

Ameritube LLC
1000 N. Hwy 77, Hillsboro TX 76645

Revision Level:
E

Procedure No.
QM-001

Revision Date:
11/1/18

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Date	Description Of Change	Signature	Rev. Level
4/30/2012	ALL	Jeremy Wilson	A
8/9/2012	Revised Quality Policy and added 1.7.1	Jeremy Wilson	B
4/23/12	Adjusted paragraph numbering starting at 8.0	Joseph Ravitsky	C
10-29-13	Changed scrap percentage to yield percentage 1.4; added an amended document to reflect calibration times 7.12; changed time set for Management Review 5.7; added clause for customer satisfaction survey 8.2.1; added stipulations for internal audit times and insurance of auditor to not audit his/her own work 8.2.2	Shawn Franks	D
11/1/18	Updating to ISO 9001:2015 Standard as reference document 2.7, 4.8.1,	Joseph Ravitsky	E

Procedure Approval:

Company Title:

Date:

Quality Manager

4/30/2012

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Introduction

1.1. Purpose of Ameritube LLC

Ameritube LLC developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of Ameritube LLC meets the requirements of the international standard ISO 9001 (2008). This system addresses the design, development, and servicing of the company's products.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

1.2. Scope of this Document

This document establishes company policy, process requirements and operational procedures for Ameritube LLC quality management system. This quality management system is prepared, implemented and maintained in accordance with the requirements of ISO 9001 (2008), with the exclusion of the design element.

1.3. Quality Policy

Ameritube LLC is committed to the quality management system and will comply with its requirements and continually improve system effectiveness in meeting customer expectations.

- 1.3.1. Ameritube LLC believes customer satisfaction is directly related to satisfying all design requirements, on time delivery, documentation and pricing. These items are measurable and data is used to improve the quality process.
- 1.3.2. Every employee understands that they are directly responsible for quality and customer satisfaction. Employees use the quality management system daily as they perform their assigned functions.

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1.4. Quality Objectives

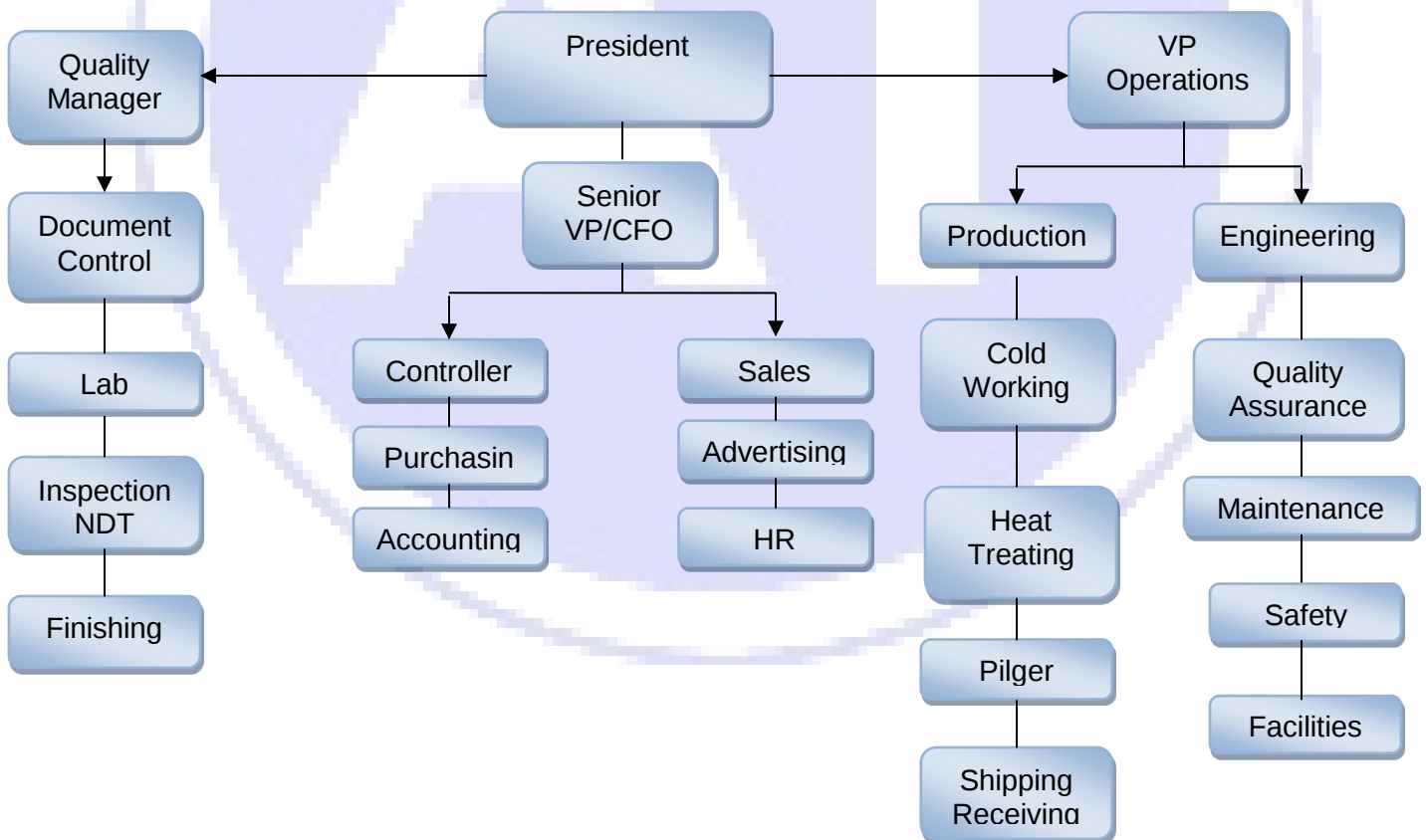
Objectives for the quality management system have been communicated through the president of Ameritube LLC. These measurable quality objectives include:

- All personnel are committed to understand and comply with the established policies, requirements and procedures referenced in this document, as applicable to their areas of responsibilities
- On time delivery at 95% or better
- Customer returns of nonconforming material less than 2%
- Critical suppliers will be approved, 100%
- Yield will be no less than 80% of total production
- All critical measuring equipment will be maintained on an established calibration cycle
- Corrective and preventive actions will be addressed within 5 working days and resolved within 10 working days, longer, if the situation requires additional time, as agreed upon by all parties involved

1.5. Customer Focus

Ameritube LLC's vision is to be our customer's preferred "Supplier-of-Choice" by striving to be the best at what we do. Ameritube LLC will build and maintain a relationship with our suppliers and customers to ensure that quality is never compromised.

1.6. Organization Chart



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1.7. Ameritube LLC is broken down into 4 core processes:

1.7.1. Management

Process Name	Quality Manual Para.	Quality Management System
Document Control	4.8.3	QMS-002
Record Control	4.8.4	QMS-003
Internal Audit	8.8.2	QMS-004
Corrective Action	8.11.2	QMS-006
Preventive Action	8.11.3	QMS-007

1.7.2. Product Realization Process QMS-008

1.7.2.1. Sales

Process Name	Quality Management System	QMS Paragraph
Inside Sales	QMS-008	5.4 – 5.15
Purchase Order	QMS-008	5.10

1.7.2.2. Production

Process Name	Quality Management System	QMS Paragraph
Job Traveler Process	QMS-008	5.16
Manufacturing Process	QMS-008	5.45
Inspection Process	QMS-008	5.53
Nonconforming Product Process	QMS-005	

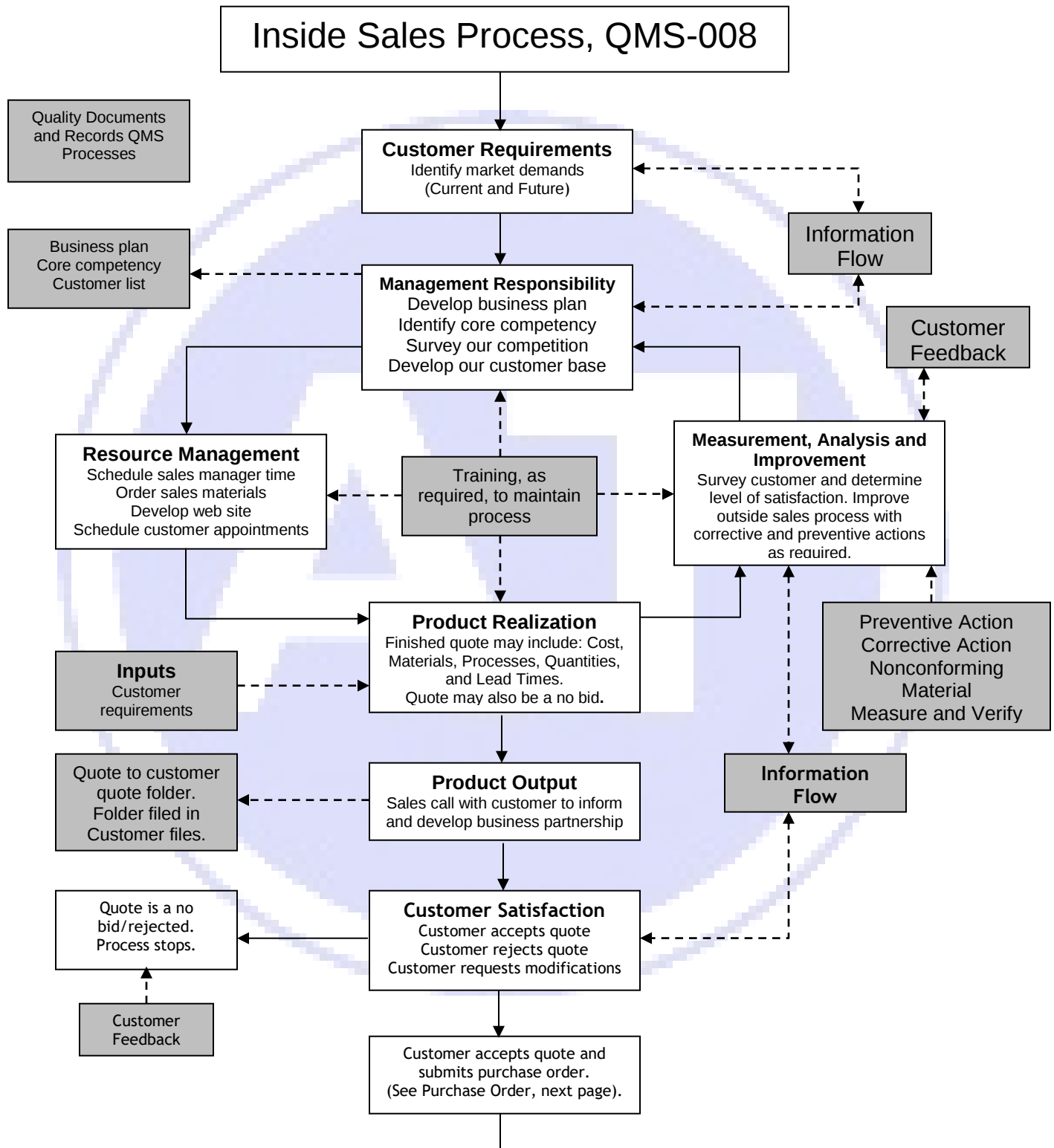
1.7.2.3. Supply Chain

Process Name	Quality Management System	QMS Paragraph
Purchasing Process	QMS-009	
Receiving Process	QMS-008	5.77
Shipping Process	QMS-008	5.85

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1.7. Product Realization Process cont.

