Specialized Turning, Inc.'s Quality Manual

Rev 9

Describing the
Quality Management System

Based on
AS9100 (C)

Approved by

Chip Holm
President

Exclusions:

Sec 7.3 - Design Control as Specialized Turning has no design responsibility. All products are produced to customer designs and specifications.

Sec 7.5.1.4, Post Delivery Support as Specialized Turning has no responsibility for providing customer service contracts**. Item 7.5.1.4.b is controlled via section 8.3 and P 14.0, Control of Nonconforming Product.**

Such exclusions do not affect the organizations ability of responsibility to provide product that meets customer and/or applicable statutory and regulatory requirements.

For the purposes of the QMS, Specialized Turning will be referred to as STI.

Table of Contents

Quality Manual

Approvals

Title	Signature	Date
President:	_____	
General Manager:	_____	
Quality Manager:	_____	

Manual Revision Number & Description	Date
REVISIONS PREVIOUS TO 6 ARE UNACCOUNTED FOR DUE TO	
TOTAL PAPER LOSS FROM FLOOD	10/2010
REV 6 – QMS Salvaged at this revision	12/2010
REV 7 – Massive overhaul to become relevant to AS9100 C	1/2012
REV 8 – Additional changes to prepare for Stage 1 audit complete change to QP-1 to be more process based.	6/2014
Rev 9 – move exclusions to pg 1, clarified note 1 pg 8, clarified note 4 pg 9, clarified exclusion 7.5.1.4 on pg 19	3/12/15

1.0 Introduction

History

Specialized Turning, Inc. traces its roots back to 1935 when Don Carter, a watchmaker, recognized the need for small precision machining services for local industry. Through the years the company has transformed into a modern CNC machine shop specializing in low volume manufacturing of precision components for discriminating customers in the aerospace, medical, process control and instrumentation and calibration industries.

Scope

Specialized Turning, Inc. Quality Management System's apply to all aspects of the process and operational controls used by Specialized Turning to provide quality products to our customers and comply with all applicable statutory and regulatory requirements. The Quality Management System's policies, process flows, procedures, work instructions and other supporting documentation describe the processes and how they are performed in order to ensure conformance to the SAE AS9100 and Quality Management System Standards. Specialized Turning Quality Management System's include processes for the continual improvement of these systems.

Specialized Turning, Inc. specializes in turning diameters 10" and under on components that require tolerances to .0002" or less than 6 microns, and milling dimensions up to 22" Long X 17" Wide X 12" High. Specializing in thin walls and intricate details such as weld preps and special radius forms Specialized Turning, Inc. is able to meet the most demanding specifications with regard to run out, concentricity and parallelism. Most customers have incoming inspection due to the critical mission critical components sourced from Specialized Turning, Inc.

Our machining capabilities run across all aluminum, brass, bronze, stainless, plastic, titanium, Inconel, and super alloys. Specialized Turning, Inc. is an expert at turning and milling operations utilizing contemporary machining and metrology techniques. With our focus on precision turning, milling, and their secondary operations associated with hard to machine materials, Specialized Turning, Inc.'s expertise is focused on a niche market.

We employ an aggressive continuous improvement mindset and encourage employee involvement in increasing quality, set-up reduction, customer service, and eliminating wastes to increase the value of our services. Specialized Turning, Inc. employs Lean Manufacturing techniques and Six Sigma principles to expose problematic and inefficient areas in need of improvement.

Finally, Specialized Turning, Inc. also utilizes the most current and advanced computer software for quotation, order entry, cost tracking and document management. We strive to increase the value of our services through a continuous improvement program focused on the customer.

Vision Statement

To achieve customer satisfaction through the on time delivery of: defect free, lean manufactured, cost-competitive products.

Quality Policy

Specialized Turning, Inc. strives for excellence through Continuous Improvement techniques and tools built on: customer focus, strengthening the organizational and operational effectiveness of the company, and profitable returns. We promote the full involvement and empowerment of all employees and create a safe, comfortable, and regulatory compliant work environment to achieve these objectives.

As part of our commitment to our customers, Specialized Turning, Inc. will establish and maintain an AS9100 Quality Management System.

Mission Statement

We realize that in order to improve we must strive for outstanding performance in every aspect of the business. In order to accomplish this goal it is essential that all employees at Specialized Turning are driven by the following fundamental values without compromise:

- Always put the customer first, and always b**e** responsive in a timely manner to their problems.

- Create an enjoyable, positive work environment that helps our employees work as a team, grow, motivate them to take responsibility, provides them with the initiative and authority to act, and also give them a clear understanding that they can make a difference in the business and reward them for our success as a team.

- Identify those suppliers who have the same commitment to excellence that we do and form a true partnership to ensure each other long-term success.

- To practice Lean Manufacturing and Continuous Improvement techniques throughout all aspects of the company to provide our customers with the best service possible.

2.0 References

The following referenced documents are indispensable for the application of this document. The latest editions of the referenced documents apply;

ISO 9000	Quality Management Systems – Fundamentals and vocabulary
ISO 9001	Quality Management System – Requirements
AS 9100	Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations

3.0 Terms and Definitions

For the purpose of this document, the terms and definitions given in ISO 9000 and AS9100 apply.

4.0 Quality Management System

4.1 General requirements

STI shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall,

a) determine the processes needed for the quality management system and their application throughout the organization,
b) determine the sequence and interaction of these processes,
c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
e) monitor, measure (where applicable) and analyze these processes, and
f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.[1]

[1] Processes needed for the quality management system referred to above shall **include key QMS processes for Management, Manufacturing Support, Manufacturing and Quality Support –**

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. [2]
Control of such outsourced processes shall be identified within the quality management system. The type and extent of control to be applied to these outsourced processes shall be defined within the QMS. [3]

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,
b) a quality manual,
c) documented procedures required by this International Standard,
d) documents needed by the organization to ensure the effective planning, operation and control of its processes,
e) records required by this International Standard.

STI shall ensure that personnel have access to and are aware of relevant QMS documentation and changes.

4.2.2 Quality Manual

STI shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions[4],
b) the documented procedures established for the quality management system, or reference to them, and
c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,

---

[2] An outsourced process is a process that the organization needs for its QMS and which the organization chooses to have performed by an external party.

[3] Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customers, statutory and regulatory requirements. The type and extent of control applied to the outsourced process can be influenced by factors such as; potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements, the degree to which the control of the process is shared, the capability of achieving the necessary control through the application of section 7.4

c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,
f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the QMS are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. STI shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. The documented procedure shall define the method for controlling records created by and/or retained by suppliers to STI.

Where records are stored in an electronic form, the integrity of the system and the back-up procedures shall be appropriately validated. These records without possibility of change by software shall be traceable to the original documentation.

