

# QUALITY SYSTEMS

ISO 9001:2015

Clause 8.0 – 10.0

# AQS 115

## QUALITY SYSTEMS & AUDITING PRINCIPLES

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*Any opinions, findings, and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the National Science Foundation.*

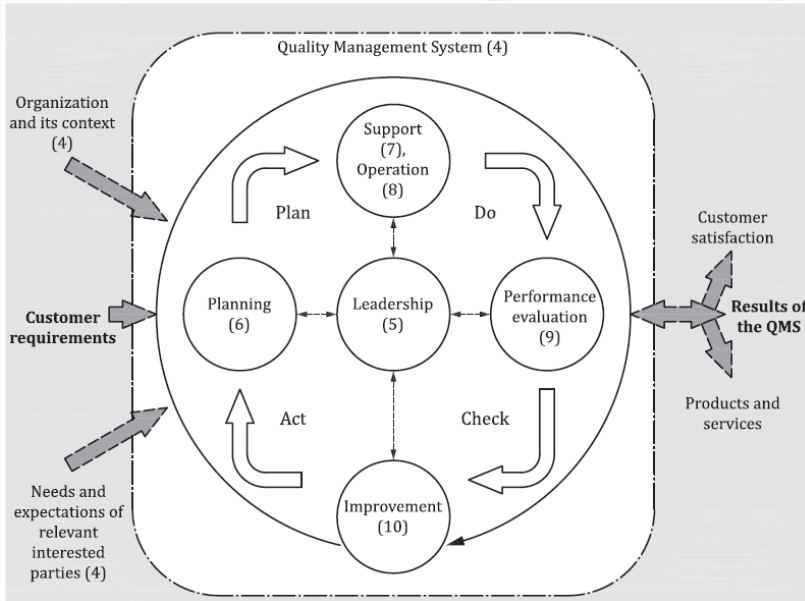
Developed as part of NSF ATE Grant  
#1304474

# GENERAL QUALITY PRINCIPLES

- Customer Focus
  - *Understand current & future needs; exceed expectations*
- Leadership
  - *Establish unity of purpose and direction of organization*
- Engagement of People
  - *People at all levels of the organization are involved*
- Process Approach
  - *Efficient completion of activities and utilization of resources*
- Improvement
  - *Continual improvement of performance*
- Evidence-based Decision Making
  - *Data and information analysis*
- Relationship Management
  - *Mutually beneficial relationship with suppliers*

# Quality System Process Overview

ISO 9001:2015



- **Plan:** Establish Objectives and processes required
- **Do:** Implement the processes
- **Check:** Measure and monitor the processes and report results
- **Act:** take action to improve performance of the QMS based on results

# ISO 9001:2015

- Clause 8.0 Operation

*This clause focusses on taking product/service to market*

*Dealing with realization of product/service from*

*development of idea, soliciting requirements, post-delivery activities and handling non-conforming outputs*

# ISO 9001:2015

- Clause 8.0 Operation

Covers the core of the organization's business operation

The organization needs to “...plan, implement and control the processes needed.” (internal and outsourced)

process criteria

controlling the process(es) within the criteria

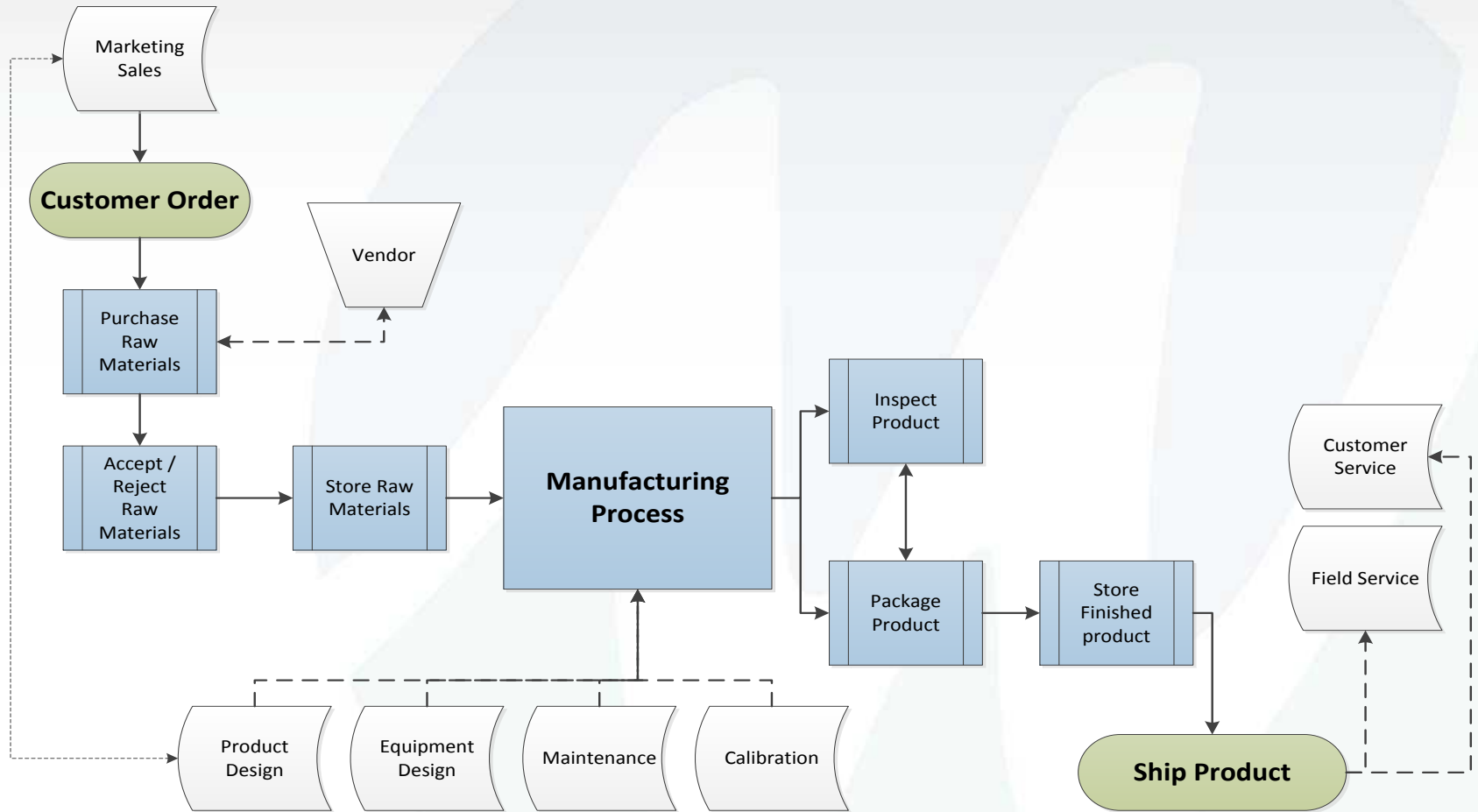
planning change

addressing unintended changes (as necessary)

# ISO 9001:2015

- Clause 8.0 Operation
  - 8.1 Operational planning and control
  - 8.2 Requirements for products and services
  - 8.3 Design and development of products and services
  - 8.4 Control of externally provided processes/products/services
  - 8.5 Production and service provision
  - 8.6 Release of products and services
  - 8.7 control of nonconforming outputs

# MANUFACTURING OVERVIEW



[https://www.youtube.com/watch?v=KY1rE\\_Ncasc](https://www.youtube.com/watch?v=KY1rE_Ncasc)

