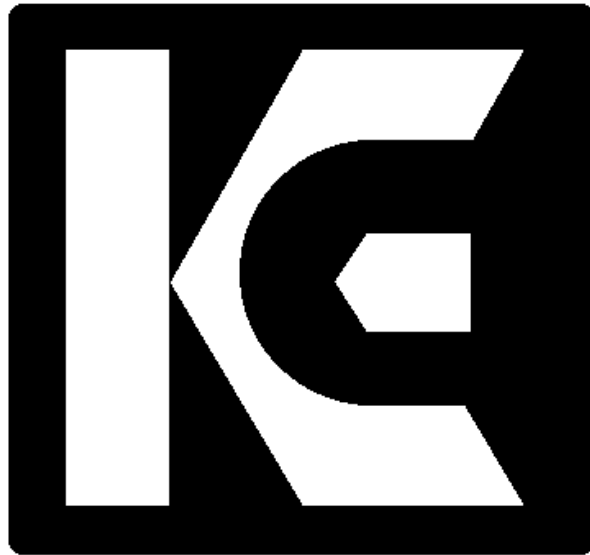


Karas Engineering



AS9100 QUALITY MANAGEMENT SYSTEM MANUAL

Revision A
September 01, 2009

Statement of Commitment and Authority

Commitment

This Quality Management System Manual (QMSM) delineates the processes, procedures and practices that must be followed by Karas Engineering Company, Inc. in the fabrication of products and provision of services to assure conformance with the requirements of Aerospace Standard AS9100, *Quality Management Systems - Requirements for Aviation, Space and Defense Organizations*, revision B. Karas Engineering is committed to assuring customer satisfaction by producing safe, reliable products that meet the applicable contractual, regulatory and statutory requirements.

Karas Engineering has formulated a formal Quality Policy (reference QP 5.3) and has identified Quality Objectives (reference QP 5.4.1) that are measurable and consistent with our Quality Policy.

This Quality Management System Manual (QMSM) applies to the Karas Engineering facility located at 44 Old State Street #20 in New Milford, CT 06776.

All Karas Engineering personnel are responsible for delivering "Quality" products and services to the Aviation, Space and Defense industries as well as any other industries/customers that require compliance to AS9100/ISO 9000. Specific activities, methods, and responsibility assignments of the Quality Management System are prescribed within this manual and additional controlled implementing procedures that are developed on an as needed basis in compliance with the requirements of the AS9100 standard. These implementing documents are developed and are in place prior to performing the activities they address.

Authority

The Quality Management Representative has the total authority and an unlimited responsibility for assuring implementation of this Quality Management System Manual, identifying quality problems, ensuring that solutions are provided, and verifying implementation. He/She ensures the promotion of customer requirements throughout the organization. He / She has the authority to limit processing or stop work as required. He /She has the organizational freedom including sufficient independence from cost and schedule considerations with unlimited access to top management to resolve quality management issues. He / She shall keep the President advised as to the performance of the quality management system and any need for improvement.

Denny Karas
President, Karas Engineering

Revision Control

Revision A – Initial Release – 9/01/2009

AS9100 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

1.0) Scope

Scope of Registration:

This Quality Manual describes the policies and the quality management system of the Karas Engineering organization. The quality management system described in this manual meets the requirements of the ISO 9001:2000 standard and AS 9100 Revision B standard. The scope of the quality system is defined below:

Karas Engineering manufactures and machines product in accordance with customer design drawings.

Karas Engineering activities are conducted at 44 Old State Road in New Milford, Ct 06776.

The Quality Management System's explicit boundaries of control are defined by this Quality Manual and apply only to activities identified above.

Sequence and Interaction of Processes:

Direct processes include management planning, external and internal customer relations, control of design and fabrication documents, purchasing, and production. Indirect processes include document and records controls, management responsibility, resource management, and measurement, analysis, and improvement. These processes are described in the Quality Manual and the Quality Management System Procedures Manual.

The following is a text explanation of the sequence and interaction of processes. They are implemented as a "Plan-Do-Check-Act" cycle applicable to the Leadership Team and each process.

Plan

The Leadership Team provides general oversight and control of internal and outsourced processes and the authorization of the Quality Manual, documents, and records required to ensure the quality management system has the structure to achieve desired objectives.