Records of product origin, conformity and shipment shall be maintained for a minimum of 5 years, or as required by contract.

Records shall be available for review by customers in accordance with contract requirements and shall remain legible, readily identifiable and retrievable.

5.0 Management Responsibility

5.1 Management Commitment

STI top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by;

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
b) establishing the quality policy,
c) ensuring that quality objectives are established,
d) conducting management reviews, and
e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction. Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not or will not be met.

5.3 Quality policy

Top management shall ensure that the quality policy[5];

a) is appropriate to the purpose of the organization,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization, see appendix C.

5.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement
c) ensuring the promotion of awareness of customer requirements throughout the organization, and

[5] Quality Policy is stated in section 1.0 of the manual identified as Introduction/ Quality Policy

d) the organizational freedom and unrestricted access to top management to resolve quality management issues.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

STI top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained.

5.6.2 Review input

The input to management review shall include, as a minimum, information on;

a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system, and
g) recommendations for improvement.

5.6.3 Review output

The output from the management review shall include, at a minimum, any decisions and actions related to;

a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

6.0 Resource Management

6.1 Provision of resources

STI shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its

b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. Note: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the QMS.

6.2.2 Competence, Training and Awareness

STI shall;

a) determine the necessary competence for personnel performing work affecting conformity to product requirements
b) where applicable provide training or take other actions to achieve the necessary competence,
c) evaluate the effectiveness of training or other actions taken,
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) maintain appropriate records of education, training, skills and experience.[6]

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace, and associated utilities,
b) process equipment; both hardware and software, and
c) supporting services; such as transport, communication or information systems.

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements. Human factors to be considered include; safety rules, protective equipment, and ergonomics. Physical factors to be considered include; heat, light, hygiene, humidity, cleanliness, vibration, pollution and airflow.[7]

7.0 Product Realization

7.1 Planning of product realization

---

[6] Reference section 4.2.4

[7] The term work environment relates to those conditions under which work is performed including physical, environmental and other factors such as noise, temperature, humidity, lighting

STI 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.

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

a) quality objectives and requirements for the product, (considering - product and personal safety, reliability, availability, maintainability, producibility and inspectability, suitability of parts and materials used in products, selection and development of embedded software, recycling or final disposal of product at the end of its life.
b) the need to establish processes and documents, and to provide resources specific to the product,
c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance.
d) records needed to provide evidence that the realization processes and resulting product meet the requirements[8]
e) configuration management appropriate to the product,
f) resources to support the use and maintenance of the product.

The output is this planning shall be in a form suitable for the organization's method of operations.

7.1.1 Project Management

As appropriate to the organization and the product, the organization shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

The organization shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product

a) assignment of responsibilities for risk management,
b) definition of risk criteria; e.g., likelihood, consequences, risk acceptance,
c) identification, assessment and communication of risks throughout product realization,
d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and
e) acceptance of risks remaining after implementation of mitigating actions.

7.1.3 Configuration Management

The organization shall establish, implement and maintain a configuration management process that includes, as appropriate to the product

a) configuration management planning,
b) configuration identification,

c) change control,
d) configuration status accounting, and
e) configuration audit.

7.1.4 Control of Work Transfers

The organization shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work; e.g., from one organization facility to another, from the organization to a supplier, from one supplier to another supplier, and to verify the conformity of the work to requirements.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product
The organization shall determine;

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,[9]
b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) statutory and regulatory requirements applicable to the product, and
d) any additional requirements considered necessary by the organization

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization'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;

a) product requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved,
c) the organization has the ability to meet the defined requirements
d) special requirements of the product are determined, and
e) risks, i.e., new technology, short delivery timeframe, have been identified.[10]

Records of the results of the review and actions arising from the review shall be maintained.[11]

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.
Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

---

[9] Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services and supplementary services such as recycling or final disposal.
[10] Reference section 7.1.2

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,
b) inquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

7.3 Design and development

Note: This section is not applicable to STI, as it does not perform or maintain design responsibility.[12]

7.4 Purchasing

7.4.1 Purchasing Process

The organization shall ensure that purchased product conforms to specified purchase requirements.

The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's 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 shall be maintained.

The organization shall:

a) maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family),
b) periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls to be implemented,
c) define the necessary actions to take when dealing with suppliers that do not meet requirements,
d) ensure where required that both the organization and all suppliers use customer-approved special process sources,
e) define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on their approval status, and f) determine and manage the risk when selecting and using suppliers (see 7.1.2).

7.4.2 Purchasing information

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

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel,
c) quality management system requirements,
d) the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,
e) requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics,
f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,
g) requirements regarding the need for the supplier to
   - notify the organization of nonconforming product,
   - obtain organization approval for nonconforming product disposition,
   - notify the organization of changes in product and/or process, changes of suppliers, change of manufacturing facility location and, where required, obtain organization approval, and
   - flow down to the supply chain the applicable requirements including customer requirements,
h) records retention requirements, and,
i) right of access by the organization, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

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

Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective control of quality and does not absolve the organization of its responsibility to provide acceptable product and comply with all requirements.

Verification activities can include;
- obtaining objective evidence of the conformity of the product from the supplier (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records),
- inspection and audit at the supplier's premises,
- review of the required documentation,
- inspection of products upon receipt, and

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

Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained. STI does not provide delegation of inspection authority and therefore takes this requirement as an exclusion.[13]

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

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable;

a) the availability of information that describes the characteristics of the product,
b) the availability of work instructions, as necessary,
c) the use of suitable equipment,
d) the availability and use of monitoring and measuring equipment,
e) the implementation of monitoring and measurement,
f) the implementation of product release, delivery and post-delivery activities.[14]
g) accountability for all product during production (e.g., parts quantities, split orders, nonconforming product),
h) evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,
i) provision for the prevention, detection and removal of foreign objects,
j) monitoring and control of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements, and
k) criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

Planning shall consider, as applicable,

- establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,
- designing, manufacturing and using tooling to measure variable data,
- identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and
- special processes.[15]

---

[13] Reference page 2 – Exclusions

[14] STI, with the exception of customer returns and/or complaints, has no contractual post delivery requirements; ref see 7.5.1.4, and page 2 – exclusions

7.5.1.1 Production Process Verification

The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

7.5.1.2 Control of Production Process Changes

Personnel authorized to approve changes to production processes shall be identified.

The organization shall control and document changes affecting processes, production equipment, tools, or software programs.

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

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.

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

7.5.1.4 Post Delivery Support[16] **Section 7.5.1.4 is taken as a exclusion as STI has no post-delivery contractual obligations. Item b of this section is controlled via section 8.3 of this manual and P14.0.**

7.5.2 Validation of processes for production and service provision.

STI shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. As a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

These are often referred to as Special Processes.

