QMS-001

Quality Management System Manual

Conforms to ISO 9001 and AS9100

Approved by:	Title	Signature
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REVISION HISTORY

Revision	Release date	Changes/Comments
A	July 19, 2016	Acquisition by PARPRO. Rewrite to replace previous revision of 022. Added design & development and post-delivery support.
B	Nov 16, 2016	Remove medical device quality requirement from QMS-001
C	Sep 12, 2017	Rewrite to implement ISO 9001/AS9100 latest rev
D	May 31, 2018	Add contract review to QMS process flow; update design KPI; add KPI review for effectiveness of risks and opportunities management; add statement that in-process verifications are determined from risk management process
E	Apr 29, 2021	Update QA Responsibility, Management Representative, section 8.1.4 adding QP 8.1, Appendix 2, 3, 4, 5
F	July 30, 2021	Appendix 3, 4 & 5 Updated. Section 9.3 updated to include Management Review Procedure. Update QA Responsibility, Management Representative
G	August 9, 2022	Update President, Design Center Location.
H	May 3, 2023	Update to exclude Design from QMS. Removed all reference to design and development.
I	Sep 14, 2023	1. Page 19 changed Contract Review to a Core process. 2. Page 21 added Contract Review turtle diagram.

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1 INTRODUCTION

PARPRO Technologies, Inc. (PTI) is a full-service contract manufacturing company. PTI's main capabilities include printed circuit board assemblies, cables & wire harnesses, electro-mechanical assemblies, and testing according to customer-provided design and specifications. PTI's customers are from the aerospace/defense, medical device, automotive, telecommunications and other industrial markets.

2 PURPOSE

This quality management system (QMS) manual is established to provide direction for ensuring product conformity and customer satisfaction. Product quality and customer satisfaction are obtained through planning, execution, monitoring and continual improvements. PTI reviews and revise this manual as necessary to meet the latest requirements of ISO 9001 and AS9100, and any applicable statutory and regulatory requirements.

3 TERMS & DEFINITIONS

Terms and definitions used in this document are in reference to ISO 9001 and AS9100.

4 CONTEXT OF THE ORGANIZATION

4.1 Organization and Its Context

Top management has reviewed and analyzed relevant aspects that determine the strategic direction of the company. This includes internal and external issues that are of concern to PTI and its relevant interested parties. Such issues are documented, reviewed, and updated as appropriate per **QP 4.1 Context of Organization, Risks and Opportunities**.

4.2 Needs and Expectations of Interested Parties

The issues determined per 4.1 above are summarized through an analysis of risks facing PTI and its relevant interested parties. The information is used by top management to determine the company's strategic direction. The information is monitored, reviewed and updated as conditions and situations change. See **QP 4.1 Context of Organization, Risks and Opportunities** for details.

4.3 QMS Scope

This quality manual is established to ensure product conformity and customer satisfaction. The applicability of this quality manual related to PTI's Manufacturing & support.

Exclusions – PARPRO manufactures and tests products in accordance with customer-provided design and specifications. Therefore, design and development of ISO 9001 and AS9100, Section 8.3 is excluded from PAPRO quality management system.

4.4 QMS and Its Processes

The QMS is monitored and continually improved in accordance with the International Standards, customer and applicable statutory and regulatory requirements. PTI uses a process approach for its management system. By identifying the core processes within the organization and managing each of these discretely, this ensures product conformity and customer satisfaction. Appendix 1 outlines the core QMS processes, inputs, outputs, and their interactions. Appendices 2 to 5 illustrate the turtle diagrams for each core process. Each core process contains:

- Applicable inputs and outputs
- Process owner(s)
- Applicable responsibilities and authorities
- Applicable risk and opportunities
- Support resources
- Criteria and methods needed to ensure the effectiveness of the process
- Objectives related to the process

Any process performed by a third party is considered an "outsourced process" and must be controlled. The outsourced process is managed in accordance with section 8.4.

5 LEADERSHIP

5.1 Leadership and Commitment

5.1.1. General

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
- ensuring that the Quality Policy and quality objectives are established for the QMS and are aligned with the strategic direction and the context of the organization
- ensuring the integration of the QMS requirements into the organization's business processes
- promoting the use of the process approach and risk-based thinking
- ensuring that the resources needed are available
- communicating the importance of effective quality management and of conforming to the QMS requirements
- ensuring that the management system achieves its intended results
- engaging, directing and supporting persons to contribute to the effectiveness of the management system
- promoting continual improvement
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility

5.1.2. Customer Focus

PTI makes customer requirements and customer satisfaction its top priorities. This is accomplished by:

- assuring customer and applicable statutory and regulatory requirements are determined and met
- determination and resolution of risks and opportunities
- maintaining the focus on enhancing customer satisfaction
- measurement and monitoring of product conformity and on-time delivery performance. Appropriate action is taken if planned results are not or will not be achieved.

