QMS-002

Quality Management System Manual

Conforms to ISO 13485

Approved by:	Title	Signature
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REVISION HISTORY

Revision	Date	Changes/Comments
A	11/10/2016	Create new QMS manual for medical device mfg. This separates the medical device quality requirements from QMS-001, which previously covered ISO 9001/AS9100 and ISO 13485 requirements
B	01/20/2017	Add exclusion for sterilization, implantable device, Installation and Servicing; add references to QP 8.2 and QP 8.4
C	4/19/2017	Add documentation structure and update org chart
D	5/09/2018	Update to meet ISO 13485:2016 requirements

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1 INTRODUCTION

PARPRO Technologies, Inc. (PTI) provides electronic manufacturing services for the medical device industry. The medical device product and services provided by PARPO include printed circuit board assemblies, cables & wire harnesses, electro-mechanical assemblies, and test. PARPRO manufactures and tests the medical device products according to customer-provided design and specifications. PARPRO does not market, install, or service finished medical devices to the end users.

2 SCOPE

This quality manual is established to provide direction for assuring product conformity and customer satisfaction. Product quality and customer satisfaction are obtained through planning, execution, monitoring and improvements. PTI reviews and revises this manual as necessary to meet the latest requirements of ISO 13485 and any applicable regulatory requirements.

Exclusions – PTI's medical device manufacturing is a build-to-print service. Thus design and development of ISO 13485, Section 7.3 is excluded from this quality system.

Non-Applications – PTI does not perform the following activities defined in ISO 13485. Thus they are non-applicable in this quality system.

- Implantable medical device – Section 7.5.9.2
- Sterilization – Section 7.5.5 and 7.5.7
- Installation and servicing of medical devices – Section 7.5.3 and 7.5.4

Company site – This quality manual is used by PTI's manufacturing facility in Santa Ana, CA. It's not applicable to other PTI sites.

3 TERMS & DEFINITIONS

Terms and definitions used in this document are in reference to ISO 9001 and ISO13485.

4 QUALITY MANAGEMENT SYSTEM

4.1 General

PTI implements and maintains the effectiveness of the QMS in accordance with the ISO Standards, customer, and applicable regulatory requirements. Process approach is used for the management system. Core processes within the organization are identified and managed discretely to achieve customer satisfaction. Outsourced processes are managed per section 7.4 herein. Appendix 1 defines the core processes and their interactions. Appendix 2 to 5 illustrate the turtle diagrams for each core process. Each core process contains:

- applicable inputs and outputs
- process owner(s)
- responsibilities and authorities
- support resources
- criteria and methods needed to ensure the effectiveness of the process
- objectives related to the process

4.2 Documentation Requirements

PTI's quality management system documentation is structured with four tiers:

- Tier I: Quality policy, QMS manual
- Tier II: QMS process procedures
- Tier III: Work instructions, drawings, product specifications, and etc.
- Tier III: Forms, records, reports and etc.

The processes for controlling, approving, and implementing QMS documents is define by **QP 5.1, Document and Data Control** and **QP 5.3, Engineering Change Order**. These procedures ensure:

- Documents are uniquely identified, revision controlled, and legible
- Documents are reviewed, updated and approved prior to use
- Only latest versions of applicable documents are available at point of use
- Applicable standards of external origin (e.g. ISO and IPC) are controlled
- Prevention of unintended use of obsolete documents
- Customer supplied documents are reviewed, released and controlled

Documents and records are retained and maintained to demonstrate evidence of conformity to requirements and of the effective operation of the quality management system. **QP 16.1, Control of Records** defines the processes for identification, storage, protection, retrieval, retention and disposition of records. Copy of obsolete documents are retained for at least the lifetime of the medical device as defined by the customer or as specified by the relevant regulatory requirements. Records are made available to customer when requested.

5 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Top management provides evidence of its leadership and commitment to the quality management system by:

- taking accountability for the development, implementation and effectiveness of the QMS
- communicating the importance of meeting customer as well as regulatory requirements to all levels of the organization
- ensuring that the Quality Policy and quality objectives are established
- conducting management review to ensure the management system achieve its intended results
- ensuring that the resources needed are available

5.2 Customer Focus

PTI makes customer requirements and customer satisfaction its top priorities. This is accomplished by assuring customer and applicable regulatory requirements are determined and met. Appropriate actions are taken if planned results are not or will not be achieved.

5.3 Quality Policy

Top management has developed the quality policy that governs the day-to-day operations to ensure quality and customer satisfaction.

PARPRO Technologies quality policy:

PARPRO Technologies is committed to meet or exceed customer's expectations by:

- *delivering product on time and per specifications,*
- *complying with requirements, maintaining and continually improving the effectiveness of the quality management system*

PTI reviews the quality policy annually or as needed for continuing suitability and ensures the quality policy is communicated and understood within the organization.

5.4 Planning

Top management establishes the quality objectives and key measures as outlined in Table 1. The performance of the quality objectives is reviewed periodically. Risks and opportunities identified from planning and review are addressed to prevent or reduce undesired effects.