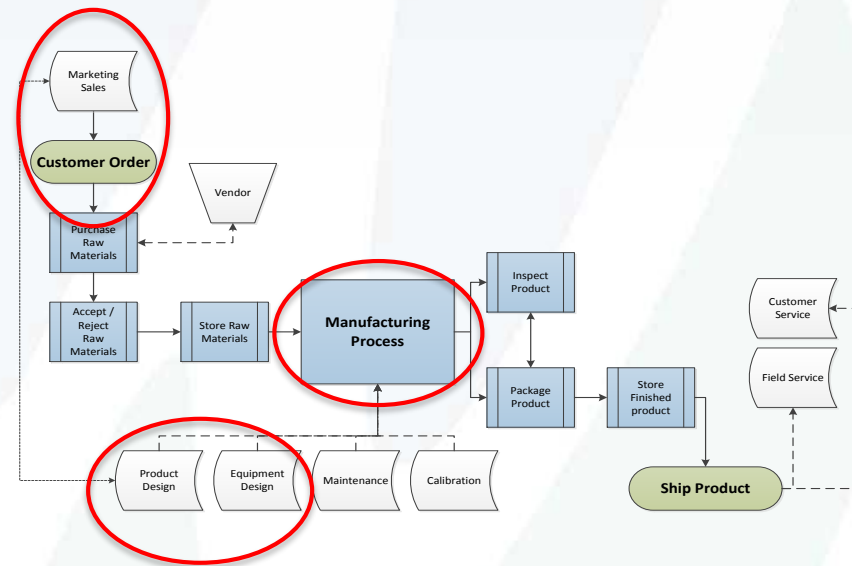
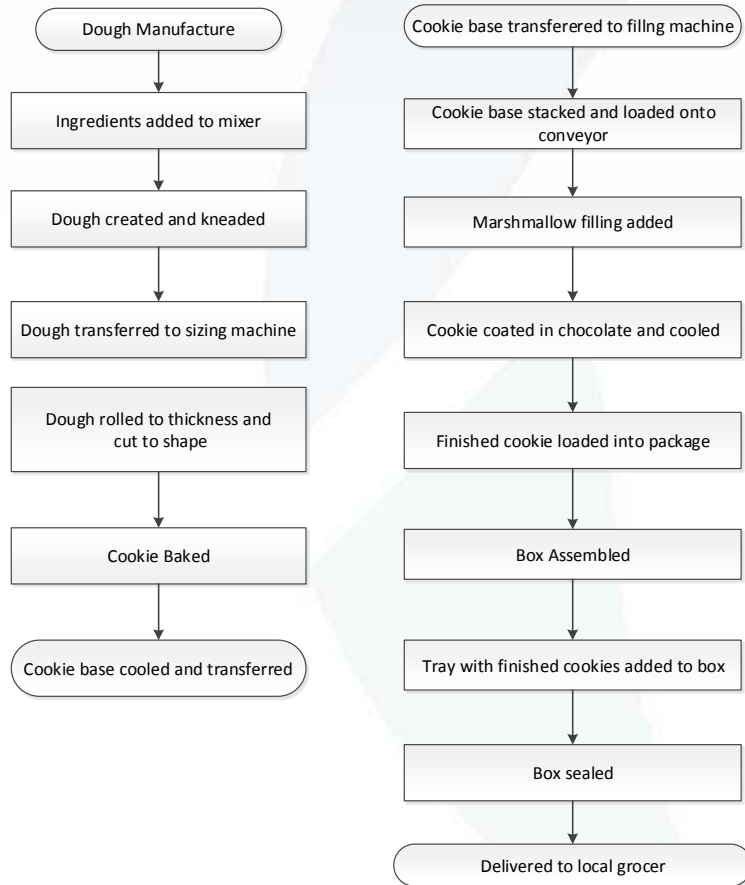


# MANUFACTURING OVERVIEW

## Marshmallow Cookie

Two step process

- 1) make cookie base
- 2) add filling/coat and package



# Clause 8.1 Operational Planning & Control

- Determine the requirement for the products/services intends to deliver
  - Which processes are required to realize the process
  - Which characteristics are required to accept/reject product/service
  - What resources are needed
  - Agreement of verification/validation activities
- Implement the planned arrangements
- Risks/issues must be mitigated; changes tracked as program progresses
  - Includes both internal and outsourced

# Clause 8.2 Requirements for Products & Services

- 8.2.1 Customer Communication
  - Products/services
  - Inquiries
  - Contracts / orders
  - Changes
  - Customer supplied product
  - Contingency actions
- 8.2.2 Determination of Requirements
  - Process to determine what does customer need; can organization meet the claims

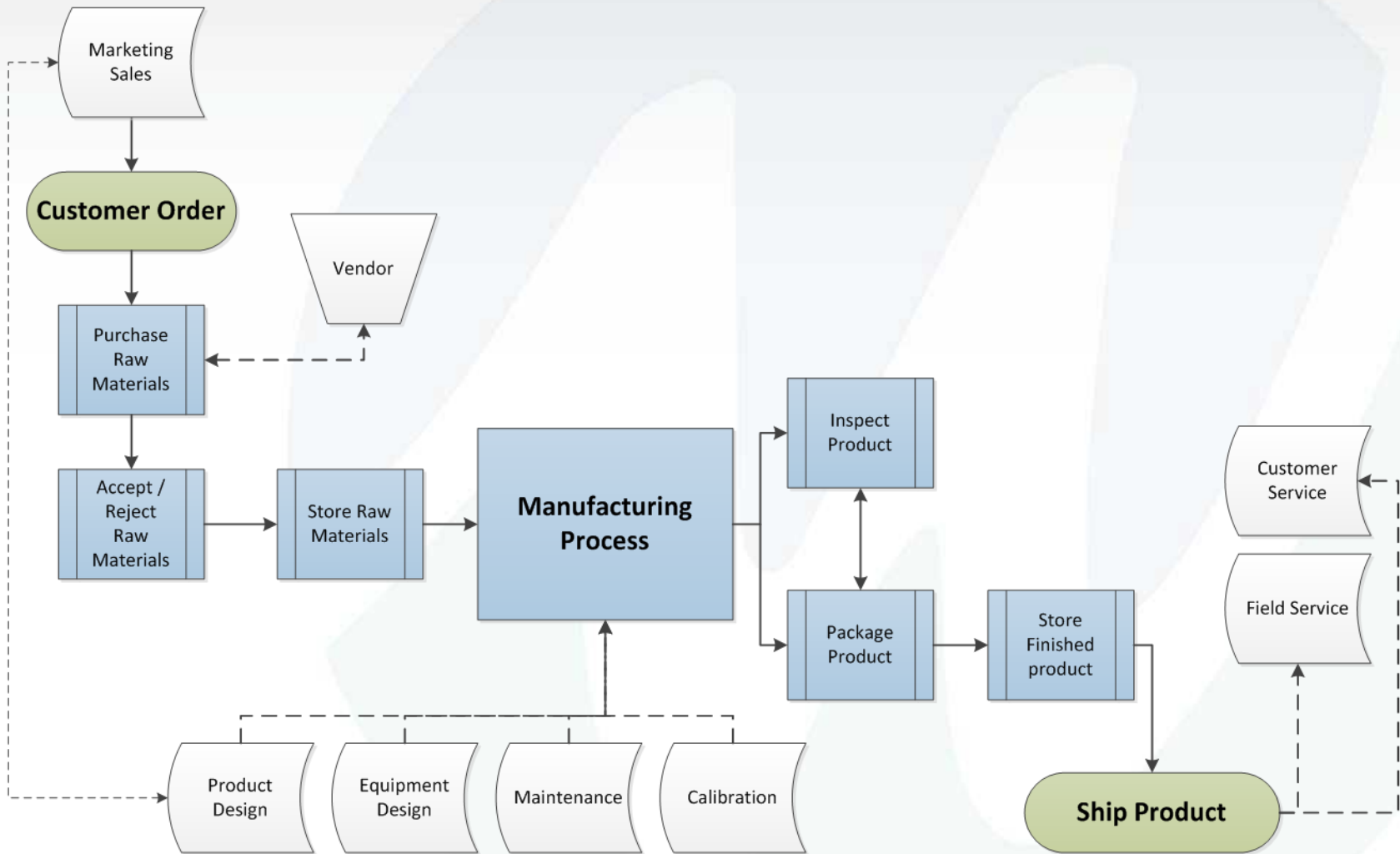
# Clause 8.2 Requirements for Products & Services

- 8.2.3 Review of Requirements
  - Can organization meet customer requirements
- 8.2.4 Changes
  - Documentation amended and relevant persons made aware of changes to requirements

