

AQS 115

QUALITY SYSTEMS & AUDITING PRINCIPLES

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QUALITY MANAGEMENT SYSTEMS

- ISO 9001:2015
- Clause 4.0 – 7.0



ISO 9001:2015E

- 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...”*
- Third party certification bodies provide independent confirmation
 - Accreditation organizations authorize certification bodies

Accreditation - Exemplar Global (formerly RABQSA)

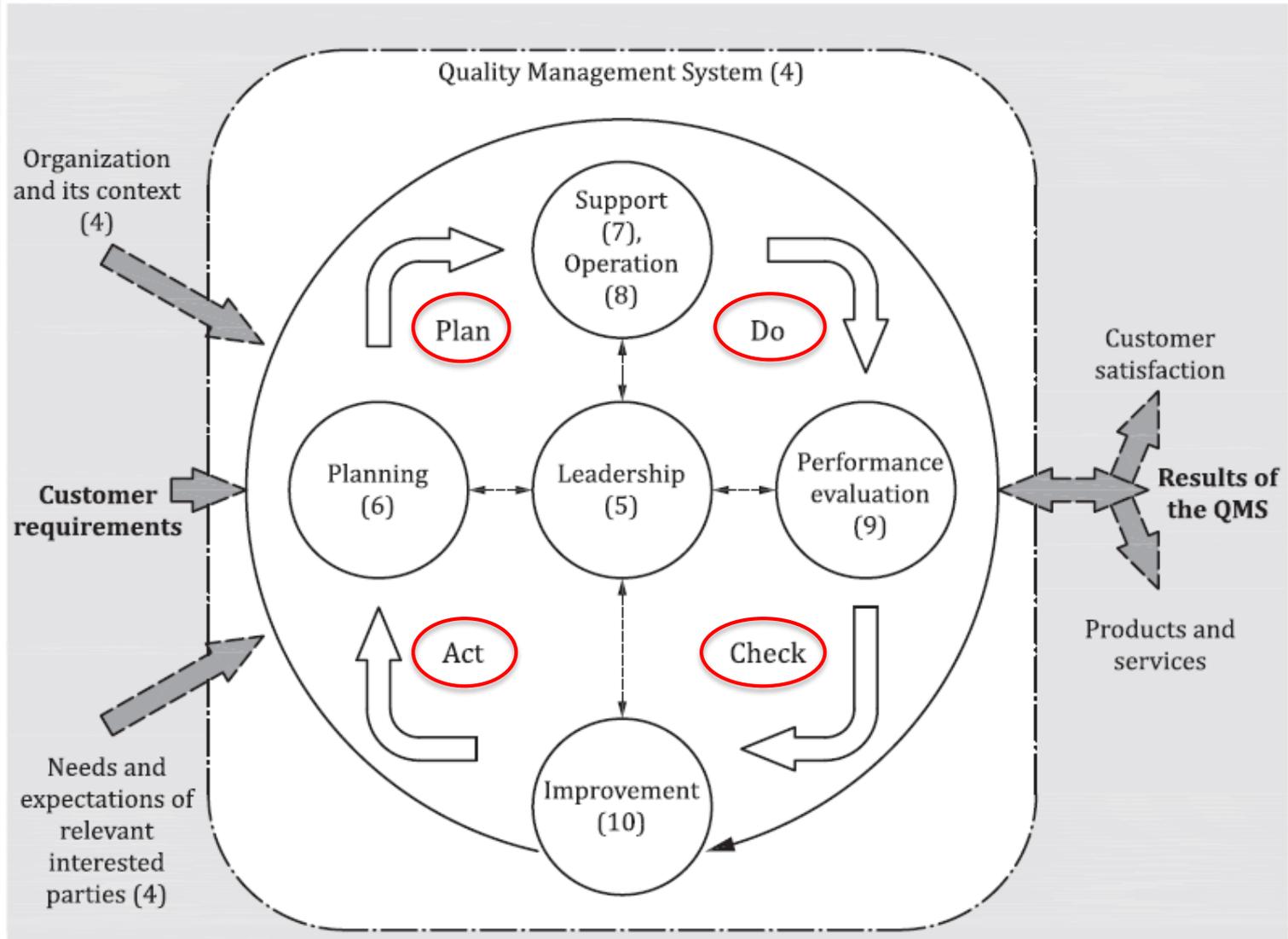
Certification – LRQA (Lloyds Registrar Quality Assurance LTD)
BSI (British Standards Institute Group)