When change is needed, PTI reviews the purpose of the changes and their potential consequences. PTI determines responsibility, authority, and resources in a panned manner to implement changes.

Table 1 – Quality Objectives & Key Measures

Quality Policy	Quality Objective	Key Measures
Meet or exceed customer expectation	Customer satisfaction	Customer satisfaction / product acceptance rate
Delivering product on time	On-time delivery	On-time delivery performance
Per customer specification	Conforming to customer requirements	Product conformity metrics
Maintaining the effectiveness of the QMS	Improvement	Improvement metrics

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Table 2 summarizes the responsibility and authority within the organization. Top management ensures that responsibilities and authorities are communicated within the organization. Personnel, who manage, perform and verify work affecting quality are provided the necessary independence and authority to perform their jobs. Individuals are aware of the scope, responsibility and authority of their functions. **Form 1, Organization Chart** outlines the organization structure.

5.5.2 Management Representative

The VP of Quality Assurance is assigned as the QMS representative. The VP of Quality Assurance has responsibility and authority that include:

- ensuring that the required QMS processes are established, implemented and documented
- reporting to top management on the performance of the quality management system and any need for improvement
- promotion of awareness of applicable regulatory and customer requirements throughout the organization

Table 2 - Responsibility and Authority

Responsibility and authority	Process owners and/or departments
Quality management system & Planning	Top management / VP of QA
QMS Documentation	Quality assurance / VP of QA
Management Review	Top management / VP of QA
Resource management	Top management
Human resources	Top management
Product realization	Manufacturing / C.O.O.
Customer rltd processes	Program management / engineering / QA
Purchasing	C.O.O. / Material Manager
Control of measuring and monitoring devices	Quality assurance / manufacturing / VP of QA
Measurement, analysis and improvement	Top management / VP of QA
Internal Audit	Quality assurance / VP of QA
Monitoring and measuring of processes	Top management / process owners
Monitoring and measuring of product	Quality control / test / Manufacturing management
Control of nonconforming product	Manufacturing / Quality assurance / VP of QA
Continual improvement	Top management / VP of QA
Corrective action and preventive action	Process owners / Quality assurance / VP of QA

5.5.3 Internal Communication

Top management ensures that relevant information is communicated through all levels of the organization so that

- customer requirements are available and understood
- the quality policy and quality objectives are understood and reviewed for their effectiveness
- the quality management system requirements defined in the procedures are available, implemented and understood

The communication methods include but are not limited to:

- Use of QA processes such as nonconforming report, corrective and preventive action, and customer complaints
- Use of the data analysis results/charts
- Use of the internal audit results
- Management and employee meetings
- Formal and informal training and instruction
- A MIS system including e-mails and ERP system
- Quality and manufacturing procedures and work instructions
- Shop travelers including customer supplied specifications
- Open door policy which allows any employee access to top management

5.6 Management Review

Top management conducts management review at least once annually to ensure continued suitability, adequacy and effectiveness of the QMS. The review covers the following inputs:

- Quality policy & objectives
- Results of audits
- Customer feedback, complaint handling and reporting to regulatory authorities
- Process performance and product conformity
- Status of corrective and preventive action

- Follow-up actions from previous management reviews
- Changes that could affect the quality management system
- Recommendations for improvement
- Applicable new or revised regulatory requirements

Output from the management review includes decisions and actions related to:

- improvement needed to maintain the suitability, adequacy, and effectiveness of the QMS and its processes
- improvement of product related to customer requirements
- changes needed to respond to applicable new or revised regulatory requirements
- resource needs

6 RESOURCE MANAGEMENT

6.1 Provision of Resources

Top management identifies the resource requirements and ensures that the company provides resources to

- implement the QMS and to maintain its effectiveness
- meet applicable regulatory and customer requirements

6.2 Human Resources

PTI ensures employees performing product assembly, inspection, test, and other work affecting product quality are competent. The competency is based on the appropriate education, training, skills and experience. Managers and supervisors determine the necessary competence required for the personnel working within their respective areas. Competence is assessed through testing or review of past experience during the hiring process or on-the-job training. Managers and supervisors monitor the performance of their employees during the day-to-day activities in order to identify training needs. On-the-job or classroom training is provided as required. **QP 18.1, Training**, defines these activities in detail.

Training and communication ensure PTI personnel are aware off:

- the quality policy and relevant quality objectives
- employees' contribution to the effectiveness of the QMS and the benefits of improved performance
- the implication of not conforming with the QMS requirement
- relevant QMS documented information and changes thereto
- employee's contribution to product conformity and safety
- the importance of ethical behavior

6.3 Infrastructure

Top management plans for and provides an infrastructure suitable for the operation. The planning includes the buildings, equipment and personnel necessary to support services, production, verification, and delivery activities.

Documented requirements for maintenance activities, including their frequency, are established when such activities or lack thereof can affect product quality. **MP 11.1, Equipment Control, Calibration & Maintenance** defines the process 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.

