Process Mapping and Process-Based Internal Audits

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Today's Topics

- Why Are We Doing This?
- Process Terminology
- Process Mapping Symbols
- Different Ways to Visualize a Process
- Bakeries: A Practical Example
- Process Approach to Auditing

Why Are We Doing This?

- Outcomes should matter to certified organizations and to bodies, such as PJR, offering accredited certification.
  - Some organizations get certified because of customer mandates or to “fly the flag.”
  - There is a push for certification bodies to not just look for conformity to requirements but for clear measures of true process improvement.
  - After all, shouldn’t organizations derive benefit from accredited certification?

Outcomes Matter

- An accredited QMS certification process must ensure the following:
  - An organization's QMS must meet the requirements of the relevant standard.
  - The QMS analyzes and understands customer requirements and is aware of relevant statutory and regulatory requirements.
  - Product characteristics have been defined.

Outcomes Matter

- An accredited QMS certification process must ensure the following:
  - **The QMS has identified and manages the processes needed to achieve the expected outcomes.**
  - The QMS aims to prevent nonconformities and has processes in place to correct nonconformities, analyze root cause and take corrective action. *(Focus of PJR's Root Cause and Systemic Corrective Action Seminars).*
  - **The organization is monitoring, measuring and continually improving the effectiveness of its QMS.**

Outcomes Matter

- An accredited EMS certification process must ensure the following:
  - The organization is managing its environmental impacts.
  - The organization is demonstrating commitment to preventing pollution, meeting legal requirements and **continually improving environmental performance.**

Outcomes Matter

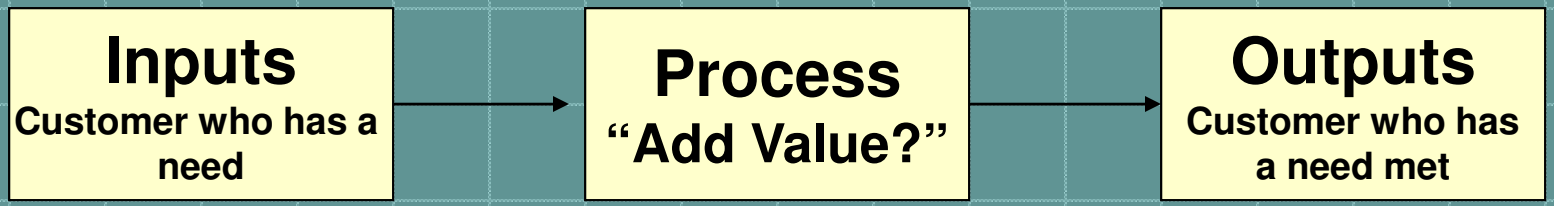
- Today's seminar focuses on helping your organization accomplish the following:
  - **The QMS has identified and manages the processes needed to achieve the expected outcomes.**
  - **The organization is monitoring, measuring and continually improving the effectiveness of its QMS.**
  - **The organization is continually improving its environmental performance.**

The Basics

Process Mapping Terminology

Terminology

- Process – a sequence of steps, activities, decisions or tasks that transforms inputs into outputs.
  - We talk about "adding value." This is when the outputs of a process are of greater value than the inputs.



Terminology

- Process Boundaries – designated start and end points of a process.
  - Should be logical
  - Must be determined before a process can be described.
  - Usually defined as a “customer with a need” and a “need being met.”

Terminology

- Process Inputs – any product or service used in the process
  - People
  - Equipment
  - Material
  - Documentation
  - Environment
- Suppliers – provide the needed inputs for a process
  - Internal Suppliers
  - External Suppliers

Terminology

- Outputs – a product or service created by the process that is of value to the customer.
  - Evidence that work has been completed.
  - Must be specific
  - **Output of one process is often the input of another.**
- Customers – individuals who benefit from the products or services produced by the process
  - Internal customers
  - External customers

Terminology

- Customer requirements – needs, wants or expectations that internal or external customers have for the output of the process
  - May be written or unwritten
- Process owners – an individual(s) who is/are accountable for the process.
  - Determined by the process boundaries
  - May be a team of people

Terminology

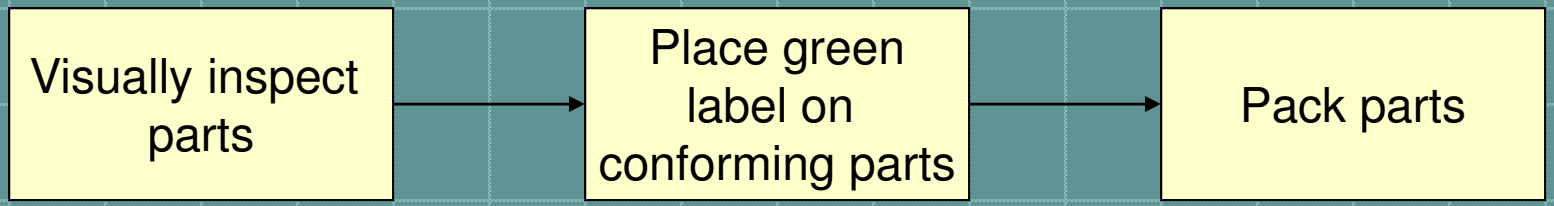
- Process Approach – the application of a system of processes within an organization, together with the identification and interactions of these processes, and their management.
  - Processes should be **automatic** and **instinctive** to all personnel.