Validation shall demonstrate the ability of these processes to achieve planned results.

STI shall establish arrangements for these processes as applicable;

---

[15] Reference7.5.2

[16] **Reference page 1 – Exclusions**

a) defined criteria for review and approval of the process,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records,
e) revalidation.

7.5.3 Identification and traceability

Where appropriate, STI shall identify the product by suitable means throughout product realization.

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

STI shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

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

Traceability requirements may include

- identification to be maintained throughout the product life,
- the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination; e.g., delivery, scrap,
- for an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and
- for a product, a sequential record of its production, manufacture, assembly, and/or inspection/verification, to be retrievable.

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization 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, the organization shall report this to the customer and maintain records.[17]

Customer property can include material, products, tooling and intellectual property and personal data.

7.5.5 Preservation of product

STI shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity of requirements. As applicable preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Preservation of product shall also include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for

a) cleaning,
b) prevention, detection and removal of foreign objects,
c) special handling for sensitive products,
d) marking and labeling including safety warnings,
e) shelf life control and stock rotation, and
f) special handling for hazardous materials

7.6 Control of monitoring and measuring devices

STI shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall maintain a register of the monitoring and measuring equipment, and define the process employed for their calibration/verification, including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

The organization 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.

The organization shall ensure that environmental conditions are suitable for the calibrations, inspection, measurement and testing being carried out.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, 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.[18]
b) be adjusted or re-adjusted as necessary;
c) have identification in order to determine its calibration status,
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage*;* The organization shall establish, implement and maintain a process for the recall of monitoring and measurement equipment requiring calibration or verification.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

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

satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

8.0 Measurement, Analysis and Improvement

8.1 General

STI shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity to product requirements,
b) to ensure conformity of the quality management system, and
c) 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.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. Organizations shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, repeat jobs, compliments, and dealer reports.

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system;

a) conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organization, and
b) is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained.[19]

The management responsible for the area being audited shall ensure that any necessary corrections and corrective 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.[20]

8.2.3 Monitoring and Measurement of Processes

The organization 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.

When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring and measuring appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the QMS.

In the event of process nonconformity, the organization shall
- take appropriate action to correct the nonconforming process,
- evaluate whether the process nonconformity has resulted in product nonconformity,
- determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
- identify and control any nonconforming product in accordance with clause 8.3.

8.2.4 Monitoring and Measurement of Product

STI shall monitor and measure the characteristics of the product to verify that product requirements have been met.

This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements.[21] Evidence of conformity with the acceptance criteria shall be maintained.

Measurement requirements for product acceptance shall be documented and shall include

a) criteria for acceptance and/or rejection,
b) where in the sequence measurement and testing operations are performed,
c) required records of the measurement results, at a minimum, indication of acceptance or rejection, and

[19] Reference 4.2.4
[20] Reference 8.5.2. See ISO 19001 for guidance

d) any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified the organization shall ensure they are controlled and monitored in accordance with the established processes.

When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use; i.e., matching the sampling plan to the criticality of the product and to the process capability.

Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Records shall indicate the person(s) authorizing release of product for delivery to the customer.[22]

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

The release of product and delivery of service to the customer shall not proceed until the planned arrangements[23] have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The organization shall ensure that all documents required to accompany the product are present at delivery.

8.3 Control of nonconforming product

STI shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

The organization's documented procedure shall define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.

Where applicable STI shall deal with nonconforming product by one or more of the following ways:

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

[22] Reference 4.2.4

d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started;
   - The organization's nonconforming product control process shall provide for timely reporting of delivered nonconforming product;
   - Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory authorities.

e) by taking actions necessary to contain the effect of the nonconformity on other processes or products.

Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the organization responsible for design.
NOTE Authorized representative includes personnel having delegated authority from the design organization.

STI shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

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

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.[24]

8.4 Analysis of data

The organization 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 effectiveness 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 data shall provide information relating to;

a) customer satisfaction,
b) conformity to product requirements,[25]
c) characteristics and trends of processes and products including opportunities for
d) preventive action,[26] and
e) suppliers.[27]

8.5 Improvement

8.5.1 Continual improvement

[24] Reference 4.2.4
[25] Reference 8.2.4
[26] Reference 8.2.3 and 8.2.4

The organization 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, management reviews, and customer feedback.

The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results. Note : Continual Improvement can result from lessons learned, problem resolutions and the benchmark of best practices.

8.5.2 Corrective action

The organization 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 shall be established to define requirements for;

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken,
f) reviewing the effectiveness of the corrective action taken
g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,
h) specific actions where timely and/or effective corrective actions are not achieved, and
i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

8.5.3 Preventive action

The organization 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 shall be established to define requirements for;

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken, and
e) reviewing the effectiveness of preventive action taken.

Appendix A (Section 1)

Procedure No.	Rev No.	Title	Reference AS 9100C
P 4.0	rev. 8	Quality Management System & Document Requirements	Sec 4.0
P 5.0	rev. 7	Management Responsibility	Sec 5.0
P 6.0	rev. 8	Resource Management	Sec 6.0
P 7.0	rev. 21	Product Realization	Sec 7.0
P 8.0	rev. 11	Customer Related Processes	Sec 7.0
P 9.0	rev. 7	Design & Development	Sec 7.0
P 10.0	rev. 13	Purchasing	Sec 7.0
P 11.0	rev. 7	Control of Monitoring and Measuring Equipment	Sec 8.0
P 12.0	rev. 12	Monitoring and Measurement Analysis	Sec 8.0
P 13.0	rev. 8	Internal Auditing	Sec 8.0
P 14.0	rev. 10	Control of Nonconforming Product	Sec 8.0
P 15.0	rev. 6	Continual Improvement	Sec 8.0

Work Instructions

WI 6.0-7	Hazardous Waste Checklist Work Instruction	Rev 1
WI 7.0-1	Tumbling Work Instruction	Rev 3
WI 7.0-2	Honing Work Instruction	Rev 2
WI 7.0-3	Lockout/Tagout Work Instruction	Rev 2
WI 7.0-4	Cleaning Product Work Instruction	Rev 5
WI 7.0-5	Stress Relieving Work Instruction	Rev 3
WI 7.0-6	Packaging Work Instruction	Rev 2
WI 7.0-7	Foreign Object Detection and Elimination	Rev 1
WI 7.0-8	Saw Work Instruction	Rev 1
WI 7.0-9	Band Saw Work Instruction	Rev 1
WI 7.0-10	EDM Work Instruction	Rev 1
WI 7.0-11	FOD Work Instruction	Rev 1
WI 7.0-12	Re-Kitting Work Instruction	Rev 1
WI 7.0-13	Kitting Work Instruction	Rev 1
WI 7.0-14	Coolant Mixing Station Work Instruction	Rev 1
WI 7.0-15	De-Burring Standard Work Instruction	Rev 1
WI 7.0-16	Vapor Blast Work Instruction	Rev 1