6.4 Work Environment

PTI ensures the work environment is safe and in compliance with federal and local safety and environmental regulations. Physical, social, or psychological conditions are evaluated as required. PTI identifies and manages the conditions of the work environment needed to achieve product conformity per **QP 7.20, Facility Management**.

Personnel who are required to work temporarily under special environmental conditions within the work environment will be trained or is supervised by a trained person.

Prior to accepting the return of contaminated or potentially contaminated product, special arrangements will be established and documented in order to prevent contamination of other product, the work environment or personnel.

7 PRODUCT REALIZATION

7.1 Planning of Product Realization

Planning of production realization includes quality objectives, resources, requirements, and risk management. The established processes demonstrate the product meeting customer and applicable regulatory requirements with objective evidence of

- required verification, validation, monitoring, inspection and test, handling, storage, and traceability specific to the product together with the criteria for product acceptance
- records that demonstrate the processes and resulting product meeting the requirements

When a customer contract requires requirements such as part 820 QSR of CFR 21 or other regulatory requirements that are not covered by this QMS, Quality Assurance will develop a supplemental Quality Plan in close cooperation with the customer. The plan will include requirements in addition to this QMS.

7.1.1 Risk Management

Risks associated with product realization are identified and managed in order to meet contractual requirements, quality objectives and to achieve customer satisfaction. **QP 7.1, Risk Management** defines the process in detail.

When risk management requires mitigation activities in addition to the established assembly processes and QMS procedures, the program manager will communicate the requirements to and coordinate such activities with the appropriate process owners.

7.1.2 Configuration Management

PTI plans, implements, and controls configuration activities to ensure the identification and control of physical and functional attributes throughout the product cycle. Configuration management activities are defined by the following procedures:

- QP 5.1 Document and Data Control
- QP 5.3 Engineering Change Order
- QP 7.2 Configuration Control & Maintenance
- QP 7.5.3 Identification & Traceability

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Requirements related the product determined by PTI include product specifications, requirements for delivery and post-delivery activities, requirements related to the intended use, and applicable regulatory requirements.

7.2.2 Review of Requirements Related to the Product

PTI determines the product requirements from customer-provided documents. The following are reviewed and captured:

- product requirements, including applicable regulatory requirements
- contract or order requirements
- risks and PTI's ability to meet the defined requirements

A quotation is completed and delivered to the customer when it's determined that the product requirements can be met. **QP 3.1, Contract Review** defines the activities in more detail.

PTI must confirm customer's requirements when the customer provides no documented statement of requirements. When product requirements are changed, PTI reviews the new requirements and ensures relevant documents are updated. Customer changes are communicated and implemented according to **QP 5.3, Engineering Change Order**.

7.2.3 Customer Communication

PTI appoints a program manager to every customer. The program manager will communicate product information, contract or ordering handling, changes, and risk mitigation regarding PTI's ability to meet customer's objectives and contractual requirements. Customer feedback, including complaint and advisory notice if any are addressed by Quality Assurance in according with **QP 8.2 Customer Feedback**.

7.3 Design and Development

Excluded.

7.4 Purchasing

7.4.1 Purchasing Process

PTI is responsible for the conformity of all products purchased from suppliers, including product from sources specified by the customer. **MP 6.1, Purchasing** and **QP 6.1, Supplier Quality** define the criteria for evaluation, selection, monitoring, and re-evaluation of external providers. The established processes ensure purchased product conforms to the specifications and requirements.

7.4.2 Purchasing Information

PTI's purchasing order contains the part number, description, quantity, term and conditions (**TC 7.4.2, General Terms and Conditions of Purchase**), and other applicable specifications. Applicable quality clauses from **QC 7.4.2, Purchase Order Quality Clauses** and customer flow down requirements are identified and communicated to the external providers.

Prior to communicating the purchase order to a supplier the buyer reviews each line item for adequacy and accuracy of the specified purchasing requirements. Each purchase order is reviewed and approved prior to delivering to the supplier. Purchasing information is maintained for traceability.

7.4.3 Verification of Purchased Products

Receiving inspection is performed for ensuring purchased product meets specified purchasing requirements. Verification activities are based on risks and performance and are performed according to **QP 10.1, Receiving Inspection** and **QP 10.2, Receiving Inspection First Article Inspection.** Evidence of inspection, acceptance and rejection is maintained.

Changes if any are reviewed to determine whether these changes affect the product realization process or the product. When verification at the supplier premises is needed, the purchase order will specify the applicable quality clause in **QC 7.4.2, Purchase Order Quality Clauses**.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

PTI plans and executes production under controlled conditions. Production controls include but are not limited to:

- availability of documents and records that define the characteristics of the product as well as the results to be achieved
- availability and use of monitoring and measuring resources
- implementation of monitoring and measurement
- use of suitable infrastructure and work environment
- appointment of competent persons, including required qualification
- validation and re-validation of special processes if applicable
- implementation of actions to prevent human error
- provision for the prevention, detection and removal of foreign objects
- monitoring and control of utilities and supplies to the extent they affect conformity to product requirements
- the implementation of release, delivery and applicable post-delivery activities

PTI uses shop travelers or shop floor system to control and document the production processes. The shop traveler or shop floor system contains the following:

- the established production flow and product requirements
- process controls for key characteristics/special processes
- tooling requirements
- in-process inspection/verification
- evidence of all planned activities

PTI manufactures product in accordance with the following IPC standards. Class II is the default workmanship requirement if it's not specified by the customer.