The Basics

Process Mapping Symbols

Process Mapping Symbols

- Rectangles – used to identify a discrete activity in the process. Content of rectangle is usually a verb and direct object.
- Lines with Arrowheads – Represent the direction and flow of the activities in a process.

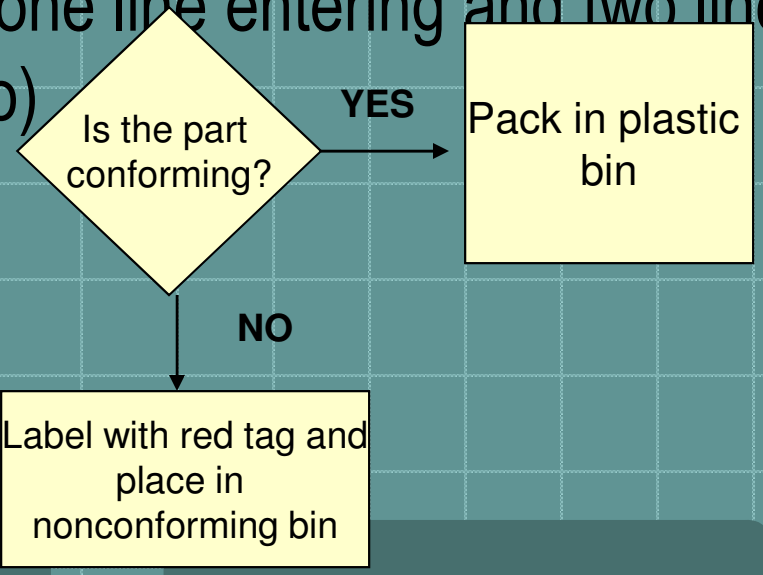


Process Mapping Symbols

- Start and end ovals – used to signify the starting point and end point of a process, the "boundaries."

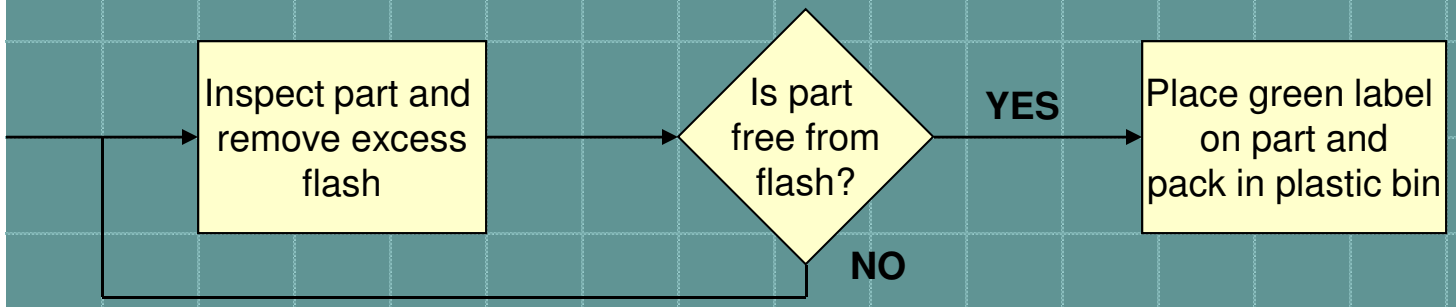
Process Mapping Symbols

- Decision Diamonds – represent a decision in a process, a question that must be answered with a yes or no.
  - Have one line entering and two lines leaving (yes and no)



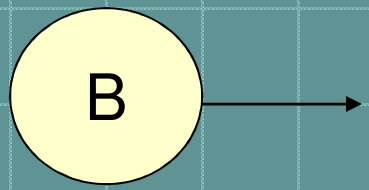
Process Mapping Symbols

- Loop – displays a part of the process that repeats itself until a specific condition is met.
  - Often takes the process back to other steps.
  - Indicate areas where activities such as rework are needed.