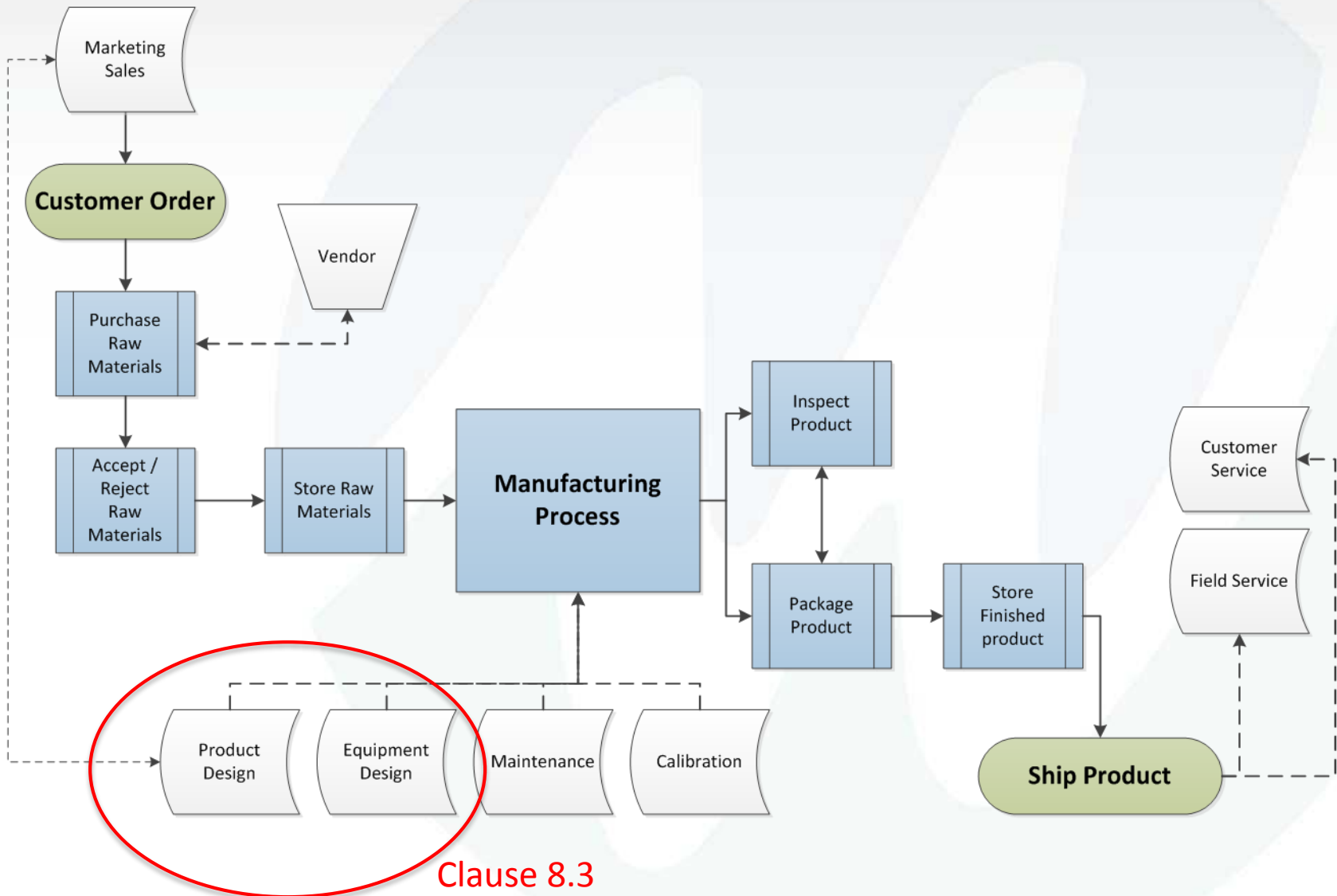
# ISO 9001:2015

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  - 8.6 Release of products and services
  - 8.7 Control of nonconforming outputs

# Clause 8 OPERATIONS



# Clause 8 OPERATIONS



# Clause 8.3 Design & Development of Products/Services

- 8.3.1 General
- 8.3.2 Planning
- 8.3.3 Inputs
- 8.3.4 Controls
- 8.3.5 Outputs
- 8.3.6 Changes



# Clause 8.3 Design & Development of Products/Services

- 8.3.1 General
  - Process to ensure activities/expectations met
- 8.3.2 Planning
  - Consider aspects of design, stages and controls
    - » Complexity, stages, reviews, verification/validation, responsibilities, authorities, etc.

# Clause 8.3 Design & Development of Products/Services

- **Validation:** confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled; documented evidence the product functions as expected (meets expectations) and processes are ready for release  
*(are you building the right thing – meet user needs)*
- **Verification:** confirmation by examination and provision of objective evidence that specified requirements have been fulfilled  
*(did you build it right – meet user specifications)*

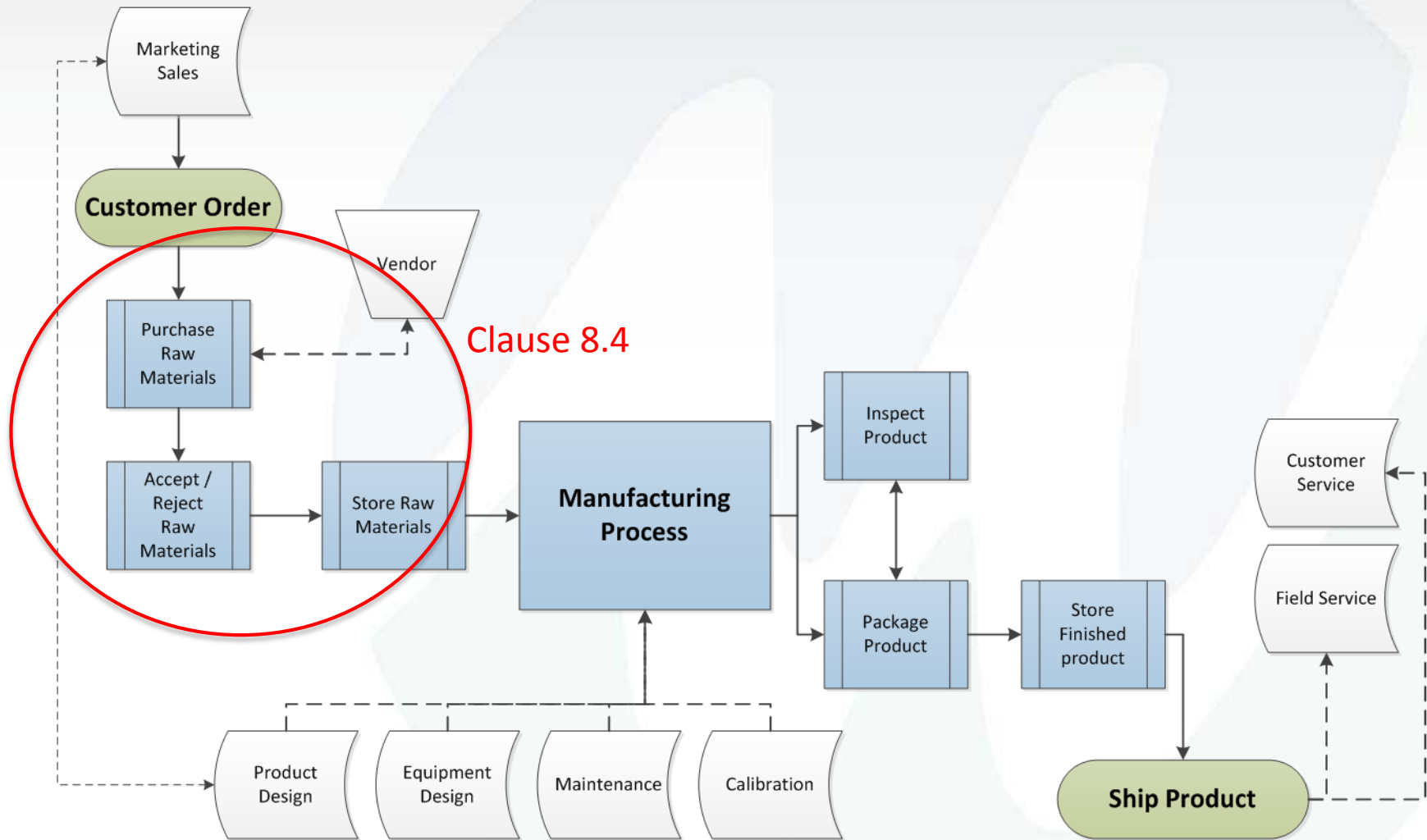
# Clause 8.3 Design & Development of Products/Services

- 8.3.3 Inputs
  - Functional and performance requirements (CTQ)
  - Potential consequences of failure
  - Regulatory
  - Internal/External resources
- 8.3.4 Controls
  - Clearly defined results
  - Reviews planned/conducted
  - Verification / validation

# Clause 8.3 Design & Development of Products/Services

- 8.3.5 Outputs
  - Meet input requirements
  - Include reference monitoring/measurement requirements (acceptance criteria)
  - Characteristics for intended purpose (safe and proper use)
- 8.3.6 Changes
  - Review/control, identification and documented information on any changes made to the design (input/output) and review

# Clause 8 OPERATIONS



# Clause 8.4 Control of Externally Provided Processes/Products/Services

- 8.4.1 General
- 8.4.2 Type & Extent of Control
- 8.4.3 Information for External Providers

# Clause 8.4 Control of Externally Provided Processes/Products/Services

- 8.4.1 General

- Suppliers need to be evaluated and selected

- » Externally provided product/service that becomes part of organizations product/service
    - » Externally provided product/service directly to the customer on behalf of the organization
    - » A process (or part) outsourced by the organization

## *Why important*

- *Ensure get what specified/paid for*
    - *Drive robust controls “upstream” to ensure most economical control of quality*
    - *Ensure ongoing ability of suppliers to continually provide conforming product/services*