5.2 Quality Policy

Top management has developed the quality policy that governs the day-to-day operations to ensure quality and customer satisfaction. The quality policy is as below:

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 policy periodically for continuing suitability and ensures the quality policy is communicated and understood within the organization.

5.3 Roles, Responsibility, and Authority

5.3.1. Responsibility and Authority

The table below defines the responsibility and authority within PTI's 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. PTI organization chart is outlined in **Form 1 Organization Chart**.

Responsibility and Authority

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

5.3.2. Management Representative

The VP of Quality and Technical Services is assigned as the QMS representative. The VP of Quality and Technical Services has the organizational freedom and unrestricted access to top management to resolve quality management issues and is responsible for:

- ensuring the QMS conforms to ISO 9001, AS9100 and that required QMS processes are established, implemented, and maintained
- reporting to top management on the performance of the QMS and on opportunities for improvement
- ensuring the promotion of customer focus throughout the organization

6 PLANNING

6.1 Risks and Opportunities

PTI takes actions to address risks and opportunities identified as part of the "Context of the Organization" defined in **QP 4.1 Context of Organization, Risks and Opportunities**, as well as through all other activities of the management system. Key Performance Indicators are established and reviewed monthly to access the effectiveness of actions taken to manage the risks and opportunities.

Product and production risks and opportunities are managed in accordance with **QP 7.1 Risk Management**. This procedure defines how risks are managed to minimize their likelihood and impact.

6.2 Quality Objectives and Planning

Top management has established the main quality objectives and key measures based on the quality policy. The table below summarizes these main objectives and key measures. Goals for the key measures are reviewed and set during management reviews. The performance is reviewed periodically. The planning of process quality objectives is defined in section 4.4 above.

Table: Quality Objectives & Key Measures

Quality Policy	Quality Objective	Key Measures
Meet or exceed customer expectation	Customer satisfaction	Customer satisfaction index or product acceptance rate
Delivering product on time	On-time delivery	On-time delivery performance
Per customer specification	Conforming to customer requirements	Product conformance metrics
Improving and maintaining the effectiveness of the QMS	Continually improve	Production and other improvement metrics

6.3 Planning of Changes

When change is needed, PTI reviews the purpose of the change and its potential consequences. PTI will determine the impact to the integrity of the QMS, resources availability, responsibility and authority in a panned manner to implement changes. Changes are reviewed, approved, and implemented per **QP 5.3 Engineering Change Order Process**.

7 SUPPORT

7.1 Resources

7.1.1 General

Top management determines and provides resources needed to implement, maintain, and continually improve the QMS effectiveness. Resources allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs obtained from external providers.

7.1.2 People

Top management ensures adequate staffing for the effective implementation of the QMS and for the operation and control of the QMS processes.

7.1.3 Infrastructure

Top management plans for and provides an infrastructure suitable for the operation. The infrastructure includes the buildings, equipment, transportation, IT and personnel necessary to support services, operations, 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.

7.1.4 Work Environment

PTI ensures the work environment is clean, 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**.

Specific environmental requirements for products are determined during quality planning and are documented in procedures, work instructions, or job documentation. Personnel who are required to work temporarily under special environmental conditions within the work environment will be trained or are supervised by a trained person.

7.1.5 Monitoring and Measuring Resources

PTI maintains a list of monitoring and measuring devices needed to provide evidence of conformity of product. The monitoring and measuring devices are suitable for the specific monitoring and measurement activities, 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.

7.1.6 Organization Knowledge

PTI determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

- internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property
- external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers

This knowledge is maintained and made available as necessary. When addressing changing needs and trends, PTI considers its current knowledge and determines how to acquire or access the necessary additional knowledge.

7.2 Competence

Employees performing product assembly, inspection, test, and other work affecting product quality are competent based on 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 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.

7.3 Awareness

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

7.4 Communication

Top management ensures that relevant information is communicated through all levels of the organization. The communication ensures:

- the quality policy and quality objectives are understood and reviewed for their effectiveness
- the quality management system requirements are available, implemented and understood
- customer requirements are available 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
- Employee orientation meetings
- Formal and informal training and instruction
- A MIS system including e-mails
- An 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

7.5 Documented Information

This QMS manual along with all other documented information are subject to review, approval, and control. **QP 5.1 Document Control**, and **QP 5.3 Engineering Change Order**, define the process for controlling, reviewing, approving, and implementing QMS documents. 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

Documented information is retained and maintained to demonstrate evidence of conformity to requirements and of the effective operation of the quality management system. Records are legible, identifiable, and retrievable. **QP 16.1 Control of Records**, defines the processes for identification, storage, protection, retrieval, and disposition of records. Records will be made available for customer review when requested.