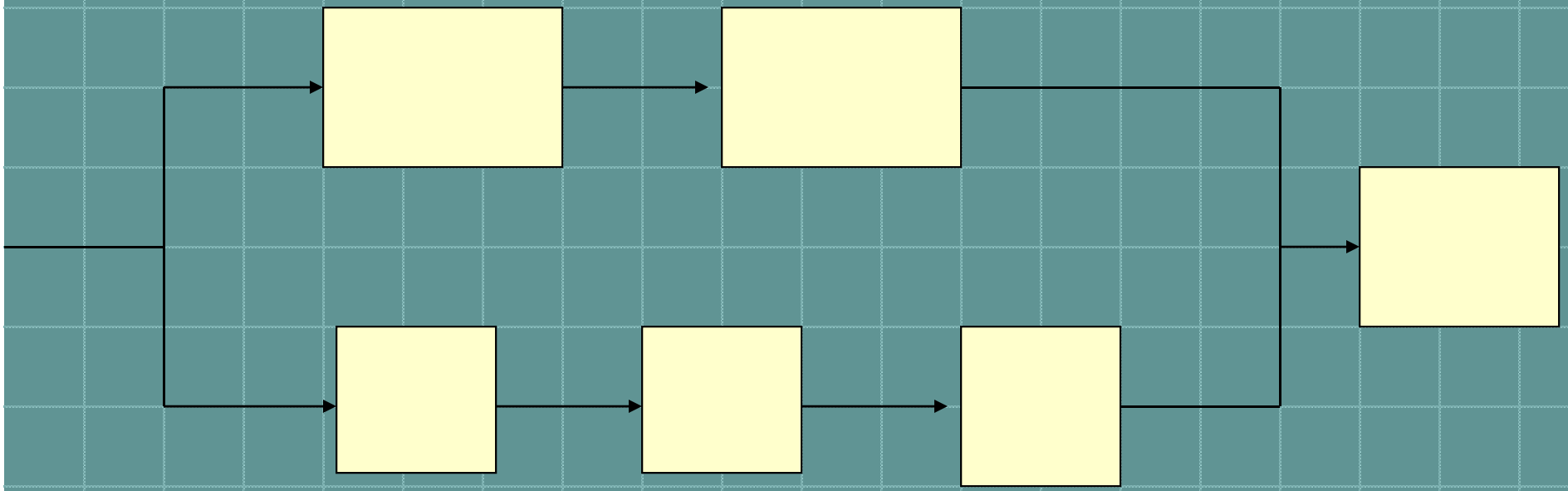
Process Mapping Symbols

- Circles – used to reference or connect another part of the process when the process continues to another page.



Process Mapping Symbols

- Parallel process – process or process steps that occur at the same time as another process.



The Basics

Different Ways to Visualize a Process

Benefits of Making a Process Visible

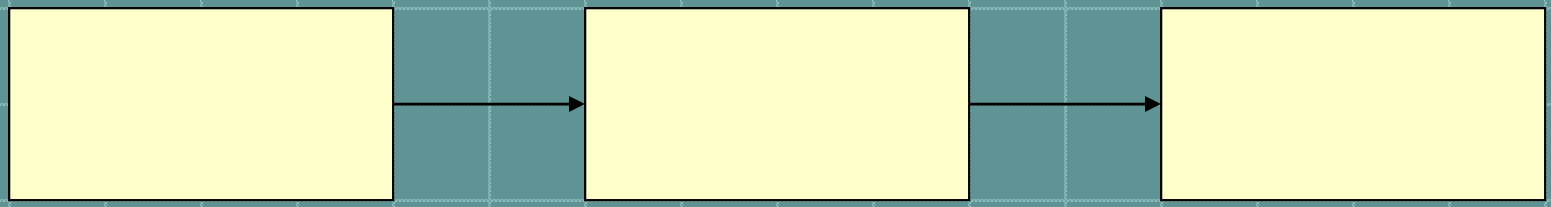
- Process Improvement
  - Allows relationships and sequences to be identified and analyzed
  - Serves as an aid to problem solving
- Education and Training
  - Way to train employees on changed processes
  - Assist in training new employees
- Documentation
  - Clarifies the **flow of work in a process**
  - Eliminates the need for lengthy procedures and work instructions in narrative format