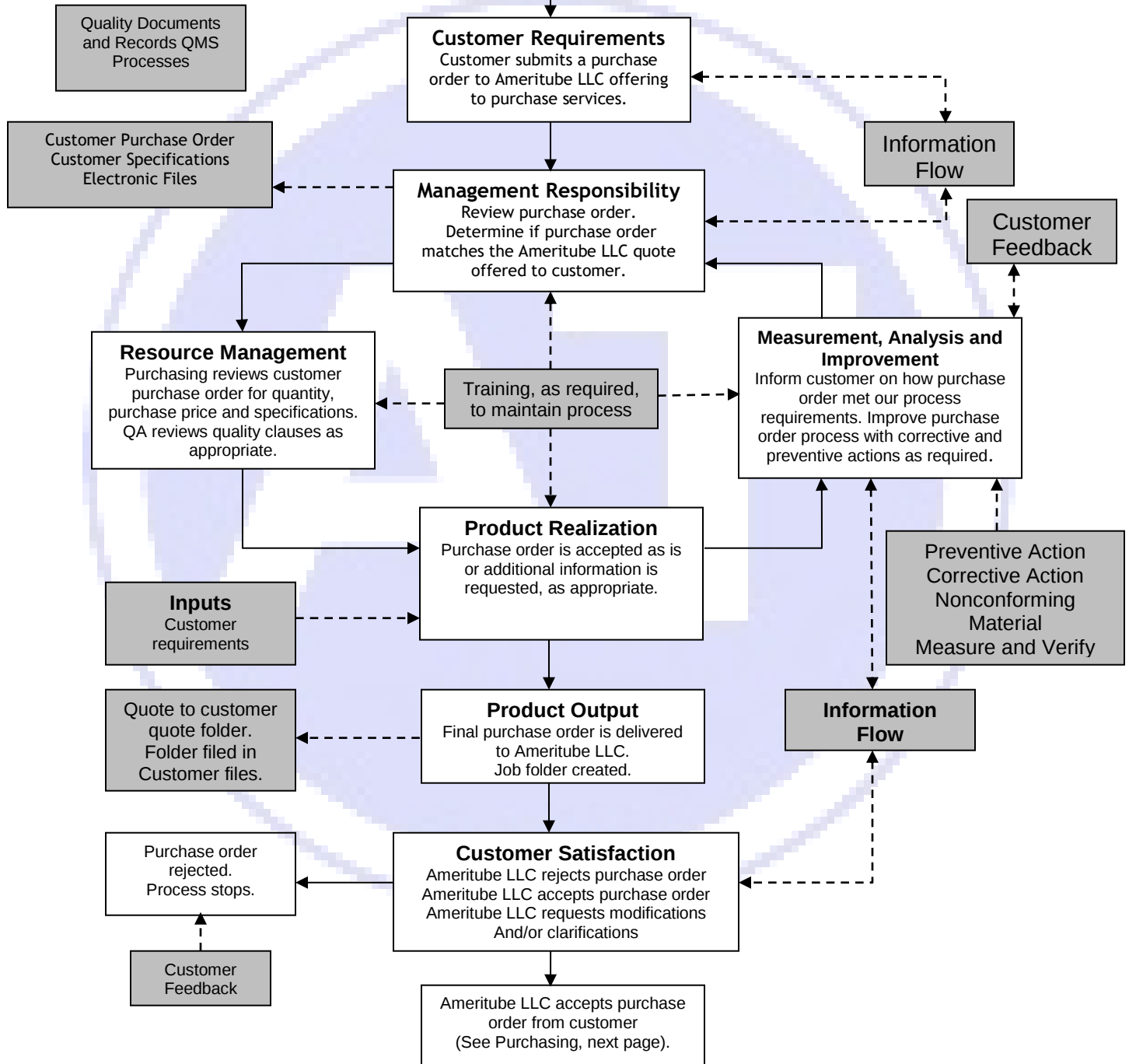


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1.7. Product Realization Process Cont.