# Clause 8.4 Control of Externally Provided Processes/Products/Services

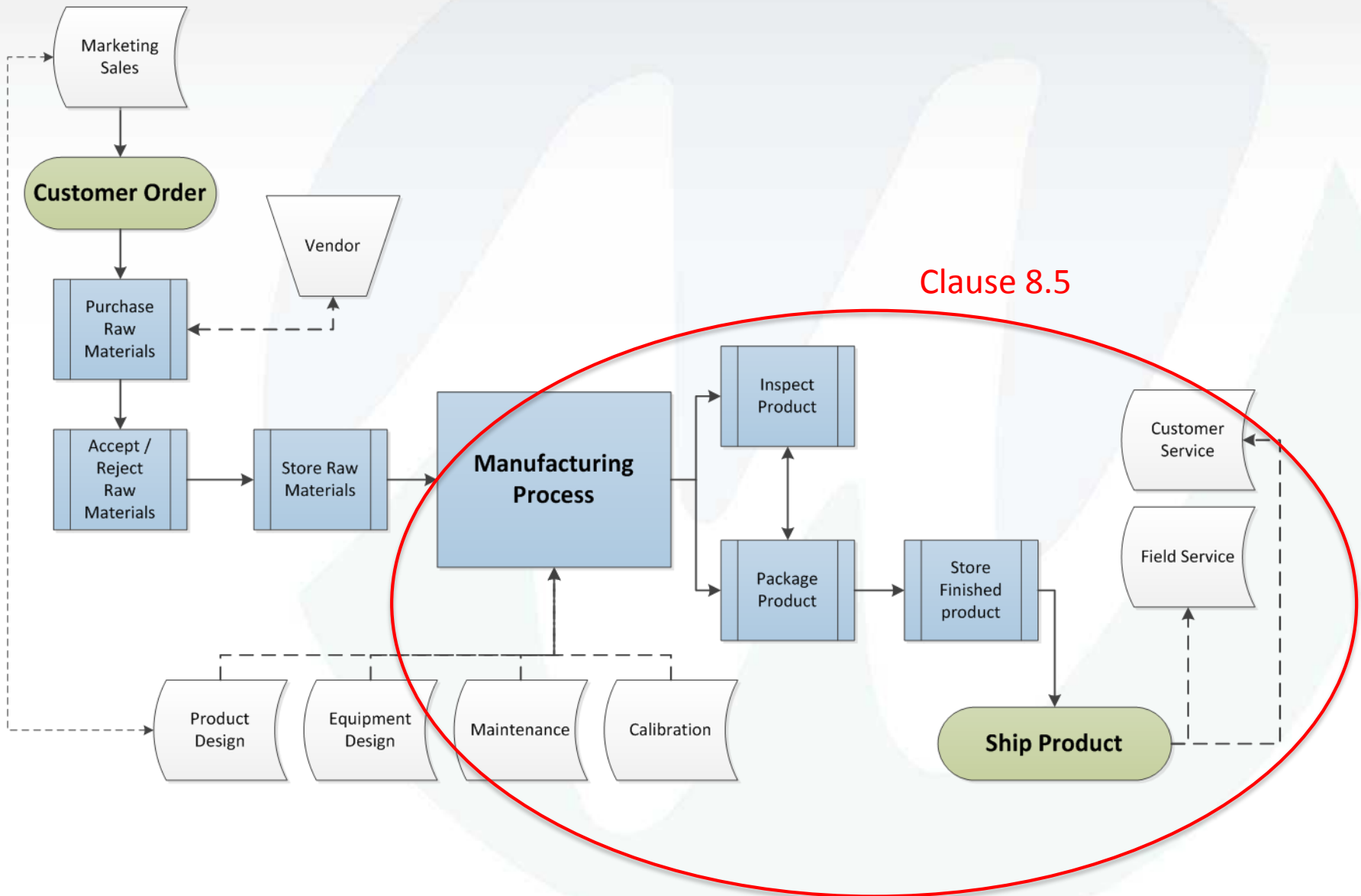
- 8.4.2 Type & Extent of Control
  - Ensure externally provided products/services do not adversely affect consistent delivery of organizations product
  - Determine and apply criteria for
    - » Evaluation, selection, performance monitoring and ability to provide per requirements
  - Define controls based on impact of externally provided
    - » Inspection, on-site audit, QMS survey, skip-lot, etc.



# Clause 8.4 Control of Externally Provided Processes/Products/Services

- 8.4.3 Information for external providers
  - Ensures communication of complete and accurate information to suppliers
    - » Detailed specifications regarding what is to be supplied (criteria for acceptance)
    - » Providing supplier expectations for their QMS regarding continuity of supply, training of personnel, equipment/processes
    - » Validation/verification activities (source inspections)

# Clause 8 OPERATIONS



# Clause 8.5 Production & Service Provision

- 8.5.1 Control of product and services provision
- 8.5.2 Identification and traceability
- 8.5.3 Property belonging to customers or external providers
- 8.5.4 Preservation
- 8.5.5 Post-delivery activities
- 8.5.6 Control of changes

# Clause 8.5 Production & Service Provision

- Organization required to control how they provide product/services
  - Product/service specifications available
  - Defined activities to product/deliver service including result specifics
  - Identify status of process outputs (monitoring/measurement) at all stages
  - Ensure customer property identified/verified/safeguarded/protected
  - Nature/extent of post-delivery activities

# Clause 8.5 Production & Service Provision

- 8.5.1 Control of product and services provision
- 8.5.2 Identification and traceability
- 8.5.3 Property belonging to customers or external providers
- 8.5.4 Preservation
- 8.5.5 Post-delivery activities
- 8.5.6 Control of changes

# Clause 8.5 Production & Service Provision

- 8.5.1 Control of product and services provision
  - Characteristics of product/service (drawing, specs, etc.)
    - Documented information available where needed (procedures, work instructions, forms, check sheets, etc.)
  - Results to be achieved for acceptability
    - Assess requirements have been fulfilled
    - Address nonconformity as necessary
  - Appropriate work environment/infrastructure
  - Competent/qualified personnel; validated ability to meet requirement
    - Prevent human error
  - Controls necessary (inspection, testing)
  - Validation/revalidation for output not easily monitored
  - Implement release/delivery/post-delivery activities

# Clause 8.5 Production & Service Provision

- Implementation
  - Identify key processes; flow chart or process map
  - Outputs for critical stages
  - Consider statistical tolerancing and sampling
  - Consider clear criteria for process capability
  - Planned maintenance activities
  - Monitor/measurement devices for product and/or processes

# Clause 8.5 Production & Service Provision

- 8.5.2 Identification and traceability
  - Identify outputs when necessary to ensure conformity of product/service
  - Identify status of outputs with respect to monitor / measurement
  - Control unique identification of outputs when traceability is necessary
    - Customer requirements (public health)
    - Containment

*Ensures status of materials known at all stages*



# Status Labeling - Production

ACCEPTED	
Mat:	
Lot #:	
P/N:	
Amt:	
By:	
Date:	
Q048	©1992 GMP Labeling

IN PROCESS	
Mat:	
Lot #:	
P/N:	
Amt:	
By:	
Date:	
S451	©1992 GMP Labeling

CONDITIONAL RELEASE	
Mat:	
Lot #:	P/N:
Amt:	
Date:	By:
Notes:	
S201	©1999 GMP Labeling, Inc.

HOLD	
Mat:	
Lot #:	
P/N:	
Amt:	Date:
Pending:	
Exp. Date:	By:
Q062	©1998 GMP Labeling

AWAITING DISPOSITION		
Lot #:		
P/N:		
Amt:	Date:	By:
Q014	© 2010 GMP Labeling	

Description		Q058
P / N	Lot/SN	
REJECTED		Amt. <input type="text"/>
By/Date	<input type="text"/>	
		<input type="checkbox"/> RM <input type="checkbox"/> WIP <input type="checkbox"/> FG
		© 1983 GMP Labeling, Inc.

