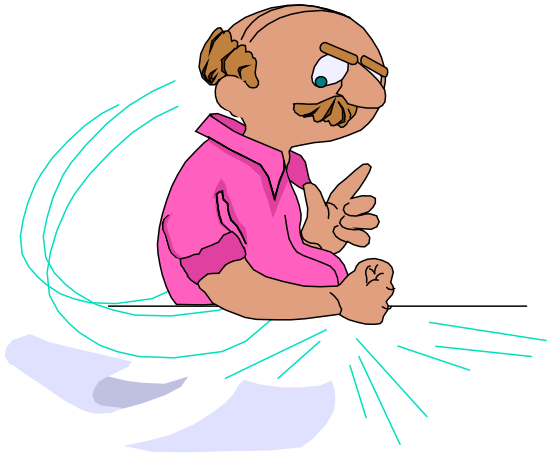
- Late
- Rude
- Annoying gestures
- Arrogant
- Unprepared
- Argumentative
- “know it all”
- Impatient
- Asks “yes” & “no” questions

No "Witch Hunting"

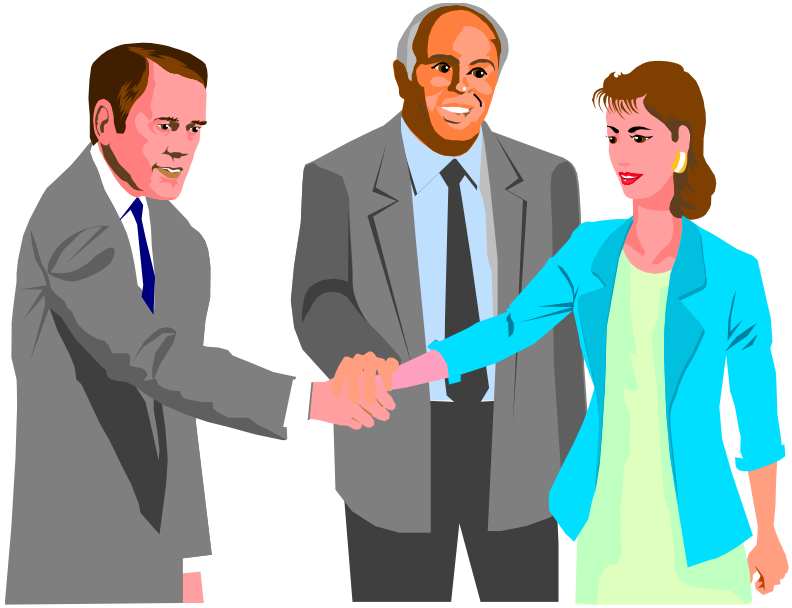


NO "WITCH HUNTING" PERMITTED!!!

Recommended Thought Process



You are not there to audit them…



...you are helping them audit themselves!

Reporting of Results

- Closing Meeting
- The Written Report

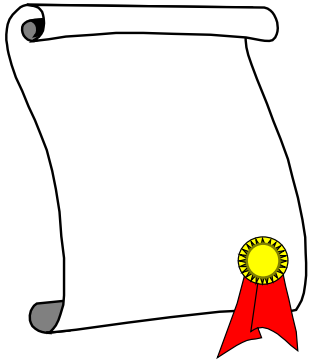
Reporting of Results

Types of Findings to Report:

- **NC** – Noncompliance. A condition or situation discovered where a requirement is not fulfilled. Correction is required to remove the noncompliant condition; Corrective Action is required to eliminate the cause of the noncompliance.
- **OFI** - Opportunity for Improvement. Although deemed compliant, the auditor believes that the system could be improved. Usually agreed with auditee when observed.
- **OBS** - An Observation. A record of something observed during the audit deemed worthy of reporting. It could be:
  - *a perceived weakness in the QMS/process,*
  - *an area where improvement of the QMS/process is recognized by the auditor,*
  - *an exceptionally good activity or improvement, or*
  - *other appropriate comment*

Closing Meeting

- Re-state the purpose for the audit
- Re-introduce the audit team members
- Report the audit results and have them verified
- Allow auditee opportunity to explain noncompliances
- State any concerns
- Obtain commitment that corrective action will be taken to correct noncompliant items
- Affirm responsibility for corrective action
- Explain content and format of written audit report, and when auditee can expect to receive it
- Express appreciation to auditee



Purposes for a Written Report

- Documents the results of the audit
- Provides an analysis of the QMS/process
- Provides a record of the nonconformances requiring corrective action
- Identifies areas needing investigation for improvement
- Acts as a record of the agreement between the auditor and auditee.

Reporting of Results

Format of the Written Report includes:

- General Information - Auditees, Dates, Auditors, etc.
- Purpose and Scope, including applicable standards and specifications, processes/areas audited, etc.
- Overview / Executive Summary - Did we pass? Is the system/process effective?
- Details (objective evidence) of findings, specifically when noncompliances are documented. *Auditee should be able to re-create your audit trail to the noncompliance!!!*
- When any responses (i.e. CAR's) are due.
- Any additional contacts
- Approvals
- Attachments - where applicable

Tucson-Old Pueblo Section
ASQ The Global Voice of Quality™

Some ways to make Internal QMS Audits more effective

- **Understand the reasons why to audit.**
- **Understand the process being audited.**
- **Understand the importance of the process being audited.**
- **Know which direction you are auditing.**
- **Determine what is the right checklist for the audit.**
- **Be professional and respectful.**
- **Provide reports that are useful, complete, and accurate.**

Tucson-Old Pueblo Section
ASQ The Global Voice of Quality™

Any More Questions?

Contact Me:

Ron Gryniewicz

ASQ Education Chair

ASQ Certified CQE, CMQ/OE

Exemplar Global QMS-LA, AS9100 AA

Use the ASQ-Tucson website:

http://www.asq0707.org/contacts/