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*

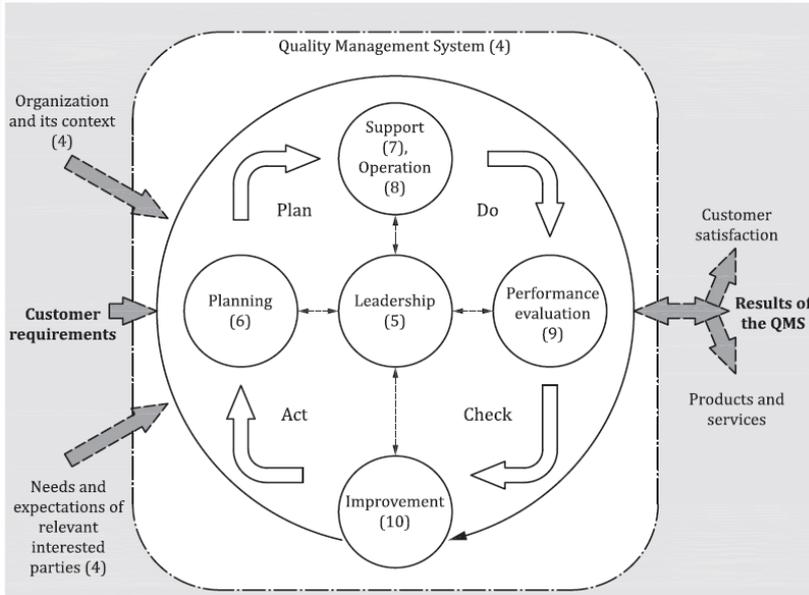
Quality System Process Overview

ISO 9001:2015



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

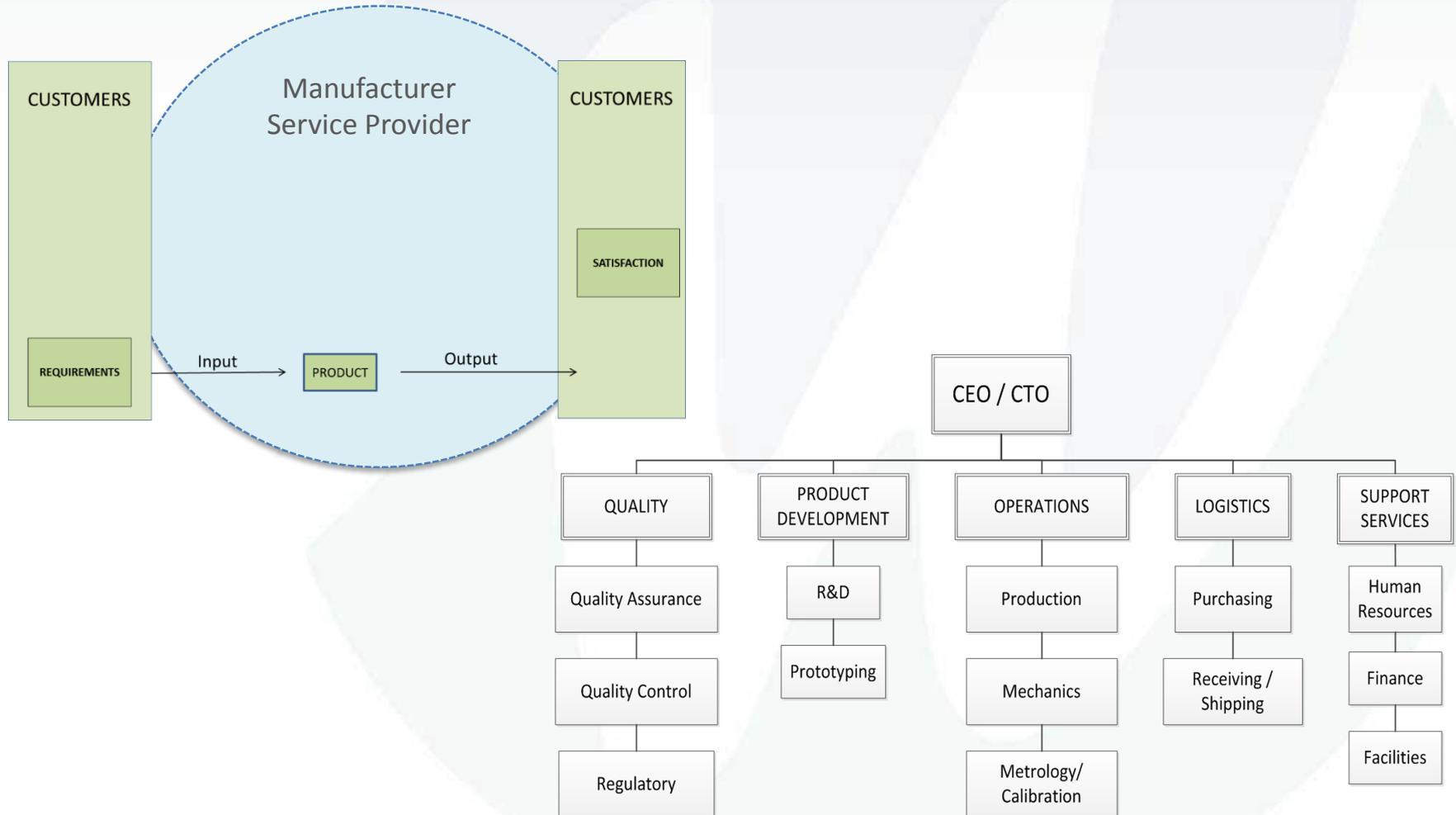
- **Clause 0 Introduction**
 - Foundation of the standard
- **Clause 1 Scope**
 - Describes extent of the standard with regards to an organization's need to manage its quality performance
 - Provide products/services that meet customer and legal requirements
 - Enhance customer satisfaction through effective application of the system
 - Requirements are generic & apply to any organization regardless of type, size or products/services
- **Clause 2 Normative Reference**
 - Describes any reference documents or annexes to the standard
- **Clause 3 Terms & Definitions**
 - Refers to ISO 9000:2015 QMS - Fundamentals and Vocabulary

