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The Global Voice of Quality™

# Internal QMS Auditing

## Why is it so difficult?

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



- **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?**



## **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**



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# **ISO9001 and AS9100 Requirements (some of them)**



## **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**



- **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.**



- **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 nonconformities.**





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



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# 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.**





## ...managing processes...

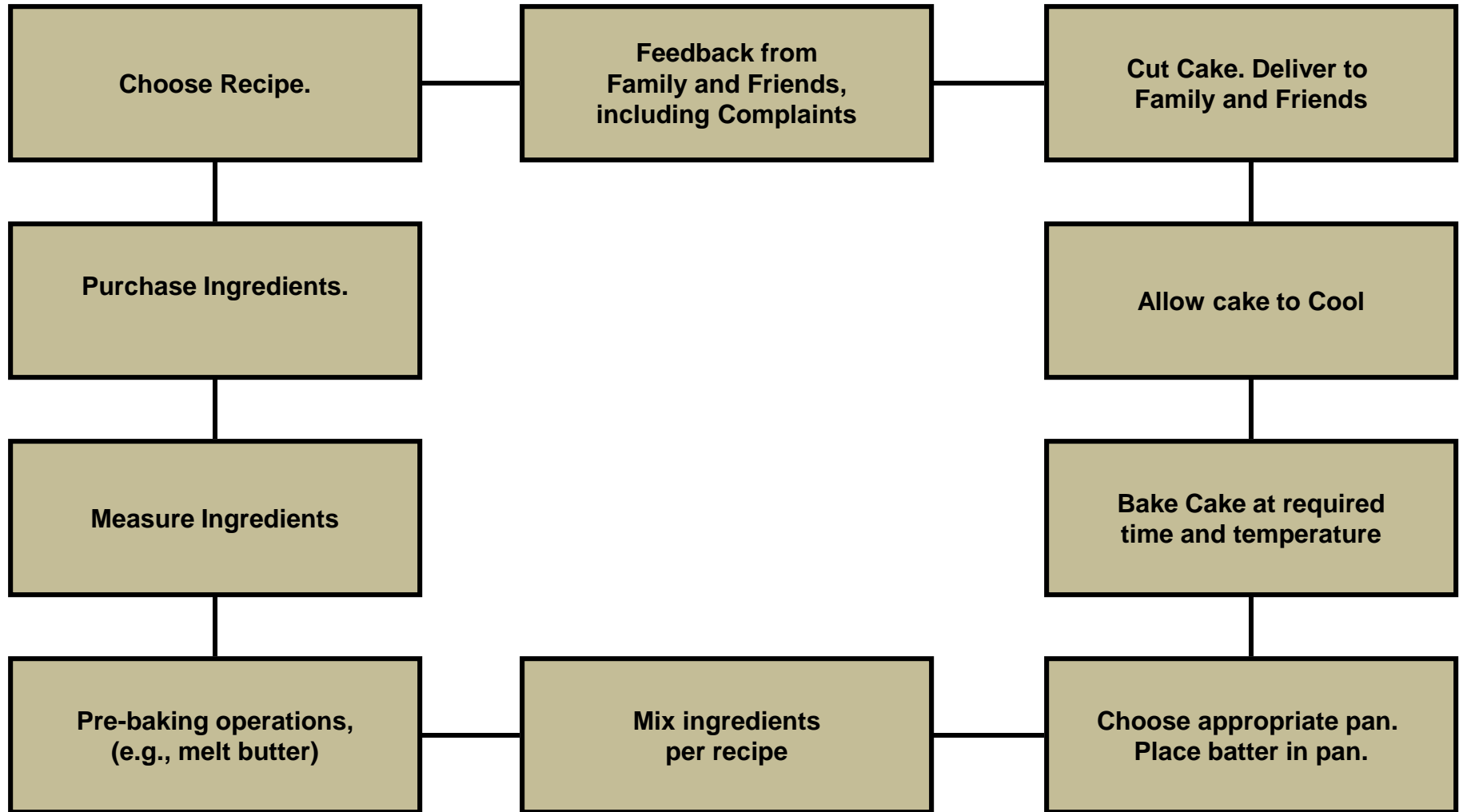
- **Determine (or identify)**
- **Provide**
- **Communicate**
- **Ensure**
- **Maintain**
- **Monitor**
- **Measure**
- **Analyze**
- **Improve**