8 OPERATION

8.1 Planning and Control

Planning of product realization is consistent with requirements from processes defined in section 4.4 and actions determined from section 6. Such planning is accomplished through:

- determining the product requirements and resources needed
- establishing criteria for the processes, the acceptance of product, and controls of the processes in accordance with the criteria
- determining, maintaining and retaining documented information to provide confidence that the processes have been carried out as planned and to demonstrate the product conformity
- determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified
- engaging representatives of affected organization functions for operational planning and control
- determining the process and resources to support the use and maintenance of the product
- determining the products and services to be obtained from external providers
- establishing the controls needed to prevent the delivery of nonconforming product to the customer

PTI appoints a program manager to manage all the products for the assigned customer. The program manager communicates and coordinates material, resource, and schedule requirements to meet the customer's objectives and contractual requirements. Program managers have access to top management to resolve issues.

Changes to operation processes are done in accordance with **QP 5.3 Engineering Change Order**.

Outsourced processes are controlled in accordance with **QP 6.1 Supplier Quality**.

When work transfer is necessary, the impacts and risks of the transfer are evaluated and managed to ensure continuing conformity. In this context, "work transfer" can mean the temporary or permanent handover of work between PTI's internal processes, between PTI and an external provider, or between external providers.

For transfers between internal processes, these are controlled through normal work planning methods. For transfers between PTI and an external provider, or between external providers, these are controlled in accordance with **QP 6.1 Supplier Quality**.

8.1.1 Operational 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.

8.1.2 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 Control
- QP 5.3 Engineering Change Order Process
- QP 7.2 Configuration Control & Maintenance
- QP 7.5.3 Identification & Traceability

8.1.3 Product Safety

Operational controls are implemented to ensure product safety during the entire product life cycle, as determined and necessary to the product. These activities may include:

- assessment of hazards and management of associated risks
- management of safety critical items
- analysis and reporting of occurred events affecting safety
- communication of these events and training of staff

8.1.4 Prevention of Counterfeit Parts

PTI considers the risks of counterfeit parts from sources other than the part's manufacturer or its authorized distributors. As a general policy, PTI procures materials from the direct manufacturer or its authorized distributors only. **QP 8.1 Counterfeit Prevention Process** contains the counterfeit prevention policy and process in more detail.

8.2 Requirements for Products

8.2.1 Customer Communication

PTI has established effective communication with customers. The program manager is the primary customer communication for:

- product requirements
- enquiries, contracts/orders, and customer changes
- customer feedback/complaint
- customer property management
- specific requirements for contingency action when needed

8.2.2 Determination of Requirements Related to the Product

PTI determines the product requirements through customer documentation. Sales and program management ensure that the customer provides a complete document package. The following are captured and reviewed:

- Product requirements, including applicable statutory and regulatory requirements and other criteria deemed necessary by PTI.
- Special requirements
- Operational risks

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.

8.2.3 Review of Requirements Related to the Product

Program management along with Purchasing, Technical Services and Quality Assurance review the requirements to ensure PTI has the capability to meet the requirements. Special requirements, critical items and key characteristics flowed down from the customer or risks identified during the review process are assessed and mitigated. When the customer requirements cannot be fully met, PTI negotiates a mutually acceptable requirement with the customer. These activities are defined in greater detail in **QP 3.1 Contract Review**.

8.2.4 Changes to Product Requirements

When customer contract or order requirements are changed, PTI reviews and implements the new requirements through the standard change process, **QP 5.3 Engineering Change Order Process**.

8.3 Design and Development

Excluded.

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

PTI is responsible for the conformity of all externally provided processes, products, and services, including 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, based on their ability to provide processes or product and services in accordance with requirements.

PTI utilizes an integrated ERP/MRP system in order to plan, execute, and control the externally provided processes, product and services.

8.4.2 Verification of Purchased Products and Services

Receiving inspection is performed in accordance with **QP 10.1 Receiving Inspection** and **QP 10.2 Receiving Inspection First Article Inspection** for the verification of purchased product and services. Verification activities include physical and visual inspection and verification of documentation such as certificates of conformity, test records, lab reports, and etc. Evidence of inspection, acceptance and rejection is maintained.

When purchased product is released for production use pending completion of all required verification activities, the material is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

In general, PTI does not delegate the verification activities to the external provider. When this becomes necessary, PTI will define the scope and requirements for the delegation. The performance of the delegated verification activities is monitored per **QP 6.1 Supplier Quality**.

