

Quality Management System input comprises the standard requirements from ISO 9001:2015 which are deployed by our organization to achieve customer satisfaction through process control.



pacific imaging

Quality Manual, ISO 9001:2015 Quality Management System

QM-01

Quality Manual Revision History

Revision	Date	Description	Approved By
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1.0 Introduction

Pacific Imaging LLC has made the “Strategic Business Decision” to develop and implement an effective Quality Management System (QMS) across all areas of the Organization. The implementation of the QMS is intended to improve and sustain the overall performance of our business, products and service. Examples of the benefits include:

- The ability to provide products and services that meet customer and applicable Statutory and Regulatory requirements.
- The ability to plan our processes and their interactions by employing the Plan-Do-Check-Act (PDCA) cycle and risk based thinking in our daily operations.
- The facilitating of opportunities to enhance customer satisfaction.
- Addressing risks and opportunities associated with its context and objectives.

The QMS Manual is considered the normative basis of reference to the International Standard and shall be used internally to provide an overview of ISO 9001:2015 requirements and how they apply at Pacific Imaging LLC. The QMS Manual is used externally to introduce the elements of our QMS to our customers and other external organizations to the extent necessary.

Quality Management Principles

Pacific Imaging LLC has adopted and realizes the benefits of Quality Management Principles into our daily activities. The intent of the Quality Management Principles is to provide a foundation to continually improve upon the Organizations performance. Subsequent sections of the QMS Manual will provide our commitments of the following QMP elements:

- Customer Focus
- Leadership
- Communications and the engagement of our people
- Process Approach
- Improvement
- Risk and Opportunity as well as evidence-based decision making
- Relationship Management

Process Approach

Pacific Imaging LLC has adopted the “Process Approach” into our daily operations including the PDCA Cycle. We have considered the utilization of Risk-Based Thinking Philosophy when developing, implementing, and improving the effectiveness of our Quality Management System. This approach will enable Pacific Imaging LLC to enhance the overall performance of the organization by effectively controlling the interrelationships and the interdependencies among the QMS Processes. The implementation of the “Process Approach” in our QMS enables:

Quality Manual, ISO 9001:2015 Quality Management System

- The understanding and consistency with achieving customer specific requirements
- The consideration of our processes based on the evaluation of data and information.

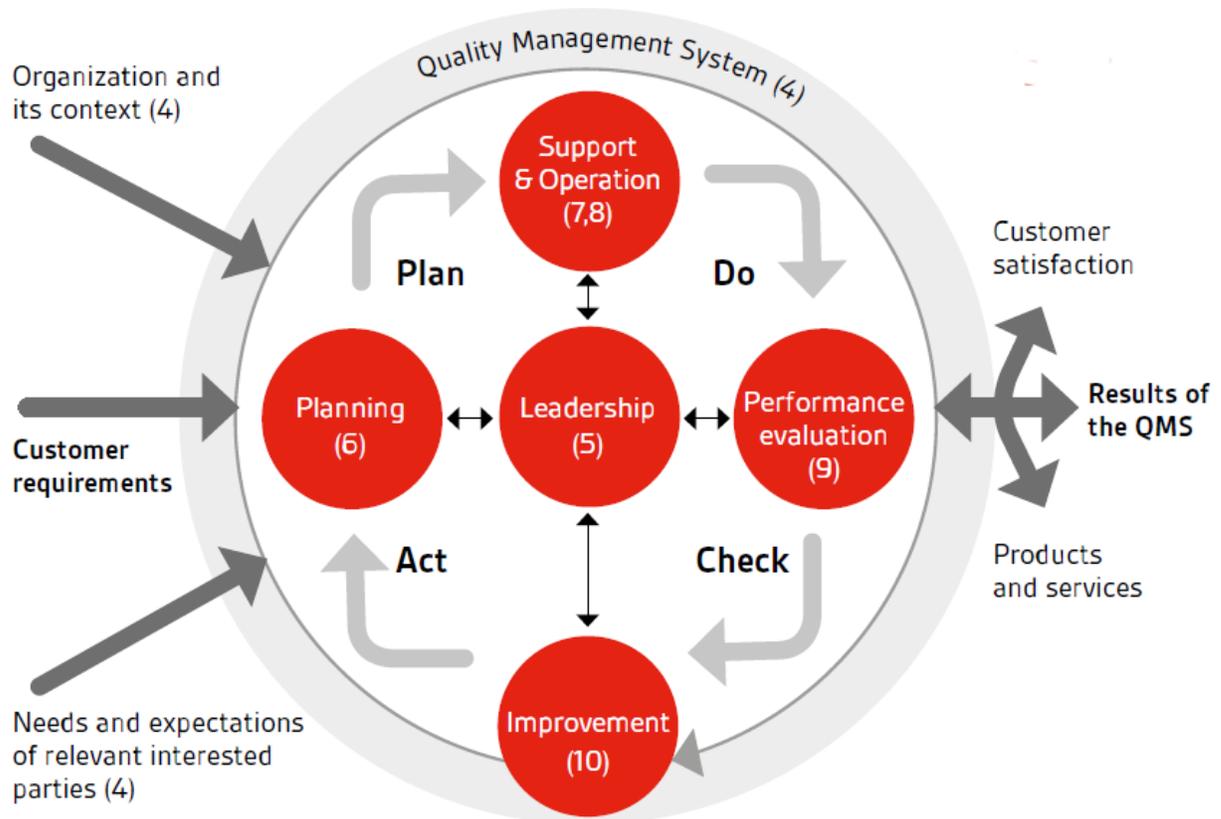


Fig. 1 - PDCA Cycle

Risk Based Thinking

The implementation of Risk-Based Thinking is an essential tool for achieving and maintaining an effective QMS. Pacific Imaging LLC effectively plans and implements various actions to address risks and opportunities to maximize the outcomes including but not limited to achieving improved results and preventing negative effects of our products, services and QMS.

Scope

The scope and intent of our QMS is to define and communicate our commitment to continually enhance customer satisfaction through:

- Effective process improvements to all systems of the business.
- To assure conformity to our customer's and applicable statutory and regulatory requirements.

- Provide policies and procedures developed and implemented with the primary focus to assure the continual compliance of the requirements of the International Standard ISO 9001:2015.

2.0 References

The following documents in whole or in part are normatively referenced or used in the preparation of this document and are indispensable for its application.

- International Standard ISO 9001:2015 Quality Management System Requirements
- International Standard ISO 31010:2009 Risk Management – Risk Assessment
- ANSI/ASQ Z1.4 – 2008 Sampling Procedures and Tables for Inspection
- ISO 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories

3.0 Definitions

For the purpose of this document the terms and definitions provide in ISO 9001:2015 apply.

4.0 About Our Organization

4.1 Organizational Context

Pacific Imaging LLC is committed to defining our position in the marketplace and understanding how relevant factors arising from legal, political, economic, social and technological issues influence our strategic direction and organizational context.

Pacific Imaging LLC identifies, analyzes, monitors and reviews factors that may affect

our ability to satisfy our customers and stakeholders, as well as; factors that may adversely affect the stability of our processes, or our management system's integrity.