**These words are repeated throughout ISO9001:2008**





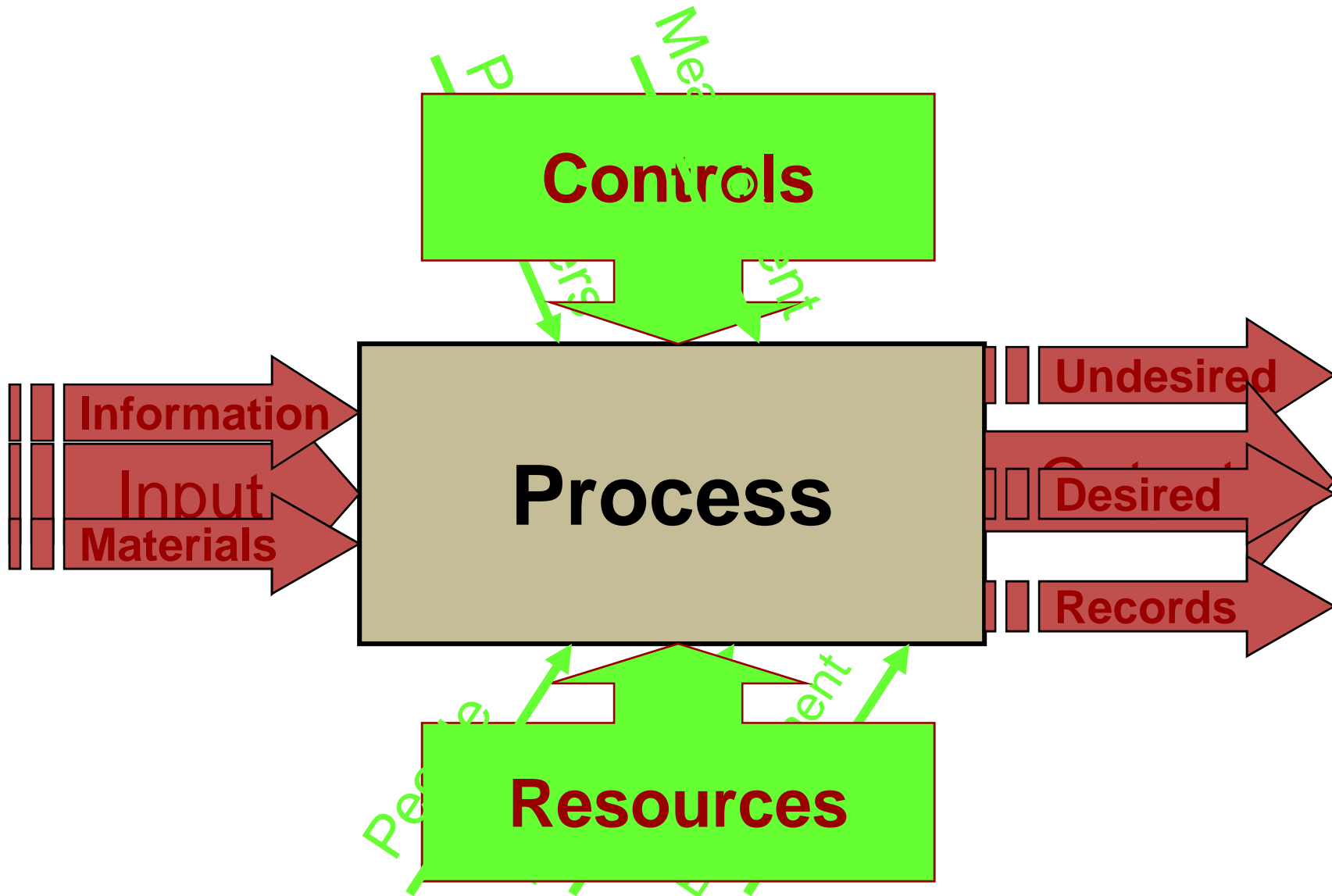
# Process: Baking a Cake

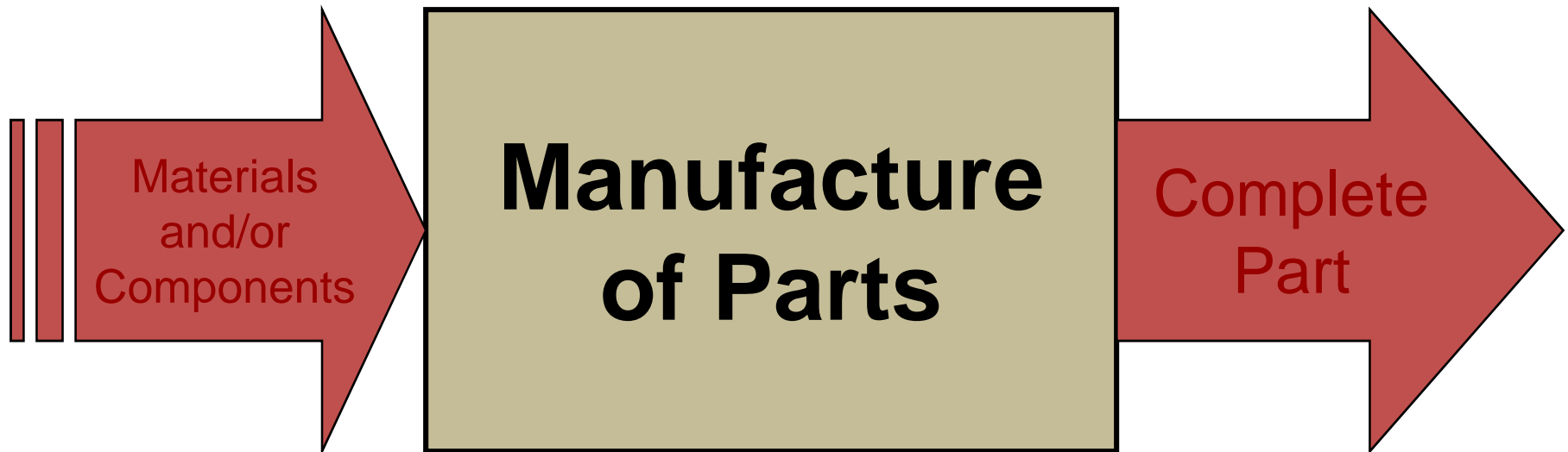






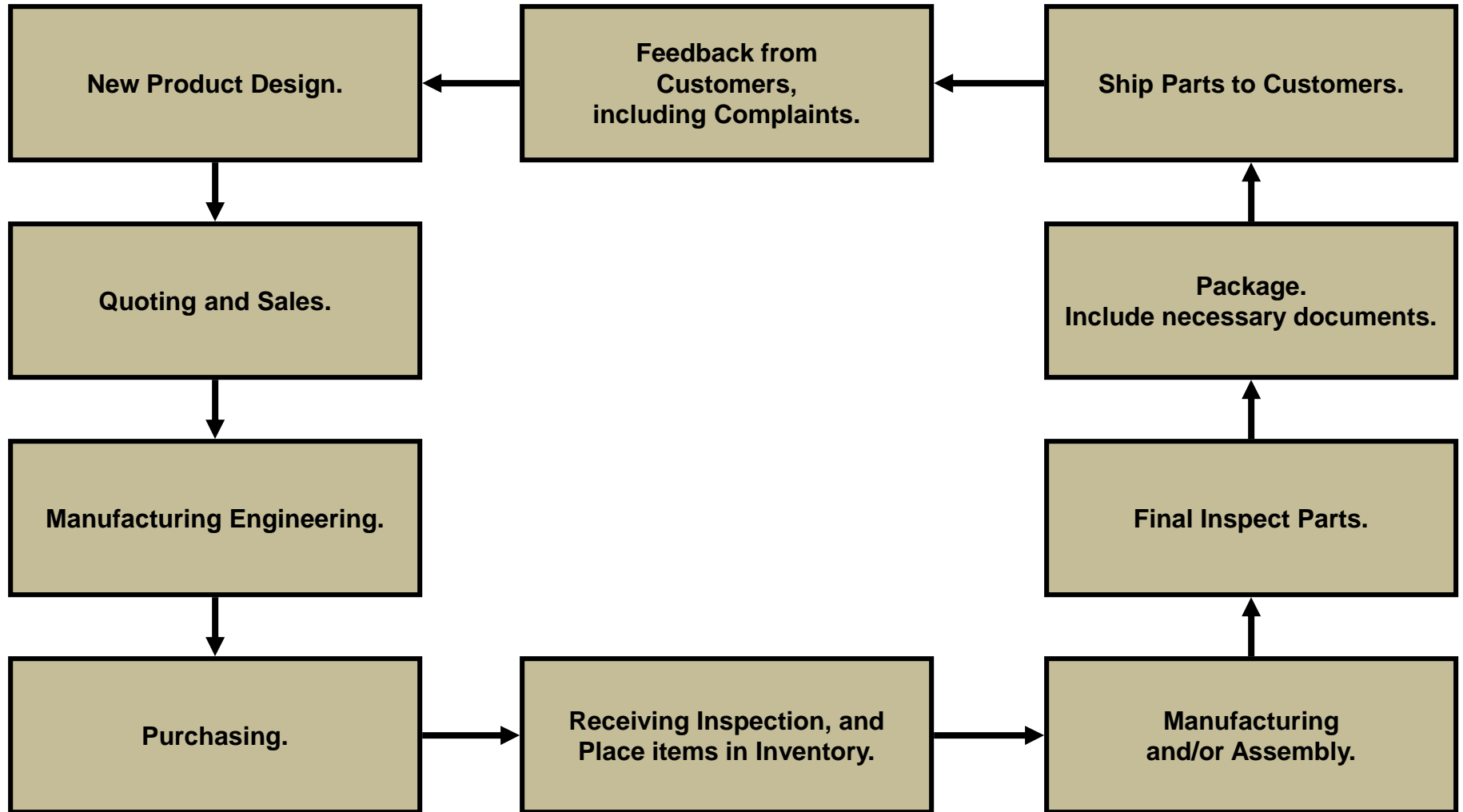
# Process Activity Diagram



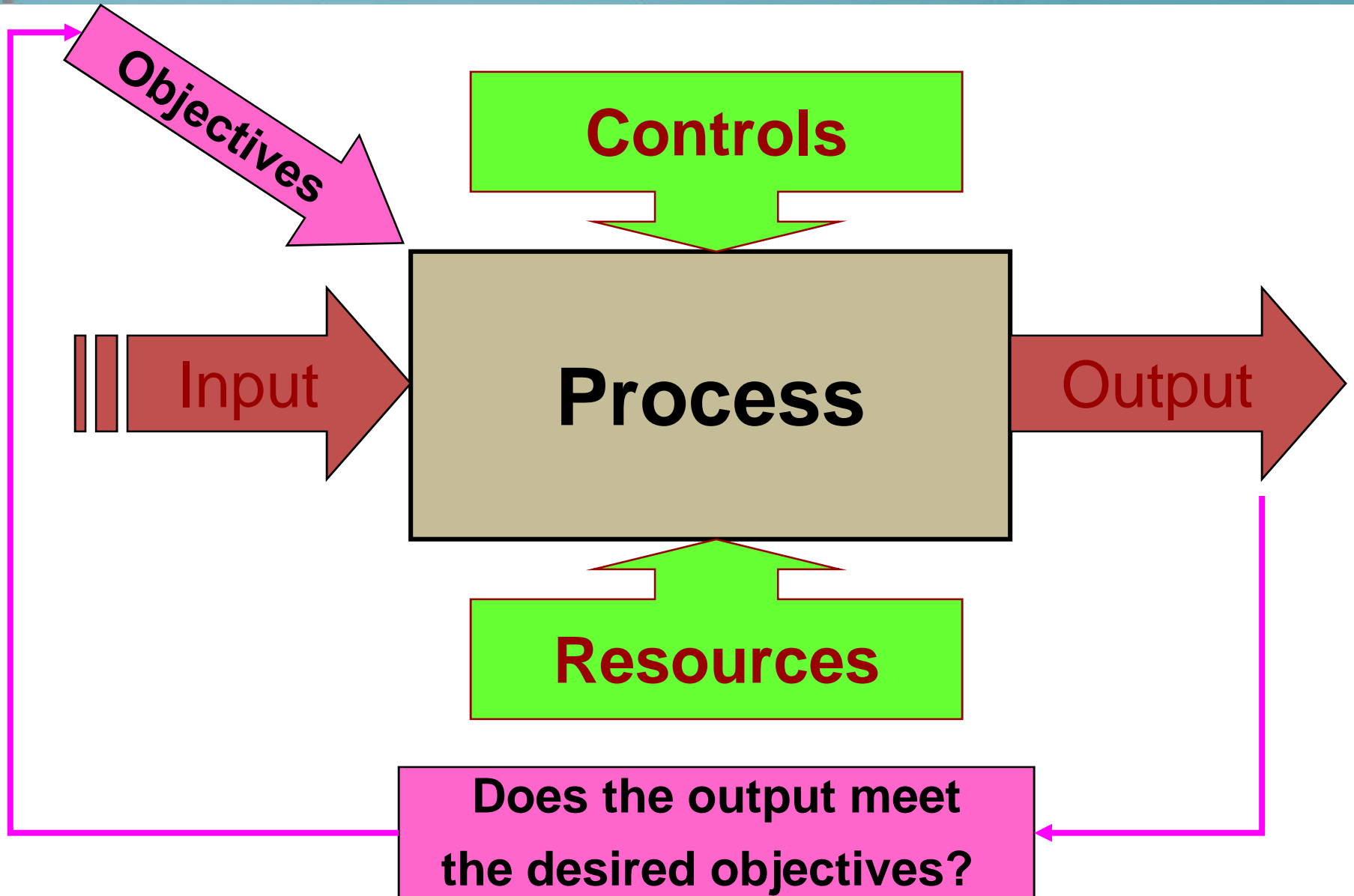