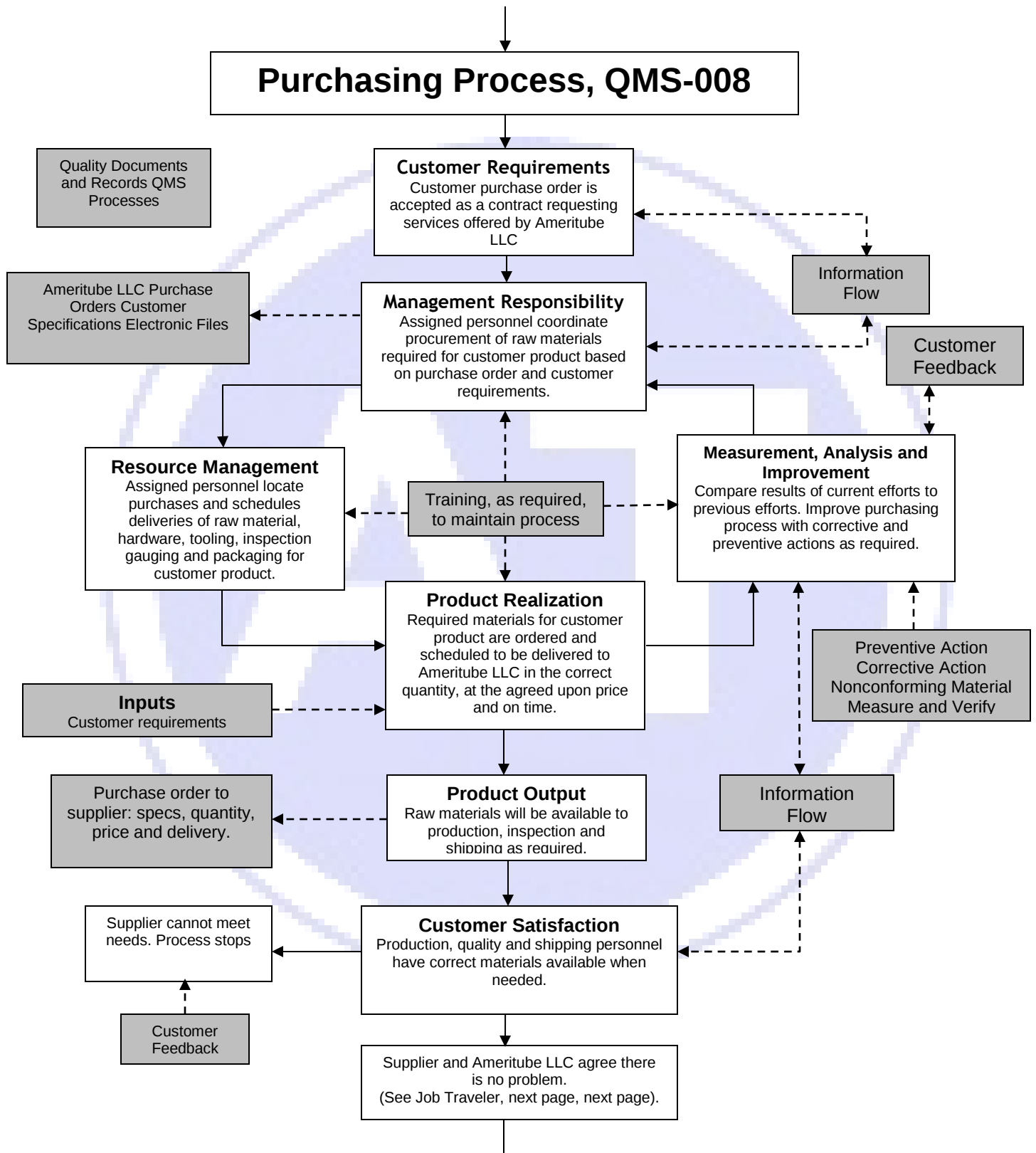
Purchase Order Process, QMS-008



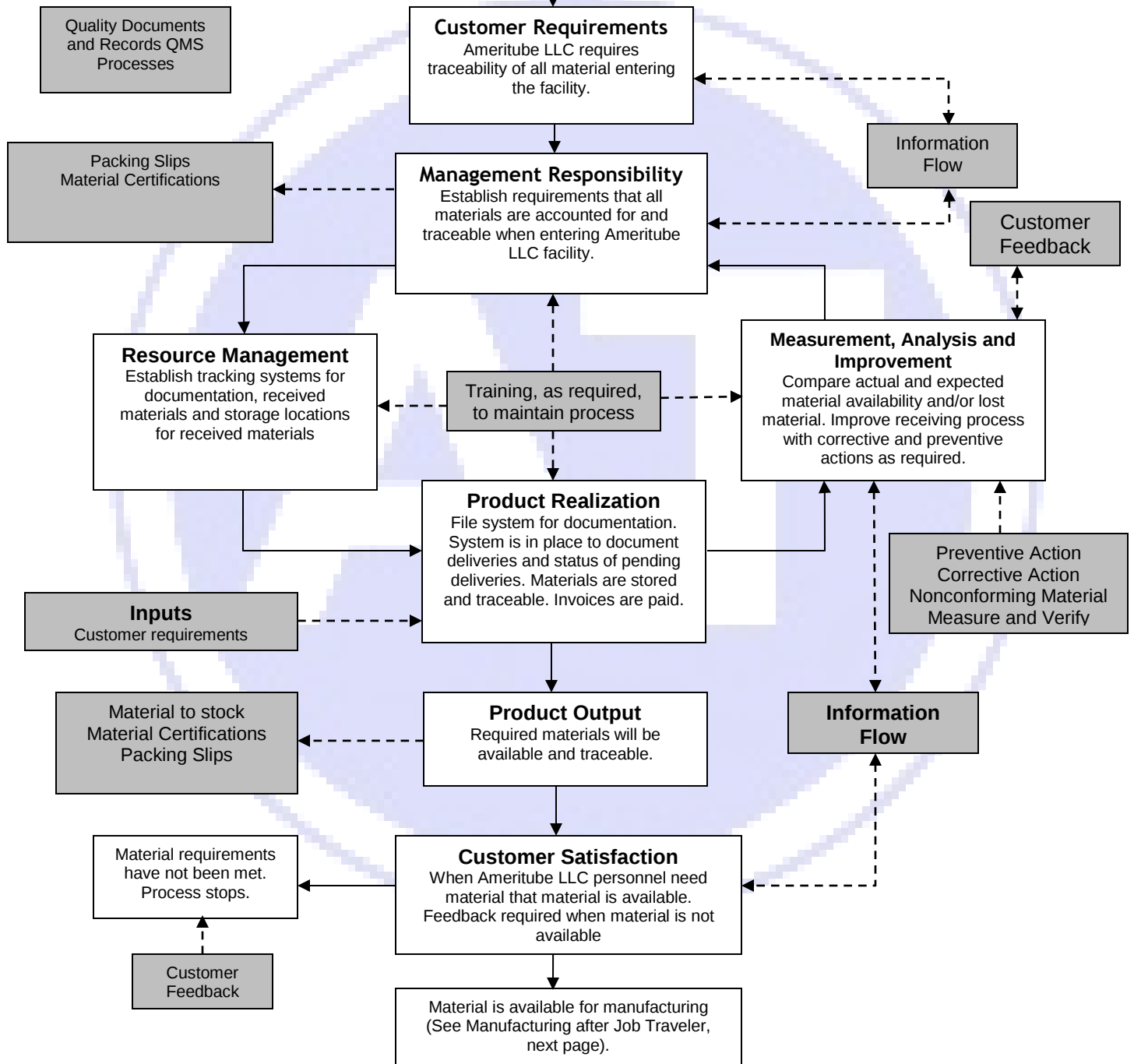
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1.7. Product Realization Process



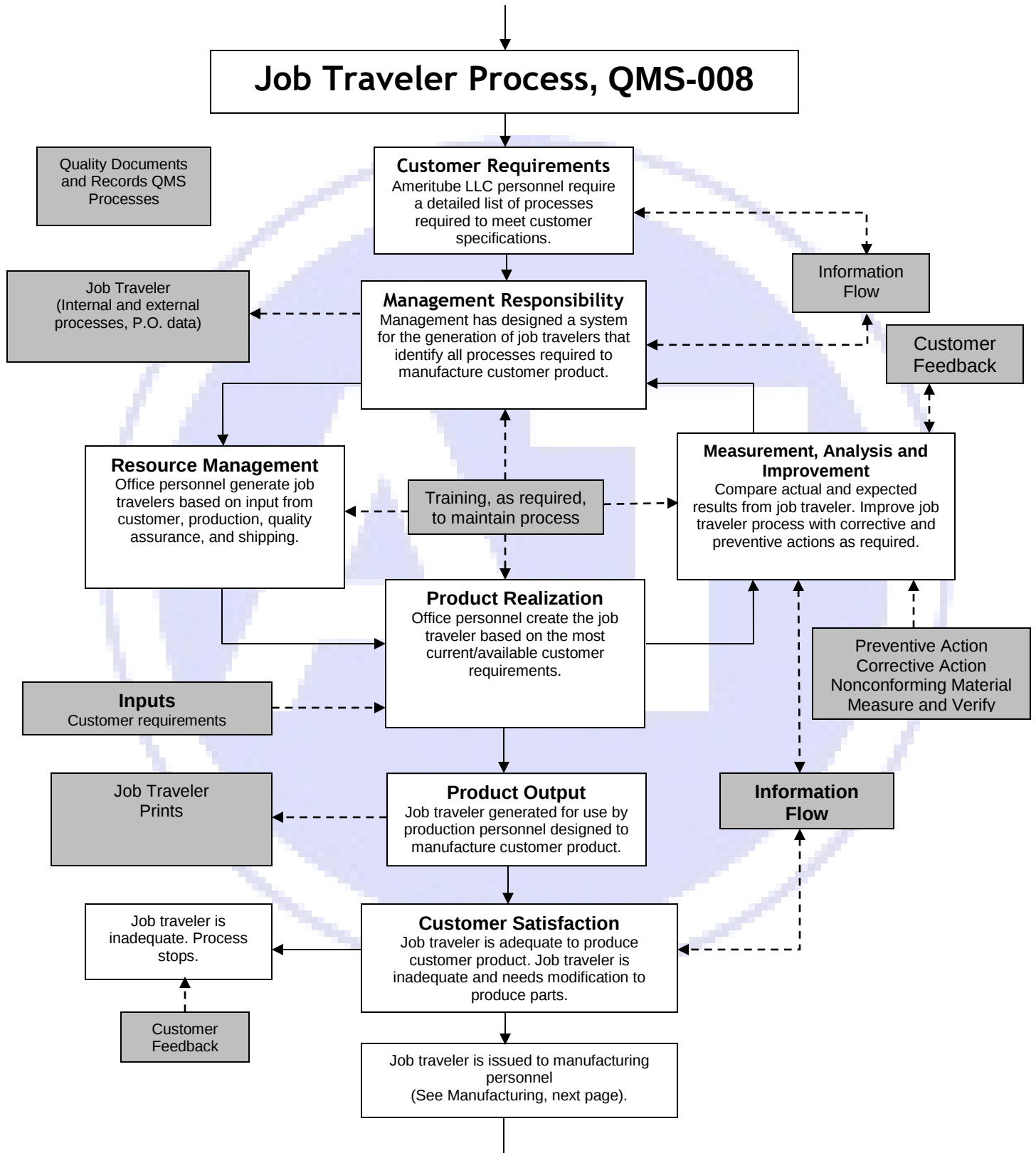
Receiving Process, QMS-008



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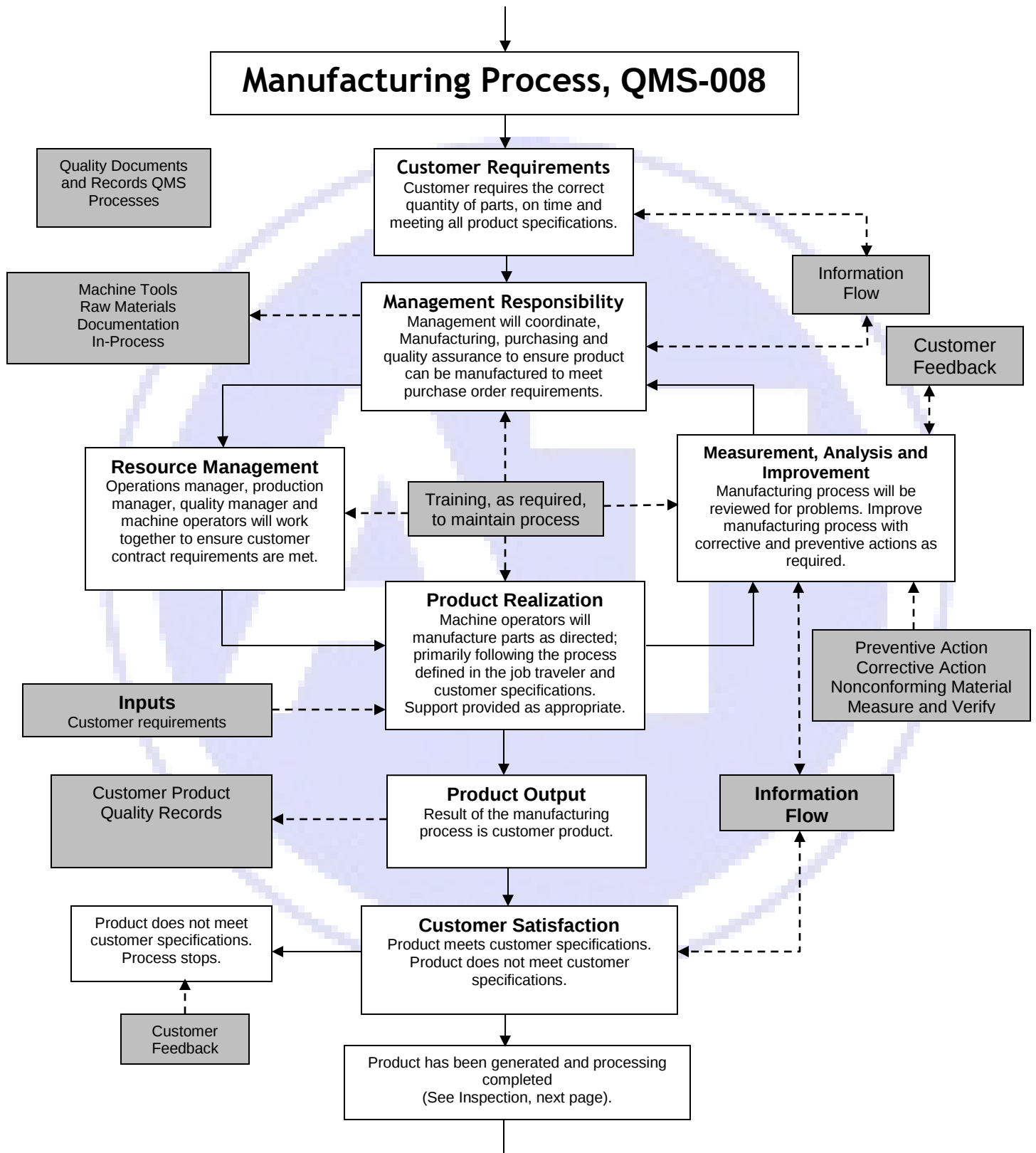
1.7. Product Realization Process