To assure that our QMS is aligned with our strategy, while taking account of relevant internal and external factors; we initially collect and analyze pertinent information in order to determine the potential impact on our context and subsequent business strategy.

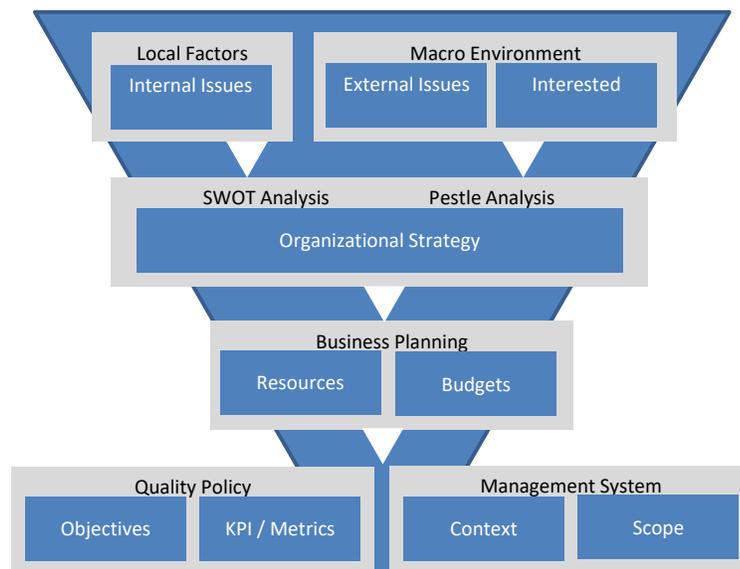


Fig. 2 – QMS Hierarchy

Pacific Imaging LLC then monitors and reviews this information to ensure that a continual understanding of each group's requirements is derived and maintained. To facilitate the understanding of our context, we regularly consider issues that influence our context during Management Review Meetings and are conveyed via minutes and business planning documents.

Internal Issues	External Issues
Market Share	Customers & Suppliers
Employees	Markets & Competition
Performance	Regulatory & Statutory
Capacity	Economic Backdrop
Values and Culture	Technology
Innovation & Knowledge	Cultural & Social

The Output from this activity is evident as an Input to the consideration of Risks and Opportunities, and the actions taken to address them (see Section 6.1 addressing Risk and Opportunity Management Framework).

The following documented information is used to describe our Organizational Context:

- Analysis of Business Plans, Strategies, and Statutory and Regulatory requirements.
- Analysis of Technology and Competitors.
- Economic Reports from relevant business sectors.
- Technical Reports from technical experts and consultants.
- SWOT Analysis Reports or schedules for internal issues.
- PESTLE Analysis Reports or schedules for external issues.
- Minutes of Meetings (Management Review Meeting Minutes), Process maps, and reports.

4.2 Relevant Interested Parties

The effect or potential effect on our organizations ability to consistently provide products and services that meet our customer and applicable statutory and regulatory requirements, Pacific Imaging LLC has determined the following:

- The Interested Parties relevant to the QMS.
- The requirements of the identified interested parties relevant to the QMS.

Pacific Imaging LLC is committed to continually monitoring, reviewing and analyzing information and relevant requirements of the interested parties to assure their requirements are effectively managed in the QMS.

4.3 Quality Management System

4.3.1 Quality Management System Scope

Pacific Imaging LLC has determined the boundaries and the applicability of the QMS and how it relates to the Business Core Competency.

Pacific Imaging LLC is committed to applying all applicable requirements of the International Standard to the intent and scope of our QMS.

The scope of our QMS shall always be available to internal and external parties and maintained as documented information. The QMS was determined, designed and implemented to cover and support the following scope:

The Scope of Activities Performed at Pacific Imaging LLC to the Requirements of ISO 9001:2015
Include:
*Design and Development, Sales and Distribution of Digital Imaging Solutions to a variety of
Industries*

4.3.2 Management System Processes

Pacific Imaging LLC has established, documented and implemented our Quality Management System (QMS) in accordance with the requirements of ISO 9001:2015. The QMS is maintained and continually improved through the use of the Quality Policy, Quality Objectives, Internal Audits, Analysis of Data, Corrective and Preventive Action and Management Review Meetings. Pacific Imaging LLC utilizes Quality Procedures (QP) to provide our employees and external providers (suppliers) with detailed “How To” instructions and requirements. The documents support the achievement of quality compliance for each of the process steps. We retain Quality System Forms (QF) which provides documented information substantiating the process inputs and outputs have been accomplished as planned.

4.3.2.1 Documented Information

Pacific Imaging LLC maintains a documented QMS as a means to ensure that products and services conform to specified requirements. The QMS consists of the following 3 Levels of documented information:

Level I Quality Manual – provides the scope of the QMS and the applicable ISO 9001:2015 Clauses contained and supported by our QMS.

Level II Quality Procedures – provides detailed requirements for each of our processes with the intent to specify who does what, when, where, how the process action/task is performed, and what documentation is used to verify that all required quality related activities had been executed as required.

Level III Quality Forms – provides objective evidence that required product or service quality and customer requirements were achieved and that the organizations QMS has been implemented as stated. Quality Forms include to tags, labels, stickers, pre-printed sheets, stamps, and other means to identify the status of materials, products, equipment, gauges and other devices used in the organization to achieve the specified requirements.

4.3.2.2 Creating and Updating

When creating and updating documented information Pacific Imaging LLC ensures the following:

- The identification and description (revision, date, approval, etc.)
- The format and media (electronic, paper hard-copy, etc.)
- The review and approval for suitability and adequacy

4.3.2.3 Control of Documented Information

Documented information required to support the effectiveness of the QMS is controlled to ensure:

- It is available and suitable for use, where and when it is needed
- It is adequately protected from loss of confidentiality, improper use or loss of integrity
- Distribution, access, retrieval and use
- Storage and preservation, including preservation of legibility
- Control of changes
- Retention and disposition

Documented Information of external origin determined to be necessary for the planning and implementation of the QMS is identified as appropriate and controlled in accordance with Quality Procedures and Forms.

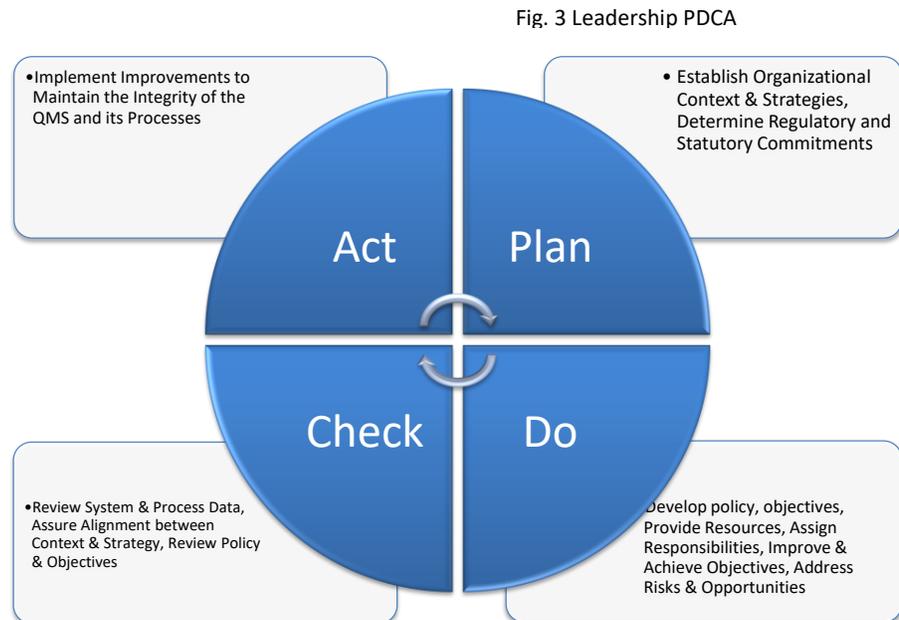
5.0 Leadership and Governance

5.1 Leadership and Commitment

Management is actively involved in implementing the QMS, and is accountable for its overall effectiveness.