8.4.3 Purchasing Information

PTI's purchasing information contains part number, description, terms and conditions (**TC 7.4.2 General Terms and Conditions of Purchase**), and other applicable specifications. 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 verified and approved prior to sending to the supplier. Purchasing information is maintained for traceability.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

PTI plans and executes production under controlled conditions. Controlled conditions include, as applicable:

- 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 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 requirements
- accountability of all products during production
- process controls for critical items, key characteristics, or applicable special processes
- in-process inspection, verification, and methods of measurement
- evidence of all planned production activities

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

- 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

8.5.1.1 Control of Equipment, Tools and Software Programs

Installation qualification is formed for new equipment prior to release for production. The installation qualification verifies the equipment functions and software programs when installed against the intended use. Equipment is maintained based on the manufacturer's recommendations and according to a suitable maintenance schedule. PTI may not use equipment requiring special environmental conditions unless feasible and required by customer contract.

Production equipment or tooling are stored in a designated, safe area to prevent potential damage. When in storage for less than one year, inspection & process setup verification prior to production

use is performed for the verification of the equipment or tooling condition. PTI owned equipment/tooling are checked for the condition once per year after it's in storage for over a year. Customer owned equipment/tooling will be returned to the customer when it's in storage for over a year.

8.5.1.2 Validation and Control of Special Processes

PTI validates production process where the resulting output cannot be verified by subsequent monitoring or measurement in accordance with **MP 7.5 Process Validation**. This includes process where deficiencies may become apparent only after the product is in use. Process validation is part of risk mitigations to demonstrate the ability of the process to achieve planned results. Arrangements for the validation process are established as applicable:

- Defined criteria for review and approval of the process
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records
- Revalidation

MP 7.5.2 Software Validation documents the procedure for the validation of computer software (and changes to such software and/or its application) used in support of production that affects the ability of the product to conform to specified requirements. Such software applications are validated prior to initial use. Records of validation are maintained.

8.5.1.3 Production Process Verification

Production processes are verified using a representative item from the first production run of a new part or assembly to verify that the process and tooling are capable of producing conforming products. Verification is repeated when changes occur that could invalidate the original results. In-process verifications are also performed. The in-process verification points are determined from the risk management per **QP 7.1 Risk Management**. Results of the verification are documented.

For customers with AS9102 first article report requirement, the report will be completed per **AS9102 Aerospace First Article Inspection Requirement.** The reports are documented on forms FRM212-1, FRM212-2, and FRM212-3.

8.5.2 Identification and Traceability

PTI maintains the identity and status of products throughout production in accordance with **QP 7.5.3 Identification and Traceability**. When a stamp is used to identify inspection or test status, the stamp is controlled per **MP 7.5.1 Control of Quality Stamps**.

8.5.3 Customer or External Provider Property

PTI identifies, protects, and safeguards customer or supplier property while it's under PTI's control or being incorporated into the product. These activities include:

- Component kits and other material received from the customer are counted and 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 job
- Customer-supplied test fixtures and assembly aids are retained based on contractual agreements. Customer-supplied test fixtures and assembly aids are identified, maintained,

and safeguarded as if they were PTI property. The customer is responsible for calibration and maintenance unless it's transferred to PTI.

PTI notifies the customer within 2 working days 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.

8.5.4 Preservation

PTI preserves the conformity of product during processing, storage, 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 shall be included when required
- Handle Electrostatic Discharge (ESD) sensitive and Moisture Sensitive Devices (MSD) per established procedures
- Ensure material and product is properly packaged per customer's specifications. If not specified by the customer, it shall be packaged in such a manner as 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 specifications and applicable statutory and regular 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 Control Program
- 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 Damage Prevention Program

8.5.5 Post Delivery Activities

PTI conducts the following post-delivery activities:

- report and investigate problems found after product delivery
- rework or repair of affected products returned from the customer per **QP 9.9 Customer Return**
- update technical documentation to include improvement learned from the post-delivery activities

Post-delivery activities are conducted in compliance with this management system. In determining the other post-delivery activities that are required, PTI considers:

- statutory and regulatory requirements
- the potential undesired consequences associated with the product
- the nature, use and intended lifetime of the product
- customer requirements and feedback
- collection and analysis of in-service data (e.g., performance, reliability, lessons learned).
- controls required for off-site work if applicable

- product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence)

8.5.6 Control of Changes

PTI controls changes affecting processes, production equipment, tools and software programs according to **QP 5.3 Engineering Change Order Process**. The results of changes to the production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

8.6 Release of Products

Products undergo inspection and/or testing to ensure they meet all predefined requirements at various stages throughout the process. Final inspection/verification is performed prior to delivery. Product cannot be released to subsequent process or to the customer without verification of conforming to the planned activities and quality requirements. PTI's production traveler contains all pre-determined inspection and/or testing steps. Product may be released with approval of relevant authority or by the customer. Such release is documented by a Process Deviation.