# Clause 8.5 Production & Service Provision

- 8.5.3 Property belonging to customers or external providers
  - Material components, tools, intellectual property, personal data
  - Identification, verify, protect
  - Report if lost/damaged/stolen

# Clause 8.5 Production & Service Provision

- 8.5.4 Preservation
  - Conformity of product must be maintained during internal processing and delivery to intended destination
    - Components and completed product
  - Includes
    - Identification
    - Handling / packaging
    - Storage
    - Protection

# Clause 8.5 Production & Service Provision

- 8.5.5 Post-delivery activities
  - Organization must meet requirements for post-delivery
    - Examples: warranty provisions, maintenance, recycling, disposal

*Consider the need during strategic, process and product planning*  
*Make clear in product literature what will be provided and how to assess*

# Clause 8.5 Production & Service Provision

- 8.5.6 Control of changes
  - Review and control changes of product/service provision
    - Planned and carried out to ensure on-going conformity with requirement
      - Legal / contractual requirement(s)
  - Documented review includes
    - Results
    - Authorization personnel identified
    - Actions needed following review

# Clause 8.5 Production & Service Provision

- 8.5.6 Control of changes

## CHANGE CONTROL PROCESS



# Clause 8.6 Release of Products/Services

- Planned arrangements required at appropriate stages to verify requirement conformance
  - Products/services not released until completed and acceptable
  - Traceability to personnel authorizing release
- Release methods can differ in form/timing/application
  - Example: Airline pilot preflight checklist  
Auto repair using test equipment and test drive
- Provide assurance products/services meet requirements during processing and after delivery
- Prevent inadvertent release of nonconforming
- Ensure changes supported by actions

# Status Labeling - Production

ACCEPTED	
Mat:	
Lot #:	
P/N:	
Amt:	
By:	
Date:	
Q048	©1992 GMP Labeling

IN PROCESS	
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AWAITING DISPOSITION		
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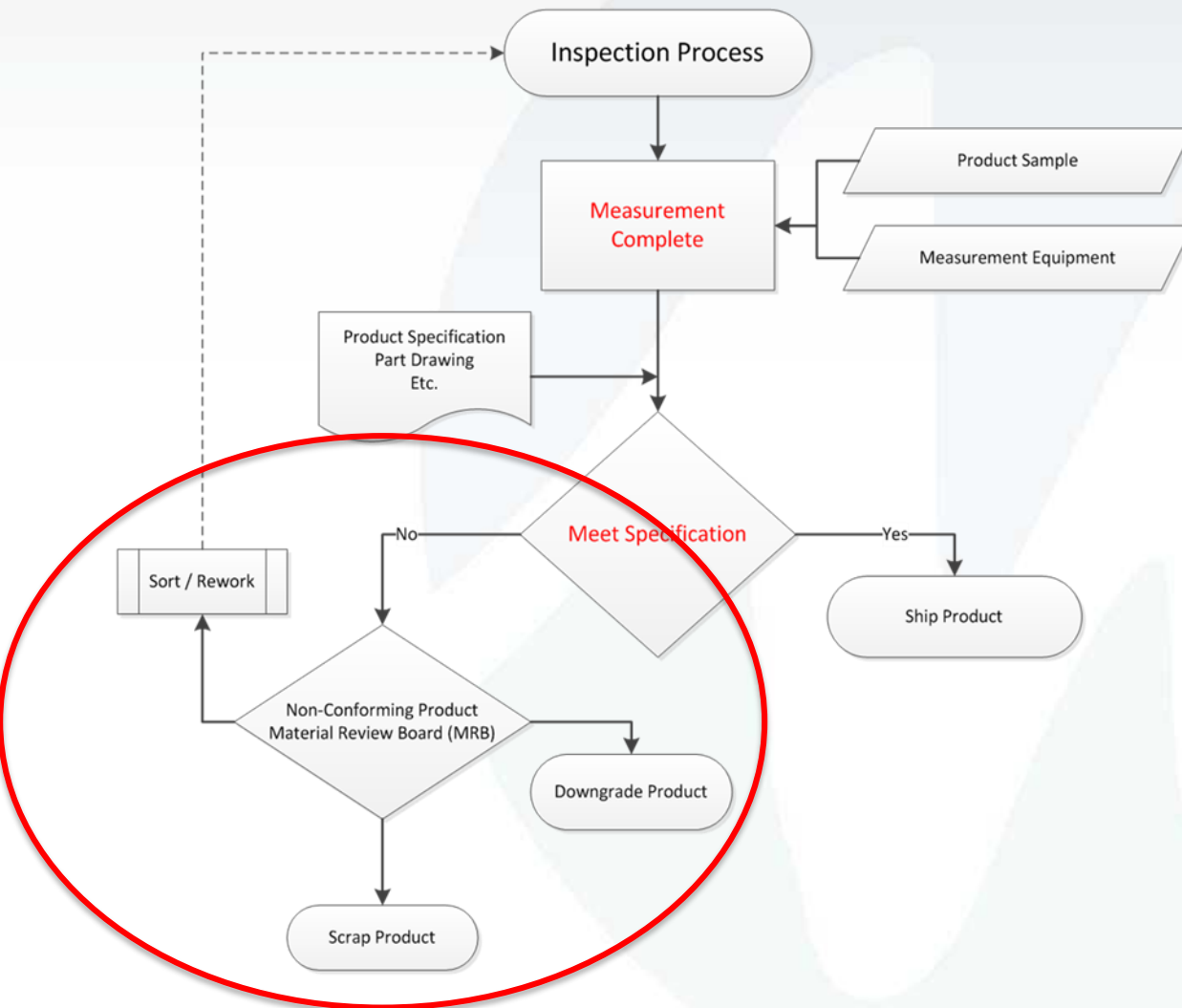
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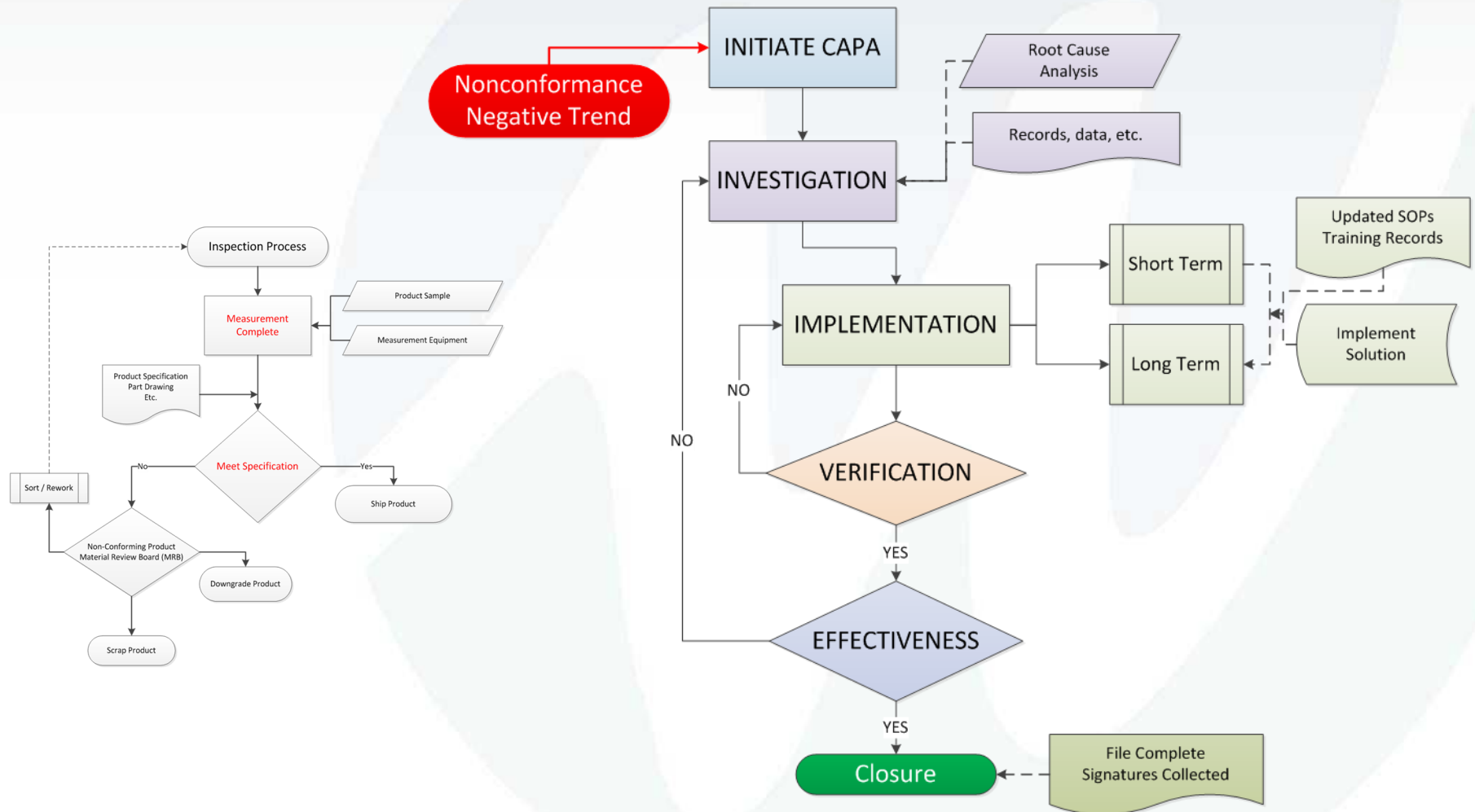
# Clause 8.7 Control of Nonconforming Outputs

- Ensure non-conforming outputs are identified and controlled
  - Prevent unintended use/delivery
    - Segregation, containment (quarantine), correction
  - Take corrective actions and verify
    - Includes after delivery
  - Ensure appropriate review of disposition