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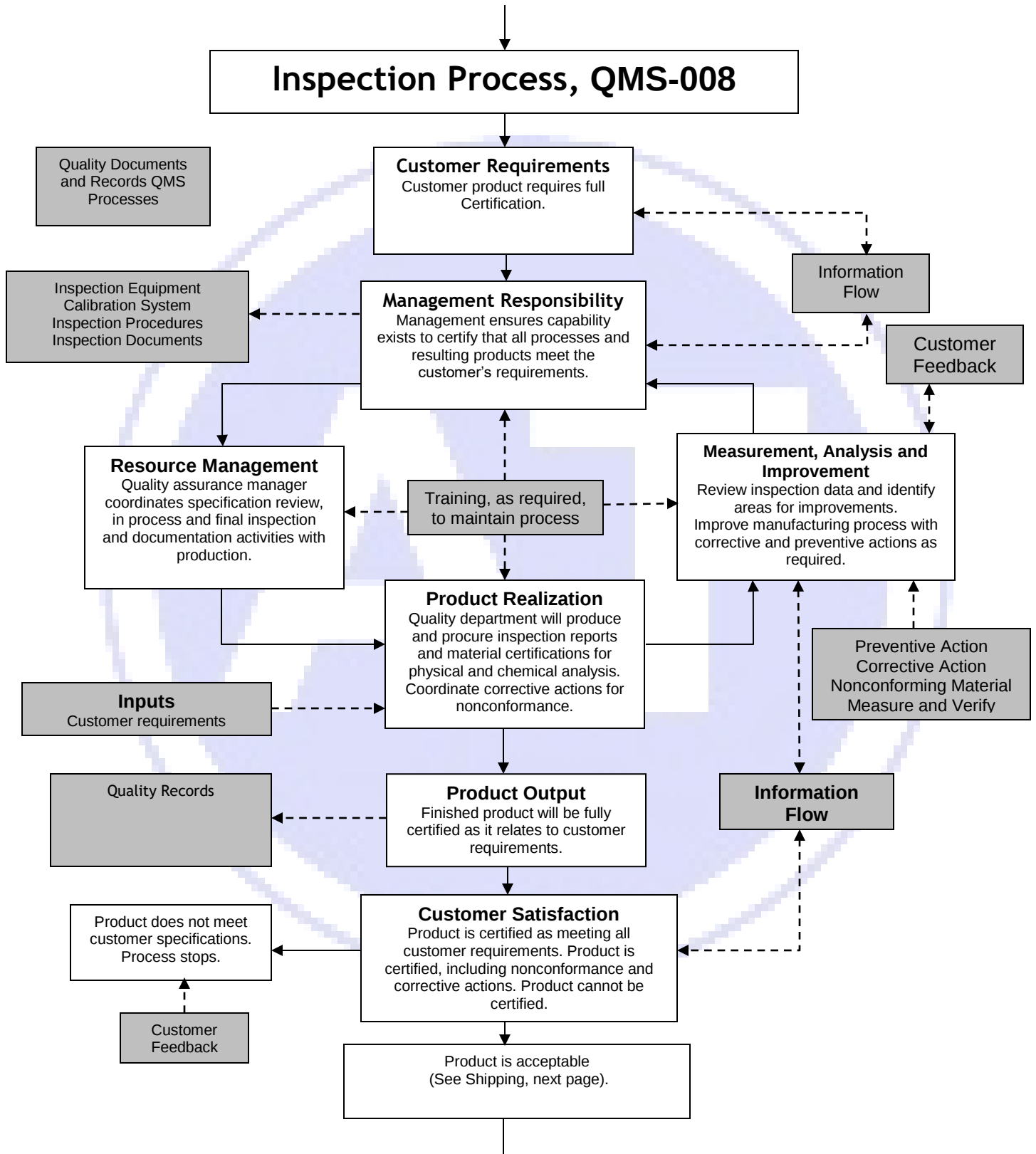
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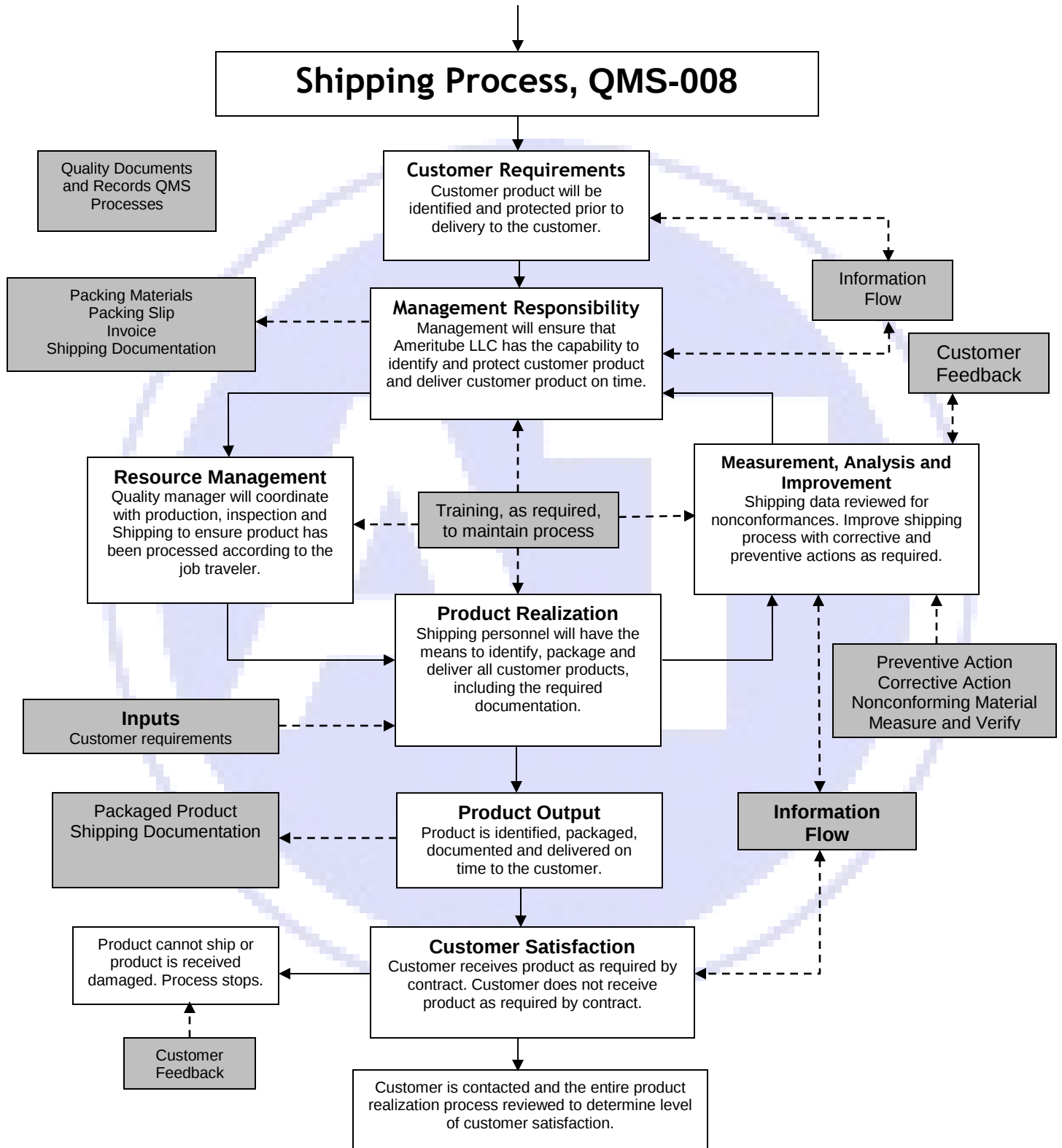


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1.7. Product Realization Process