PTI maintains the evidence of conformity with acceptance criteria and traceability to the person authorizing the release. When required, PTI provides the documented evidence demonstrating product conformity to the customer.

Activities performed prior to release of products are defined by the following procedures:

- QP 10.1 Receiving Inspection
- QP 10.2 Receiving Inspection First Article Inspection
- QP 10.3 PCBA Inspection
- QP 10.4 Electro-Mechanical and Cable Harness Inspection
- MP 10.7 Test

8.7 Control of Nonconforming Outputs

PTI ensures that nonconforming products or process outputs are identified and controlled to prevent their unintended use or delivery. The controls for nonconforming outputs are defined in **QP 13.1 Control of Nonconforming Product and Process**. Nonconforming products returned by the customer are processed and controlled per **QP 9.9 Customer Returns**.

9 PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 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 is 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.

9.1.2 Customer Satisfaction

Evaluation of customer satisfaction include product acceptance rate, on-time delivery, customer complaints, and customer corrective action requests. PTI has established improvement processes that address deficiencies identified by the customers. Refer to **QP 8.2 Customer Feedback Process** for details.

9.1.3 Analysis and Evaluation

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 satisfaction
- product conformity
- characteristics and trends in processes and products including opportunities for preventive action
- supplier performance
- the effectiveness of actions taken to address risks and opportunities

9.2 Internal Audit

PTI conducts internal quality audits at planned intervals per **QP 17.1 Internal Audit** to verify that the QMS:

- conforms to established requirements and the latest ISO 9001 and AS9100 standards
- is implemented, maintained, and continually improving the effectiveness

9.3 Management Review

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

- the status of actions from previous management review
- changes in external and internal issues that are relevant to the QMS
- performance and effectiveness of the QMS
    - customer satisfaction
    - the extent to which quality objectives have been met
    - Process performance and product conformity
    - Nonconformities and corrective and preventive actions
    - Monitoring and measurement results
    - Results of audits
    - supplier performance
    - on-time delivery performance
- the adequacy of resources
- the effectiveness of actions taken to address risks and opportunities
- Recommendations for improvement

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

- opportunities for improvement

- need for changes to the QMS
- resource needs
- risks identified

QP 11.1 Management Review Procedure define these activities with more details.

10 IMPROVEMENT

10.1 General

PTI uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible. Improvement is driven by an analysis of data related to:

- conformity of products and services
- the degree of customer satisfaction
- the performance and effectiveness of the management system
- the effectiveness of planning
- the effectiveness of actions taken to address risks and opportunities
- the performance of external providers
- other improvements suggested by employees