Management has initiated and fully supports the vision and strategic direction for the continued sustainability and enhancement of the QMS. Top Management has initiated and fully supports the Quality Policy and Quality Objectives.

Management is committed to the development and implementation of the QMS and to support continually improving its effectiveness. Management provides direction to the integration of the QMS requirements into each process of the organization and is committed to promoting the use of the Process Approach and Risk Based Thinking, as well as the engagement and motivation of employees throughout the QMS.



5.1.1 Quality Management System

The Quality Management system at Pacific Imaging LLC has been developed in accordance with the requirements of ISO 9001:2015. The Quality Management System consists of four levels of documentation. The documented Quality Management System consists of:

- Quality Manual
- Quality Procedures
- Quality Forms
- Quality Records

The Quality Management System at Pacific Imaging LLC has been developed with support and input of Top Management within the organization. This Top Management Input is illustrated through the Company Quality Policy, Quality Objectives and Management Review Meetings.

Top management shall provide evidence of its commitment to the development and implementation of the QMS and maintain efficient operations by:

- Communicating to company personnel the importance of meeting customer as well as statutory, and regulatory requirements.
- Establishing the quality policy.
- Ensuring that quality objectives are established.
- Conducting management reviews.
- Ensuring the availability of resources.

5.1.2 Customer Focus

Pacific Imaging LLC ensures customer requirements and expectations are clearly defined, understood and achieved at all levels of the organization. Pacific Imaging LLC is committed to achieving customer satisfaction and will accomplish this by understanding and mitigating risks and opportunities that may affect the conformity of products and services and to assure Statutory and Regulatory requirements are identified and achieved according to the applicable clauses of the QMS Manual, Quality Procedures, and Quality Forms.

5.1.3 Quality Policy

Top Management has initiated and communicated the Quality Policy throughout the organization and made it available to relevant interested parties as appropriate. The Quality Policy is appropriate to the purpose and context of the organization and supports its strategic direction. It provides the framework for setting Quality Objectives, satisfying applicable requirements and supports the organizations commitment to continual improvement of the QMS.

TOP MANAGEMENT SHALL ENSURE THAT THE QUALITY POLICY:

- Is appropriate to the purpose of Pacific Imaging LLC.
- Includes a commitment to comply with customer and regulatory requirements and to maintain the effectiveness of the QMS.
- Provides framework for establishing and reviewing quality objectives.
- Is communicated and understood within Pacific Imaging LLC.
- Is reviewed and revised for continuing suitability at Management Review Meetings.

Quality Policy

At Pacific Imaging LLC, our commitment is to be a leader in the Sale and Distribution of digital imaging devices, that provides affordable solutions to the industries we serve.

To achieve and maintain the effectiveness of the Business Quality Management System, the Pacific Imaging LLC team follows and adheres to the intent of our company and quality policies.

5.1.3.1 Establishing the Quality Policy

The Quality Policy is appropriate to the purpose and context of the organization and supports its strategic direction. It provides the framework for setting Quality Objectives, satisfying applicable requirements and supports the organizations commitment to continual improvement of the QMS.

5.1.3.2 Communicating the Quality Policy

Top Management has initiated and communicated the Quality Policy throughout the organization and made it available to relevant interested parties as appropriate.

5.2 Roles, Responsibilities and Authorities

Top Management shall ensure that the responsibilities and authorities are defined, documented and communicated within Pacific Imaging LLC. Top Management is responsible for providing leadership and quality philosophy. The interrelationship of all personnel who manage, perform and verify work affect quality is defined and ensures the independence and authority necessary for them to perform these tasks. The Management Representative is responsible for providing QMS management and each employee is responsible for quality in their respective areas.

The Organization Chart has been established to provide the interrelation and reporting structure of personnel within the organization. The Management Representative has been appointed by the President to oversee and manage the overall effectiveness and compliance of the QMS. The Management Representative has the following Responsibility and Authority to:

- Ensure QMS conformance to ISO 9001:2015
- Ensure interaction of processes and their ability to achieve planned results

- Report to Top Management on the results achieved by the QMS, possibilities for improvements and the need of changes or innovations
- Maintain QMS integrity when planning and implementing changes
- Promote awareness of customer focus throughout the organization
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS
- Resolve all matters pertaining to quality issues

5.3 Communications

5.3.1 Internal Communications

Top Management is committed to implementing and developing the QMS and this commitment is defined by our policies, procedures and objectives. Pacific Imaging LLC ensures that our policies are understood, implemented, maintained throughout all levels of the organization through printed distribution of our policy statements and through periodic management review of policy statements and improvement objectives. Pacific Imaging LLC communicates our Quality Policy and Objectives to all employees. The Quality Manager has the authority to communicate the policy and objectives throughout the organization.

5.3.2 External Communications

The Quality Manager has the organizational freedom and unrestricted access to resolve matters pertaining to the QMS as well as to be the company liaison with external parties including customers and vendors on all matters pertaining to the QMS.

6.0 Management System Planning

6.1 Addressing Risks and Opportunities

The overall aim of Risk and Opportunity Management within Pacific Imaging LLC is to ensure that organizational capabilities and resources are employed in an efficient and effective manner to take advantage of opportunities and mitigate risks.

Top Management is responsible for



incorporating Risk Based Thinking into our Organizations culture. This includes the establishment of Risk Management Policies and Targets to ensure effective implementation of Risk and Opportunity Management Principles and Activities by:

1. Providing sufficient resources to carry out risk and opportunity management activities
2. Assigning Responsibilities and Authorities for risk and opportunity management activities
3. Reviewing information and results from audits and Risk and Opportunity Management Activities

The scope of Pacific Imaging LLC 's Risk and Opportunity Management process includes the assessment of the internal and external issues identified in Section 4.1 and the assessment of the needs and expectations of any interested parties identified in Section 4.2. Risk and Opportunity Management is undertaken as part of Pacific Imaging LLC 's daily operations and is captured within the following hierarchy:

1. Strategic Level
2. Program Level
3. Department Level
4. Process Level

Establishing such a hierarchy for capturing risk and opportunity ensures that each is managed at the most appropriate level within our organization. Typically the following categories are assigned to each level in the hierarchy as shown in the table below:

Business Hierarchy	Risk / Opportunity
Strategic Level	Budgets & Profitability
Program Level	Performance & Efficiency
Department Level	Resources & Targets
Process Level	Evaluation & Assurance

Pacific Imaging LLC classifies it's "risk" as the amount of risk that we are willing to accept in pursuit of an opportunity or the avoidance of risk where each pertains to product and or system conformity, and which reflect the following considerations:

1. Risk Philosophy
2. Capacity to take on or mitigate risk
3. Our Objectives, Business Plans and respective Stakeholder demands

6.2 Quality Objectives

Quality Objectives have been established at all corresponding levels and processes throughout the organization to implement the Quality Policy, meet and exceed requirements for products and processes and to improve the QMS and its performance.