- IPC J-STD-001: Requirements for Soldered Electrical and Electronic Assemblies
- IPC-A-610: Acceptability of Electronic Assemblies
- IPC/WHMA-A-620: Requirements and Acceptance for Cable and Wire Harness Assemblies

7.5.2 Cleanliness of Product

Products produced by PTI meets the requirement specified by IPC-A-610, IPC-A-620, and/or J-STD-001 standards. Special process is developed when customer's requirements differ from the IPC standards.

7.5.3 Installation Activities

PTI does not provide installation services for medical device.

7.5.4 Servicing Activities

Servicing of medical device is not a requirement for PTI. Components manufactured by PTI that need to return for warranty or other services will follow the standard RMA process per **QP 9.9, Customer Return**.

7.5.5 Particular Requirements for Sterile Medical Devices

Not applicable to PTI business

7.5.6 Validation of Processes for Production and Service Provision

PTI validates production processes 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. Validation is performed per **MP 7.5, Process Validation**. Process validation is part of the risk management to demonstrate the ability of the process to achieve planned results. Arrangements for the validation process are established as applicable:

- define criteria for review and approval of the process
- equipment qualification and qualification of personnel
- use of specific methods, procedures, and acceptance criteria
- requirements for records
- revalidation and approval of changes to the processes

Computer software in support of production or quality management system that affects the ability of the product to conform to specified requirements is validated prior to use. The validation is based on the risk associated with the use of the software. **MP 7.5.2, Software Validation** documents the process for the validation of software and changes to the software and/or its application.

7.5.7 Validation of Processes for Sterilization

Not applicable to PTI business

7.5.8 Identification

All products in the control of PTI are assigned with a unique identifiable part number in accordance with **QP 7.5.3, Identification and Traceability**. Materials returned to PTI are identified and distinguished from conforming product per **QP 9.9, Customer Return**.

7.5.9 Traceability

PTI controls, records, and maintains product traceability in accordance with **QP 7.5.3, Identification and Traceability**. When stamp is used to identify inspection or test status, the stamp is controlled per **MP 7.5.1, Control of Stamps**.

7.5.10 Customer Property

PTI identifies, protects, and safeguards customer property provided for use or incorporation into the product.

- Component kits and other material received from the customer are verified against the customer-supplied documentation. Shortages and or discrepant material are communicated to the customer.
- Customer-supplied product is identified from the time received until the assemblies are completed. Excess consignment material is shipped back to the customer upon completion of the shop order.
- Customer-supplied test fixtures, tools and assembly aids are identified, maintained, and safeguarded. In general, customer is responsible for the calibration and maintenance of customer-owned equipment unless it's transferred to PTI.

PTI immediately (within two days) notifies customer if any customer-owned property is lost, damaged or found unsuitable for use. Records of notification and arrangements for replacement, repair, or return to the customer are maintained.

7.5.11 Preservation of Product

PTI preserves the conformity of product during processing, storage, handling, and delivery to the intended destination. Controls for product with limited shelf life and hazardous materials are established as applicable. PTI is committed to:

- Maintain appropriate identification of parts, materials and product from receipt through delivery to the customer. Safety warnings are included when required.
- Handle Electrostatic Discharge (ESD) sensitive material and Moisture Sensitive Devices (MSD) according to established procedures.
- Ensure material and product is properly packaged according to customer's specifications. If not specified by the customer, the product is packaged per PTI procedure to protect the product from transit damage.
- Ensure material and product is properly stored to maintain traceability and shelf life control if applicable
- Ensure product is in accordance with product specifications and applicable regulatory requirements.
- Maintain product cleanliness and prevent foreign object damage.

These activities are defined by the following procedures:

MP 9.5	Material Control – Stockroom
MP 15.2	ESD Sensitive Material Handling
MP 15.3	Material Handling
MP 15.4	Chemical Storage & Control of Expiration Dates
WI 15.2	Moisture Sensitive Device Handling
WI 7.5.5	Foreign Object Debris/Damage Program

7.6 Control of Monitoring and Measuring Devices

PTI maintains a list of monitoring and measuring devices needed to provide evidence of conformity of product. The monitoring and measuring devices are calibrated or verified at specified intervals, against measurement standards traceable to international or national measurement standards. PTI also maintains a process for recall of monitoring and measuring devices requiring calibration or verification.

MP 11.1, Equipment Control, Calibration & Maintenance defines the process 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.

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Measurement and monitoring activities are performed to ensure product and process conformity and to maintain the effectiveness of the quality management system. Such measurement and monitoring activities are defined per **QP 9.1, Process Control**.