WI 7.0-17	Sand Blast Work Instruction	Rev 1
WI 7.0-18	1st Piece Work Instruction	Rev 1
WI 7.0-19	PMS Checklist Work Instruction	Rev 1
WI 7.0-20	Hazardous Waste Checklist Work Instruction	Rev 1
WI 7.0-21	Dynisco Op #10/#20 Work Instruction	Rev 1
WI 7.0-22	Flow Body Deburring Work Instruction	Rev 1
WI 7.0-23	Immersion Separator Work Instruction	Rev 1
WI 7.0-24	Tumbling (Large Model) Work Instruction	Rev 1
WI 7.0-25	Dynisco Parts Counting Work Instruction	Rev 1
WI 7.0-26	Ultrasonic Cleaning Work Instruction	Rev 3
WI 7.0-27	Furnace Calibration Work Instruction	Rev 1
WI 7.0-29	Quick Books Inventory Work Instruction	Rev 1
WI 7.0-30	Quick Books Shipping-Senior Aero W.I.	Rev 1
WI 7.0-31	Quick Books Shipping-Fluke/DHI W.I.	Rev 1
WI 7.0-32	QuicBooks Receiving P.O. Work Instruction	Rev 1
WI 7.0-33	Quick Books Price Change Work Instructions	Rev 1
WI 8.0-1	Risk Assessment Work Instruction	Rev 1
WI 11.0-1	Calibration Work Instruction	Rev 1

Appendix A (Section 2)

Statutory and Regulatory Requirements

EEOC / Managed via Employment Practices

C.F.R. / Managed via Employment Practices

OSHA / Managed via Safety Practices

DEP / Managed via Environmental Practices

EPA / Managed via Hazardous Materials Communications and Controls

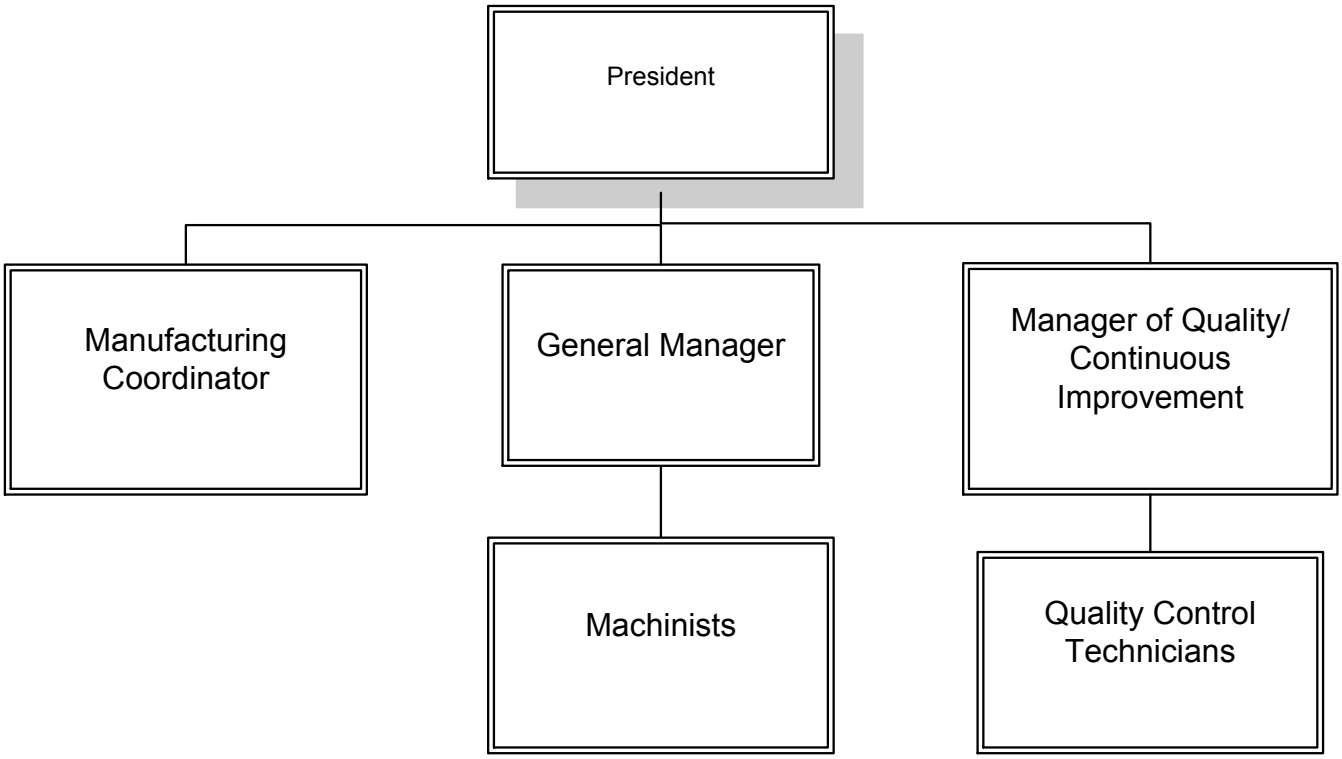
ITAR / Managed via Export & Documentation Control

DFAR / Managed via Purchasing for Domestic – Qualified Countries Specialty Metals Control

FAR and DPAS / Managed via Contract Review for Federal Acquisition and Defense Related Delivery Priority Rating

Customer Statutory Requirements found in Working Documents File of the Public F: Drive

Appendix B Organization Chart



Appendix D QMS Processes

QMS Process 1 – Management

Key elements 5.1-5.6 – Management Responsibilit
(Reference STI Procedure P5.0).

Support Elements 4.1-4.2 – Quality Management System
(Reference STI Procedure P4.0).
6.1 - Provision of Resources
(Reference STI Procedure P6.0, FC6.0-1,
6.2 – Human Resources
(Reference STI Procedure P6.0, FC 6.0-2,
6.3 – Infrastructure
(Reference STI Procedure P6.5.3)
6.4 – Work Environment
(Reference STI Procedure P6.5.4)
8.1 – Monitoring, Measuring, and Improvement
(Reference STI Procedure P12.5.1)
8.2.1 – Customer Satisfaction
(Reference STI Procedure P12.5.2)
8.2.2 – Internal Audit
(Reference STI Procedure P13.0)
8.2.3 – Monitoring and measurement of processes
(Reference STI Procedure P12.5.3)
8.4 – Analysis of Data
(Reference STI Procedure P12.5.5)
8.5.1 – Improvement
(Reference STI Procedure P15.0)
8.5.3 – Preventative Action
(Reference STI P15.0, FC15.0-1, F 15.0-2)