Quality Objectives are strategic, apply to the entire Organization and shall:

- Be consistent with the Quality Policy
- Be measurable and monitored
- Take into account applicable requirements
- Be communicated
- Be updated as appropriate
- Be relevant to conformity of products, services and enhance customer satisfaction

Quality Performance Objectives are measurable targets for improving operational performance to ensure process conformity and customer satisfaction. They apply to all departments and functions having direct responsibility for activities that require improvement. Performance Objectives and Goals are established by management and through employee involvement and monitored within the framework of Management Reviews.

Pacific Imaging LLC retains documented information on the status of Quality Objectives. If shortfalls are identified, management may revise objectives, issue corrective action requests, or take other appropriate action to address the issue.

6.3 Planning for Change

When changes to the QMS are deemed necessary, Pacific Imaging LLC shall ensure the change will comply with the requirements of ISO 9001:2015 and shall consider:

- The purposes of the changes and their potential consequences
- The integrity of the QMS
- The availability of resources
- The allocation or re-allocation of responsibilities and authorities

7.0 Support

7.1 Resources

7.1.1 General

Pacific Imaging LLC is fully committed to providing adequate resources required for the establishment, implementation, maintenance and continual improvement of the QMS. Our committed resources include:

- Competent employees
- State of the industry equipment
- Well maintained work environment
- Financial Resources

The process for determining and communicating resource requirements is an integral part of our management review process. Our infrastructure resource considerations include:

- Management Review Meeting inputs and outputs
- Capabilities and constraints on existing internal and external resources
- Requirements and expectations provided by our external providers/vendors

7.1.2 People

Pacific Imaging LLC identifies personnel training needs, provides required training, and evaluates the effectiveness of training provided. Personnel assigned to perform specific tasks, operations, and processes are qualified on the basis of appropriate education, experience or training. Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of Quality Objectives. Records of personnel qualifications and training are maintained.

7.1.2.1 Competence

Pacific Imaging LLC has determined to the extent necessary the below elements of competence for people performing the work that may affect the effectiveness of the QMS:

- Ensure employees are competent on the basis of their training, education and experience.
- Initiate Job Descriptions including specific competency provisions.
- Measure employee performance on an annual basis.
- Take actions when necessary to assist employees that exhibit less than desirable results.

7.1.2.2 Awareness

Pacific Imaging LLC has determined to the extent necessary persons performing work are:

- Aware of the Quality Policy
- Aware of relevant Quality Objectives
- Aware of their contribution to the effectiveness of the QMS, including improved performance
- Implications of noncompliance to our QMS requirements

7.1.2.3 Communication

- Pacific Imaging LLC has determined internal and external communication relevant to the QMS, including the subject of the communication, when communication occurs, participant and effective ways of communication.

7.1.3 Infrastructure

Pacific Imaging LLC has determined and provided resources necessary for the establishment, implementation, maintenance and continual improvement of the QMS. Our infrastructure resource considerations include:

- Buildings, workspace and associated utilities
- Equipment (including hardware and software)
- Transportation resources
- Information and communication technology

As new infrastructure requirements are determined to be necessary they will be documented in Quality Plans and other documents as required.

7.1.4 Operational Environment

Management identifies and manages the human and physical factors of the work environment considered to be important to control processes and to achieve conformance of products and services. Evaluations include:

- Assessment of product requirements to identify where human and/or physical factors will affect product quality this is also conducted during advanced product quality planning.
- Assessment of current work environment conditions to determine if the work environment is suitable to achieve conforming product.
- Implementation of work environment improvements needed to achieve conforming product.
- Continual assessment of work environment to ensure that adequate human and physical factors are maintained.

7.1.5 Monitoring and Measurement Tools

Pacific Imaging LLC has determined the necessary monitoring, measurement and resources to be initiated across our QMS. The structure of internal resources includes but is not limited to:

- Monitoring and measurement equipment
- Documented Procedures and Forms
- Competent and Qualified Personnel

Documented procedures outline the processes that control monitoring and measurement equipment used to accept products during production and service operations. The procedures also include controls prior to and after delivery of products to our customers. Appropriate documented information is maintained and provides objective evidence of compliance and conformity.

7.1.6 Organizational Knowledge

Pacific Imaging LLC considers the specific knowledge necessary for each operation and considers this as an important resource to ensure our people and processes are consistent and will achieve conformity of the products and services provided by the Organization. Specific Organizational knowledge is defined, maintained and available to the extent necessary within appropriate procedures.

8.0 Operations

8.1 Operational Planning and Control

Pacific Imaging LLC defines the expectation and implements controls for each of our QMS processes. The planning of controls is required to ensure consistent acceptability of products and services. Planning processes include the definition of Quality Objectives, development for required processes, establishment for appropriate verification programs, and the requirement for records necessary to demonstrate the products and processes conform to intended requirements. Operational planning and control is required prior to new and or revised products or processes being implemented. During the Planning phase management shall identify:

- Requirements for the products or services
- Criteria for the processes and the acceptance of products and services
- Resources needed to achieve conformity to the product or service requirements
- Control of the processes in accordance with the criteria
- Documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of the products and services to their requirements

The output of operational planning and control includes documented Quality Plans, resource requirements, processes, equipment requirements, procedures, test data, and design outputs.