# Basic QMS Processes









## 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)**



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## Internal QMS Auditing

# Status and Importance

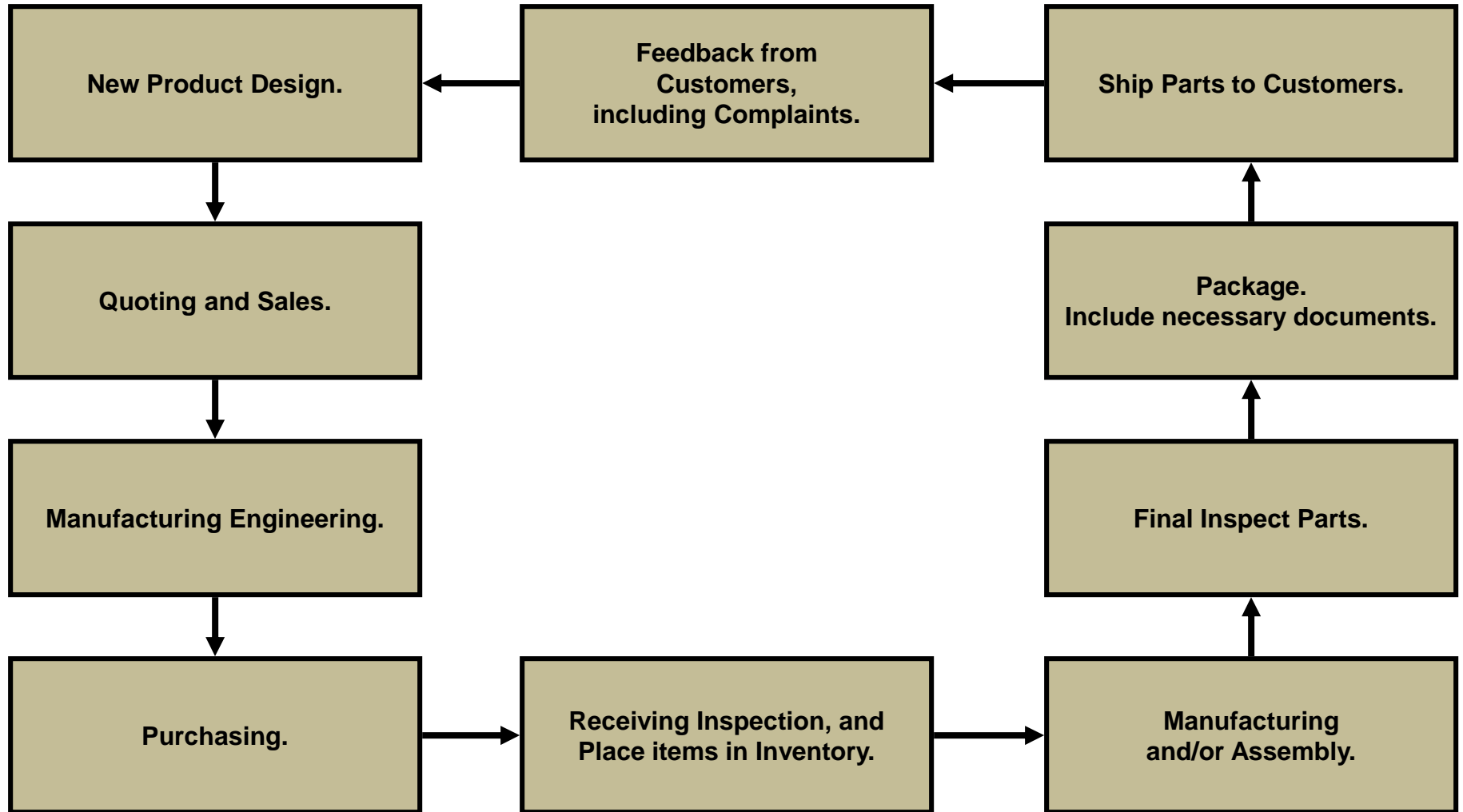


- **COPs – Customer Oriented Processes**  
(core processes, typically are the product realization processes)
- **SOPs – Support Oriented Processes**  
(support to one or more COPs)
- **MOPs – Management Oriented Processes**  
(apply to all COPs, SOPs, and other MOPs)





# Core Processes





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



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



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## Internal QMS Auditing

# Audit Paths



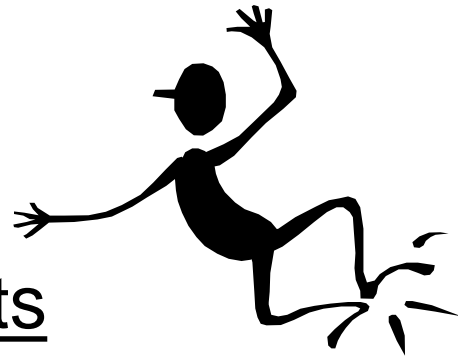
- Trace Forward.
- Trace Backward.