KPI's – Customer Satisfaction, Audit Findings, Accidents

Process Owner – Chip Holm, President

QMS Process 2 – Manufacturing Support

Key Elements	7.1 – Plan of Product Realization – Quality Planning (Reference STI Process P7.5.1) 7.2.1 – Quote Process (Reference STI Process P8.5.1 FC8.0-1) 7.2.2 – Review of Requirements Related to the Product (Reference STI Procedure P8.5.2 FC8.0-2) 7.4.1 – Purchasing Process (Reference STI Procedure P10.0, FC10.0-1) 7.4.2 – Purchasing Information (Reference STI Procedure P10.0. F10.0-4)
Support Elements;	4.2.4 – Control of Records (Reference STI Procedure P4.5.5, F4.0-1, FC4.0-2) 5.4.1 – Quality Objectives (Reference STI Procedure P5.0, F5.0-7) 7.1.1 – Project Management (Reference STI Procedure P7.0) 7.1.2 – Risk Management (Reference STI Procedure P8.0, WI8.0-1) 7.1.3 – Configuration Management (Reference STI Procedure P7.5.1) 7.1.4 – Control of Work Transfers (Reference STI Procedure P7.5.6) 7.2.3 – Customer Communication (Reference STI Procedure P8.5.3, FC8.0-5) 8.2.3 – Monitoring and Measurement of Processes (Reference STI Procedure P12.5.3)

KPI's – Supplier Quality, Supplier Delivery, Time from RFQ to Quote

Process Owners: Craig Winslow-General Manager, Chip Holm-President, Gianni Miceli -Mfg. Coordinator

QMS Process 3 – Manufacturing (PEAR)

Key Elements	7.5 – Product Realization (Reference STI Procedure P7.0) 7.5.1 – Control of Production and Service Provision (Reference STI Procedure P7.5.1 - 7.5.7) 7.5.1.2 – Control of Production Process Changes (Reference STI Procedure P7.5.2, F7.0-25) 7.5.1.3 – Control of Production Equipment, Tools and Software Programs (Reference STI Procedure P7.5.2, F7.0-21, PMS) 7.5.2 – Validation of Processes for Production and Service Provision (Reference STI Procedure P10.5.6 FC10.0-3) 7.5.3 – Identification and Traceability (Reference STI Procedure P7.5.3) 7.5.4 – Customer Property (Reference STI Procedure 7.5.4) 7.5.5 – Preservation of Product (Reference STI Procedure 7.5.5)
Support Elements;	4.2.4 – Control of Records (Reference STI Procedure P4.5.5, F4.0-1, FC4.0-2) 5.4.1 – Quality Objectives (Reference STI Procedure P5.0, F5.0-7) 6.3 – Infrastructure (Reference STI Procedure P6.5.3) 8.2.3 – Monitoring and Measurement of Processes (Reference STI Procedure P12.5.3) 8.2.4 – Monitoring and Measurement of Product (Reference STI Procedure P12.5.4)

KPI's – On-Time-Delivery (OTD), Internal Scrap and Rework

Process Owner: Craig Winslow – General Manager

QMS Process 4 – Quality Support (PEAR)

Key Elements

8.1 Measurement, Analysis, and Improvement
(Reference STI Procedure P12.0)
8.2.4 – Monitoring and Measurement of Product
(Reference STI Procedure P12.5.4)
8.3 – Control of Nonconforming Product
(Reference STI Procedure P14.0)
8.5.1 – Continual Improvement
(Reference STI Procedure P15.5.1)
8.5.2 – Corrective Action
(Reference STI Procedure P15.0, FC15.0-1, F15.0-1)

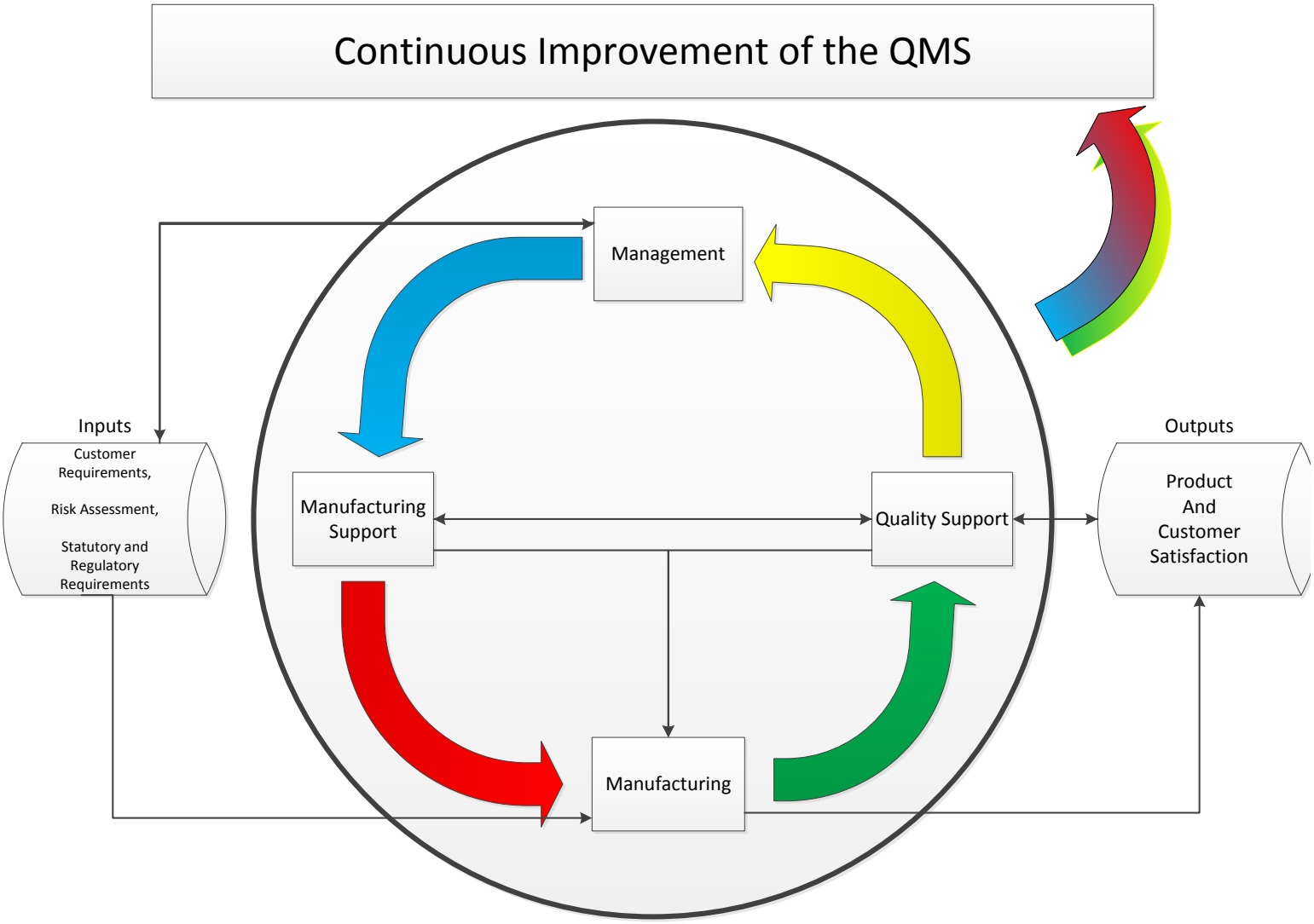
Support Elements;