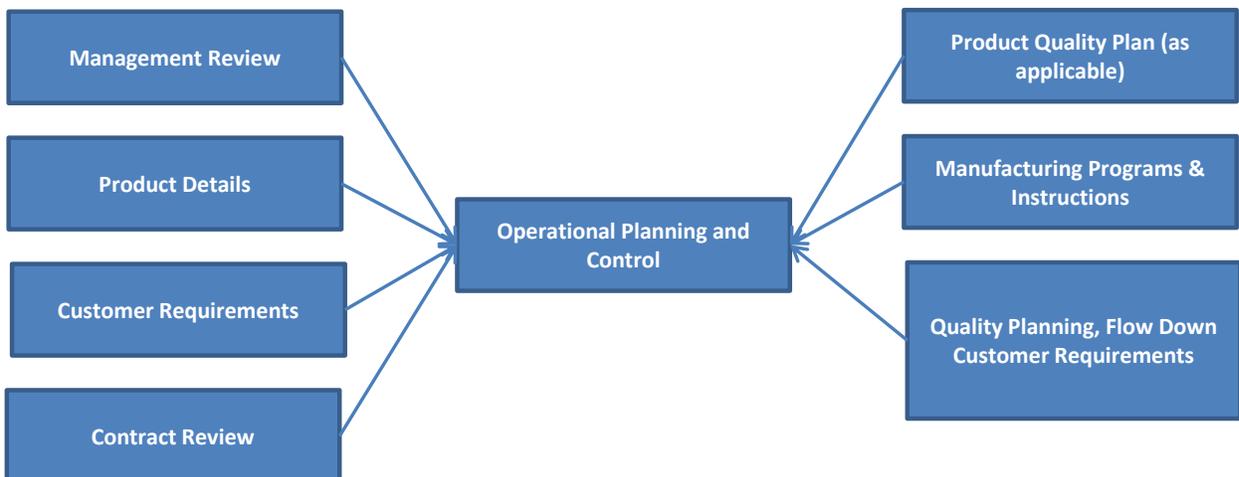


Fig. 5 Operational Planning and Control

8.2 Customer Requirements

8.2.1 Customer Communications

Pacific Imaging LLC has implemented an effective system for with customers, the system includes but is not limited to:

- Information relating to product and service information
- Inquiries, contracts, and order handling, including amendments
- Customer Feedback, including customer complaints
- Specific requirements for contingency actions when relevant

8.2.2 Determination of Requirements

Pacific Imaging LLC requires that all customer specific requirements for products and services are clearly defined by the customer including but not limited to:

- Applicable statutory and regulatory requirements
- Requirements considered necessary by Pacific Imaging LLC
- Acceptance that Pacific Imaging LLC can meet the products and services provided

8.2.3 Review of Requirements

Pacific Imaging LLC ensures we have the ability to meet the requirements for products and services to be offered to customers. Management conducts a contract / product review prior to committing to supply products and services to a customer. The review process at a minimum consists of the following:

- Requirements specified by the customer including requirements for delivery and post-delivery activities
- Requirements not stated by the customer but necessary for the intended use when known
- Requirements specified by the organization
- Statutory and regulatory requirements applicable to the products and services
- Contract or order requirements differing from those previously expressed

Pacific Imaging LLC ensures contracts, purchase orders or other requirements differing from those previously defined are reviewed and approved prior to incorporating into our business systems. We retain applicable documented information of the initial review and any new/revised customer or applicable external party requirements for the product or service provided.

8.2.4 Changes in Requirements

Pacific Imaging LLC ensures relevant documented information is amended and that relevant persons are made aware of the changes to requirements, when the requirements for products and services are changed.

8.3 Design and Development of Products

8.3.1 General

Pacific Imaging LLC employs a stage gate approach to the performance of Design and Development activity. The Design and Development shall take into account customer needs, Design Inputs, Regulatory and Statutory requirements.

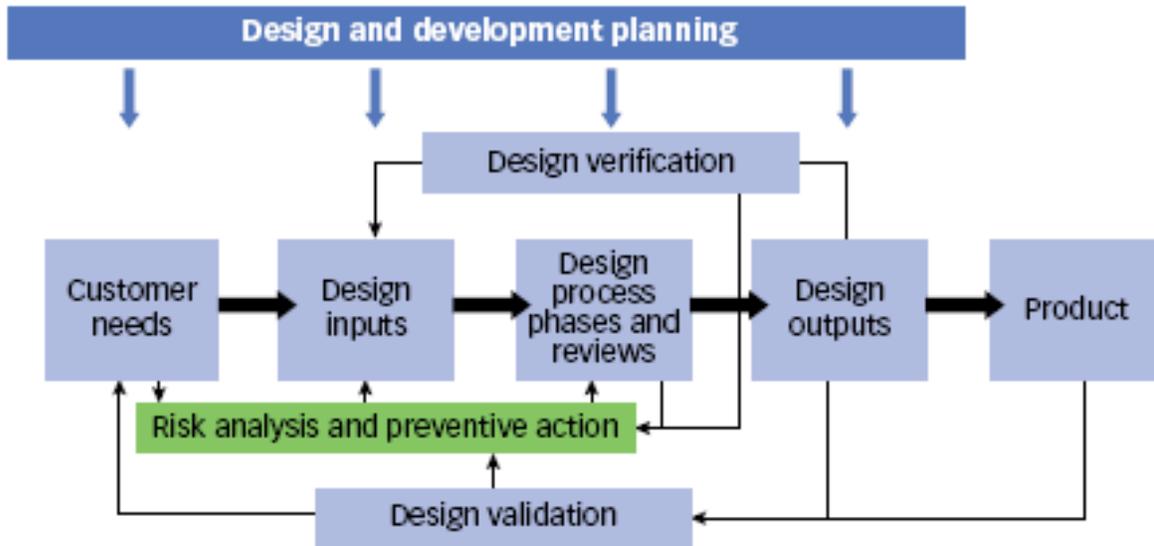


Fig. 6 Design and Development Process

8.3.2 Design and Development Planning

The Design team shall plan and control the design and development and risk management of product at all phases. All regulatory requirements must be determined at the initial stages of contract review and acceptance.

- a) Design and development stages, including responsibilities and authorities, action plans and assignments.
- b) Review, verification, and validation as appropriate to each design and developmental stages.
- c) Responsibilities and authorities for design and development.

The Design team shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be documented, and updated as appropriate, as the design and development progresses.

8.3.3 Design and Development Inputs

Inputs relating product requirements shall be determined and records maintained. These inputs include:

- a) Functional, performance and safety requirements according to intended use,
- b) Applicable statutory and regulatory requirements,

- c) Information derived from previous similar designs, and inputs shall be reviewed for adequacy,
- d) Other requirements essential for design and development, and
- e) Output(s) of risk management.

Requirements shall be complete, unambiguous and not in conflict with each other.

8.3.4 Design and Development Controls

Product Design and Development activities will be controlled through verification at various stages of the process. Verifications shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Validation shall be completed prior to the delivery or implementation of the product.

Records of the results of validation and any necessary actions shall be maintained.

8.3.5 Design and Development Outputs

The outputs of design and development shall be provided in a form suitable that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall:

- a) Meet the input requirements for design and development
- b) Provide appropriate information for purchasing, production and for service provision,
- c) Contain or reference product acceptance criteria, and
- d) Specify the characteristics of the product that are essential for its safe and proper use.

Records of the design and development outputs shall be maintained

8.3.6 Design and Development Changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained

8.4 Control of Suppliers and External Processes

8.4.1 General

Pacific Imaging LLC maintains responsibility for the quality of all products purchased from external providers, excluding customer designated sources. Procedures ensure products and services being

provided by external sources will conform to our customer's requirements. Examples of our controls include:

- A documented Approved Vendor List (AVL)
- The review of external providers performance

8.4.2 Purchasing Controls

Pacific Imaging LLC uses Purchase Orders to define the product or services to be purchased. Purchase Orders are created using Proprietary Software system, by designated people within the organization.

Pacific Imaging LLC ensures that externally provided processes, products and services do not adversely affect our ability to consistently deliver conforming products and services to our customers. Vendors demonstrating inadequate performance will be required to implement corrective actions. Poor performing vendors will be replaced.