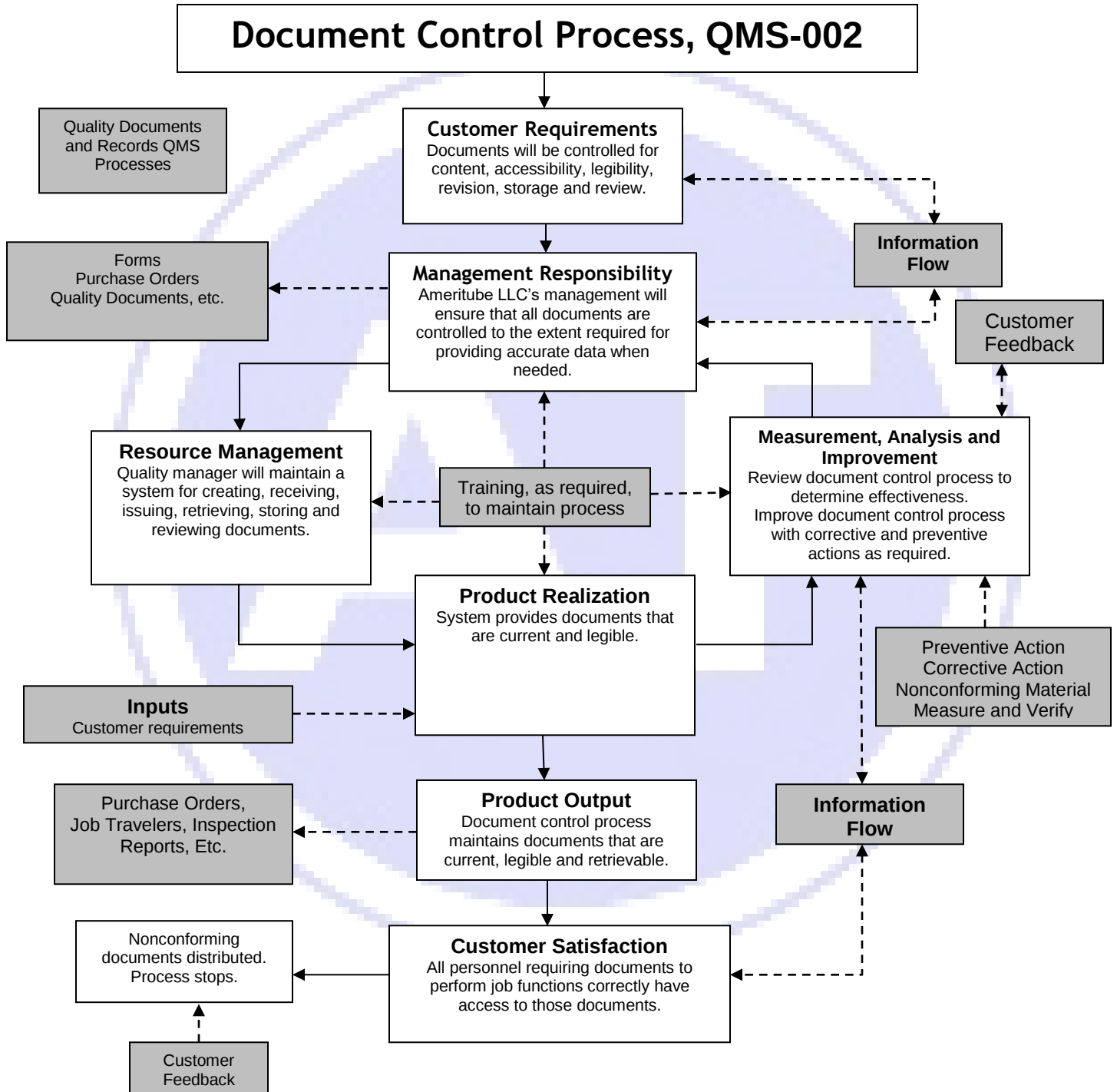


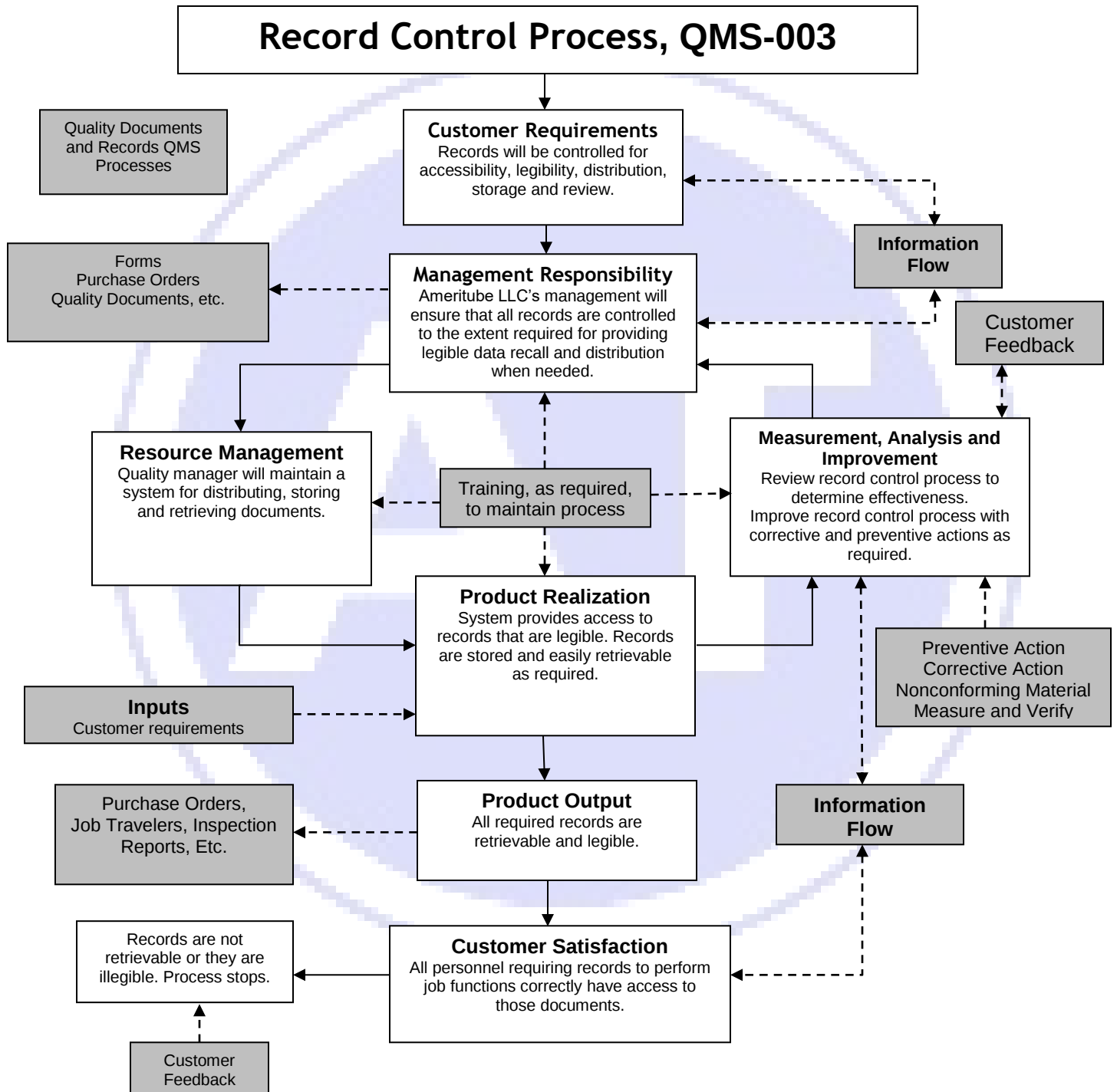
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1.7 Product Realization Process – Supporting Processes

Processes used as required defining, implementing, monitoring, maintaining and improving effectiveness of the quality management system that supports Ameritube LLC's product realization process.