Flow of Work in a Single Process

- Block Diagrams
- Process Maps
  - VISIO
  - Microsoft

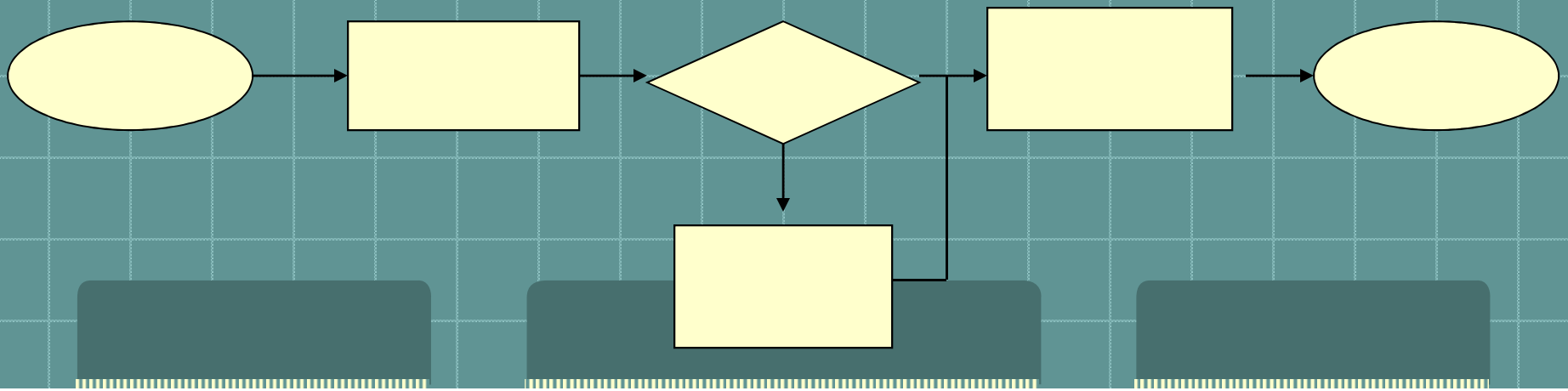
Block Diagram

- Simple schematic of the major steps of a process
  - Uses rectangles or “blocks” and arrows
  - Answers the question: “What is the process?”



Process Map

- Detailed schematic of the steps, activities or tasks that shows how something is done
  - Shows decision points and feedback loops
  - Answers the question: "What is the process and how does it work?"



Sequence and Interaction of Processes

- Shows the interrelationship of **all** of an organization's processes
  - This is different that block diagrams and process maps of single processes.
  - Don't forget outsourced processes!
- Requirement of ISO 9001:2008 and ISO 14001:2004

Sequence and Interaction of Processes

- Relevant ISO 9001:2008 clauses
  - ***"The organization shall identify the processes needed for the quality management system and their application throughout the organization,*** [4.1a]
  - ***determine the sequence and interaction of these processes,*** [4.1b]

Sequence and Interaction of Processes

- Relevant ISO 9001:2008 clauses
  - *"The organization shall establish and maintain a quality manual that includes… **a description of the interaction between the processes of the quality management system."*** [4.2.2c]

Sequence and Interaction of Processes

- Relevant ISO 14001:2004 clause
  - *"The environmental management system documentation shall include a description of the main elements of the environmental management system and their interaction…"* [4.4.4c]

Wake Up!
This is the Most Important Slide

- Before we can talk about a sequence and interaction of all processes of an organization, we must first:
  - **Determine the processes of an organization (STEP 1)**
    - This is a critical but often not performed step.
    - Many organizations simply construct a block diagram or process map of their main (manufacturing) process – **This is not sufficient and does not meet the intent of ISO 9001:2008.**
    - Required by clause 4.1a of ISO 9001:2008 and clause 4.4.4c of ISO 14001:2004.

Stay Up!
This Slide is Just as Important

- Bring staff together from various departments/functions and brainstorm the processes of your organization. **(Step 1)**
- For this exercise, put ISO 9001:2008 and ISO 14001:2004 away. Better yet – forget they exist!
  - Processes shouldn't be named after headings or sub-headings of the standard.
  - Processes should be unique to your organization and match the language your employees speak.

Stay Awake!

- Once you determine the processes of your organization, focus on each process individually **(Step 2)**:
  - Determine the boundaries of each individual process
  - Generate a list of steps of the process
    - Should be broken down until further breakdown no longer contributes additional value.
    - Write each step on an index card or sticky note
  - Sequence the steps
    - Easy to move index cards or sticky notes
    - Required by clause 4.1b of ISO 9001:2008

Remember the Theme…

- Remember the theme of today's presentation… Outputs Matter!
  - **The organization is monitoring, measuring and continually improving the effectiveness of its QMS.**
- For each process, the organization must identify a measure of process performance and an associated target. **(Part of Step 2)**
  - Key performance indicator (KPI)
  - Required by clause 4.1e of ISO 9001:2008 and clause 4.3.3 of ISO 14001:2004.

Remember the Theme…

- Inappropriate measures of processes
  - Improve customer satisfaction
  - Strive to continually improve all processes
  - Improve delivery performance
  - Reduce employee turnover
  - Lower PPM

Remember the Theme…

- There should be a measure of process effectiveness for each identified process of the organization.
- Some appropriate examples include:
  - Maintain a close ratio of at least 30% for all quotations
  - Scrap rate of ≤2%
  - Manufacturing process efficiency of ≥95%
  - Receive corrective action plans for all internal audit nonconformities within 30 days
  - Completion of all planned internal audits
- Measurables may be “variable” or “attribute” in nature.

Remember the Theme…

- What happens when a target isn't met?
  - Corrective action is required per clause 8.2.3 of ISO 9001:2008:
    - *"The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes... When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product."*
  - Consider also clause 8.4c of ISO 9001:2008:
    - *"The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system… The analysis of data shall provide information relating to… characteristics and trends of processes and products including opportunities for preventive action…"*
  - Are we trending in the right direction?