The type and extent of control depends upon the supplier / material. The Purchasing Manager, President, Design Team Personnel or Material Planner is responsible to select new suppliers. Whenever necessary other personnel are also involved in the selection and evaluation of suppliers. Record of evaluations and any necessary actions arising from the evaluation shall be maintained:

- Consideration to Supplier's capability to meet Pacific Imaging LLC 's quantity and quality requirements.
- Initial approval of new suppliers and subsequent monitoring by the joint effort of Purchasing and other departments.

8.4.3 Purchasing Information

Purchasing documents are reviewed for adequacy and approved by purchasing personnel prior to release. Purchasing documents clearly describe the product or service to be provided.

The Purchasing Department is responsible for issuing purchase orders and maintaining relevant documentation. Purchasing information shall describe the product to be purchased, including where appropriate:

- Any specific quality / regulatory requirements.
- Information such as P.O. number, part number, quantity ordered and the delivery schedule.
- Parts are ordered per blueprint.

Pacific Imaging LLC shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

To the extent required for traceability, Pacific Imaging LLC shall maintain relevant purchasing information, i.e. documents and records.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Pacific Imaging LLC plans and implements production and service provision under controlled conditions and as required by specific job requirements. Examples of controls include:

- Availability of information that define characteristics and results to be achieved
- Availability of competent and effectively trained personnel and adequate equipment
- Availability and use of suitable monitoring and measurement equipment and resources
- Evidence that all manufacturing and inspection operations have been completed as planned

Production is typically defined as procurement of assemblies from external providers and packaging as a final assembly for shipment to the end user.

Service provisions include warranty, service, maintenance, returns and training.

8.5.2 Identification and Traceability

Pacific Imaging LLC identifies parts and products by suitable means throughout production. Marking methods will be described in the applicable operations procedures for affected departments. Where traceability is a requirement, the organization controls and records the unique identification of the outputs. According to the level of traceability required by contract, regulatory or other established requirement, our procedures provide for the following:

- Identification to be maintained throughout the processes including delivery and post-delivery
- Identification of sub-components and those of the next higher assembly

8.5.3 Property Belonging to Customers or External Providers

Pacific Imaging LLC exercises care with property belonging to customers or external parties while it is under our control or being used. Procedures are established for the control, storage, maintenance and accounting of customer / government furnished materials, tooling, and equipment including data used for design, production and or inspection provided to the organization for the performance of work under a specific contract or contracts.

8.5.4 Preservation

Pacific Imaging LLC preserves the conformity of parts and products during internal processing and delivery to intended destination including outside services. Procedures include instructions for identification, handling, packaging, storage and protection. Preservation of outputs also includes, where applicable:

- Cleaning
- Prevention, Detection and Removal of Foreign Objects
- Special handling for sensitive outputs
- Marking and labeling including safety warnings

- Special Handling for hazardous materials

The shipping department ensures that documents required by the contract / order to accompany the product are present at time of delivery and are protected against loss or deterioration.

8.5.5 Post-Delivery Activities

Pacific Imaging LLC maintains documented information of all products delivered to our customers. The extent of post-delivery activities includes consideration of our customer's requirements and received feedback.

8.5.6 Control of Changes

Pacific Imaging LLC shall review and control changes for production or service operations to the extent necessary to ensure continuing conformity of customer or internal requirements. Changes for production may be initiated as a result of:

- Modernization based on the context of the organization analysis results
- Needs of interested parties or customer feedback
- Manufacturing department when vulnerability is detected or opportunities for improvement are identified

Management reviews and monitors changes that affect production or outside services and ensures change documentation and information is distributed and controlled. Records of results of the review of changes, the person authorizing the change and any necessary actions arising from the review are maintained in accordance with applicable procedures.

8.6 Release of Products and Services

Pacific Imaging LLC monitors and measures the characteristics of the product in Receiving Inspection, In-Process Inspection and Final Inspection to verify that requirements have been met. Documented procedures have been established for product inspection. Documented records and information of inspections include evidence of conformity with the acceptance criteria and traceability to the person authorizing release. Records of inspection are maintained.

8.7 Control of Nonconforming Process Outputs, Product and Services

Pacific Imaging LLC ensures that products or services that do not conform to established requirements are identified and controlled to prevent their unintended use or delivery. Records of nonconformities are maintained and include the following:

- Description of nonconformity
- Description of actions taken
- Description of concessions obtained
- Identification of the authority deciding the action in respect to the nonconformity.

When nonconforming product is corrected it is re-inspected to the original specifications and requirements to ensure it conforms to customer stated requirements. When a nonconforming condition is identified after delivery, Pacific Imaging LLC will take appropriate action according to the effects or potential effects of the nonconformity.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

The objectives of Monitoring, Measurement, Analysis and Evaluation are:

- Process Criteria
- Product Characteristics
- Performance and effectiveness of the QMS

Results from monitoring and measurement are evaluated. Informational reports are presented to management for general review and making decisions on opportunities for improvement.

9.1.2 Customer Satisfaction

Pacific Imaging LLC monitors information relating to customer perception of our continual ability to fulfill their requirements. Maintaining customer satisfaction is one of the principal objectives of the QMS. Collecting and analyzing customer feedback and complaints, and customer satisfaction is conducted during Management Review. Customer Satisfaction is used by management to identify opportunities for improvement.

9.1.3 Analysis and Evaluation

Pacific Imaging LLC performs necessary analysis and evaluates appropriate data and information initiated from monitoring and measurement and uses the results to evaluate conformity of products and services, customer satisfaction, performance of the QMS, performance of external providers, and the need for improvement of the QMS.

9.2 Internal Audit

Pacific Imaging LLC plans and conducts internal audits at planned intervals. Internal audits are conducted to verify Quality activities and related comply with planned expectations including customer contractual requirements and other QMS requirements as deemed necessary and applicable. The Management Representative is responsible for organizing and coordinating the internal audit to ensure that the audit scope, frequency, and methods are defined and the following requirements are satisfactorily achieved:

- Definition of audit responsibilities

- Definition of requirements for planning and conducting the audit including taking appropriate corrective actions without undue delays
- Assurance of auditor independence
- Communication of audit results to management

9.3 Management Review

9.3.1 General

Pacific Imaging LLC Management Review process is planned and includes the following considerations:

9.3.2 Inputs

Assessment of the QMS is based upon a review of information inputs to the Management Review. Input examples include:

- The status of actions from the previous Management Review
- Changes in external and internal issues that are relevant to the QMS
- Customer satisfaction and feedback from relevant interested parties
- The extent to which Quality Objectives have been met
- Process performance and conformity of products and services
- Nonconformities and corrective actions
- Audit results

In addition Management Review Inputs shall include the adequacy of Resources, the effectiveness of actions taken to address Risks and Opportunities and opportunities for improvement. Results of Management Reviews shall be maintained.

9.3.3 Outputs

Management Review Outputs include decisions and actions related to the following:

- Opportunities for improvement
- Changes needed to the QMS
- Resource needs

Management Review documents and information shall be recorded and maintained.