10.2 Corrective Action

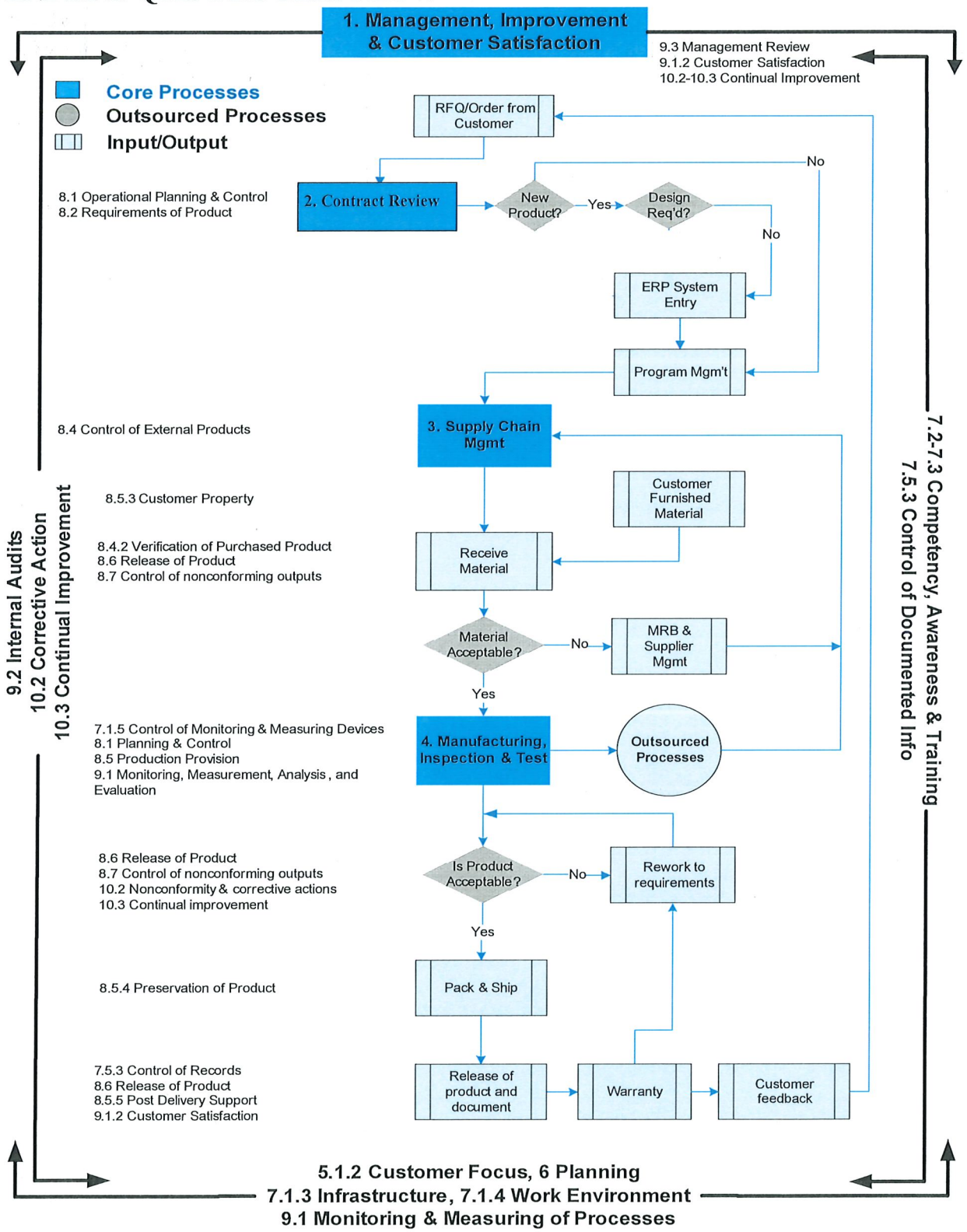
Corrective action is taken to eliminate the causes of nonconformities in order to prevent recurrence. PTI also takes preventive actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. **QP 14.1 Corrective and Preventive Action** defines the process for these activities.

10.3 Continual Improvement

Through the process effectiveness reviews, PTI works to continually improve the suitability, adequacy and effectiveness of the quality management system. This includes seeking opportunities for improvement and monitor the effectiveness of the improvement activities.

11 APPENDIX

APPENDIX 1: QMS PROCESS FLOW



APPENDIX 1: CORE PROCESS TURTLE DIAGRAM - MGMT/IMP/CS

What: What are the materials, equipment, and other resources for the process?

Materials:
All

Equipment:
Facility, Computer, & Equipment

Software & Other Resources:
MS Office, Job Shop, Paper Port

Personnel:
All Personnel

Who: Who applies the resources?

Process Owner(s):
Top Management & Management Representative

Personnel Training & Competency Requirements:
See Job Descriptions

Supporting Process Owners:
1. Program Management
2. Manager of Quality
3. Manager of Quality
4. Top Management
5. Manager of Quality
6. COO
7. Manager of Quality
8. Top Management
9. Manager of Quality
10. Management Representative
11. Manager of Quality
12. Manager of Quality
13. Manager of Quality
14. Manager of Quality

Inputs:
Quality Policy & Objectives, KPI Data, QMS Documents & Records, evaluation of competency, effectiveness of training, results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the quality, management system, and recommendations for improvement, competency evaluations.

Input Requirements:
System must be reviewed by Management
System must be audited a minimum of once annually

Input is from the Output of which Process:
Entire QMS

1. Management, Improvement & Customer Satisfaction

Applicable AS9100 Section(s): all

Outputs:
Quality Policy & Objectives, KPI Targets, Master Documents List, Manual, Procedures, Work Instructions, Forms, Training Plans, Corrective & Preventive Actions, Management Review Action Items, improvement of the effectiveness of the quality management system and its processes, improvement of product related to customer requirements, and resources. Training programs.

Output Requirements:
Responsibilities & Authorities must be Assigned. Management Representative must be appointed. Training, CPAR's and Processes must be assessed for effectiveness. Nonconformances must be contained.

Output is the Input to which Process:
Entire QMS

How: How is this process controlled?