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

ISO 9001:2015

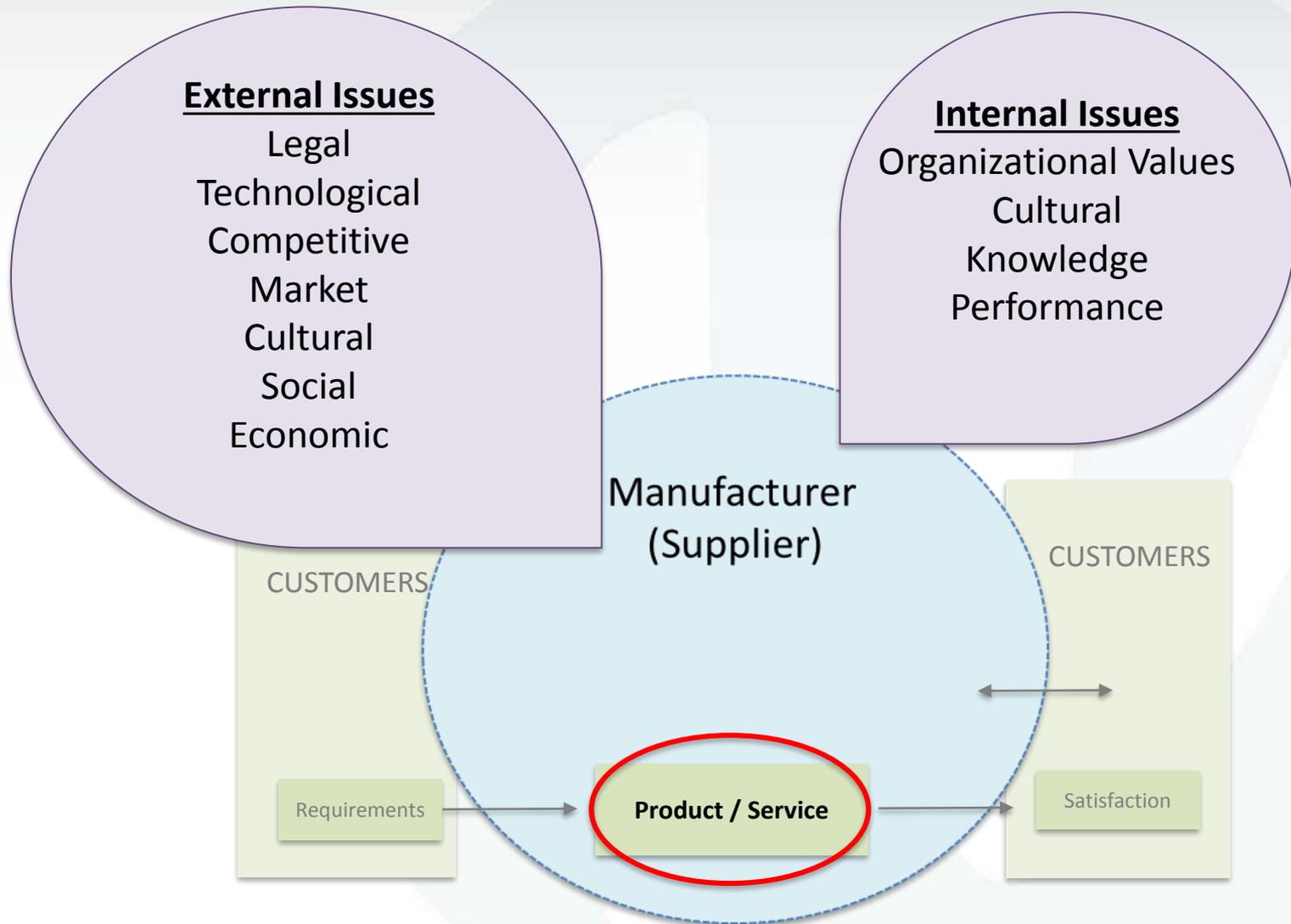
- 4.0 Context of the Organization



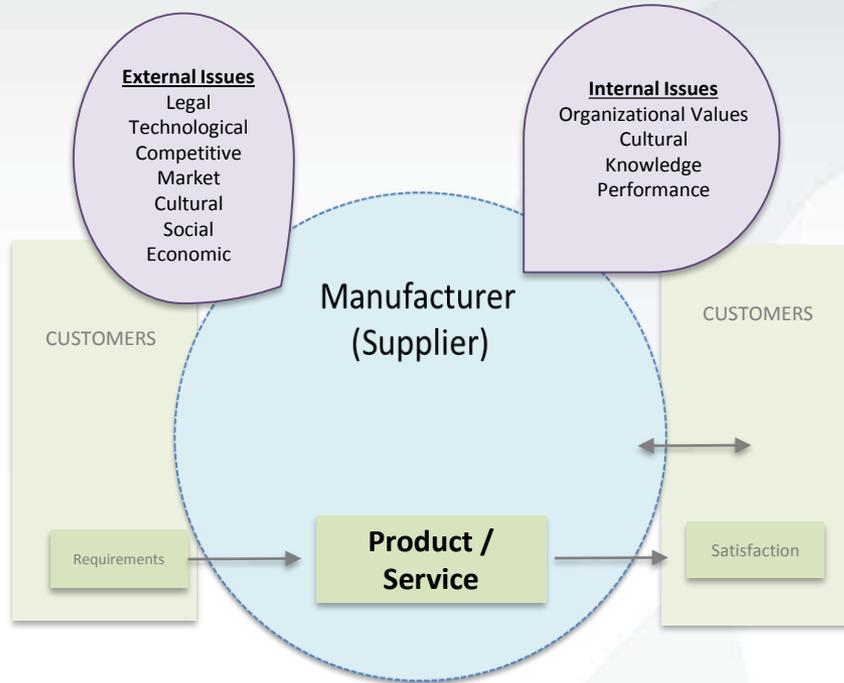
ISO 9001:2015

- 4.0 Context of the Organization
 - Determine internal/external issues that can impact or are relevant to strategic direction of the organization
 - Include interested parties (regulators, suppliers, subcontractors, etc.)
 - Overall QMS system scope documents and records

Clause 4.1 Understanding Organization



Clause 4.1 Understanding Organization



Example:

Company XYZ manufactures chemical additives for the cement industry.

They employ 2000 people, and have plants in multiple locations throughout North America (including Canada & Mexico).

The additives are shipped via trucking lines and in container ships.

What are possible External and Internal Issues?