10.0 Improvement

10.1 General

Pacific Imaging LLC determines and selects opportunities for improvements and implements necessary actions to meet customer requirements and enhance customer satisfaction. Examples of Improvement include:

- Improving products and services to meet requirements as well as to address future needs and expectations
- Correcting, preventing, and reducing undesired effects
- Improving the performance and effectiveness of the QMS

10.2 Nonconformity and Corrective Action

Pacific Imaging LLC initiates actions to eliminate the cause of nonconformities in order to prevent recurrence. Corrective Actions are appropriate to the effects of the nonconformities encountered. When nonconformity occurs, corrective action procedures are initiated and implemented. Examples of actions taken include:

- Taking action to control and correct nonconformity
- Reviewing and analyzing the nonconformity
- Determining the causes of nonconformity
- Determining if similar nonconformities exist, or could potentially occur
- Implementation of any action needed
- Review of the effectiveness of any corrective actions taken
- Updating Risks and Opportunities determined during planning if necessary
- Making changes to the QMS if necessary

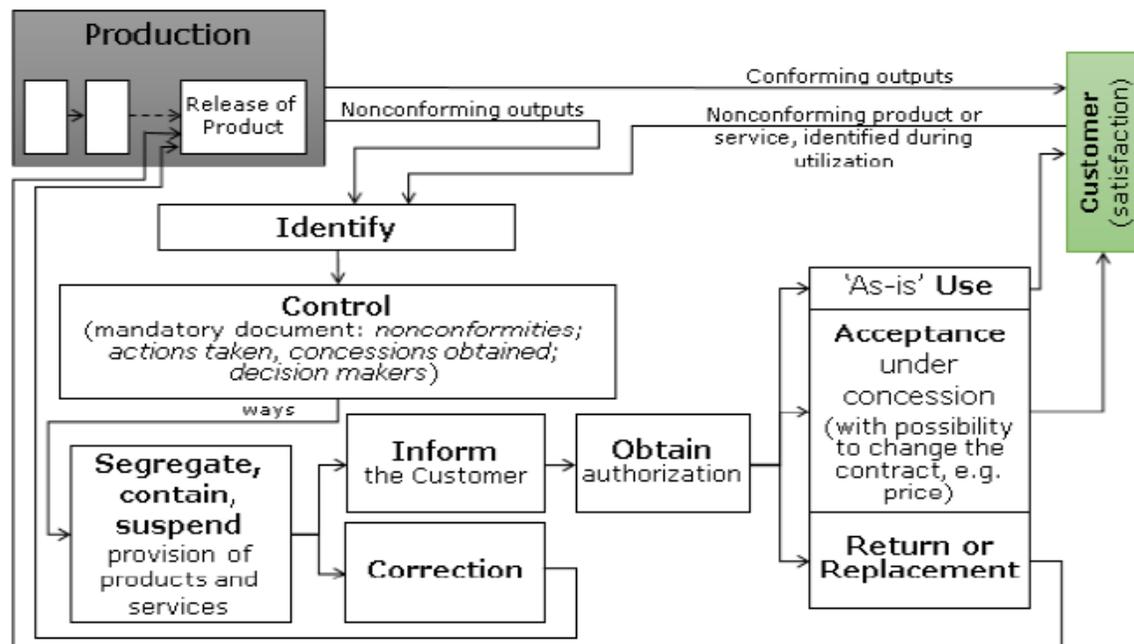
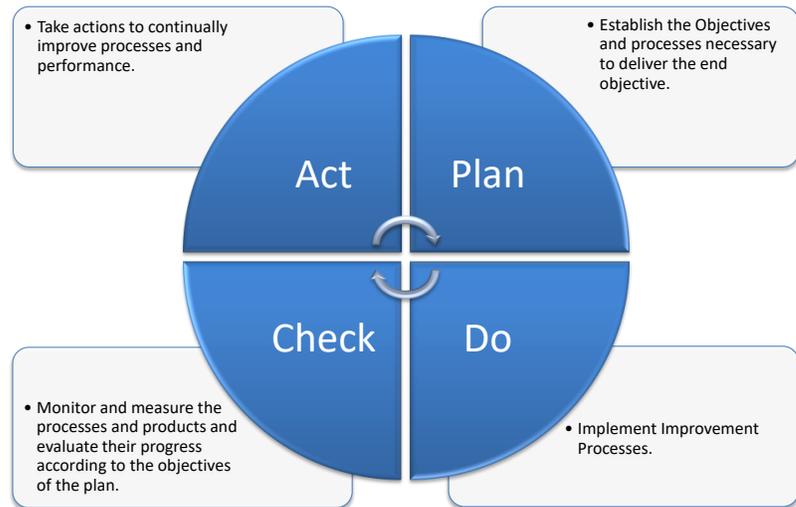


Fig. 7 Control of Nonconforming Outputs

10.3 Continual Improvement

Pacific Imaging LLC initiates actions to continually improve the suitability, adequacy and effectiveness of the QMS. Continual improvement techniques and processes are applied to areas of the business that have an impact on the quality of our products and services. We analyze and take necessary actions on the results of improvement projects which are documented as inputs into the Management Review Meetings, as well as from Management Review Outputs. The implementation of the “Process Approach” including the PDCA Cycle provides verifications that our QMS is robust, and the achievement of effective process performance.