Stay Awake!

- Earlier we learned that the output of one process is the input of another.
  - Watch for these linkages as you construct process maps for individual processes.
- These linkages will help you determine the sequence and interaction of all processes of your organization **(Step 3).**

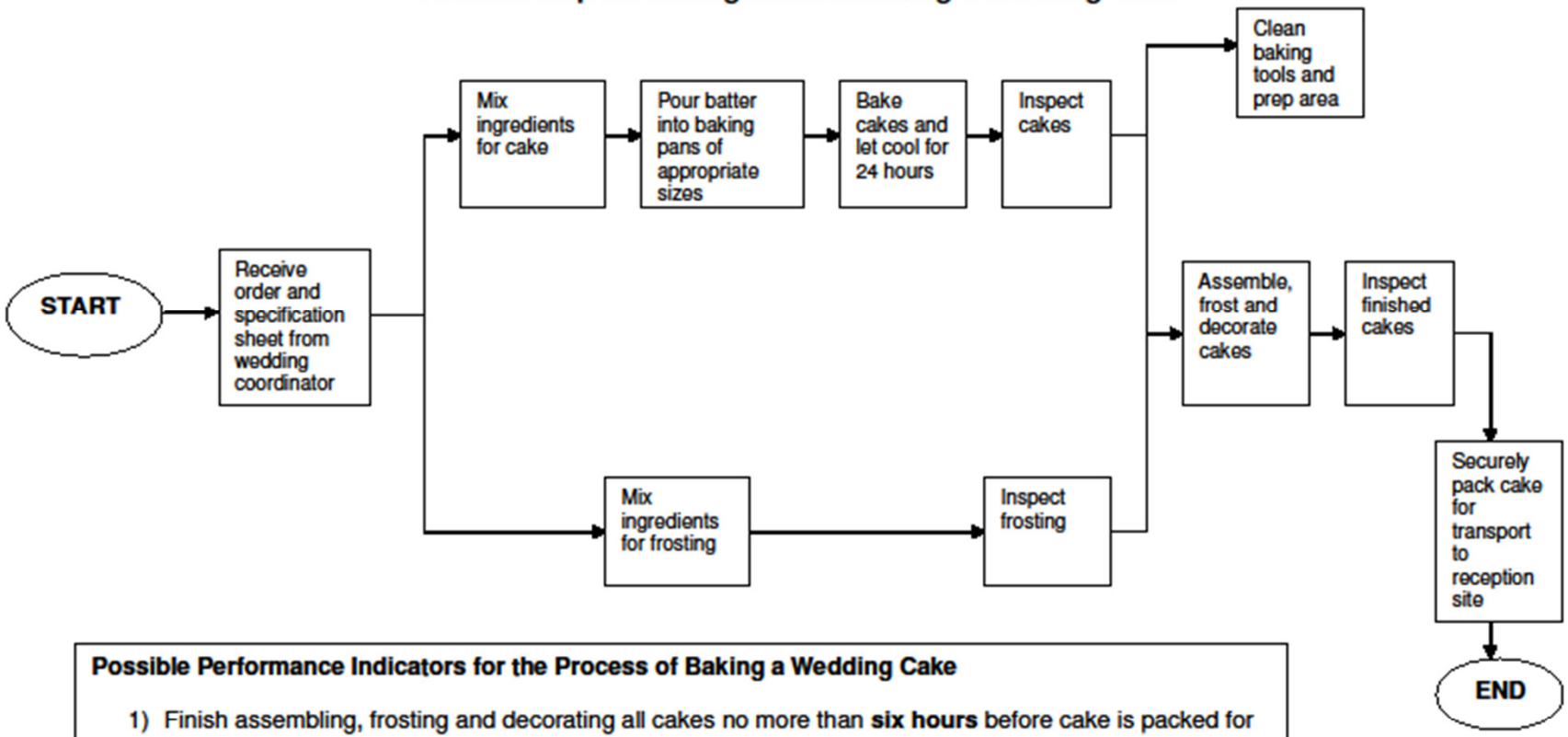
Bakeries

A Practical Example

Bakeries – Block Diagram for a Single Process

- Following is an example of a block diagram or process map for a bakery specializing in wedding cakes.
  - Input: Receive specification sheet and order for a wedding cake.
  - Output: Wedding cake ready for delivery.
- Appropriate measures of effectiveness (KPI) for the process of baking and decorating a wedding cake are also included.
- Repeat this exercise for all processes in your organization.