Clause 4.1 Understanding Organization

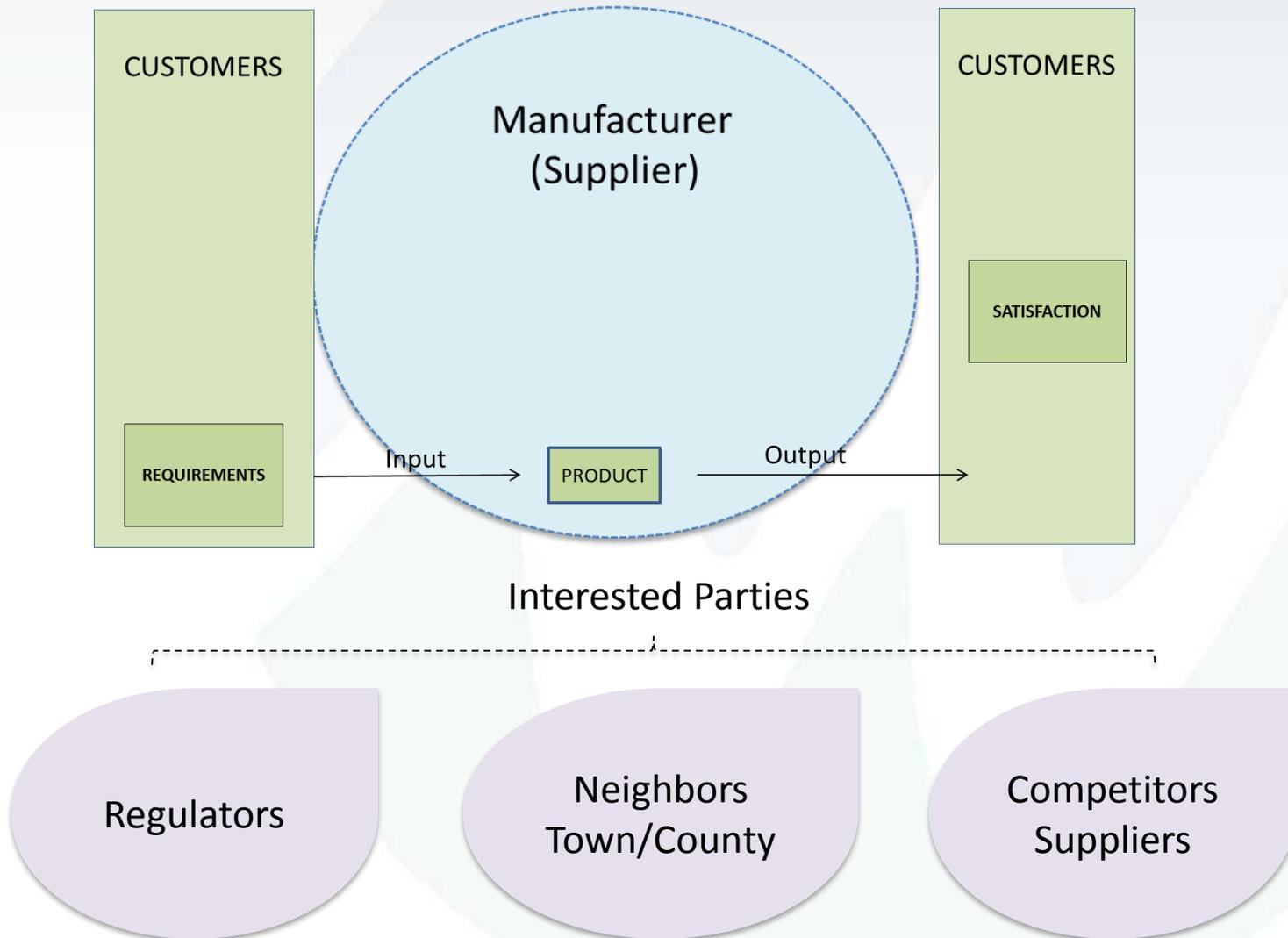
Example:

- Company XYZ manufactures chemical additives for the cement industry.
- They employ 2000 people, and have plants in multiple locations throughout North America (including Canada & Mexico).
- The additives are shipped via trucking lines and in container ships.

What are possible External and Internal Issues?

- External Issues
- Internal Issues

Clause 4.2 – Interested Parties



Clause 4.2 Interested Parties

Example:

- Company XYZ manufactures chemical additives for the cement industry.
- They employ 2000 people, and have plants in multiple locations throughout North America (including Canada & Mexico).
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Who are Interested Parties?

What are their needs/expectations?

Clause 4.2 Interested Parties

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Who are Interested Parties?

What are their needs/expectations?

- Customers
- Staff
- Suppliers
- Regulators
- Owners / Shareholders
- Surrounding Community

Clause 4.2 Interested Parties

Example:

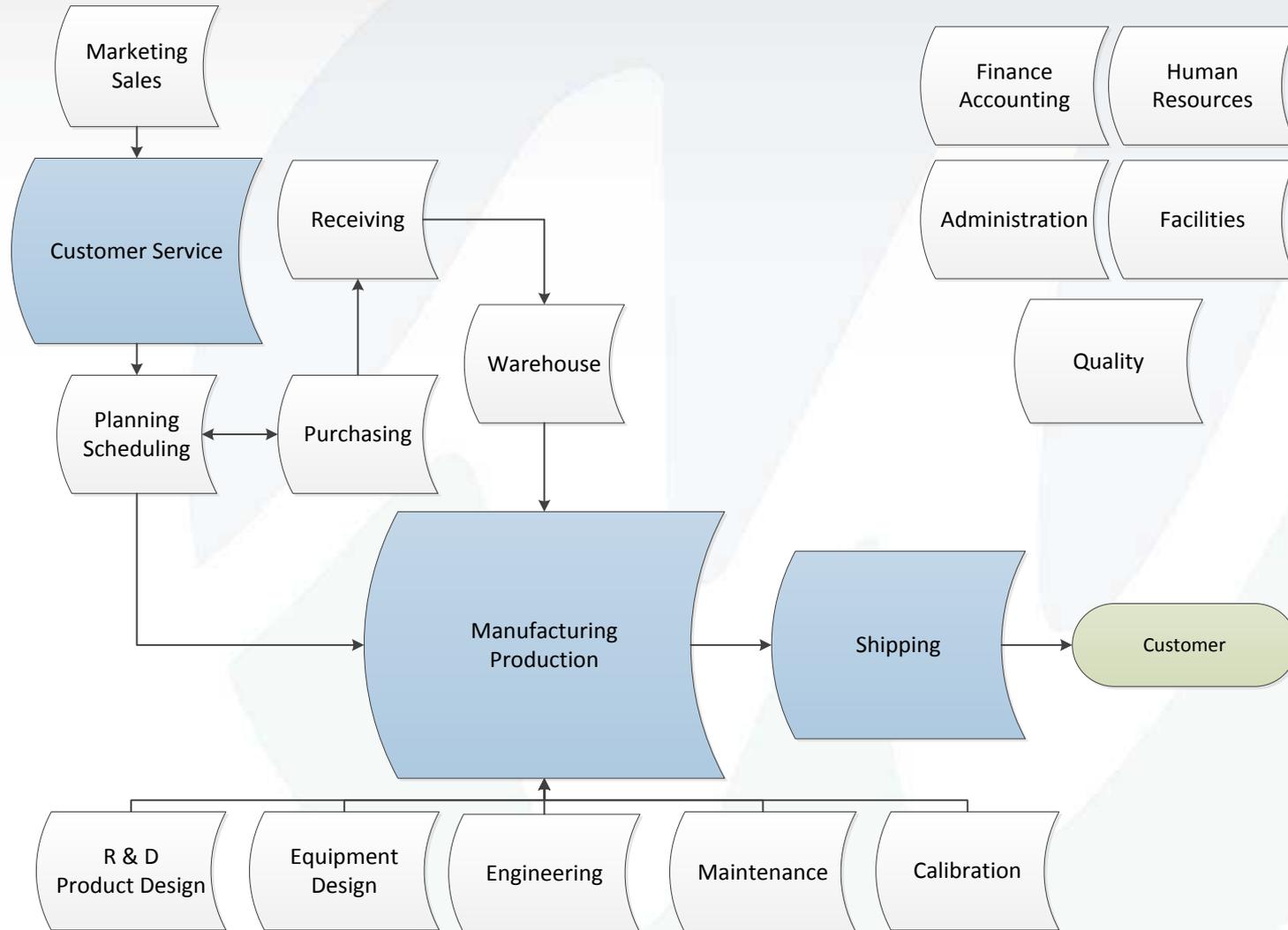
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Who are Interested Parties?

What are their needs/expectations?

- **Customers**
 - Products that meet requirements
 - Terms & Conditions
- **Staff**
 - Training & support
 - Safe working conditions
 - Continuity of employment
- **Suppliers**
 - Clear specification of what is to be delivered
 - Terms & Conditions
- **Regulators**
 - Complying with requirements
- **Owners / Shareholders**
 - ROI
 - Maintaining Compliance
 - Customer Satisfaction
- **Surrounding Community**
 - Minimal/no disruption
 - Safety concerns