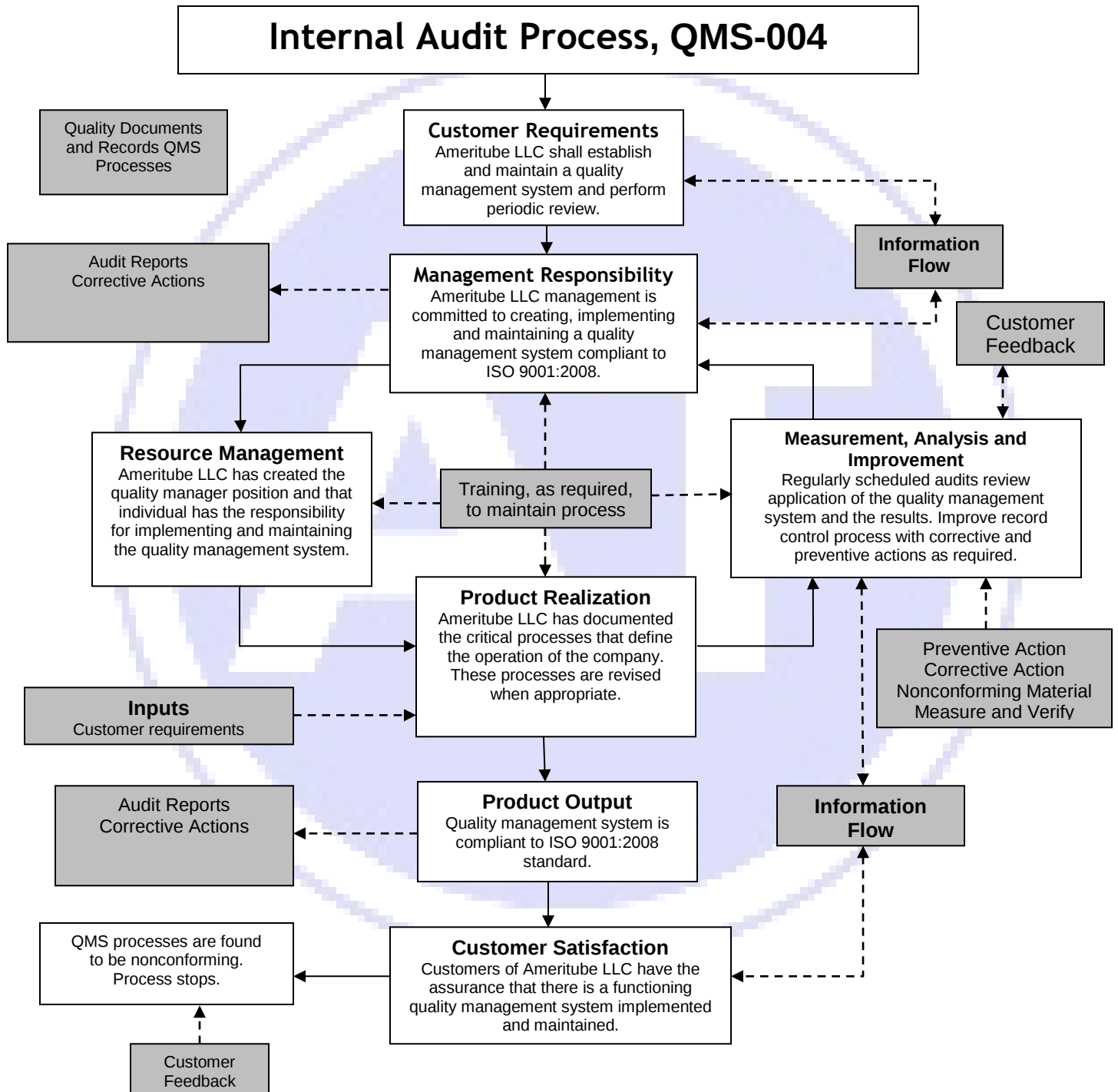


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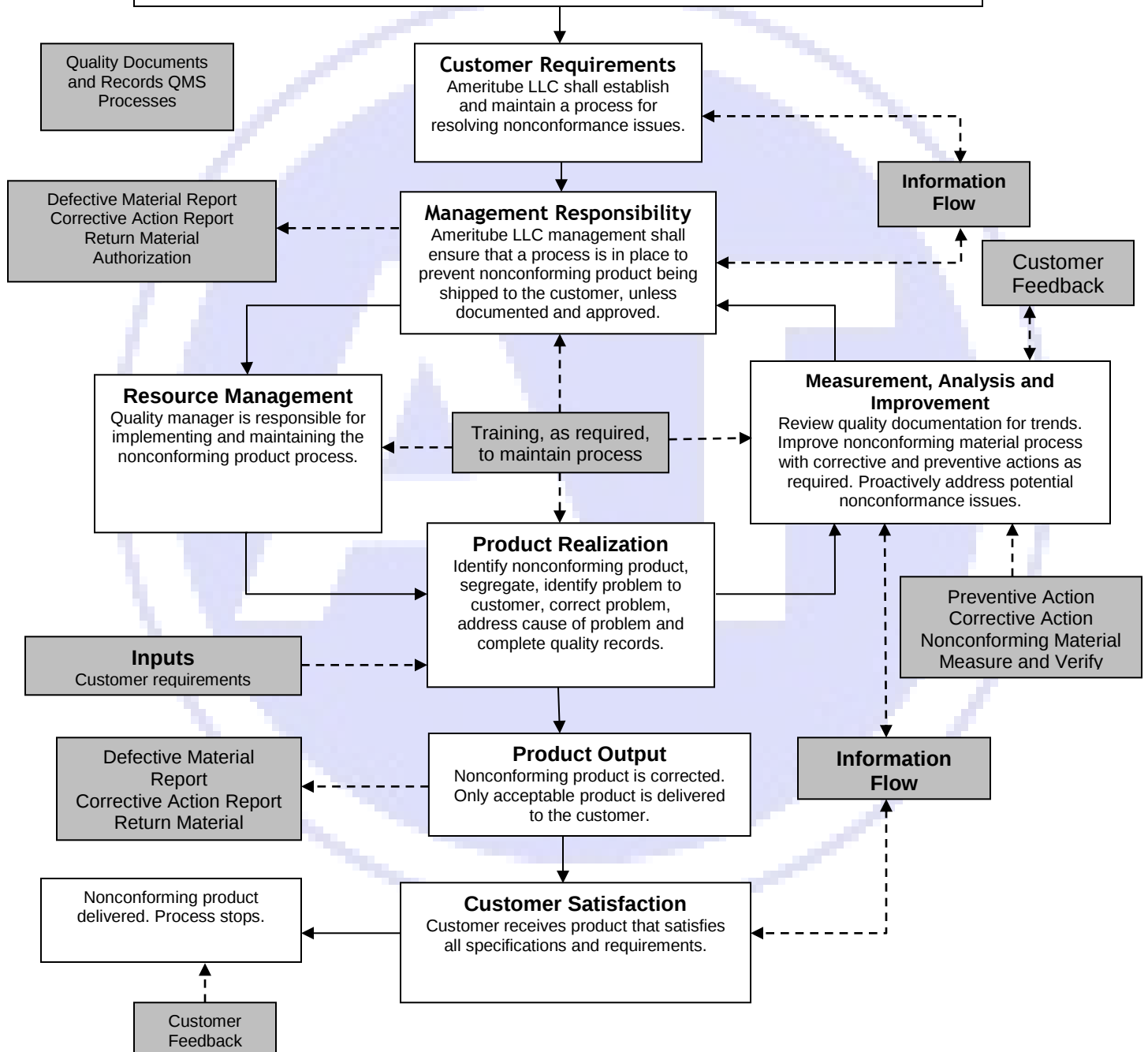
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1.7 Product Realization Process – Supporting Processes

Processes used as required defining, implementing, monitoring, maintaining and improving effectiveness of the quality management system that supports Ameritube LLC's product realization process.

Nonconforming Product Process, QMS-005

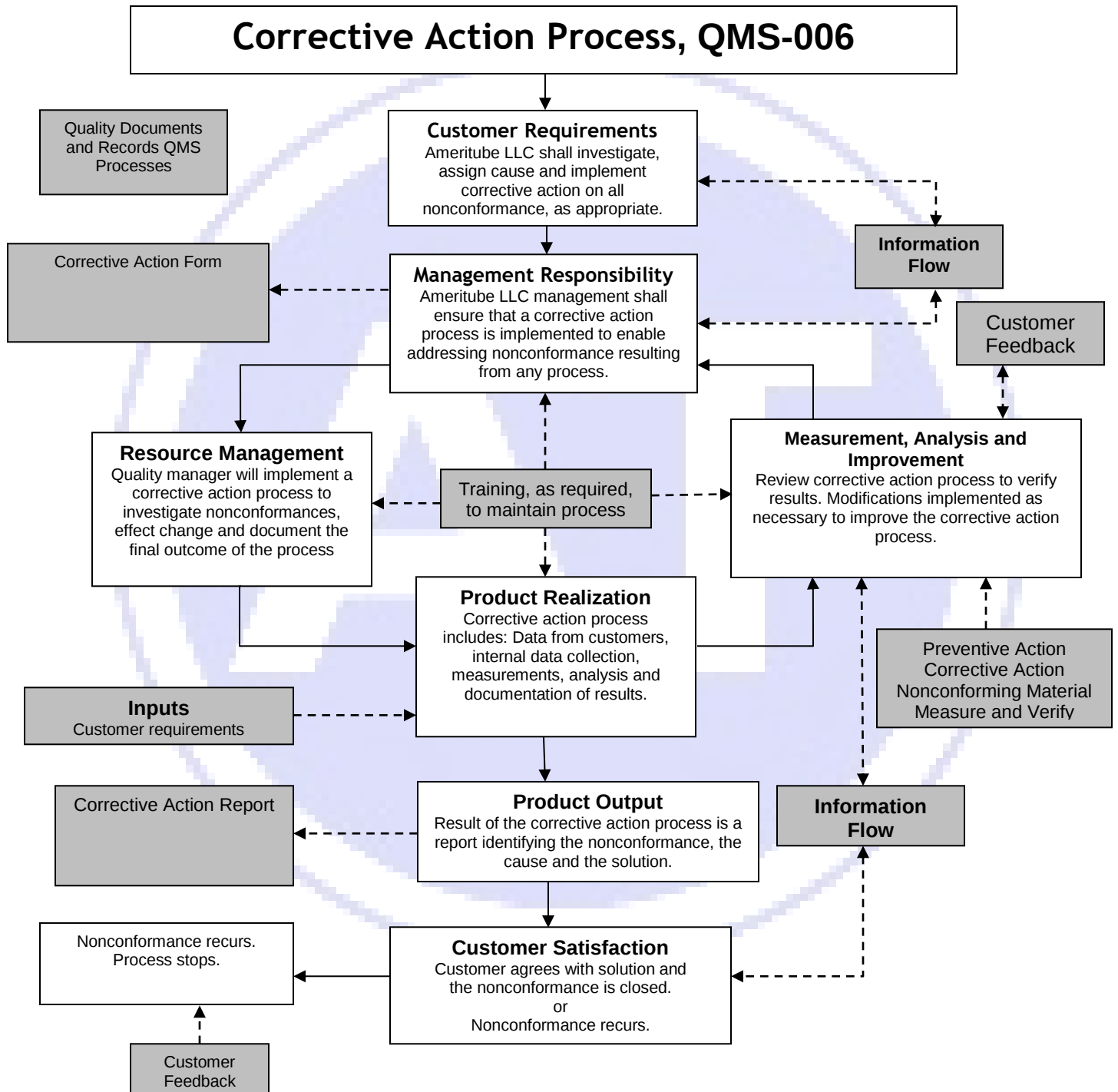


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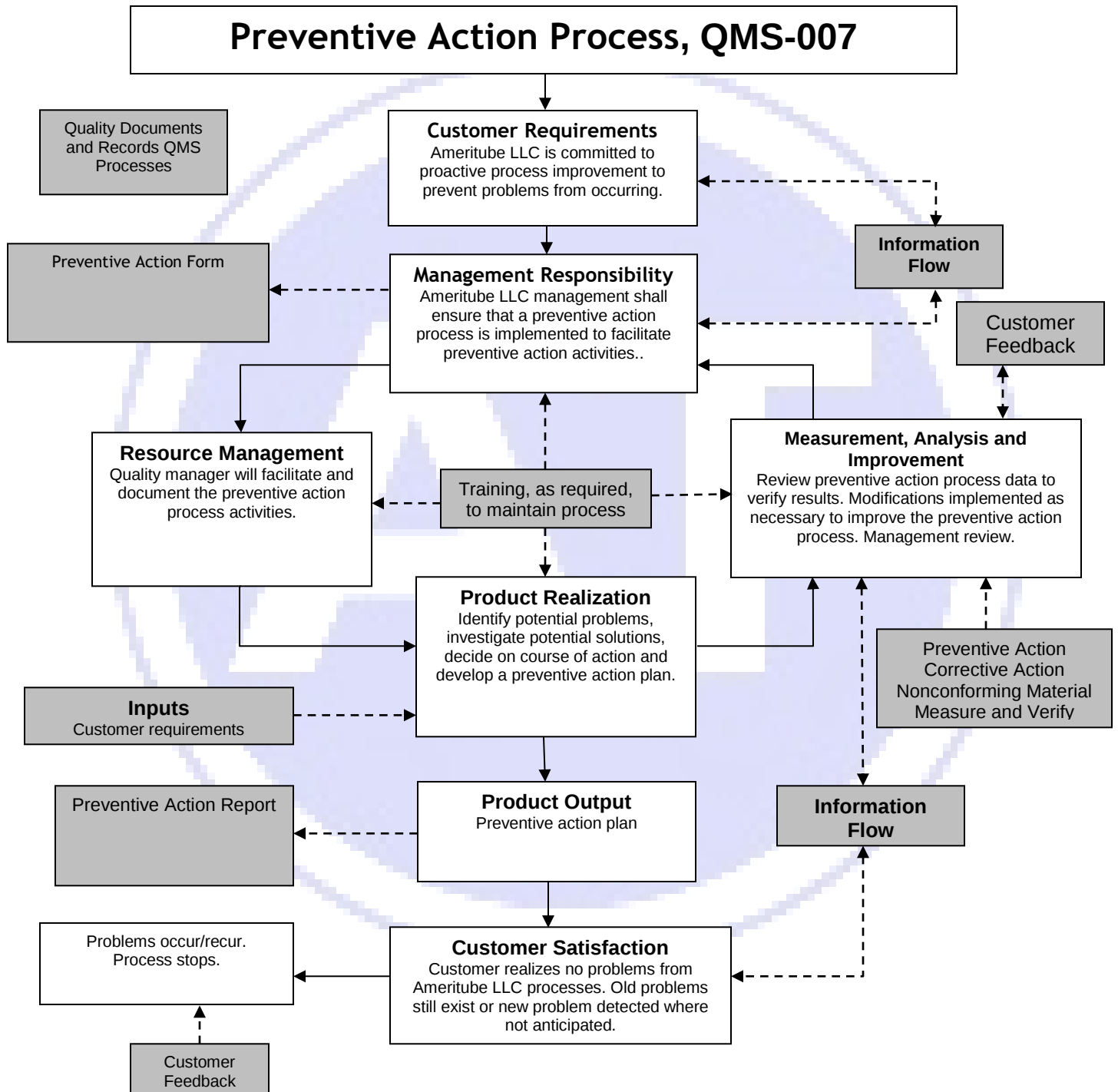


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2. Reference Documents

2.7. ISO Documents

- ISO 9001 : 2008 QMS – Requirements
- ISO 9001: 2015

2.8. Other Documents

- ANSI/NCCL Z540-1-1994 Calibration Laboratories and Measuring and Test Equipment - General Requirements

2.9. Order of Precedence

1. Contract
2. Engineering Documentation
3. Ameritube LLC Manufacturing "Quote Sheet" (Tender)
4. Manufacturing Process Plan

3. Glossary

Product Realization - Product realization is the term used to describe the work that the organization goes through to develop, manufacture, and deliver the finished goods or services.