The effectiveness of the quality management system are monitored through internal audits, analysis of data and measurement of customer satisfaction. Quality performance data, internal audit results, customer feedback, and key performance metrics are monitored and periodically reviewed to identify opportunities for improvement.

8.2 Monitoring and Measurement

8.2.1 Feedback, Complaint and Reporting to Regulatory Authorities

PTI collects and monitors data from customer to determine whether customer's requirements are met. Customer feedback, complaint, and/or reporting to regulatory is documented per **QP 8.2, Customer Feedback Process**. The information gathered from the customer is analyzed for potential input into risk management. Operational risk documents are updated when the customer information affects the risk management process.

8.2.2 Internal Audit

PTI conducts internal audits to verify that the QMS:

- Conforms to established requirements, the International standard, and applicable regulatory requirements
- Is effectively implemented and maintained

Internal audit is performed per **QP 17.1, Internal Audit** and it is conducted once per year. Internal audit can be completed within 2 months of the due date or as needed to address changes or deficiencies.

8.2.3 Monitoring and Measurement of Processes

Processes are monitored and as applicable measured to assure that customer requirements are met. The extent and priority of process monitoring is based on the criticality of the process for meeting customer requirements. When planned results are not achieved, PTI will take appropriate correction and corrective actions to ensure conformity of the product.

8.2.4 Monitoring and Measurement of Product

Inspection and test control points throughout the assembly process are established to verify product conformance to the specified requirements. Trained inspectors are assigned to the control points. Verification and acceptance of the product are documented on the shop traveler. The following procedures define these activities:

- QP 10.1 Receiving Inspection

- QP 10.3 PCBA Inspection
- QP 10.4 Electro Mechanical and Cable Harness Inspection
- MP 10.7 Test

PTI maintains the evidence of conformity to the acceptance criteria. The identity of the person authorizing the release of product is recorded and maintained on the shop traveler.

8.3 Control of Nonconforming Product

PTI ensures that nonconforming products or process outputs are identified and controlled to prevent their unintended use or delivery. **QP 13.1, Control of Nonconforming Output** defines the process. Nonconforming products returned by customer are processed and documented per **QP 9.9, Customer Return**.

Nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the identity of the person(s) authorizing the concession is maintained.

When nonconforming product is detected after deliver, PTI informs the customer within one day. Advisory notice is issued to the customer if any issue is found after delivery of the components. Advisory notice to the regulatory agent, if any, is handled by the customer. All traceability information including material, part number, lot number, serial number, and other necessary information is provided to customer.

Documented process for product needing rework is reviewed and approved prior to performing the task. Determination of any adverse effect of the rework upon product is made and documented. Reworked product is re-verified to demonstrate conformity to the requirements.

8.4 Analysis of Data

PTI determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources. See **QP 8.4, Analysis of Data** for detail. The results of data analysis provide information on:

- Customer feedback
- Product conformity
- Characteristics and trends of processes and products including opportunities for preventive action
- Supplier performance
- Audit results

8.5 Improvement

8.5.1 General

Improvements are identified and implemented to ensure and maintain the continued suitability, adequacy and effectiveness of the quality system. Improvements are driven by analysis of data related to:

- conformity of products and services
- customer feedback/satisfaction

- quality policy and objectives
- effectiveness of actions taken to address risks
- performance of external providers