Process Map for Baking and Decorating a Wedding Cake



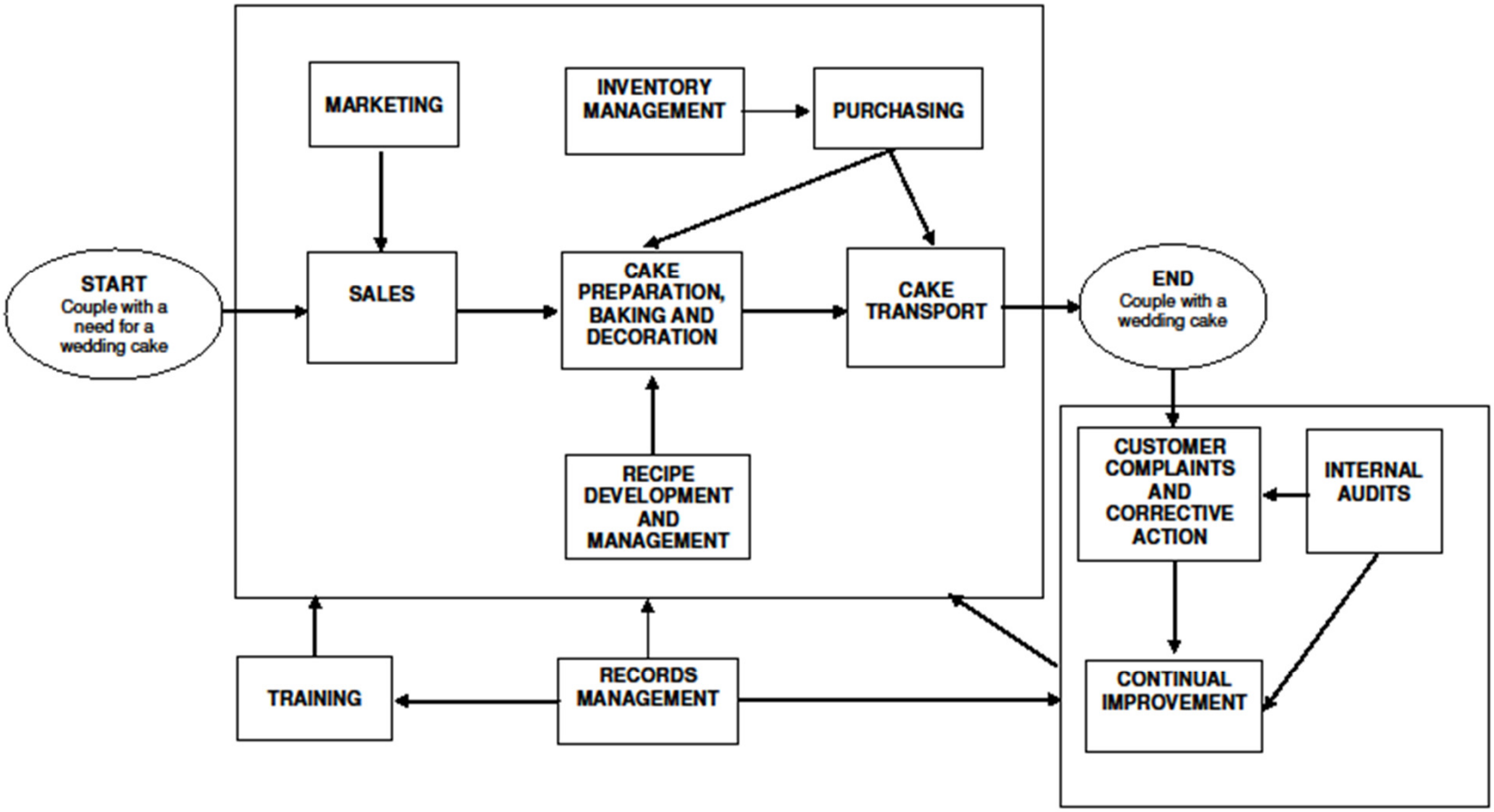
Possible Performance Indicators for the Process of Baking a Wedding Cake

1) Finish assembling, frosting and decorating all cakes no more than **six hours** before cake is packed for transport
2) **Zero** customer complaints every month
3) **Zero** instances of nonconforming cakes every month

Bakeries – Sequence and Interaction of Process

- Following is an example of a sequence and interaction of processes for an entire organization, our bakery.
- Note this is different than a block diagram or process map of a single process.

SEQUENCE AND INTERACTION OF PROCESSES FOR A BAKERY



Process Approach to Auditing

Process Approach to Auditing

- Different than a checklist audit
  - Checklists turn the requirements of the standard into questions.
  - Checklist questions never change or grow with the process.
- Internal audits should be one driver of process improvement
  - A process approach to internal audits does just that.