Appendix

A1 - Correlation Matrix

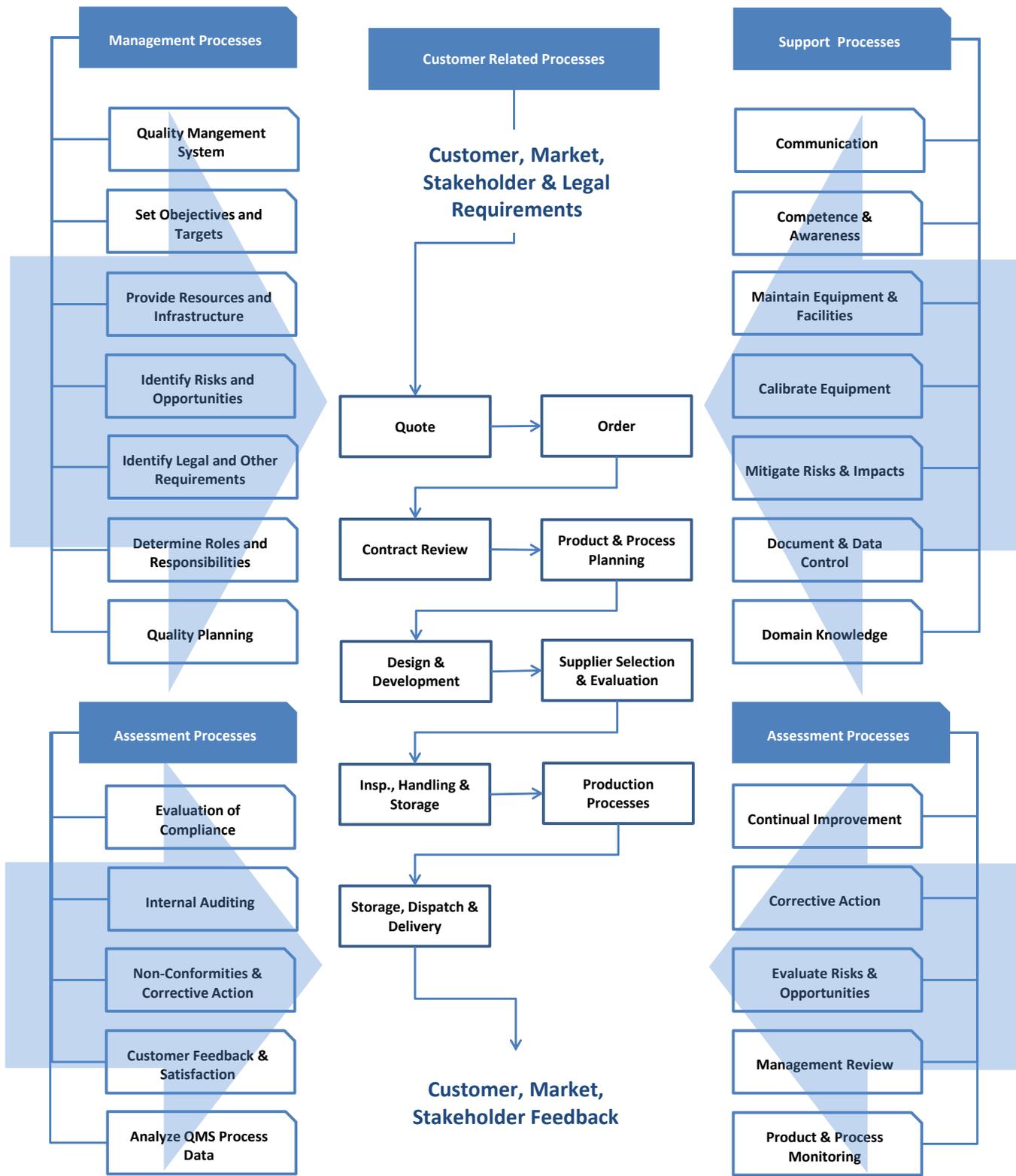
This Section provides a Matrix to correlate the requirements of ISO 9001:2015 against the relevant sections in this document.

ISO 9001:2015	This Document
4.0 Context of the Organization	4.0 About Our Organization
4.1 Understanding the Organization and its Context	4.1 Organizational Context
4.2 Needs and Expectations of Interested Parties	4.2 Relevant Interested Parties
4.3 Scope of the Quality Management Systems	4.3.1 Management System Scope
4.4 Quality Management System and its Processes	4.3.2 Management System Processes
5.0 Leadership	5.0 Leadership and Governance
5.1 Leadership and Commitment	5.1 Leadership and Commitment
5.1.1 Quality Management System	5.1.1 Quality Management System
5.1.2 Customer Focus	5.1.2 Customer Focus
5.2 Quality Policy	5.1.3 Quality Policy
5.2.1 Establishing the Quality Policy	5.1.3.1 Establishing the Quality Policy
5.3 Roles and Responsibilities	5.2 Roles, Responsibilities and Authorities
6.0 Planning for the Quality Management System	6.0 Management System Planning
6.1 Actions to Address Risk and Opportunities	6.1 Addressing Risk and Opportunities
6.2 Quality Objectives and Planning to Achieve Them	6.2 Quality Objectives
6.3 Planning of Changes	6.3 Planning for Change
7.0 Support	7.0 Support
7.1 Resources	7.1 Resources
7.1.1 General	7.1.1 General
7.1.2 People	7.1.2 People
7.1.3 Infrastructure	7.1.3 Infrastructure
7.1.4 Environment for the Operation of Processes	7.1.4 Operational Environment
7.1.5 Monitoring and Measuring Resources	7.1.5 Monitoring and Measuring Tools
7.1.6 Organizational Knowledge	7.1.6 Organizational Knowledge
7.2 Competence	7.1.2.1 Competence
7.3 Awareness	7.1.2.2 Awareness
7.4 Communication	7.1.2.3 Communication
7.5 Documented Information	4.3.2.1 Documented Information

ISO 9001:2015	This Document
7.5.2 Creating and Updating	4.3.2.2 Creating and Updating
7.5.3 Control of Documented Information	4.3.2.3 Control of Documented Information
8.0 Operation	8.0 Operations
8.1 Operational Planning and Control	8.1 Operational Planning and Control
8.2.1 Customer Communications	8.2.1 Customer Communications
8.2.2 Determining Requirements Related to Products	8.2.2 Determining Requirements
8.2.3 Review of Requirements Related to the Products	8.2.3 Review of Requirements
8.2.4 Changes to Requirements for Products / Services	8.2.4 Changes to Requirements
8.3 Design and Development of Products	8.3 Design and Development of Products
8.3.1 General	8.3.1 General
8.3.2 Design and Development Planning	8.3.2 Design and Development Planning
8.3.3 Design and Development Inputs	8.3.3 Design and Development Inputs
8.3.4 Design and Development Controls	8.3.4 Design and Development Controls
8.3.5 Design and Development Outputs	8.3.5 Design and Development Outputs
8.3.6 Design and Development Changes	8.3.6 Design and Development Changes
8.4 Externally Provided Products and Services	8.4 Control of Suppliers and External Processes
8.4.1 General	8.4.1 General
8.4.2 Type & Extent of Control of External Provision	8.4.2 Purchasing Controls
8.4.3 Information for External Providers	8.4.3 Purchasing Information
8.5 Production and Service Provision	8.5 Production and Service Provision
8.5.1 Control of Production and Service Provision	8.5.1 Control of Production and Service Provision
8.5.2 Identification and Traceability	8.5.2 Identification and Traceability
8.5.3 Customer or External Providers Property	8.5.3 Property Belonging to Customers or External Providers
8.5.4 Preservation	8.5.4 Preservation
8.5.5 Post Delivery Activities	8.5.5 Post Delivery Activities
8.5.6 Control of Changes	8.5.6 Control of Changes
8.6 Release of Products and Services	8.6 Release of Products and Services
8.7 Non-Conforming Process Outputs and Products	8.7 Control of Non-Conforming Process Outputs, Products and Services
9.0 Performance Evaluation	9.0 Performance Evaluation
9.1 Monitoring, Measurement, Analysis and Evaluation	9.1 Monitoring, Measurement, Analysis and Evaluation
9.1.1 General	9.1.1 General

ISO 9001:2015	This Document
9.1.2 Customer Satisfaction	9.1.2 Customer Satisfaction
9.1.3 Analysis and Evaluation	9.1.3 Analysis and Evaluation
9.2 Internal Audit	9.2 Internal Audit
9.3 Management Review	9.3 Management Review
9.3.1 General	9.3.1 General
9.3.2 Management Review Inputs	9.3.2 Inputs
9.3.3 Management Review Outputs	9.3.3 Outputs
10.0 Improvement	10.0 Improvement
10.1 General	10.1 General
10.2 Non-Conformity and Corrective Action	10.2 Non-Conformity and Corrective Action
10.3 Continual Improvement	10.3 Continual Improvement

A2 – Sequence and Interaction of Processes



A3 – Organizational Chart