Procedures:
QP 4.1 Context of Organization
QP 5.1 DOCUMENT AND DATA CONTROL
QP 5.3 ENGINEERING CHANGE ORDER
QP 7.1 Risk Management
QP 8.2 Customer feedback
QP 8.4 Analysis of Data
QP 9.1 PROCESS CONTROL
QP 13.1 CONTROL OF NONCONFORMING PRODUCT
QP 14.1 CORRECTIVE AND PREVENTIVE ACTION
QP 16.1 CONTROL OF QUALITY RECORDS
QP 17.1 INTERNAL AUDIT
QP 18.1 TRAINING
QP 11.1 Management Review

Work Instructions/Flow Charts:
All WI's

Records (Forms & Logs, etc...):
All Records

Supporting processes:
1. Outsourcing
2. Control of Documents
3. Control of Records
4. Management Review
5. Competence Training & Awareness
6. Infrastructure
7. Work Environment
8. Customer Satisfaction
9. Internal Audit
10. M&M of Processes
11. M&M of Product
12. Control of NCP
13. Analysis of Data
14. Continual Improvement

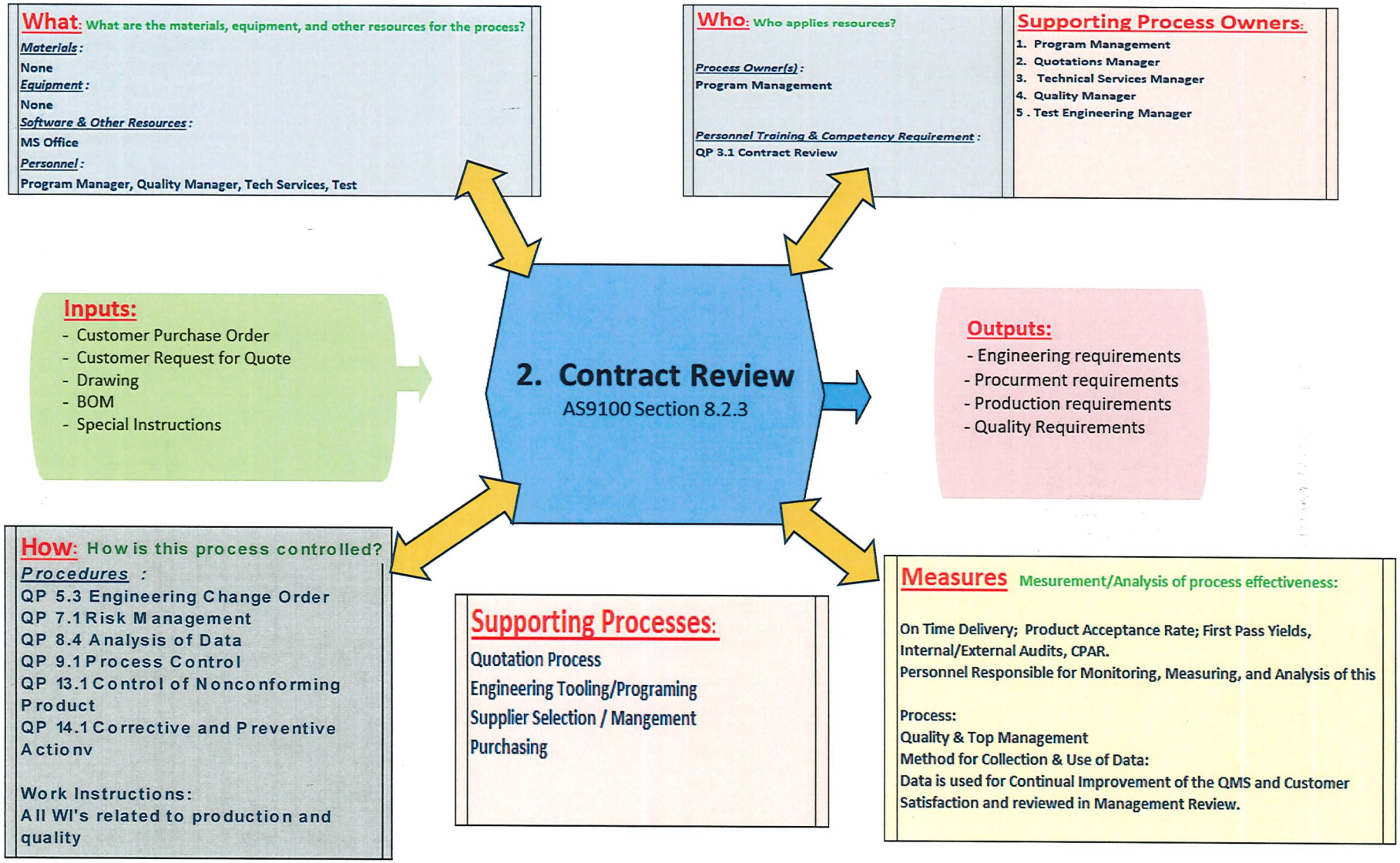
Measure: *Measurement/Analysis of process effectiveness.*

Measurement and Metric Selection:
On Time Delivery; Product Acceptance Rate; First Pass Yields, Internal/External Audits, CPAR.