8.5.2 Corrective Action

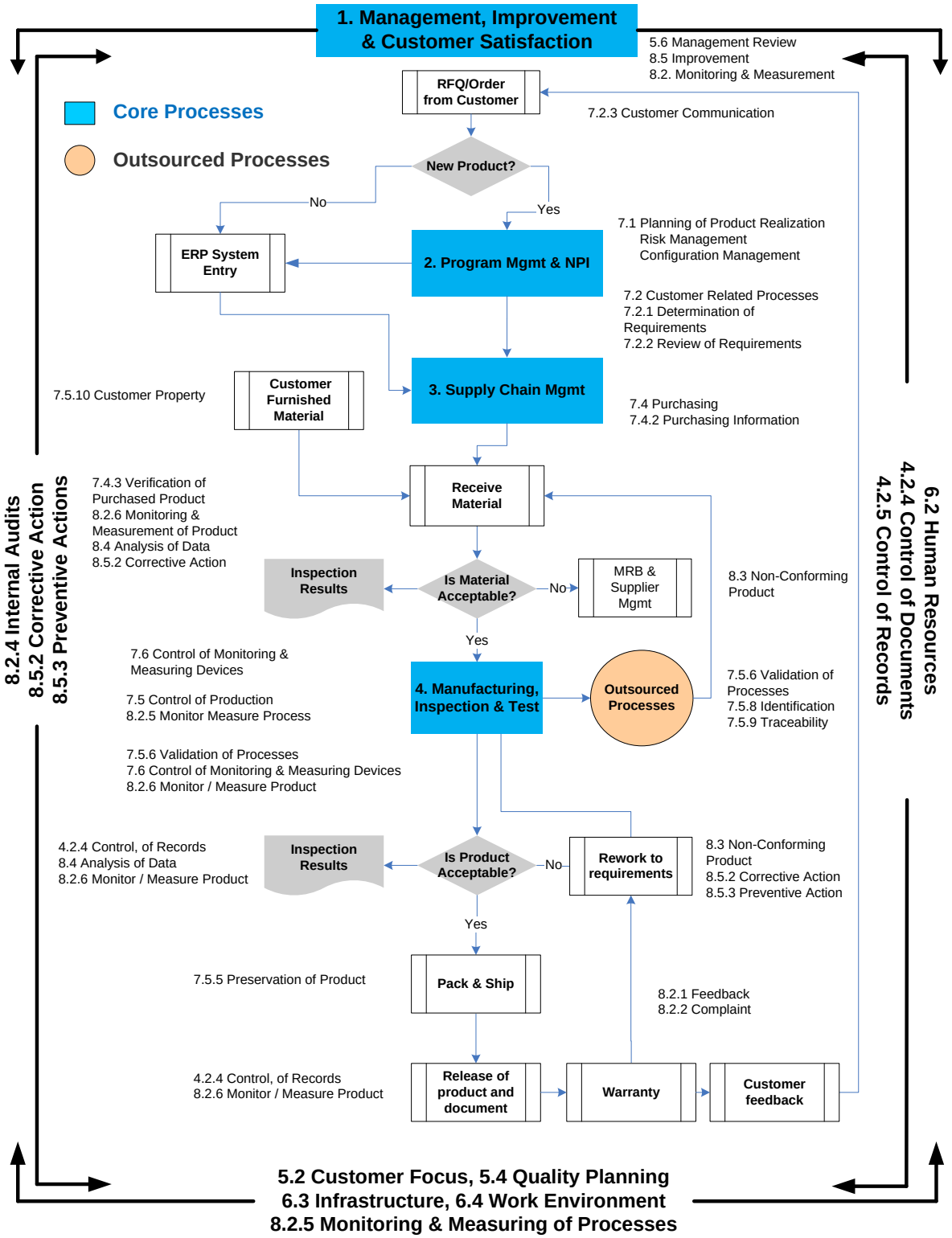
Corrective action is taken to eliminate the cause of nonconformities in order to prevent recurrence. Corrective action is taken without undue delay. Any action taken is reviewed to ensure its effectiveness. **QP 14.1, Corrective & Preventive Action** defines the process.

8.5.3 Preventive Action

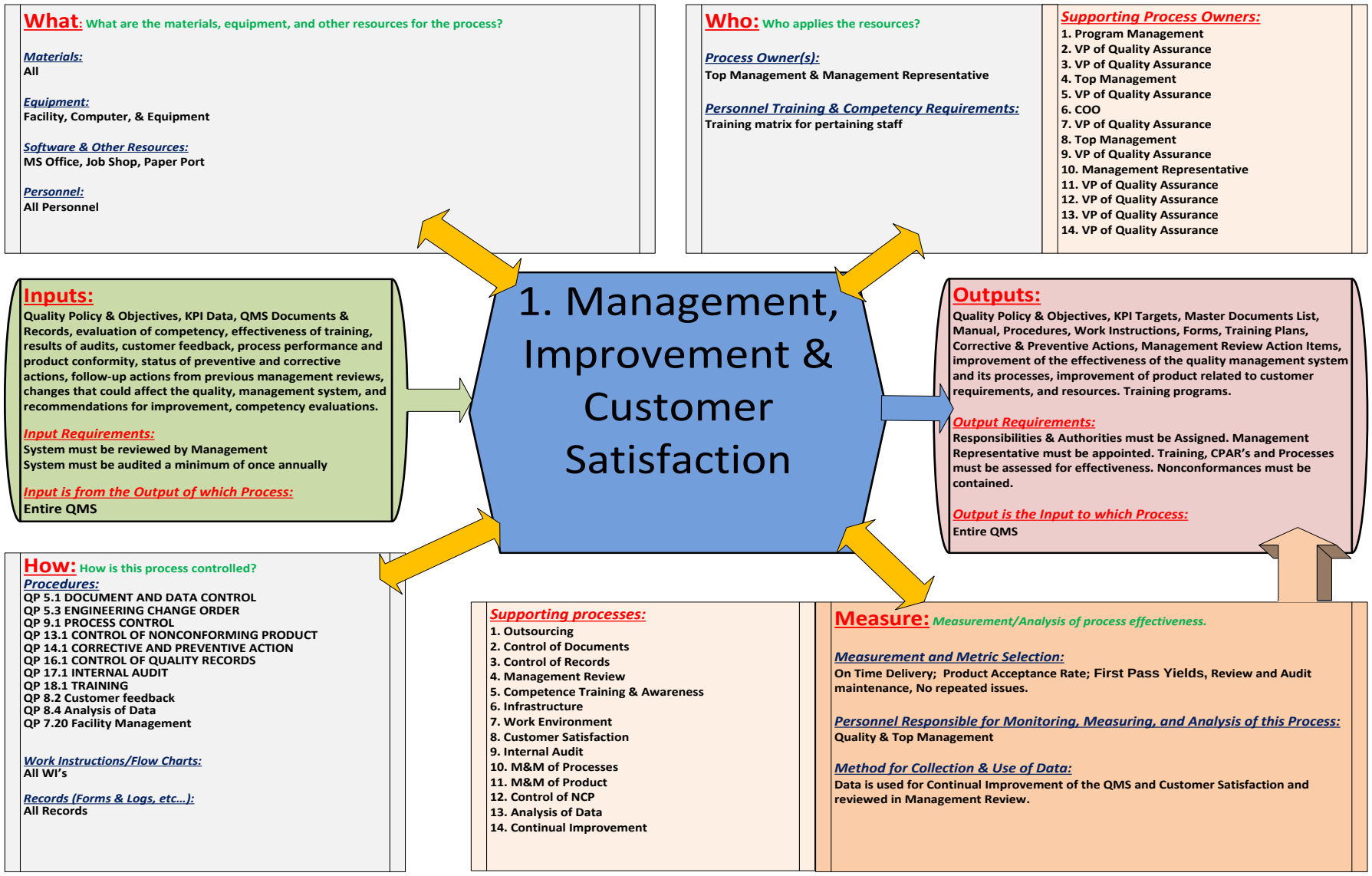
Preventive action is taken to eliminate the cause of potential nonconformities. Preventive action may be prioritized to maximize the return on investment. Action taken is reviewed to ensure its effectiveness. **QP 14.1, Corrective & Preventive Action** defines process. Risks are evaluated in various phases of product realization to proactively prevent potential nonconformities.