Process Approach to Auditing

- Need to get away from the idea that an internal audit should confirm your management system addresses all the shalls or requirements of a standard.
  - Importance of a tool such as PJR Form F-191 or equivalent documents

Table for verification of the completeness of the process oriented auditing versus ISO 9001:2000-based standards and applicable customer-specific requirements

PROCESS	4.1	4.2	5.1	5.2	5.3	5.4	5.5	5.6	6.1	6.2	6.3	6.4	7.1	7.2	7.3	7.4	7.5	7.6	8.1	8.2	8.3	8.4	8.5	Customer-specific	Customer-specific	Customer-specific	Customer-specific	Customer-specific
Marketing		X			X	X				X	X	X								X			X					
Sales		X		X	X	X				X	X	X		X						X			X					
Purchasing		X			X	X				X	X	X				X				X			X					
Cake Preparation, Baking and Decoration		X			X	X				X	X	X	X				X	X		X	X		X					
Cake Transport		X			X	X				X	X	X					X			X	X		X					
Inventory Mgmt.		X			X	X				X	X	X								X			X					
Records/Doc. Mgmt.		X			X	X				X	X	X								X			X					
Internal Audits		X			X	X				X	X	X								X			X					
Training		X			X	X	X		X	X	X	X								X			X					
Customer Comp./CA		X		X	X	X				X	X	X		X					X	X	X		X					
Cont. Improvement	X	X	X	X	X	X	X	X		X	X	X							X	X		X	X					
Recipe Development and Management		X			X	X				X	X	X	X		X					X			X					

Process Approach to Auditing

- Once you know your management system processes address all the requirements of the standard, then you can audit processes as your organization has defined them.
  - Keep in mind the requirements of section 4.1 of ISO 9001:2008 as you audit the processes of your organization.

ISO 9001:2008, section 4.1

- *"The organization shall identify the processes needed for the quality management system and their application throughout the organization,* [4.1a]
- *determine the sequence and interaction of these processes,* [4.1b]
- *determine criteria and methods needed to ensure that both the operation and control of these processes are effective,* [4.1c]
- *ensure the availability of resources and information necessary to support the operation and monitoring of these processes,* [4.1d]
- *monitor, measure and analyze these processes, and* [4.1e]
- *implement actions necessary to achieve planned results and continual improvement of these processes."* [4.1f]

Process Approach to Auditing

- Development of an audit working document that focuses on:
  - Process inputs
  - Process outputs
  - Competencies required for the process
  - Requirements for the process (procedures, work instructions, customer drawings)
  - Equipment and other resources
  - Measures of process effectiveness

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ISO 9001:2000 Audit Working Document

Auditee Organization:	Audit Number:	Audit Type: (RA, RC, SA #)	Date:
Wedding Bells Bakery	A2008-02458	RA	1/29-30/2008

Process Name Internal Audits	**Process Owner/Contributors** Quality Manager (Simon Roberts) is process owner and Lead Auditor. A Wedding Coordinator (Cindy Pinkerton) and Baker (Oscar Icing) are members of the audit team.
Process Inputs Internal audit schedule (QF-058) Key performance indicator data - used to identify problematic parts of processes Customer complaint data	**Process Outputs** Completed audit working documents and possibly nonconformity reports
Resources Needed Laptop Pens and pencils Hair bonnet or equivalent and aprons for audits of baking process	**Competencies Required** Lead Auditor and audit team members must be competent in ISO 9001:2000 and knowledgeable of all processes of the organization. Team members must complete three supervised audits with the Lead Auditor. Lead Auditor must complete QF-100, Auditor Evaluation Form, after each supervised audit,
Associated Documents .Internal Audit Procedure (QP-08) Audit working document (F-12) Nonconformity Reports (F-13) Recipe cards Procedures Manual Sequence and Interaction of processes (part of quality manual) ISO 9001:2000 standard	**Process Measureables** All internal audits scheduled for a month must be completed. Receive corrective action plans for all nonconformity reports within 30 days of date of issue.

Process Name: Internal Audits
Copy and use additional pages if necessary.

Audit Notes	Audit Trails (to follow-up)	√
Last audit of all processes was completed in November 2007. Reviewed audit working documents for all processes. Good notes of conformity and nonconformity were present. Five nonconformities were initiated and logged on the Corrective Action Log as NCRs #93-#97. Corrective action plans for #93-96 were submitted within two weeks of the audit. A corrective action plan still hasn't been submitted for #97. NCR Corrective action plans for NCRs for NCRs #93-96 were sound - good root cause and corrective action. #96 has actually been fully verified and close on the log. Relates to not all recipe cards being controlled. Verified that all recipe cards are now controlled (correction) and that new recipe cards are automatically entered into the electronic database (corrective action).		☐
Last audit was conducted by Simon Roberts and Cindy Pinkerton. Cindy told me this was her second supervised audit that was witnessed by Simon. Simon said he attended a Lead Auditor training course to become familiar with standard and has worked in many departments at the Bakery, so he is familiar with many of the operations. Cindy said Simon trained her in-house and gaver her an exam.	Follow-up on F-100 Auditor Evaluation forms for Cindy's first and second supervised audits and completed exam. Follow-up on Simon's training certificate.	☐
Audit schedule is generated by the Lead Auditor. Simon said that they have received complaints about cake transport and one particular transportation service provider, E-Z transport. Plan to do more audits of Cake Transport in 2008.	Look at audit schedule to see if more audits of Cake Transport process are scheduled.	☐
Reviewed key performance indicator data: All scheduled audits for 2007 were completed - full system audit in May 2007 and full system audit in November 2007. Corrective action plans for nonconformities were not always submitted within 30 days of the issue date of the NCR. Asked Simon for corrective action - he didn't have any. NCR		☐
Revision Date of Internal Audit Procedure (2/14/06) Revision Date of NCR form (8/26/06) Interviewed Cindy and Oscar about the quality policy and how it relates to their role as internal auditors. Good responses.	Verify rev. dates against controlled document list.	☐