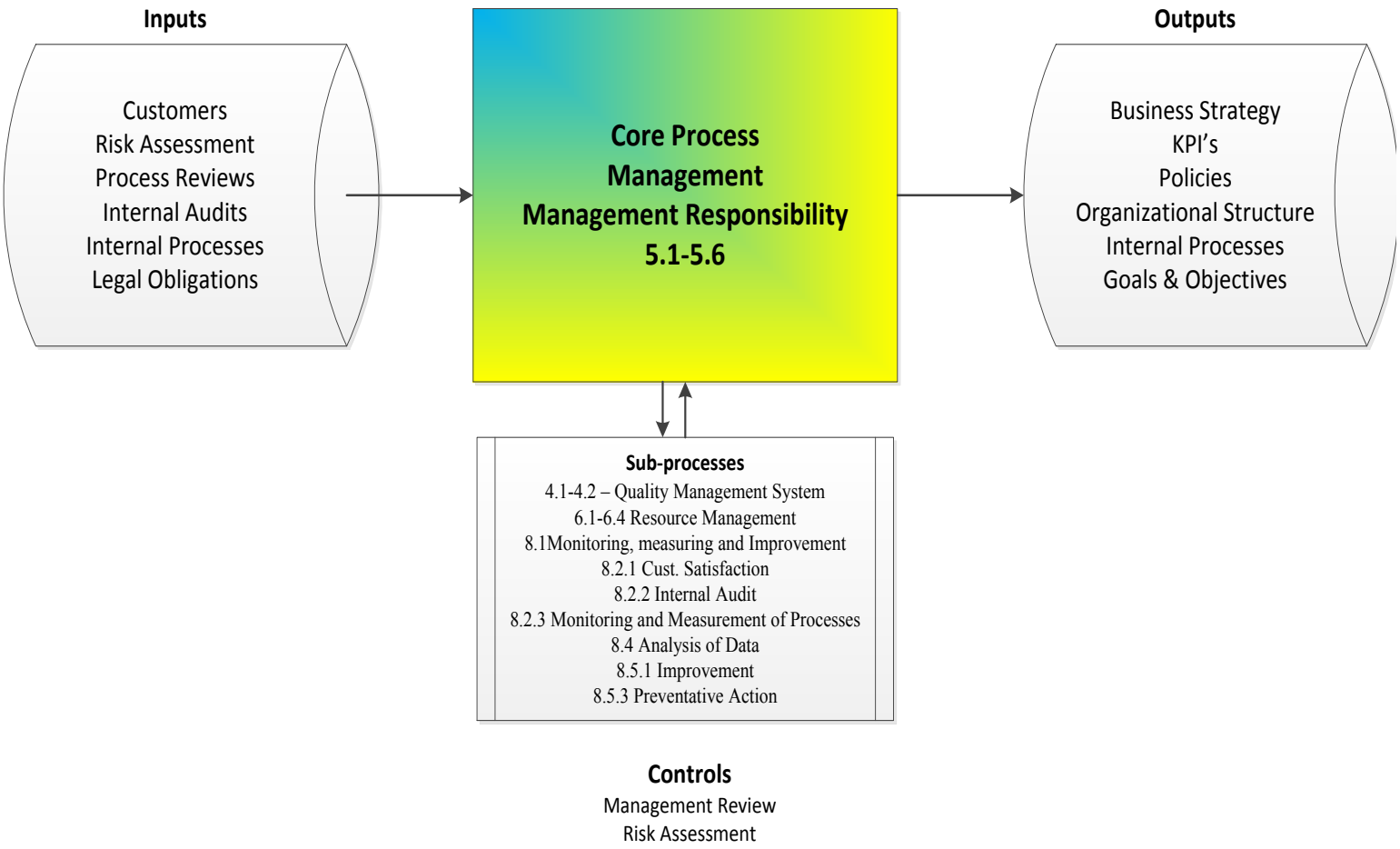
4.2.4 – Control of Records
(Reference STI Procedure P4.5.5, F4.0-1, FC4.0-2)
5.4.1 – Quality Objectives
(Reference STI Procedure P5.0, F5.0-7)
7.4.1-7.4.3 – Purchasing
(Reference STI Procedure P10.0)
7.5.1.1 – Production Process Verification
(Reference STI Procedure P12.5.4 F12.0-5)
7.6 – Control of Monitoring and Measuring Equipment
(Reference STI Procedure P11.0)
8.2.2 – Internal Audit
(Reference STI Procedure P13.0)
8.2.3 – Monitoring and Measurement of Processes
(Reference STI Procedure P12.5.3)
8.4 – Analysis of Data
(Reference STI Procedure P12.5.5)