4. Quality Management System

4.7. General Requirements

In accordance with the requirements of the international standard ISO 9001:2008, Ameritube LLC has established, documented, implemented and maintained a quality management system and continually improves its effectiveness.

Ameritube LLC shall:

- Identify the processes needed for the quality management system and their application throughout the organization
- Determines the sequence and interaction of the processes
- Determines criteria and methods needed to ensure that both the operation and control of these processes are effective
- Ensures the availability of resources and information necessary to support the operation and monitoring of these processes
- Monitor, measure and analyze these processes
- Implement actions necessary to achieve planned results and continual improvement of these processes

When Ameritube LLC chooses to outsource any process that affects product conformity with requirements, the organization providing the process shall ensure control over such process. Control of such outsourced processes shall be identified within the quality management system.

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4.8. Documented Requirements

4.8.1.General

Ameritube LLC documented system shall include:

- Documented statements of a quality policy and quality objectives
- A quality manual
- Documented procedures required by the international standard ISO 9001:2008 and ISO 9001:2015
- Documents needed by the organization to ensure the effective planning, operation and control of its processes
- Quality records required by the international standard ISO 9001:2008 and ISO 9001:2015
- Any additional quality system requirements imposed by the customer and/or applicable regulatory authorities as the need arises

4.8.2.Quality Manual

Ameritube LLC has developed and maintains a quality manual that includes:

- The scope of the quality management system, including details and justification for any exclusions (refer to Section 1.2 of ISO 9001:2008)

4.8.3.Control of Documents

Ameritube LLC documents required by the quality management system are controlled. Ameritube LLC recognizes quality records as a special type of document and they are controlled according to requirements given in Section 4.2.4.

The documented procedure, QMS-002 Document Control, defines controls needed:

- To approve documents for adequacy prior to issue
- To review and update as necessary and re-approve documents
- To ensure that changes and the current revision status of documents are identified
- To ensure that relevant versions of applicable documents are available at points of use
- To ensure that documents remain legible and readily identifiable
- To ensure that documents of external origin are identified and their distribution controlled
- To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose
- Coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

4.8.4.Control of Quality Records

Ameritube LLC has established and controls quality records for the purpose of providing evidence of conformity to requirements and of the effective operation of the quality management system. The documented procedure, QMS-003 Record Control, defines controls needed.

Quality records shall:

- Remain legible
- Be readily identifiable and retrievable
- Have needed controls for identification, storage, protection, retrieval, retention time and disposition of quality records

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The documented procedure, QMS-003 Record Control, defines the methods for controlling records that are created by and/or retained by suppliers. All applicable records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

5. Management Responsibility

5.7. Management Commitment

Ameritube LLC top management shall provide evidence of commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- Communicating to the organization the importance of meeting customer, statutory and regulatory requirements
- Establishing the quality policy
- Ensuring that quality objectives are established
- Conducting quarterly management reviews
- Ensuring the availability of resources

5.8. Customer Focus

Ameritube LLC top management shall ensure that customer needs and expectations are:

- Determined
- Converted into requirements
- Fulfilled with the aim of achieving customer satisfaction

See Sections 7.2.1 and 8.2.1.

5.9. Quality Policy

Ameritube LLC top management shall ensure that the quality policy:

- Is appropriate to the organization
- Includes a commitment to comply with the requirements and continually improve the effectiveness of the quality management system
- Provides a framework for establishing and reviewing quality objectives
- Is communicated and understood within the organization
- Is reviewed for continuing suitability

Refer to Section 1.3 for full text of Ameritube LLC's quality policy.

5.10. Planning

5.10.1. Quality Objectives

Ameritube LLC top management shall ensure that quality objectives (see Section 1.4 and Section 7.1) are:

- Established
- Measurable
- Consistent with the quality policy
- Adequate for meeting all product requirements
- Established at relevant functions/levels within the organization

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5.10.2. Quality Management System Planning

Ameritube LLC top management shall ensure that:

- The planning of the quality management system is carried out in order to meet the requirements given in Section 4.1, as well as the quality objectives in Section 1.4
- The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

5.11. Responsibility, Authority and Communication

5.11.1. Responsibility and Authority

Ameritube LLC top management shall ensure that functions and interrelationships, including responsibilities and authorities are:

- Defined
- Communicated within the organization

This is accomplished through the use of:

- Job descriptions
- Performance appraisals
- Organization charts

5.11.2. Management Representative, Quality Manager

Ameritube LLC top management has appointed a member of management, with the title of Quality Manager, who, irrespective of other responsibilities, has responsibility and authority to:

- Ensure that processes needed for the quality management system are established, documented, implemented, and maintained
- Report to top management on the performance of the quality management system and any need for improvement
- Ensure the promotion of awareness of customer requirements throughout the organization
- Act as liaison with external parties on matters relating to the quality management system
- The organizational freedom to resolve matters pertaining to quality

5.11.3. Internal Communications

Ameritube LLC top management shall ensure that appropriate communication processes are established between various levels and functions within the organization and that communication takes place regarding the effectiveness of the quality management system.

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5.12. Management Review

5.12.1. General

Ameritube LLC top management shall review the quality management system at least once a year to:

- Ensure its continuing suitability
- Adequacy
- Effectiveness
- Assess opportunities for improvement
- Evaluate the need for changes, including the quality policy and quality objectives

Review Input

Management review input shall include:

- Results of internal and external audits
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement

5.12.2. Review Output

Information output from management review to appropriate recipients shall include any decisions and actions related to:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resources needed

6. Resource Management

6.7. Provisions of Resources

Ameritube LLC shall study processes, determine and provide the resources needed:

- To implement and maintain the quality management system
- To continually improve quality management system effectiveness
- To enhance customer satisfaction by meeting customer requirements

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6.8. Human Resources

6.8.1.General

Ameritube LLC personnel performing work affecting product quality are competent to process the work based on appropriate education, training, skills and experience.

6.8.2.Competence, Awareness and Training

Ameritube LLC shall:

- Determine the necessary competence for personnel performing work affecting product quality
- Provide training and take other actions necessary to satisfy these needs
- Evaluate the effectiveness of actions taken
- Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
- Maintain appropriate records of education, training, skills and experience (see Section 4.2.4)

6.9. Infrastructure

Ameritube LLC shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. The infrastructure at Ameritube LLC includes:

- Building, workspace and associated utilities
- Process equipment including hardware and software
- Supporting services including transportation and communication

6.10. Work Environment

Ameritube LLC shall determine and manage the work environment necessary to achieve conformity to product requirements including, but not limited to:

- Lighting
- Cleanliness

7. Product Realization

7.7. Planning of Product Realization

Ameritube LLC shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see Section 4.1).

In planning product realization, Ameritube LLC shall determine the following, as appropriate:

- Quality objectives and requirements for the product
- The need to establish processes, documents and provide resources specific to the product
- Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance
- Records needed to provide evidence that the realization processes and resulting product fulfill requirements (see Section 4.2.4)
- The identification of resources to support operation and maintenance of the product

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The output of this planning shall be in a form suitable for the Ameritube LLC manufacturing method of operation.

The document specifying the processes of the quality management system (including the product realization processes) and the resources applied to a specific product, project or contract, is referred to as the quality plan.

7.8. Customer Related Processes

7.8.1.Determination of Requirements Related to the Product

Ameritube LLC shall determine:

- Requirements specified by the customer, including the requirements for delivery and post-delivery activities
- Requirements not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- There may be additional requirements, yet to be identified, that Ameritube LLC will satisfy upon discovery, as related to the customer's product

7.8.2.Review of Requirements Related to the Product

Ameritube LLC shall review the requirements related to the product. This review shall be conducted prior to Ameritube LLC's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- Ameritube LLC has the ability to meet the defined requirements
- Risks (e.g., new technology, short delivery time scale) have been evaluated

Records of the results of the review and actions arising from the review shall be maintained (see Section 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by Ameritube LLC before contract acceptance.

Where product requirements are changed, Ameritube LLC shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.8.3.Customer Communication

Ameritube LLC shall determine and implement effective arrangements for communicating with customers in relation to:

- Product information
- Enquiries, contracts or order handling, including amendments
- Customer feedback, including customer complaints

7.9. Design and Development

Ameritube LLC does not perform product design and claims exclusion from the requirements of Section 7.3, Design and Development.

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7.10. Purchasing

7.10.1. Purchasing Process

Ameritube LLC shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

Ameritube LLC shall be responsible for the quality of all products purchased from suppliers, including customer-designated sources

Ameritube LLC shall evaluate and select suppliers based on their ability to supply product in accordance with Ameritube LLC requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained (see Section 4.2.4). Refer to QMS-009, Purchasing Critical Materials.

Ameritube LLC shall:

- Maintain a register of approved suppliers that includes the scope of approval
- Periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented
- Define the necessary actions to take when dealing with suppliers that do not meet the requirements

7.10.2. Purchasing Information

Purchasing information shall describe the product to be purchased, including, where appropriate:

- Requirements for approval of product, procedures, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements
- The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data
- Requirements for design, test, examination, inspection and related instruction for acceptance by Ameritube LLC
- Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection investigation or auditing
- Requirements relative to supplier notification to Ameritube LLC of nonconforming product
- Requirements relative to arrangements for Ameritube LLC approval of supplier nonconforming material
- Requirements for the supplier to notify Ameritube LLC of changes in product and/or process definition and, where required, obtain Ameritube LLC's approval
- Right of access by Ameritube LLC, our customer, and regulatory authorities to all facilities involved in the order and to all applicable records
- Requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics when required

Ameritube LLC shall ensure the adequacy of specified purchase requirements prior to our communication with our supplier.