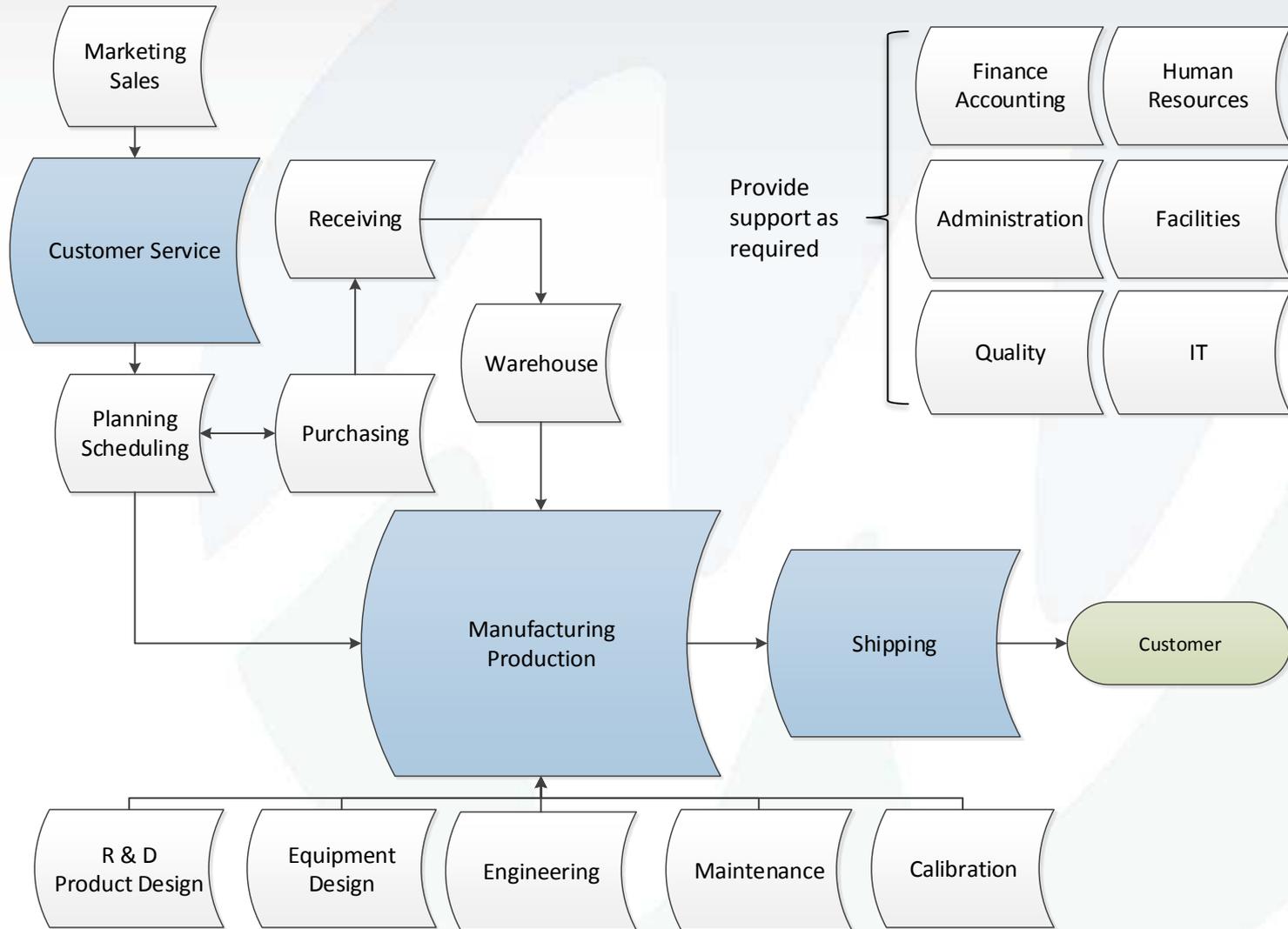
Clause 4.3 – Scope of QMS



Clause 4.4 – QMS & its Processes

- Requirements
 - Establish, implement, maintain and continually improve the QMS included the processes needed and their interaction
 - Reference standard for list of specific requirements (4.4.1)
 - Maintain documented information
 - Retain documented information

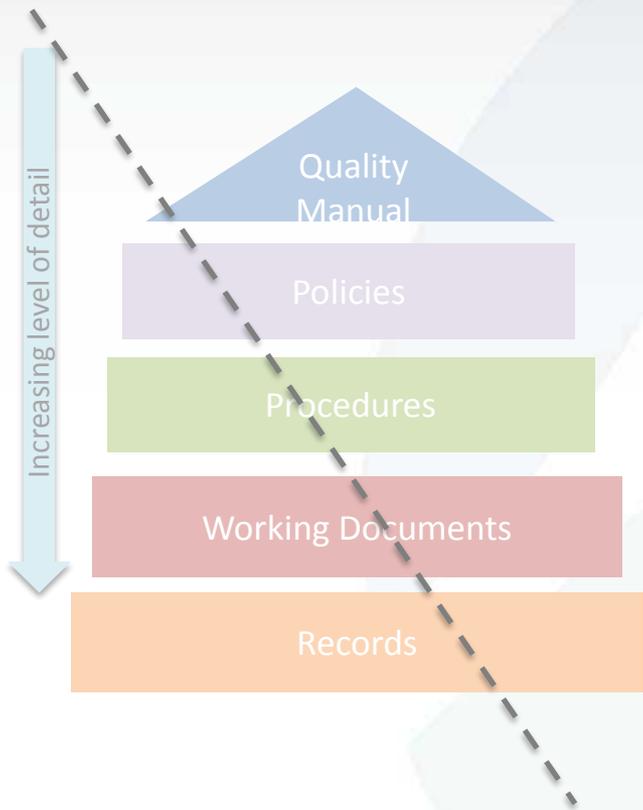
Clause 4.4 – QMS & its Processes



DOCUMENTATION



DOCUMENTATION



NOTE: ISO 9001:2015 revision no longer follows this model

Now refers to “Documented Information”

maintain documented information is equivalent to procedure

retain documented information is equivalent to records

Existing quality management systems built on original model – therefore, detail still provided

ISO 13485:2016 (medical devices) and 21CFR 210/211 (pharma) and 820 (medical devices) do specify where procedures are required

DOCUMENTATION



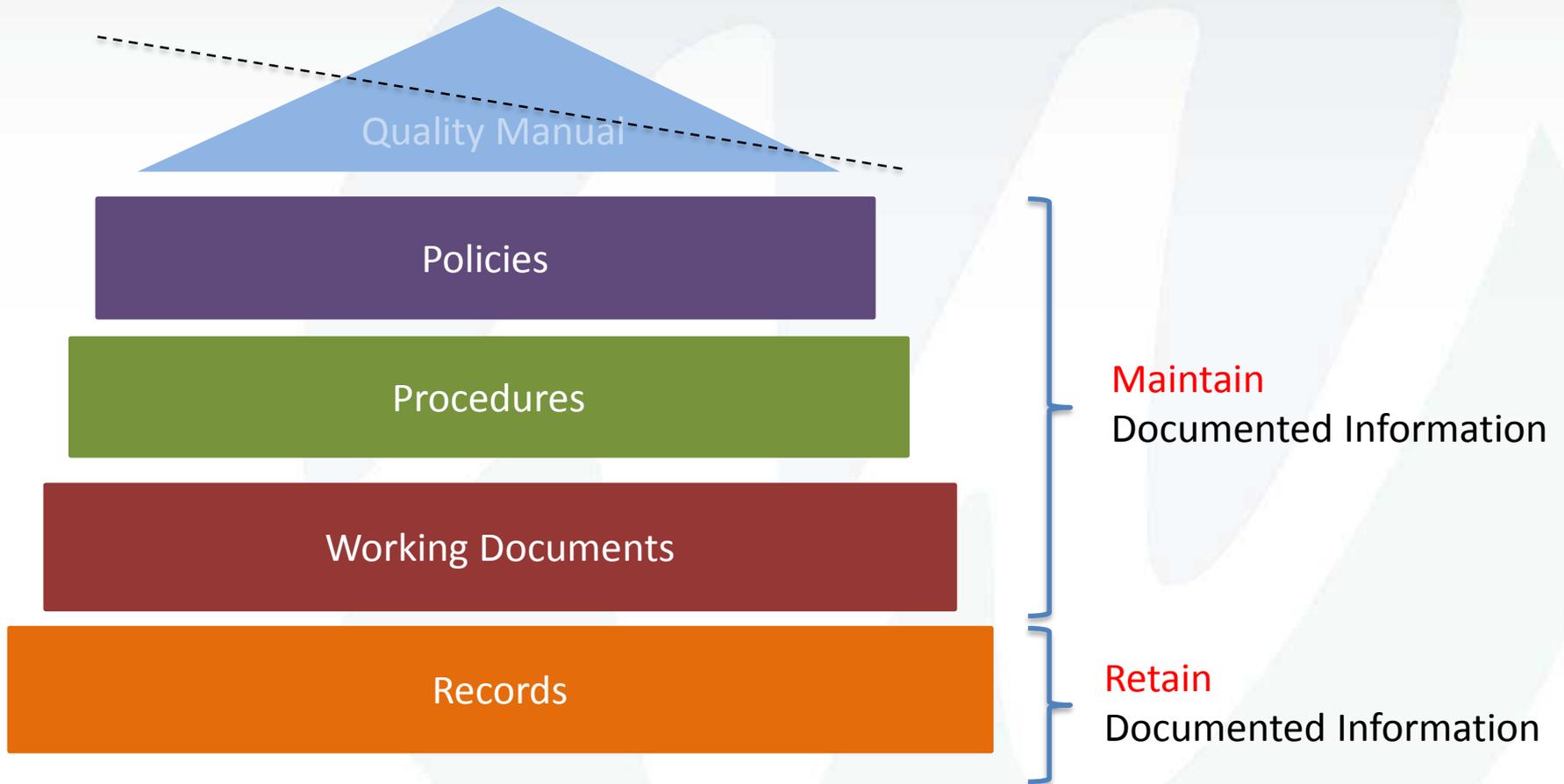
- **Quality Manual**
high level document providing overview of business operation and quality system
Note: No longer an explicit requirement for ISO 9001:2015
- **Policies**
provide general guidelines by which company conducts the various manufacturing (service) operations