- **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.**

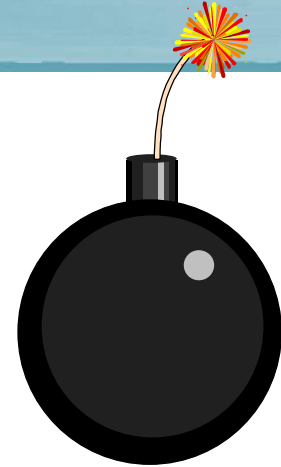


- **Begin by identifying a result (output) of the activity/process.**
- **Ask the auditee(s) how the job is performed to get the result. Allow auditee to explain fully, only asking questions when necessary.**
- **Record notes as applicable. Fill out the activity diagram.**
- **Ask for any applicable 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.**



## 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

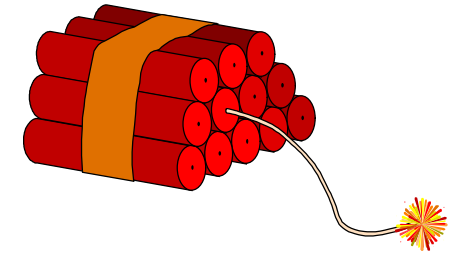
- Preparation of the audit plan may be time-consuming.
- Because of time spent reviewing documents, it may not permit an appropriate review of the actual function.





## Benefits

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



## Drawbacks

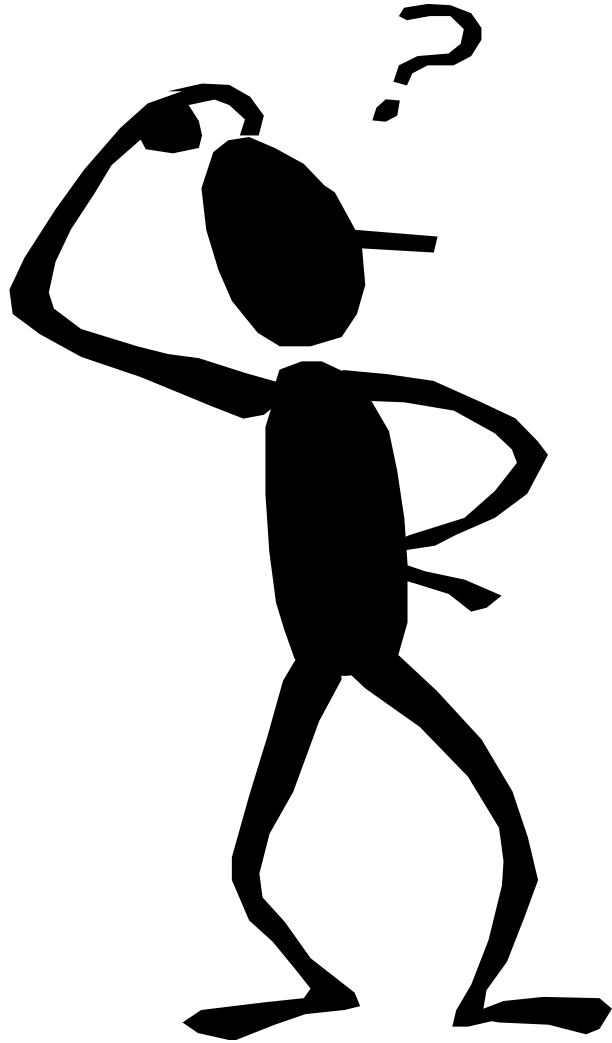
- Auditor needs to be familiar with the process before the audit.
- Without checklists, required pieces of the process can be missed, thereby missing potential noncompliances.



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# The Debate on Audit Checklists



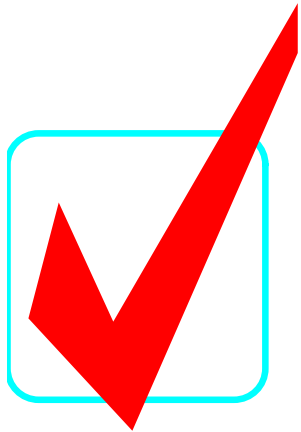
**HOW**

...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...