9 APPENDIX

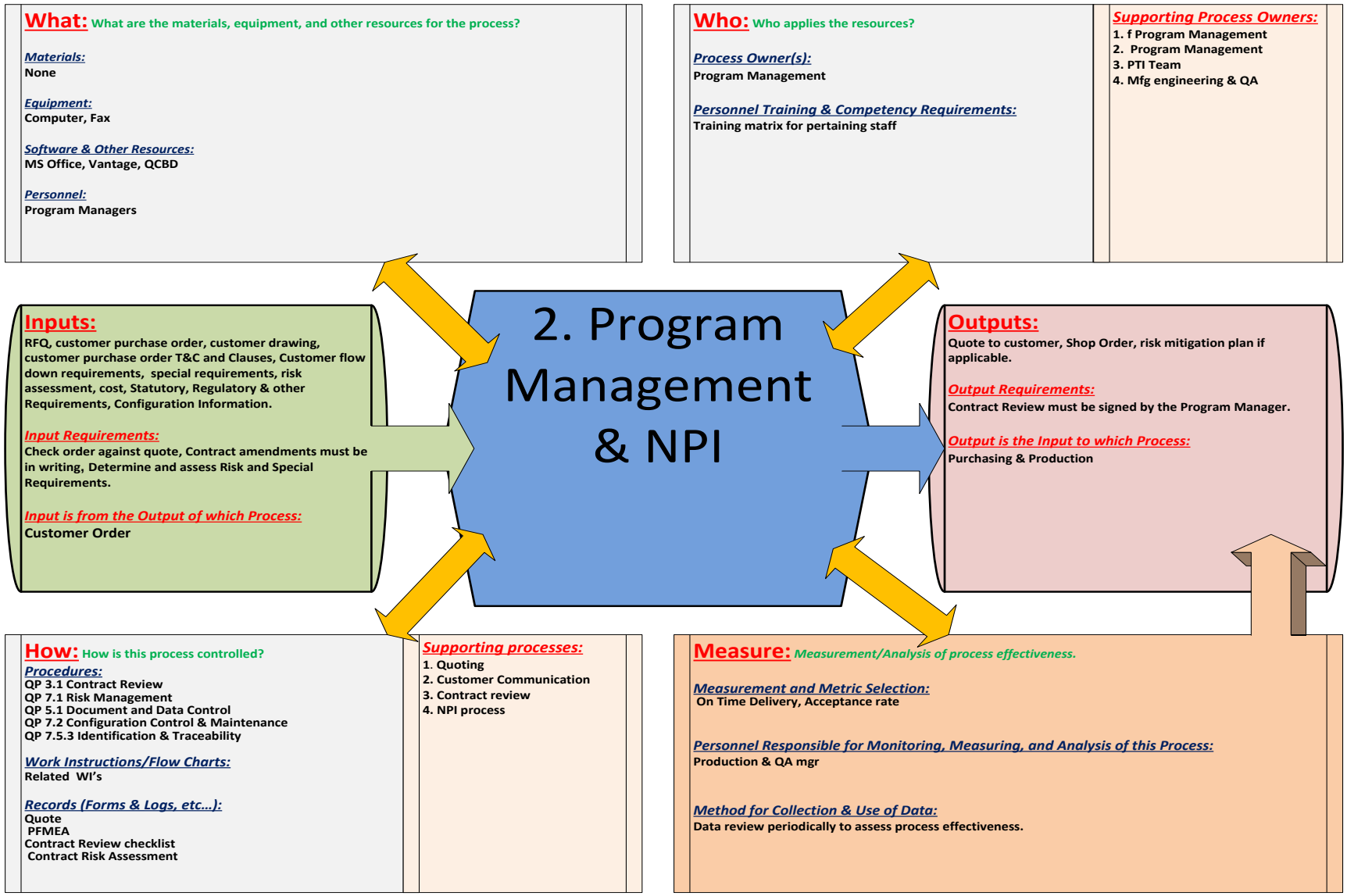
APPENDIX 1: QMS PROCESS FLOW



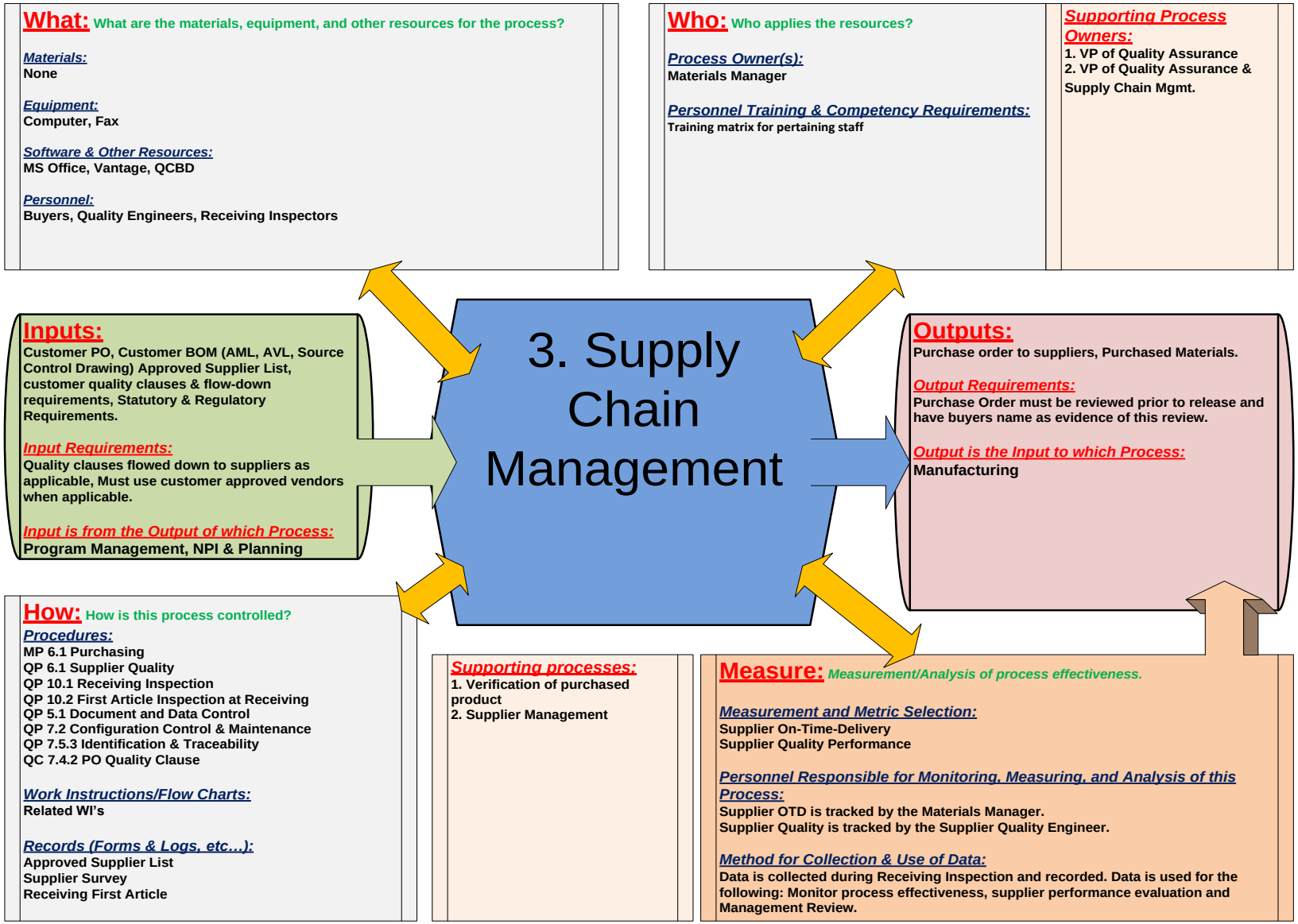
APPENDIX 2: CORE PROCESS TURTLE DIAGRAM - MGMT/IMP/CS



APPENDIX 3: CORE PROCESS TURTLE DIAGRAM – PM & NPI



APPENDIX 4: CORE PROCESS TURTLE DIAGRAM – SCM



APPENDIX 5: CORE PROCESS TURTLE DIAGRAM – MFG