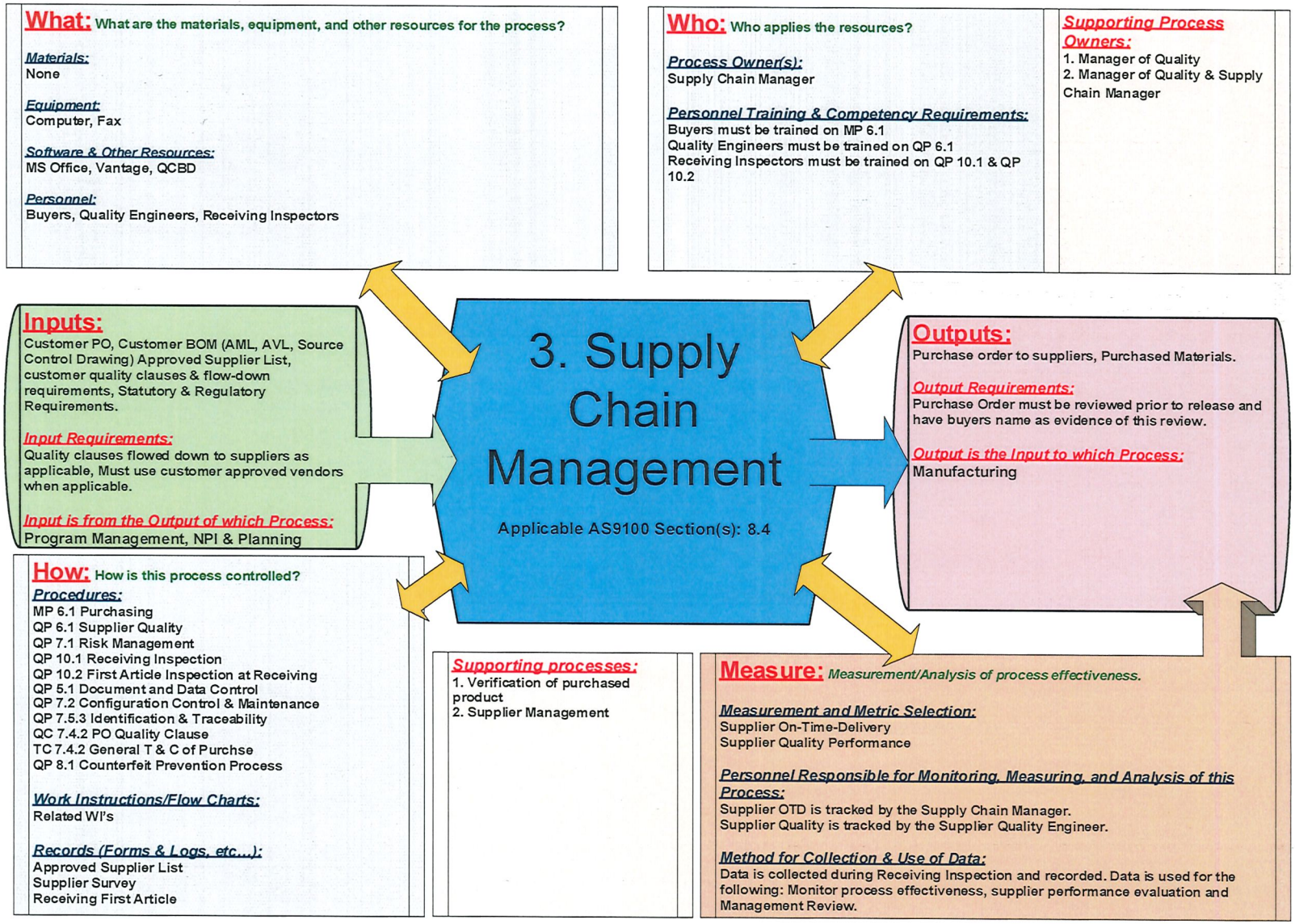
Personnel Responsible for Monitoring, Measuring, and Analysis of this Process:
Quality & Top Management

Method for Collection & Use of Data:
Data is used for Continual Improvement of the QMS and Customer Satisfaction and reviewed in Management Review.

APPENDIX 2: CORE PROCESS TURTLE DIAGRAM – CONTRACT REIVEW



APPENDIX 3: CORE PROCESS TURTLE DIAGRAM – SUPPLY CHAIN MGMT



APPENDIX 4: CORE PROCESS TURTLE DIAGRAM – MFG