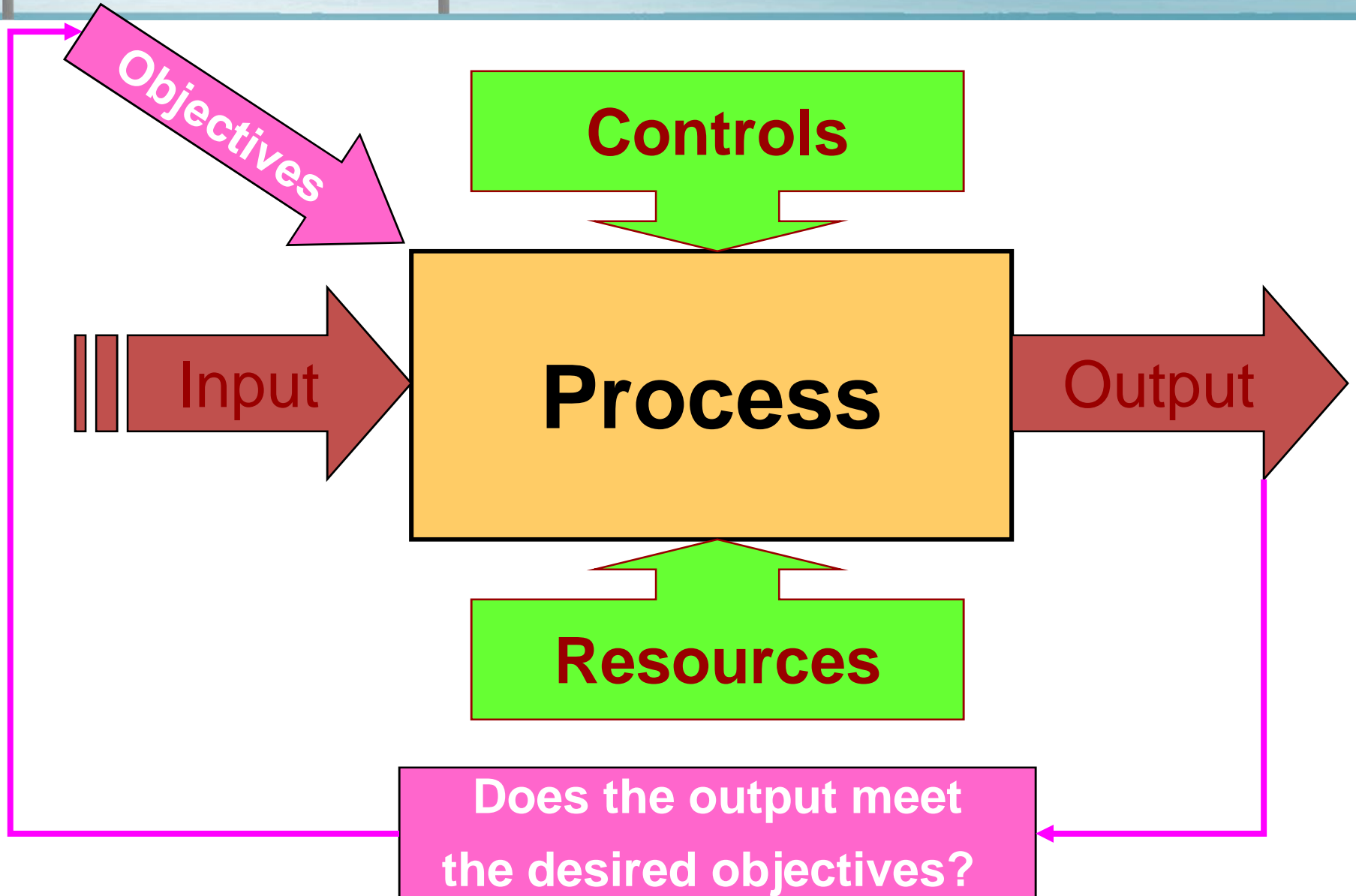
- ...Structure
- ...Discipline

## Checklists can...

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



# I identify the Process





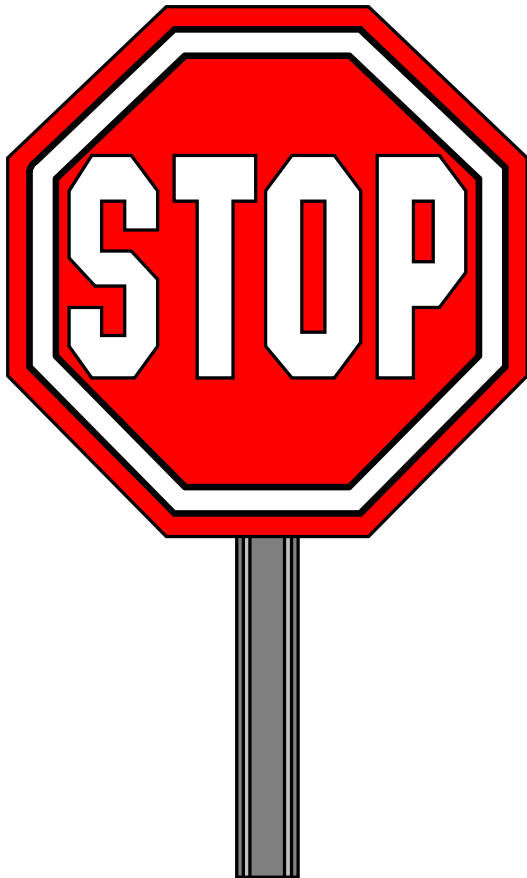
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## Internal QMS Auditing