DOCUMENTATION



- Procedures – operational detail regarding how business has implemented policies and provide general information on day-to-day operations. (SOP)
- Working Documents - detailed steps to carry-out specific task(s)
 - Work instruction
 - Test Methods
 - Product / Process / Raw material Specifications
 - Protocols
 - Etc.
- Records - documented results of completing tasks
 - Quality
 - Business

DOCUMENTATION- ISO 9001:2015



ISO 9001:2015

- Clause 5.0 Leadership

Clear emphasis on leadership (not management).

Top Management now have to demonstrate greater involvement in the operation of the organization's management system

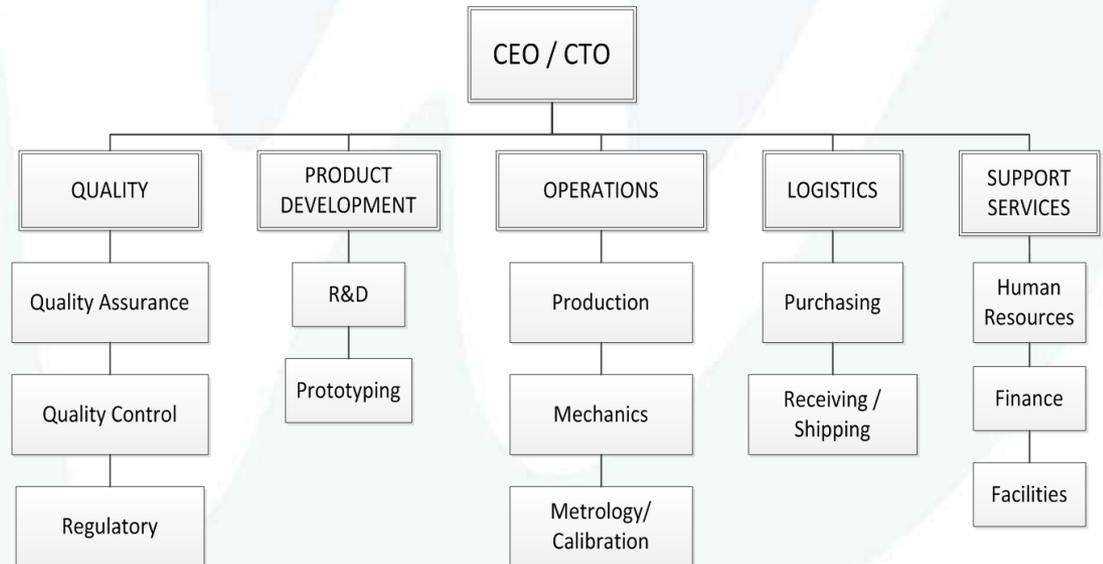
ISO 9001:2015

- Clause 5.0 Leadership

- Management commitment, integration of the QMS into business processes

- Customer focus
- Quality Policy

- Organizational roles, responsibilities, authorities



CLAUSE 5.1 – Leadership & Commitment

- Top Management (definition per ISO 9000:2015)
The person or group of people who direct and control an organization at the highest level (for the scope of the QMS).
- Demonstrate leadership and commitment by
 - Accountability of the effectiveness of the system
 - Ensure quality policy and objectives are established and compatible with strategic direction and organizational context
 - Quality policy communicated, understood and applied
 - Integration of system requirements into business processes
 - Promote process approach
- Customer Focus
 - Ensure Customer and legal requirements are determined, met and maintained
 - Determine and address risks/opportunities that can affect product/service conformity
 - Maintain enhanced customer satisfaction

CLAUSE 5.2 – Quality Policy

- Cornerstone of the QMS, and shall be
 - Appropriate or suitable for the organization
 - Contain framework for setting the quality objectives
 - Top Management commitment to meet requirements and continually improve
- Communicated, understood, available and documented.