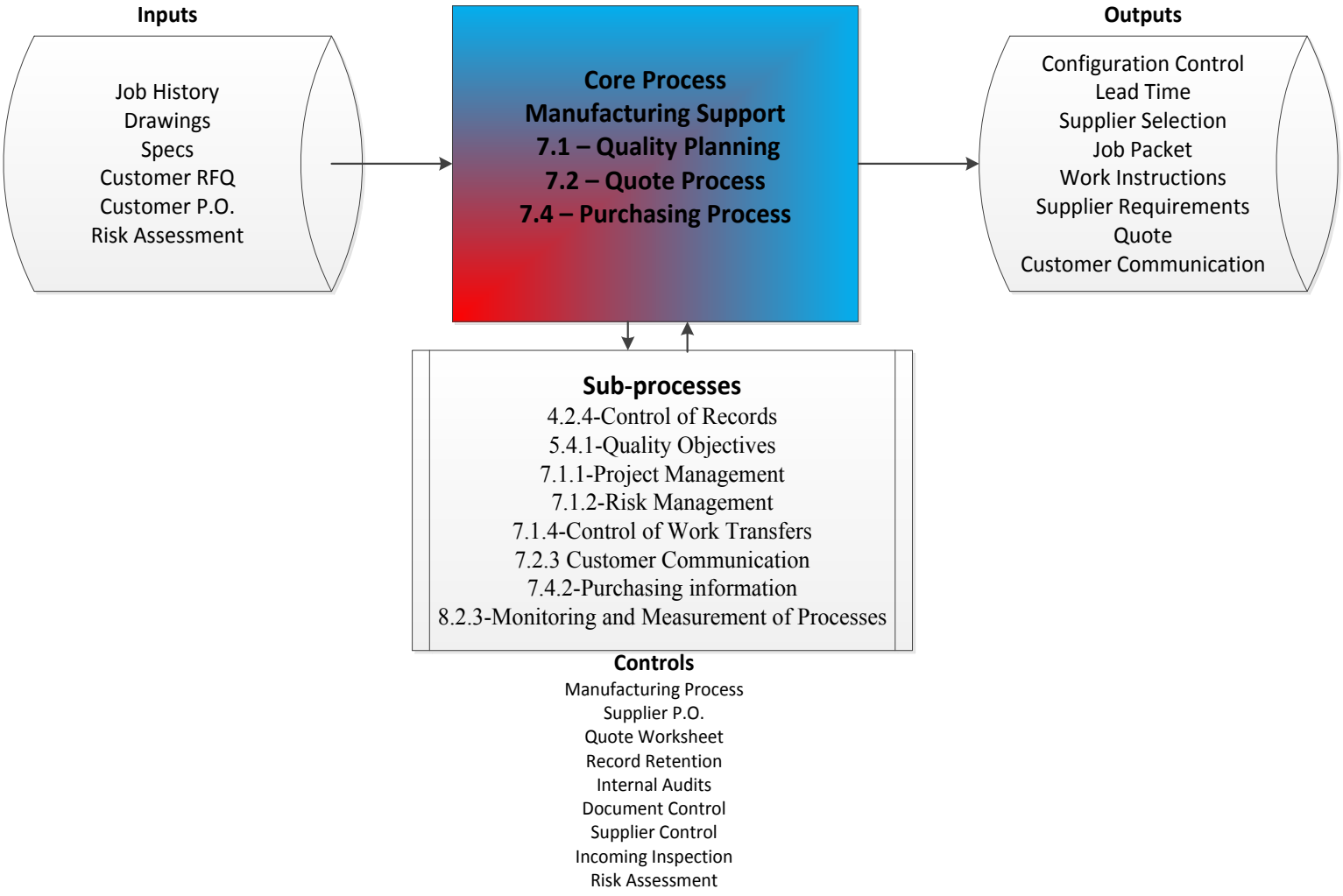
KPI's – Quality Escapes

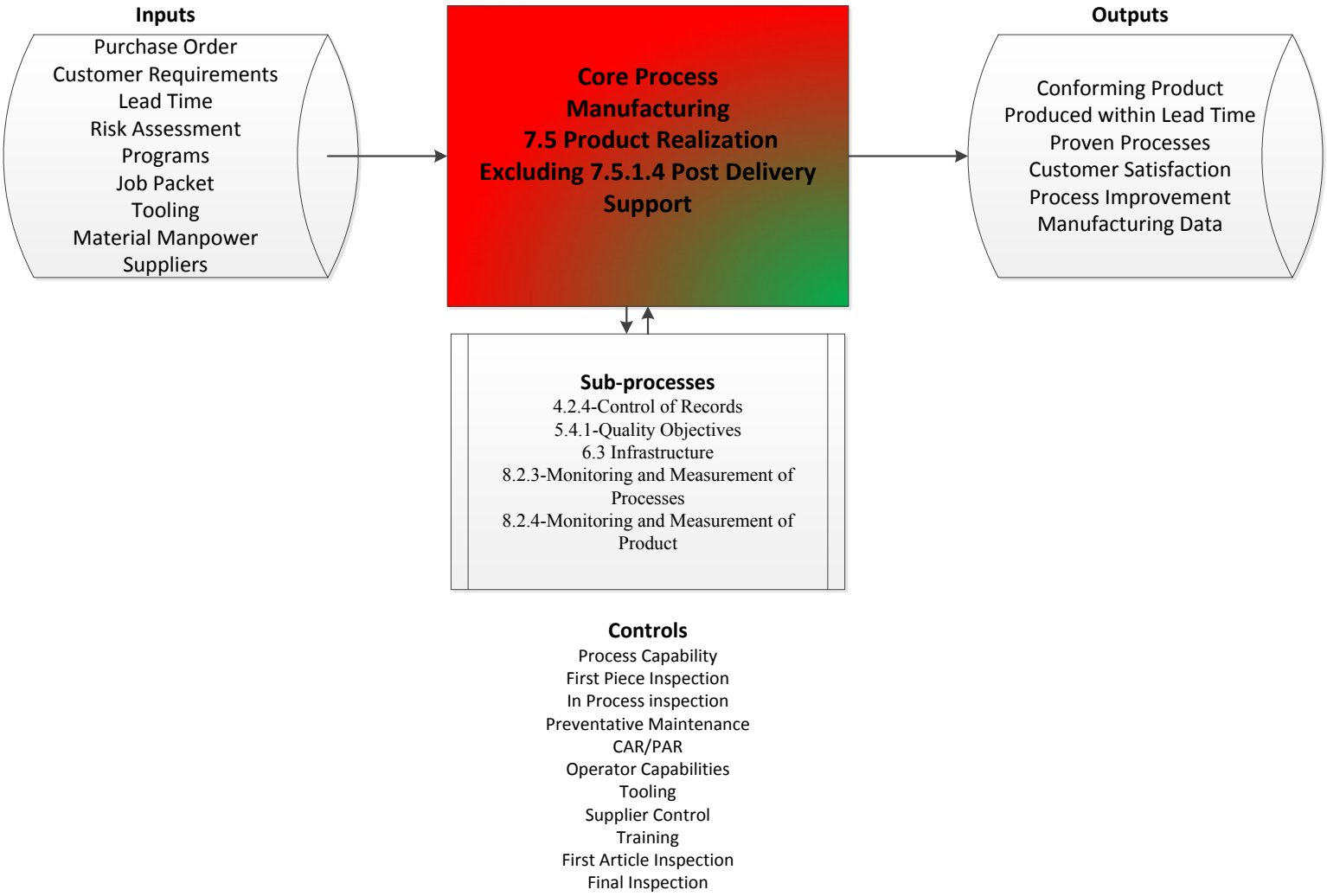
Process Owner: Chris O'Donnell – Quality Manager