# Clause 8.7 Control of Nonconforming Outputs



# Clause 8.7 Control of Nonconforming Outputs



# CAPA SYSTEM

- Initiation
  - Source
    - Customer Complaint (Adverse Event)
    - Audit Findings
    - Management Review Adverse Trend(s)
  - Team assigned based on complexity and urgency
    - Initiator
    - Investigator(s)

# CAPA SYSTEM

- Investigation
  - Root cause analysis
- Implementation
  - Immediate correction
  - Short Term
  - Long Term

# CAPA SYSTEM

- Verification
  - Review implementation
    - Documentation, training
    - Validation, change control
- Effectiveness
  - Management Review
  - Recurrence
    - 30days, 60days, 90days, etc.
    - Trend(s)
- Closure
  - File complete (documentation)
  - Signatures

# ISO 9001:2015

- Clause 9.0 Performance Evaluation

*This clause focuses on measuring and monitoring both the product and the business.*

*Gathering feedback and ensuring customer satisfaction*

# ISO 9001:2015

- Clause 9.0 Performance Evaluation
  - 9.1 Monitoring, Measurement, Analysis & Evaluation
  - 9.2 Internal Audit
  - 9.3 Management Review



# ISO 9001:2015

- Clause 9.0 Performance Evaluation
  - 9.1 Monitoring, Measurement, Analysis & Evaluation
    - 9.1.1 General
    - 9.1.2 Customer Satisfaction
    - 9.1.3 Analysis and Evaluation
  - 9.2 Internal Audit
  - 9.3 Management Review

# Monitoring, Measurement, Analysis & Evaluation

## 9.1.1 General

- Determine
  - What needs to be monitored and measured
  - Methods to ensure valid results
  - When monitoring/measuring will be performed
  - When results will be analyzed/evaluated

*Ties back to earlier clauses*

# Clause 9.1.1 General - Implementation

- Ties back to other clauses; think about/consider
  - Clause 4.4: QMS processes
  - Clause 8.1 measurement/control for operational processes
  - Clause 7.1.5 monitoring/measuring resources
- Define key indicators of performance for product/process for understanding progress toward quality objectives
  - Process mapping/ flowcharting to integrate measurement/analysis into operational planning and control

# Clause 9.1.2 Customer Satisfaction

- Requirement
  - Monitor customer perceptions regarding degree to which requirements have been met
  - Obtain information on customer views/opinions
  - Determine method for obtaining/using information

# Clause 9.1.2 Customer Satisfaction

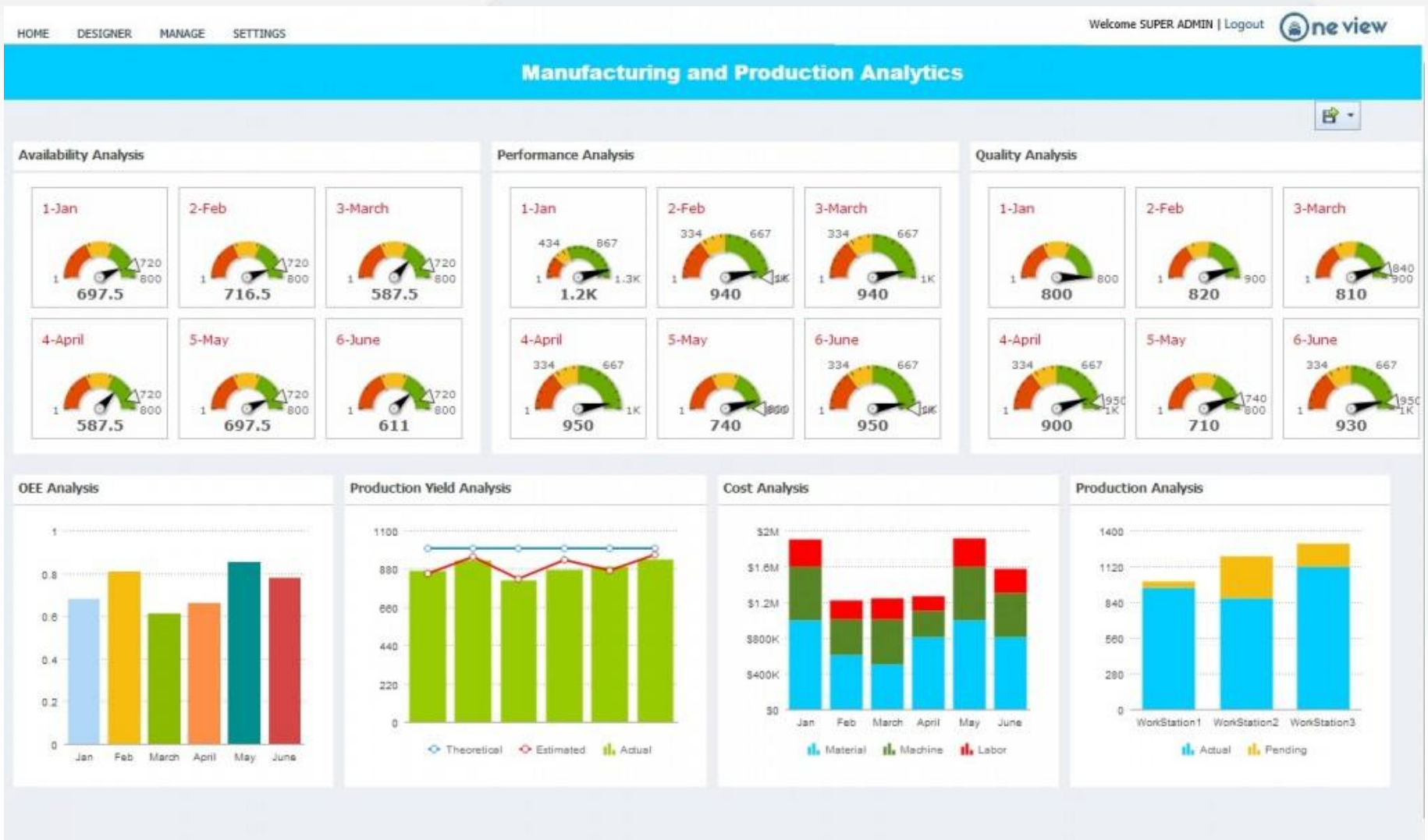
- Requirement
  - Monitor customer perceptions regarding degree to which requirements have been met
  - Obtain information on customer views/opinions
  - Determine method for obtaining/using information
- Examples of sources
  - Customer complaints / returns / warranties
  - Questionnaires / surveys / focus groups

# Clause 9.1.3 Analysis & Evaluation

- Requirement
  - Use output of the analysis of monitoring/measurement data
    - Demonstrate conformity of product/service requirements
    - Assess degree of customer satisfaction
    - Ensure conformity/effectiveness and assess performance of QMS
    - Demonstrate planning successfully implemented
    - Assess performance of external providers
    - Determine opportunities for improvement

*This will be considered as input for Management Review (Clause 9.3)*

# Dashboard Example



# ISO 9001:2015

- Clause 9.0 Performance Evaluation
  - 9.1 Monitoring, Measurement, Analysis & Evaluation
  - 9.2 Internal Audit
  - 9.3 Management Review



# Clause 9.2 Internal Audit

- Requirement
  - Planned intervals
    - Conform to ISO 9001:2015 standard AND organizations QMS
    - QMS remains effectively implemented and maintained

# Clause 9.2 Internal Audit

- Requirement
  - Planned intervals
    - Conform to ISO 9001:2015 standard AND organizations QMS
    - QMS remains effectively implemented and maintained
  - Consider status/importance of processes and areas to be audited
    - Previous audit results can be helpful
    - Audit critical areas most often (also those at risk)
      - Incorporate feedback from previous audits; customer feedback; changes impacting organization
    - Organizational changes

# Clause 9.2 Internal Audit

- Requirement
  - Planned intervals
    - Conform to ISO 9001:2015 standard AND organizations QMS
    - QMS remains effectively implemented and maintained
  - Consider status/importance of processes and areas to be audited
    - Previous audit results can be helpful
    - Audit critical areas most often (also those at risk)
    - Organizational changes
  - Documented procedure required to describe responsibilities and requirements for
    - Planning
    - Conducting
    - Scope
    - Reporting
    - Timely corrective actions

# Clause 9.2 Internal Audit

- Implementation
  - Audit Schedule
    - Individual departments
    - Processes
  - Team assignment
    - Includes lead
    - Auditors MUST be independent (objective & impartial)
  - Reporting and Follow-up
    - Retain documented information on the audit and actions taken

# Clause 9.2 Internal Audit

- Typical questions for individual areas
  - Is process identified and appropriately described
  - Are responsibilities assigned
  - Are required processes
    - Implemented / controlled
    - Maintained / improved
    - Monitored / measured (as appropriate)
    - Operated under controlled conditions
    - Effectively achieving results