Check Elements Investigated Within Process	Refer To Standard to Verify Requirements	NC	OBS/OFI
4.1 ☐	General requirements		/
4.2.1 ☐	QMS documentation		/
4.2.2 ☐	Quality manual		/
4.2.3 ☐	Control of documents / Logo Usage		/
4.2.4 ☐	Control of records		/
5.1 ☐	Management commitment		/
5.2 ☐	Customer focus		/
5.3 ☐	Quality policy		/
5.4.1 ☐	Quality objectives		/
5.4.2 ☐	QMS planning		/
5.5.1 ☐	Responsibility and authority		/
5.5.2 ☐	Management representative		/
5.5.3 ☐	Internal communication		/
5.6.1 ☐	Management review-general		/
5.6.2 ☐	Management review input		/
5.6.3 ☐	Management review output		/
6.1 ☐	Provision of resources		/
6.2.1 ☐	Human resources-general		/
6.2.2 ☐	Competence, awareness, and training		/
6.3 ☐	Infrastructure		/
6.4 ☐	Work environment		/
7.1 ☐	Planning of product realization		/
7.2.1 ☐	Determination of requirements related to the product		/
7.2.2 ☐	Review of requirements related to the product		/
7.2.3 ☐	Customer communication		/
7.3.1 ☐	Design and development planning		/
7.3.2 ☐	Design and development inputs		/
7.3.3 ☐	Design and development outputs		/

Check Elements Investigated Within Process	Refer To Standard to Verify Requirements	NC	OBS/OFI
7.3.4 ☐	Design and development review		/
7.3.5 ☐	Design and development verification		/
7.3.6 ☐	Design and development validation		/
7.3.7 ☐	Control of design and development changes		/
7.4.1 ☐	Purchasing process		/
7.4.2 ☐	Purchasing information		/
7.4.3 ☐	Verification of purchased product		/
7.5.1 ☐	Control of production and service provision		/
7.5.2 ☐	Validation of processes for production and service provision		/
7.5.3 ☐	Identification and traceability		/
7.5.4 ☐	Customer property		/
7.5.5 ☐	Preservation of product		/
7.6 ☐	Control of monitoring and measuring devices		/
8.1 ☐	Measurement, analysis and improvement-general		/
8.2.1 ☐	Customer satisfaction		/
8.2.2 ☐	Internal audit		/
8.2.3 ☐	Monitoring and measurement of processes		/
8.2.4 ☐	Monitoring and measurement of product		/
8.3 ☐	Control of nonconforming product		/
8.4 ☐	Analysis of data		/
8.5.1 ☐	Continual improvement		/
8.5.2 ☐	Corrective action		/
8.5.3 ☐	Preventive action		/

Process Summary

Process Na

Process Approach to Auditing

- Interview the process owner using the audit working document as a tool.
- Confirm interview results through observation of the process, review of process documents and records and interviews with personnel actually performing the process.

Process Approach to Auditing

- Always ask: "How do you know the process is working/improving?"
  - Link to process measurable (KPI)
  - Remember Outcomes Matter!
- Always ask: "What do you do/how do you react when the process does not meet the defined target?"

Other Techniques for Effective Internal Audits

- Remember the guidance provided in the Root Cause/Systemic Corrective Action Seminar about how to properly document an audit finding:
  - Statement of Finding
  - Objective Evidence
  - Citation of requirement not being fulfilled

Other Techniques for Effective Internal Audits

- Other techniques are listed in PJR Advisory #31
  - Set yourself up for success – Audit plan should reflect the names of the processes of your organization – not sections/clauses of the relevant standard.
  - Outputs Matter! – Make sure your audit criteria are complete. Integrate customer-specific and other requirements within your process-based internal audit.

Other Techniques for Effective Internal Audits

- Other Techniques are listed in PJR Advisory #31
  - Internal Auditor Competency – There is no requirement for a training course. There is a need for an organization to establish competency requirements for its internal auditors. There must be objective evidence internal auditors meet these competency requirements.
  - Internal auditor independence

Thank you!

Questions or Comments?

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