# 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



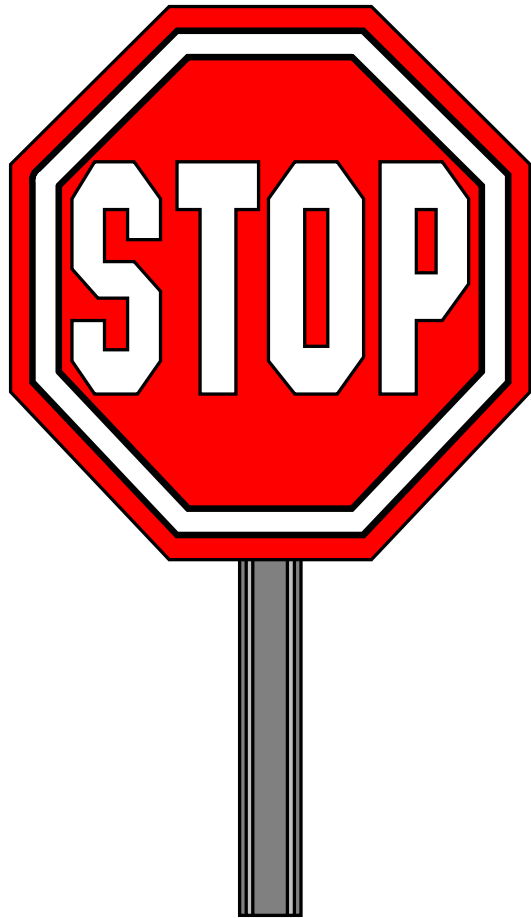
# Traits of a QMS Auditor

## 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

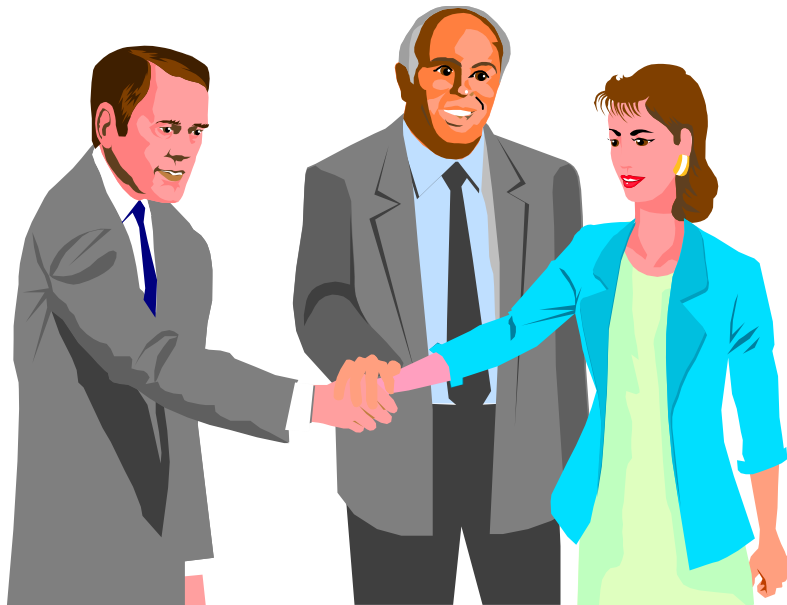
- Late
- Rude
- Annoying gestures
- Arrogant
- Unprepared
- Argumentative
- “know it all”
- Impatient
- Asks “yes” & “no” questions



**NO  
"WITCH  
HUNTING"  
PERMITTED!!!**



You are not there  
to audit them...



...you are helping  
them audit  
themselves!



# Reporting of Results

- **Closing Meeting**
- **The Written Report**



### Types of Findings to Report:

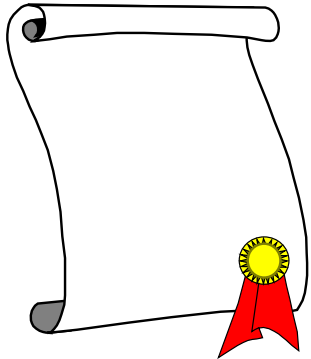
- **NC** – Noncompliance. A condition or situation discovered where a requirement is not fulfilled. Correction is required to remove the noncompliant condition; Corrective Action is required to eliminate the cause of the noncompliance.
- **OFI** - Opportunity for Improvement. Although deemed compliant, 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.





## 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



## 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.**



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Any More Questions?



## Contact Me:

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Use the ASQ-Tucson website:

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