# ISO 9001:2015

- Clause 9.0 Performance Evaluation
  - 9.1 Monitoring, Measurement, Analysis & Evaluation
  - 9.2 Internal Audit
  - 9.3 Management Review
    - 9.3.1 General
    - 9.3.2 Inputs
    - 9.3.3 Outputs

# Clause 9.3 Management Review

- Goal of Management Review is to ensure
  - Continuing suitability, adequacy and effectiveness of the QMS
  - Alignment with strategic direction of organization
- Conducted at planned intervals
- Top Managers do the review (not delegated)
- Opportunity for
  - Discovery of issues that require changes to improve effectiveness
  - Allocate (or reallocate) resources
  - Remove roadblocks to improvement
    - Prioritize decisions

# Clause 9.3 Management Review

- 9.3.2 Inputs
  - Status of actions from previous reviews
  - Changes in business horizon (external/internal)
  - QMS performance/effectiveness
    - Customer satisfaction
    - Quality objective attainment
    - Product process performance and conformity of product
    - Nonconformities and corrective actions
    - Monitoring and Measuring results
    - Audit results (Internal, Customer, Regulatory/Registrar)
    - Performance of external providers
  - Adequacy of Resources
  - Effectiveness of actions taken to address risks/opportunities
  - Opportunities for improvement



# Clause 9.3 Management Review

Scorecard Dimension	Explanation	Weight	A 100%	B 75%	C 50%	D 25%	F 0%	Example Vendor Score
<b>Costs/Pricing</b>								<b>19%</b>
Payment Terms	Risks Vendor according to Payment Terms	10%						<b>B</b>
Product Pricing	Total Order Qty of Items Purchased in Quarter Compared with Prior Quarters from All Capable Vendors	15%	<2.5X More Than Benchmark	Benchmark - 2.5X	>2.5X More Than Benchmark	>5X More Than Benchmark	>10X More Than Benchmark	<b>C</b>
Costs/Pricing Metric 3	Cost/Pricing Metric Explanation 3	1%						<b>D</b>
Manufacturing Supply Agreement	Has the Vendor Signed and Obligated by the MSA?	4%	Yes				No	<b>A</b>
<b>Supply Chain and Production</b>								<b>16%</b>
Weighted Average Lead Time	The duration of time from when an order is entered to the time the vendor has shipped the goods to the freight forwarder (Weighted by Units Shipped)	15%						<b>D</b>
Email Response Time - Purchasing	Response time taken to respond to emails with purchasing (Pages or content requested)	3%						<b>A</b>
Communication Quality - Purchasing	Quality of communication, especially emails, with purchasing	3%	Communication is clear, concise, and professional		Communication is somewhat clear, but needs improvement		Communication is unclear and unprofessional	<b>A</b>
Flexibility	The flexibility of the vendor to accommodate business requests to the level of their ability	2%	Very flexible and accommodating		Some flexibility, but needs improvement		Not flexible and unaccommodating	<b>C</b>
Late Orders	Number of POs that were shipped after agreed upon ship date without approval	3%	0				1+	<b>A</b>
MOQs	The minimum quantity or number of orders for which buying further economical to buy	3%						<b>C</b>
<b>Quality</b>								<b>14%</b>
QC Issues	Definition of QC Issues Metric	5%						<b>A</b>
Quality Metric 2	Definition of Quality Metric 2	5%						<b>F</b>
Quality Metric 3	Definition of Quality Metric 3	7%						<b>A</b>
Quality Metric 4	Definition of Quality Metric 4	3%						<b>C</b>
<b>Product Development</b>								<b>17%</b>
PD Metric 1	PD Explanation 1	6%						<b>A</b>
PD Metric 2	PD Explanation 2	4%						<b>B</b>
PD Metric 3	PD Explanation 3	4%						<b>B</b>
PD Metric 4	PD Explanation 4	6%						<b>B</b>
<b>Total</b>			<b>100%</b>					<b>65%</b>

Supplychaincowboy.com

# Clause 9.3 Management Review

- 9.3.2 Outputs
  - Decisions and Actions related to
    - Opportunities for improvement
      - Include actions to address Customer failures/expectations
      - Examples: eliminate waste; simplify (foolproof) processes; develop improved methods, etc.
    - Any needed changes to QMS
    - Resource Needs
      - Provide (assign) resources for prioritized improvement opportunities

# ISO 9001:2015

- Clause 10.0 Improvement

*“Organizations shall determine/select opportunities for improvement and implement necessary actions to meet customer requirements and enhance satisfaction.”*

# ISO 9001:2015

- Clause 10.0 Improvement
  - 10.1 General
  - 10.2 Nonconformity and corrective action
  - 10.3 Continual Improvement

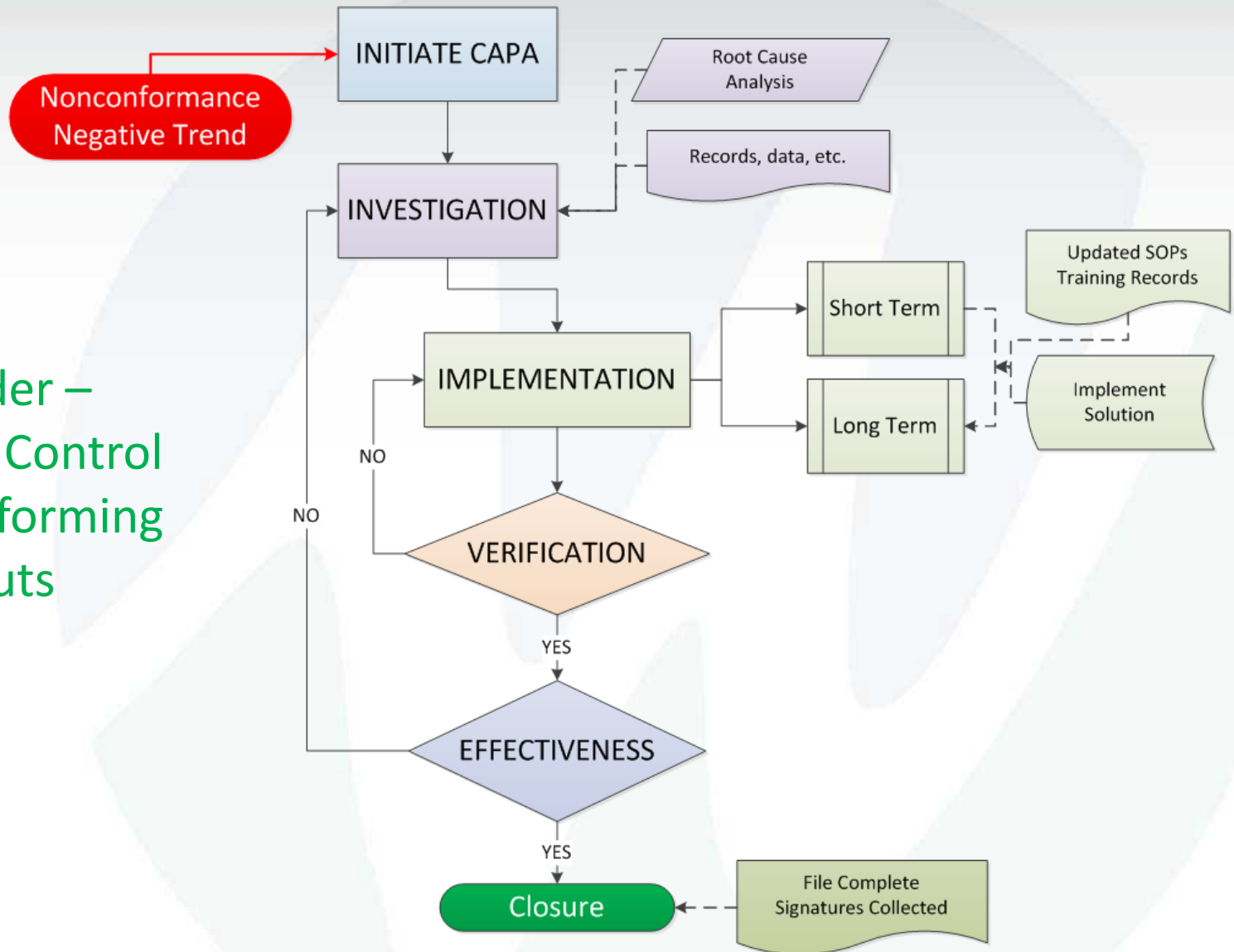
# ISO 9001:2015

- Clause 10.0 Improvement
  - 10.1 General
    - Improve products to meet requirements and future needs
    - Correct/prevent/reduce undesired effects
    - Improve performance/effectiveness QMS
  - 10.2 Nonconformity and corrective action
  - 10.3 Continual Improvement