CLAUSE 5.2 – Quality Policy

- Quality Policy
 - Ensure consistent with strategic and tactical plans
 - Promote use in marketing initiatives
 - Tie to overall mission/vision of organization
 - Easy for people to describe

CLAUSE 5.2 – Quality Policy EXAMPLE



QUALITY POLICY



Calmego Specialized Products and Specialized Castings manufacture castings. Our purpose is to produce castings to satisfy the needs and requirements of our customers as we comply with any and all legal requirements. We maximize our commitment to achieve this purpose by continually improving the quality and timeliness of our quality management system. We provide the leadership and support that this policy requires, communicate this policy throughout our organization, and provide the framework to achieve the quality objectives documented in our quality system. In the annual Management Review Meeting the top management of our organization examines the quality policy and the quality management system of our organization for relevancy.

Rev. 3, 07/03/13

Approval: *Jeff Deitering*

CLAUSE 5.3 – Organizational Roles, Responsibilities & Authorities

- Ensure responsibilities and authorities for relevant roles are assigned communicated and understood within the organization
 - Ensure QMS conforms to ISO 9001
 - Processes to deliver intended outputs
 - Report on QMS performance
 - Promote customer focus
 - Maintain QMS integrity during changes
 - Create organization charts
 - Job descriptions
 - Functional organization charts with relationships

ISO 9001:2015

- Clause 6.0 Planning

How will organization prevent/reduce undesired effects?

How will it ensure intended outcomes and continual improvement can be achieved?

CLAUSE 6.1 ACTIONS TAKEN TO ADDRESS RISK AND OPPORTUNITIES

- Risks/opportunities to be addressed are based on
 - External/internal issues
 - Needs/expectations of interested parties

CLAUSE 6.1 ACTIONS TAKEN TO ADDRESS RISK AND OPPORTUNITIES

- Internal Issue considerations
 - Internal audit / self-assessment results
 - Review of customer audits/feedback
 - Organizational performance
 - Industry benchmarks for “best practices”
 - Analysis of Quality cost data / Technology trends
- External Issue considerations
 - Economic environment
 - International trade conditions/processes/barriers
 - Competitive products/services
 - Outsourcing / Technology Trends / Regulatory Changes

CLAUSE 6.1 ACTIONS TAKEN TO ADDRESS RISK AND OPPORTUNITIES

- Planning includes
 - Address risks/opportunities
 - Integrate/implement actions into QMS
 - Evaluate effectiveness
- Options when addressing
 - Avoid risk
 - Eliminate risk source
 - Share risk
 - Take risk to pursue opportunity
 - Change likelihood/consequences

CLAUSE 6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

- Quality Objectives shall
 - Be consistent with policy
 - Measurable
 - Account for applicable requirements
 - Be relevant to product/service conformity
 - Be relevant to enhance Customer satisfaction

Communicated, monitored and updated

CLAUSE 6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

- Objectives align with policy
- Objectives align with organizational objectives
 - avoid conflicting priorities
- Align metrics with objectives
 - Measure the right things
 - Consider balanced scorecard/dashboard or similar monitoring tools

CLAUSE 6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

- Plans to achieve
 - What will be done
 - What resources are required
 - Who will be responsible
 - When will it be completed
 - How the results will be evaluated

CLAUSE 6.2 Quality Objectives



APL

DIAGNOSTIC EXPERT SINCE 1975

APL Institute of Clinical Laboratory & Research Pvt. Ltd.

Quality Objectives

Quality Control

To reduce non-conformity / deficiencies and increase Quality

Maintenance

To Reduce the Breakdown of Instrument

Training & Education

Regular Evaluation & Skill Upgradation

Results

To provide genuine and timely results with highest quality and ethical standards along with online reporting of results.

Confidentiality

To maintain strict confidentiality, privacy and restricted access to customer's data.

Marketing

To increase sales Revenue

To increase the customer satisfaction level

Purchase & Store

To receive the material only from registered Vendors and maintain minimum Stock

Central Laboratory

To provide flawless sample & data processing, handling, distribution, transfer and management.

To deliver optimum clinical supplies and sample logistics services with appropriate sample storage.

CLAUSE 6.3 PLANNING OF CHANGES

- Change Control System requirement
- Process
 - Design review
 - Verification / validation of proposed changes
 - Planned, systemic manner under controlled conditions
- Considerations
 - Purpose of changes / potential consequences
 - Integrity of QMS system
 - Availability of resources
 - Allocation/re-allocation of responsibilities/authorities

ISO 9001:2015

- Clause 7.0 Support
 - Resources: personnel, infrastructure, environment, monitoring/measuring devices, intellectual property (organizational knowledge)
 - Training, Awareness, Communication, Documented Information

ISO 9001:2015

- Clause 7.0 Support
 - 7.1 Resources
 - 7.2 Competence
 - 7.3 Awareness
 - 7.4 Communication
 - 7.5 Documented Information

Clause 7.1 Resources

- Clause 7.1.1 – 7.1.6
 - Ensure availability of human/capital resources needed
 - Ensure work environment is suitable
 - Ensure adequate infrastructure is determined/provided/maintained
 - Ensure organization knowledge (current and future)
 - Ensure product/service conformity to requirements
 - Valid/reliable results from monitoring/measuring
 - Ensure resources applied for improvement

Clause 7.2 Competence

- Ensure people have capability to provide product/service meeting customer requirements
- Ensure people have capability to ensure QMS effectiveness
 - Includes continual improvement

Clause 7.3 Awareness

- Ensure people understand why their work is important and contribution to success
- Awareness of Quality Policy throughout organization
- Awareness of consequences for not conforming to QMS

Clause 7.4 Communication

- Ensure customer satisfaction
 - Increase business by remaining “in-touch”
- Solve problems quickly/early
- Enhance alignment of activities throughout organization

Clause 7.5 Documented Information

- Clauses 7.5.1 – 7.5.3
 - Ensure consistent performance of all activities affecting quality
 - Ensure controls are in place to issue/approve documents
 - Changes in requirements are communicated
 - Personnel have up-to-date instructions/requirements
 - Prevent use of obsolete information