7.10.3. Verification of Purchased Product

Ameritube LLC shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

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Where Ameritube LLC or its customer intends to perform verification at the supplier's premises, Ameritube LLC shall state the intended verification arrangements and method of product release in the purchasing information.

Verification activities may include:

- Obtaining objective evidence of the quality of the product from suppliers(e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control)
- Inspection and audit at supplier's premises
- Review of required documentation
- Inspection of products upon receipt
- Delegation of verification to the supplier, or supplier certification

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements

Where Ameritube LLC utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. Ameritube LLC shall periodically validate test reports for raw material.

Where Ameritube LLC delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

Where Ameritube LLC or its customer intends to perform verification at the supplier's premises, Ameritube LLC shall state the intended verification arrangements and method of product release in the purchasing information.

Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and Ameritube LLC premises that subcontracted product conforms to specified requirements.

Verification by the customer shall not be used by Ameritube LLC as evidence of effective control of quality by the supplier and shall not absolve Ameritube LLC of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer

7.11. Production and Service Provision

7.11.1. Control of Production and Service Provision

Planning shall consider, as applicable:

- The establishment of process controls and development of control plans where key characteristics have been identified
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization
- The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics
- Special processes (see 7.5.2).

Ameritube LLC shall plan and carry out production and service provisions under controlled conditions. Controlled conditions shall include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment
- The availability and use of monitoring and measuring devices

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- The implementation of monitoring and measurement
- The implementation of release, delivery and post-delivery activities
- Accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product)
- Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized
- Provisions for the prevention, detection, and removal of foreign objects
- Monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality
- Criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations)

7.11.1.1. Production Documentation: Production operations shall be carried out in accordance with approved data. This data shall contain, as necessary:

- Drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1)
- A list of specific or non-specific tools required and any specific instructions associated with their use

7.11.1.2. Control of Production Process Changes: Persons authorized to approve changes to the production processes shall be identified.

Ameritube LLC shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production equipment, tools shall be documented. Procedures shall be available to control their implementation.

The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

7.11.1.3. Control of Production Equipment and Tools

Production equipment and tools shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first piece produced to design data/specification.

Storage requirements, including periodic preservation/condition checks, shall be established for production equipment or tooling in storage.

7.11.1.4. Control of Work Transferred, on a Temporary Basis, Outside Ameritube LLC's Facility:

When planning to temporarily transfer work to a location outside Ameritube LLC's facilities, Ameritube LLC shall define the process to control and validate the quality of the work.

7.11.1.5. Control of Service Operations: Where servicing is a specified requirement, service operation processes shall provide for:

- A method of collecting and analyzing in-service data

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- Actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements
- The control and updating of technical documentation
- The approval, control, and use of repair schemes
- The controls required for off-site work (e.g., Ameritube LLC's work undertaken at the customer's facilities)

7.11.2. Validation of Processes for Production and Service Provision

Ameritube LLC shall validate any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any process where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of the process to achieve planned results.

Ameritube LLC shall establish arrangements for these processes including, as applicable:

- Defined criteria for review and approval of the process followed by qualification and approval of special processes prior to use
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures in assuring control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto
- Requirements for records (see Section 4.2.4)
- Revalidation

Refer to QMS-009, Purchasing Critical Materials.

7.11.3. Identification and Traceability

Where appropriate, Ameritube LLC shall identify the product by suitable means throughout product realization. Refer to QMS-009, Purchasing Critical Materials.

Ameritube LLC shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

Ameritube LLC shall identify the product status with respect to monitoring and measurement requirements.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), Ameritube LLC shall establish and document controls for the media.

Where traceability is a requirement, Ameritube LLC shall control and record the unique identification of the product (see Section 4.2.4).

According to the level of traceability required by a contract, regulatory, or other established requirement, Ameritube LLC's system shall provide for:

- Identification to be maintained throughout the product life
- All products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch

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7.11.4. Customer Property

Ameritube LLC shall exercise care with customer property while it is under Ameritube LLC's control or being used by Ameritube LLC.

Ameritube LLC shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this condition shall be reported to the customer and records maintained (see Section 4.2.4).

7.11.5. Preservation of Product

Ameritube LLC shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection.

Preservation of product shall also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

- Cleaning
- Prevention, detection and removal of foreign objects
- Special handling for sensitive products
- Marking and labeling including safety warnings
- Special handling for hazardous materials

Ameritube LLC shall ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

7.12. Control of Monitoring and Measuring Devices

Ameritube LLC shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence on conformity of product to determined requirements (see Section 7.2.1). See Calibration, QMS-011.

Ameritube LLC shall maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Ameritube LLC shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Ameritube LLC shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Where necessary to ensure valid results, measuring equipment shall be:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded
- Adjusted or re-adjusted as necessary
- Identified to enable the calibration status to be determined
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage

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- Be recalled to a defined method when requiring calibration
- Identify calibration intervals for all measuring equipment and calibration processes

In addition, Ameritube LLC shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Ameritube LLC shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see Section 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of the computer software to satisfy the intended application shall be confirmed. This process shall be performed prior to initial use and reconfirmed as necessary.

8. Measurement, Analysis and Improvement

8.1. General

Ameritube LLC shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- To demonstrate conformity of the product
- To ensure conformity of the quality management system
- To continually improve the effectiveness of the quality management system

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

Note: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:

- Design verification (e.g., reliability, maintainability, safety)
- Process control:
 - Selection and inspection of key characteristics
 - Process capability measurements
 - Statistical process control
 - Design of experiment
 - Inspection – matching sampling rate to the criticality of the product and to the process capability
 - Failure mode and effect analysis

8.2. Monitoring and Measurement

8.2.1. Customer Satisfaction

As one of the measurements of the performance of the quality management system, Ameritube LLC shall monitor information relating to customer perception as to whether Ameritube LLC has fulfilled customer requirements. The methods for obtaining and using this information is partially obtained through a Customer Satisfaction Survey Form 05-01.

8.2.2. Internal Audit

Following procedures defined in QMS-004, Ameritube LLC shall conduct internal audits at planned intervals to verify the quality management system:

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- Conforms to the planned arrangements (see Section 7.1), to the requirements of the International Standard ISO 9001:2008 and to the quality management system requirements established by Ameritube LLC
- Is effectively implemented and maintained

An audit program shall be planned and implemented, taking into consideration the status and importance of the process and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting and maintaining records (see Section 4.2.4) shall be defined in a documented procedure, QMS-004 Internal Audits.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see Section 8.5.2).

Detailed tools and techniques shall be developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall Ameritube LLC performance.

Internal audits shall also meet contract and/or regulatory requirements. Internal Audits shall be preformed at quarterly intervals to ensure a constant improvement in the overall production and quality system put in place by Ameritube. No one person(s) shall audit their own work. A minimum of two individuals shall preform the internal audits.

8.2.3. Monitoring and Measurement of Processes

Ameritube LLC shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product is achieved.

In the event of process nonconformity, Ameritube LLC shall:

- Take appropriate action to correct the nonconforming process
- Evaluate whether the process nonconformity has resulted in product nonconformity
- Identify and control the nonconforming product in accordance with clause 8.3

8.2.4. Monitoring and Measurement of Product

Ameritube LLC shall monitor and measures the characteristics of the product to verify that product requirements are fulfilled. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see Section 7.1)

When key characteristics have been identified, they shall be monitored and controlled.

When Ameritube LLC uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of lots whose samples have nonconformities. When required, the plan shall be submitted for customer approval.

Product shall not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

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Evidence of conformity with acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see Section 4.2.4).

Product release and service delivery shall not proceed until all the planned arrangements (see Section 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

8.2.4.1. Inspection Documentation

Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production documentation, but shall include:

- Criteria for acceptance and/or rejection
- Where in the sequence measurement and testing operations are performed
- A record of the measurement results
- Type of measurement instruments required and any specific instructions associated with their use

Test records shall show actual test results data when required by specification or acceptance test plan.

Where required to demonstrate product qualification Ameritube LLC shall ensure that records provide evidence that the product meets the defined requirements.

8.3. Control of Nonconforming Product

Ameritube LLC shall ensure that products, which do not conform to product requirements, are identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product have been defined in a documented procedure, QMS-005 Nonconforming Product.

Ameritube LLC documented procedure shall define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.

Ameritube LLC shall deal with nonconforming product by one or more of the following ways:

- By taking action to eliminate the detected nonconformity
- By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- By taking action to preclude its original intended use or application

Ameritube LLC shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if:

- The product is produced to customer design
- The nonconformity results in a departure from contract requirements

Product disposition for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see Section 4.2.4).

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When a nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, Ameritube LLC shall take action appropriate to the effects, or potential effects, of the nonconformity.

In addition to any contract or regulatory authority reporting requirements, Ameritube LLC system shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity and date(s) delivered.

8.4. Analysis of Data

Ameritube LLC shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of the data shall provide information relating to:

- Customer satisfaction (see 8.2.1)
- Conformance to product requirements (see 7.2.1)
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

8.5. Improvement

8.5.1. Continual Improvement

Ameritube LLC shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2. Corrective Action

Ameritube LLC shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure, QMS-006 Corrective Action, shall be established to define requirements for:

- Reviewing nonconformities (including customer complaints)
- Determining the causes of nonconformities
- Evaluating the need for action to ensure that nonconformities do not recur
- Determining and implementing actions needed
- Records of the results of actions taken (see Section 4.2.4)
- Reviewing corrective action taken
- Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause
- Specific actions where timely and/or effective corrective actions are not achieved

8.5.3. Preventive Action

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Ameritube LLC shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure, QMS-007 Preventive Action, shall be established to define requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken (see Section 4.2.4)
- Reviewing preventive action taken

9. Related Level One Documents

- QMS-002 Document Control
- QMS-003 Record Control
- QMS-004 Internal Audits
- QMS-005 Control of Nonconforming Product
- QMS-006 Corrective Action
- QMS-007 Preventive Action
- QMS-008 Product Realization
- QMS-009 Purchasing
- QMS-010 Calibration
- QMS-011 In Process Inspection
- QMS-012 Receiving Inspection
- QMS-013 Training

10. Document Maintenance

Custodian: Quality Assurance Manager

Review Activity: Department Managers

Approval Authority: President
Quality Assurance Manager

Document Approval
Signature: _____

Date: _____