# ISO 9001:2015

- Clause 10.0 Improvement
  - 10.1 General
  - 10.2 Nonconformity and corrective action
    - React to nonconformity
      - Take action to correct
      - Deal with consequences
    - Evaluate need for action to eliminate cause(s) in order that it does not recur (occur) elsewhere
    - Implement any action needed
    - Review the effectiveness of actions taken
    - Update risks/opportunities during planning (if necessary)
    - Make changes to QMS (if necessary)
    - Retain documented information
  - 10.3 Continual Improvement

## Reminder – Clause 8.7 Control of Nonconforming Outputs



# ISO 9001:2015

- Clause 10.0 Improvement
  - 10.1 General
  - 10.2 Nonconformity and corrective action
  - 10.3 Continual Improvement
    - Consider results of analysis/evaluation and Management review outputs



# ISO 9001:2015

- Clause 10.0 Improvement
  - 10.1 General
  - 10.2 Nonconformity and corrective action
  - 10.3 Continual Improvement
    - Consider results of analysis/evaluation and Management review outputs

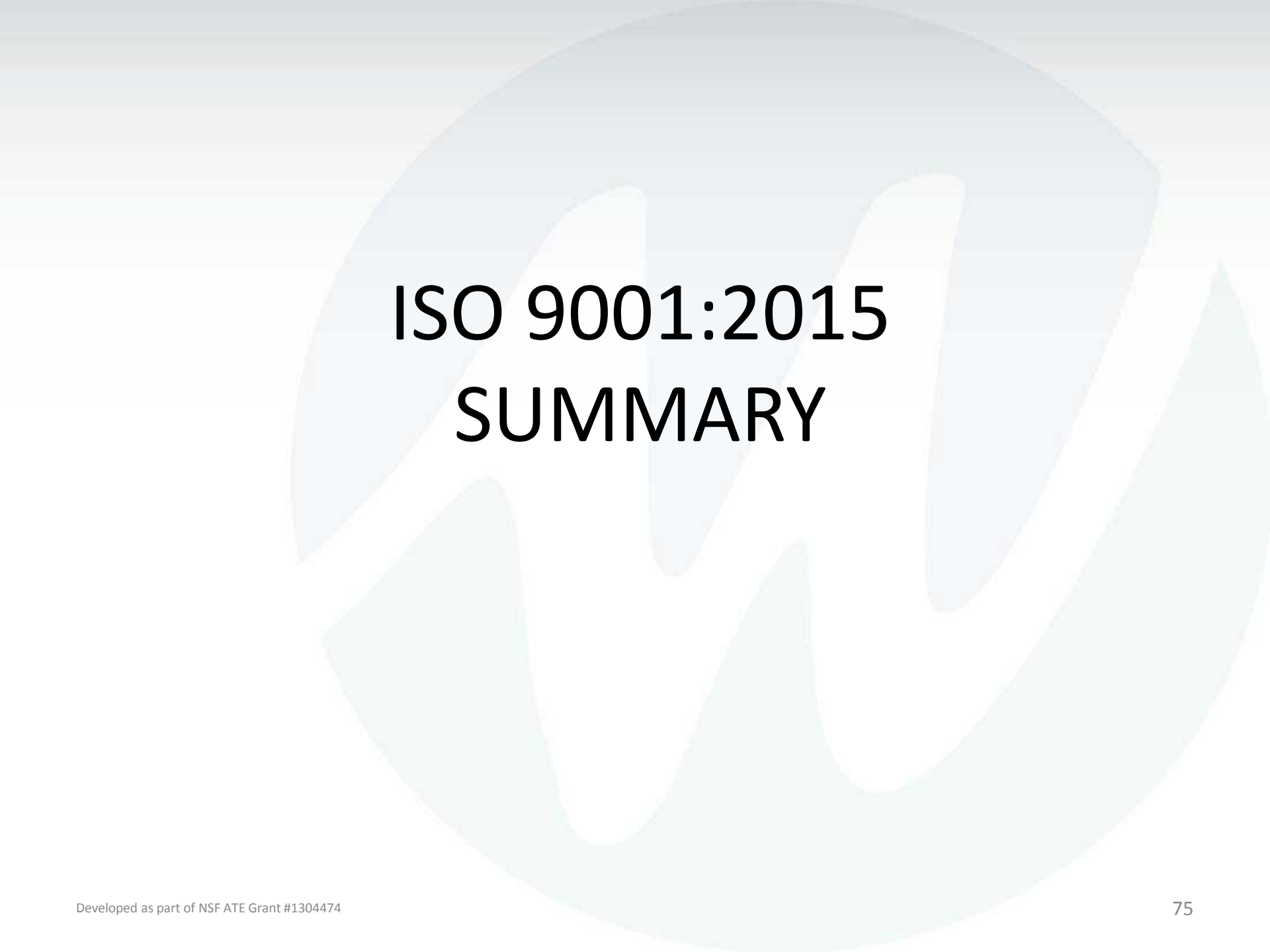
*Utilize processes within context of organization*

*Pick few key projects at a time (KISS)*

*Tie activities to customer perception for processes that align with business goals*



# ISO 9001:2015 Clause 8.0 – 10.0



# ISO 9001:2015 SUMMARY

# ISO 9001:2015 - SUMMARY

- Quality Management Systems Standard
  - “... designed to help organization ensure they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product...”*

# ISO 9001:2015

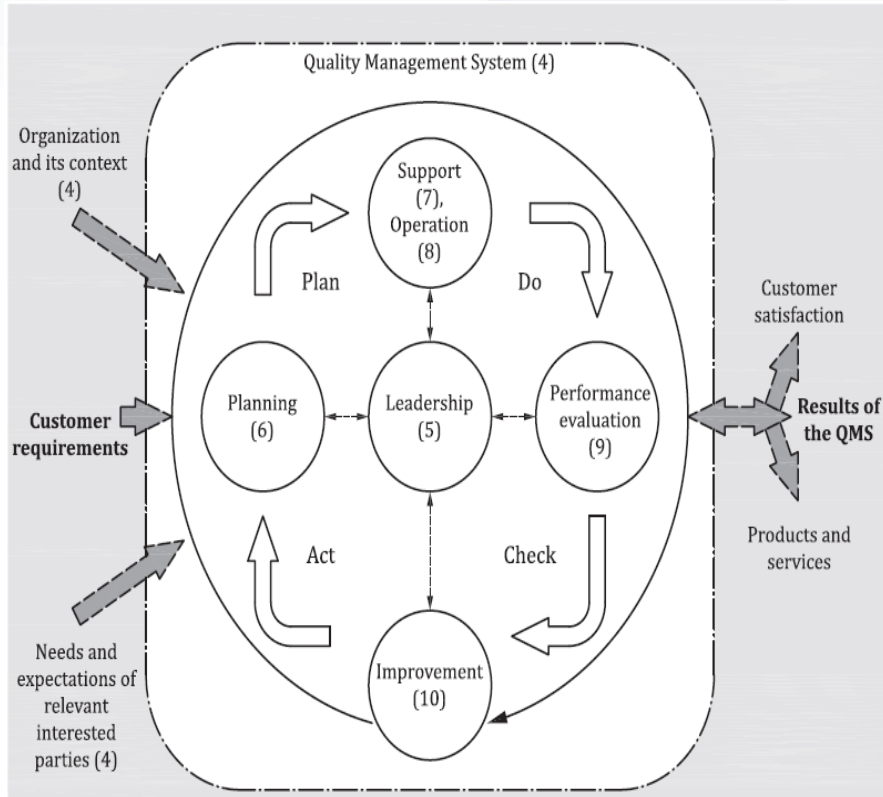
- Clause 4.0 Context of the organization
- Clause 5.0 Leadership
- Clause 6.0 Planning
- Clause 7.0 Support
- Clause 8.0 Operation
- Clause 9.0 Performance Evaluation
- Clause 10.0 Improvement

# QMS PRINCIPLES – ISO 9001: 2015

- Customer Focus
  - *Understand current & future customer needs; strive to exceed customer expectations*
- Leadership
  - *Establish unity of purpose and direction of the organization*
- Engagement of People
  - *People at all levels of an organization and their full involvement enables their abilities to be used for the organization's benefit*
- Process Approach
  - *Desired result achieved more efficiently when activities and related resources are managed as a process*
- Improvement
  - *Enhanced ability to anticipate & react to internal and external risks and opportunities*
- Evidence-based decision making
  - *Effective decisions are based on the analysis of data and information*
- Relationship Management
  - *A mutually beneficial relationship between organization & its suppliers enhances the ability of both to create value*

# Quality System Process Overview

ISO 9001:2015



- **Plan:** Establish Objectives and processes required
- **Do:** Implement the processes
- **Check:** Measure and monitor the processes and report results
- **Act:** take action to improve performance of the QMS based on results



# ISO 9001:2015 Quality Management Systems Clause 4.0 – 10.0