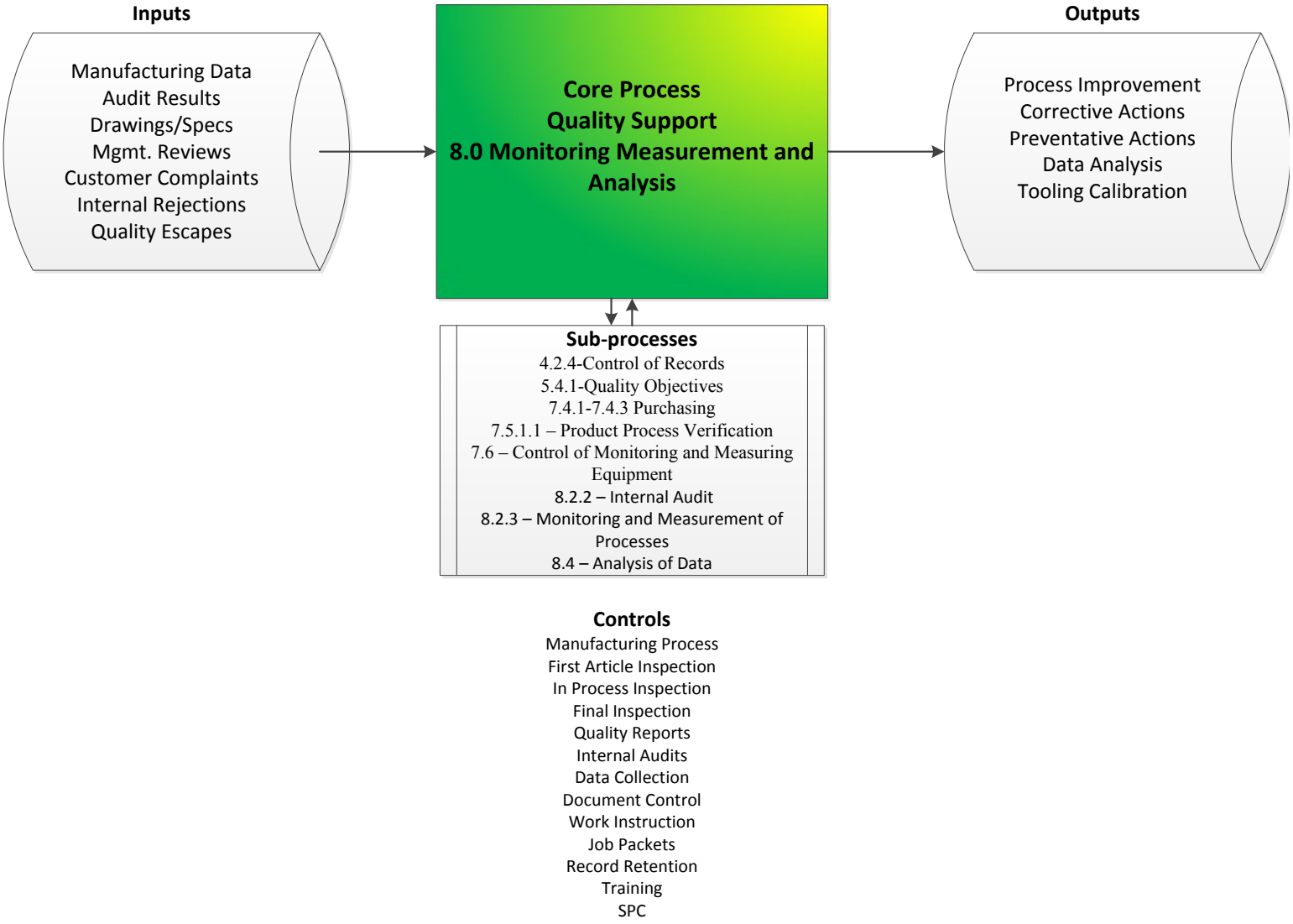
Appendix E Interrelationship of Processes




Inputs
Customers
Risk Assessment
Process Reviews
Internal Audits
Internal Processes
Legal Obligations
Core Process
Management
Management Responsibility
5.1-5.6
Outputs
Business Strategy
KPI's
Policies
Organizational Structure
Internal Processes
Goals & Objectives
Sub-processes
4.1-4.2 – Quality Management System
6.1-6.4 Resource Management
8.1Monitoring, measuring and Improvement
8.2.1 Cust. Satisfaction
8.2.2 Internal Audit
8.2.3 Monitoring and Measurement of Processes
8.4 Analysis of Data
8.5.1 Improvement
8.5.3 Preventative Action
Controls
Management Review
Risk Assessment


Inputs
Job History
Drawings
Specs
Customer RFQ
Customer P.O.
Risk Assessment
Core Process
Manufacturing Support
7.1 – Quality Planning
7.2 – Quote Process
7.4 – Purchasing Process
Outputs
Configuration Control
Lead Time
Supplier Selection
Job Packet
Work Instructions
Supplier Requirements
Quote
Customer Communication
Sub-processes
4.2.4-Control of Records
5.4.1-Quality Objectives
7.1.1-Project Management
7.1.2-Risk Management
7.1.4-Control of Work Transfers
7.2.3 Customer Communication
7.4.2-Purchasing information
8.2.3-Monitoring and Measurement of Processes
Controls
Manufacturing Process
Supplier P.O.
Quote Worksheet
Record Retention
Internal Audits
Document Control
Supplier Control
Incoming Inspection
Risk Assessment


Inputs
Purchase Order
Customer Requirements
Lead Time
Risk Assessment
Programs
Job Packet
Tooling
Material Manpower
Suppliers
Core Process
Manufacturing
7.5 Product Realization
Excluding 7.5.1.4 Post Delivery
Support
Outputs
Conforming Product
Produced within Lead Time
Proven Processes
Customer Satisfaction
Process Improvement
Manufacturing Data
Sub-processes
4.2.4-Control of Records
5.4.1-Quality Objectives
6.3 Infrastructure
8.2.3-Monitoring and Measurement of Processes
8.2.4-Monitoring and Measurement of Product
Controls
Process Capability
First Piece Inspection
In Process inspection
Preventative Maintenance
CAR/PAR
Operator Capabilities
Tooling
Supplier Control
Training
First Article Inspection
Final Inspection


Inputs
Manufacturing Data
Audit Results
Drawings/Specs
Mgmt. Reviews
Customer Complaints
Internal Rejections
Quality Escapes
Core Process
Quality Support
8.0 Monitoring Measurement and Analysis
Outputs
Process Improvement
Corrective Actions
Preventative Actions
Data Analysis
Tooling Calibration
Sub-processes
4.2.4-Control of Records
5.4.1-Quality Objectives
7.4.1-7.4.3 Purchasing
7.5.1.1 – Product Process Verification
7.6 – Control of Monitoring and Measuring Equipment
8.2.2 – Internal Audit
8.2.3 – Monitoring and Measurement of Processes
8.4 – Analysis of Data
Controls
Manufacturing Process
First Article Inspection
In Process Inspection
Final Inspection
Quality Reports
Internal Audits
Data Collection
Document Control
Work Instruction
Job Packets
Record Retention
Training
SPC