The Leadership Team executes the management responsibility process. This process includes:

- Establishment and/or review of evidence of commitment, through ongoing customer focus initiatives, quality policy and quality objective reviews, and quality management system planning;
- Assignment of responsibility and authority to key individuals to manage, operate, and verify all processes;
- Appointment of a management representative who has the responsibility and authority documented in 5.5.2a-c of the standard;
- Establishment of communication processes to members of the organization demonstrating the effectiveness of the quality management system; and
- Review of the quality management system, including outputs of the measurement, analysis, and improvement processes.

As a result of output decisions made during the management responsibility process, the Leadership Team provides inputs to the resource management process to provide the necessary resources to implement, maintain, and improve the quality management system and to enhance customer satisfaction. These provisions include:

- Human resources (including competence, awareness, and training needs) as delivered by the Human Resources Process;
- Infrastructure; and
- Work environment.

Do

After the Leadership Team provides the outputs of necessary resources, they provide improvement and planning inputs to the production planning process. This includes high-level review of quality objectives and project-specific requirements to ensure production, inspection, and record-keeping processes are sufficient. The output of the planning may be a procedure, a work instruction, a project design plan, or a combination of these.

Contract Specialists control the customer-related processes. Process Engineering personnel control the fabrication processes. These processes involve communicating with internal and/or external customers and suppliers to determine and review product requirements and to communicate with them during and after production in the event there are amendments to or complaints about meeting requirements.

Customer Specialists and Process Engineering personnel provide output of the customer-related design and development processes as inputs to the purchasing process. Purchasing personnel monitor the suppliers to ensure the supply of products and services meet applicable purchasing needs. The purchasing process includes verification of supplied products or services as they apply to purchasing agreements.

Production operators use purchased products and services from the outputs of the purchasing process as inputs to the production process. Production operators:

- Control the production processes through the use of procedures, work instructions, proper equipment, proper monitoring and measurement, and provision of products;
- Identify product in such a manner that appropriate personnel can determine the completion status at any time;
- Exercise care with customer property (including intellectual property) while it is under the organization's control and record and report any lost, damaged, or unsuitable customer property;
- Preserve product information at any stage in such a manner that it retains its conformity to customer requirements; and
- Control monitoring and measuring devices in such a manner that monitoring and measurement can be carried out in accordance with customer requirements.

The outputs of the production processes are planned to meet and/or exceed customer expectations. The results of product realization are inputs to the measurement, analysis, and improvement processes.

Check

All members of Karas Engineering are responsible for contributions to the measurement, analysis, and improvement processes. Contributions come from day-to-day and long range planning activities.

- The Leadership Team monitors the customer satisfaction process;
- The Management Representative coordinates the internal audit process;
- Quality inspection personnel execute the monitoring and measurement and nonconformance processes;
- The Leadership Team reviews data from the customer satisfaction process, the monitoring and measurement processes, corrective and preventive action processes, and the purchasing process to determine the effectiveness of the quality management system; and
- All members of Karas Engineering contribute to the improvement process (including continual improvement, corrective actions, and preventive actions).

Act

The outputs of the measurement, analysis, and improvement processes serve as inputs to the management responsibility process as the next step in the recurring process cycle. Decisions are made at management reviews to act upon continual improvement of processes. The continual cycle of planning, doing, and checking follow as described above.

The high level "Plan-Do-Check-Act" cycle is applicable within each process.

Permissible Exclusions:

Karas Engineering does not perform design and development processes and therefore considers Section 7.3 of AS9100 as a permissible exception.

2.0 Normative References

AS 9102, Aerospace First Article Inspection Requirement

AS9103, Variation Management of Key Characteristics

ISO 9001:2000, Quality Management Systems – Requirements

ISO 10007:1995, Configuration Management Systems

ISO 10012:2003, Measurement Management Systems – Requirements for Measuring Processes and Measuring Equipment

ISO 19011:2002, Guidelines for Quality and/or Environmental Management Systems Auditing

3.0 Terms and Definitions

3.1 Risk

An undesirable situation or circumstance that has both a likelihood of occurrence and a potentially negative consequence.

3.2 Special Requirements

Those requirements identified by the customer, or determined by the organization, which have high risks of being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limits of the industry's

capability, or requirements determined by the organization to be at the limits of its technical or process capabilities.

3.3 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant impact on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc., that require specific actions to ensure that they are managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.4 Key Characteristic

An attribute or feature whose variation has a significant effect on product form, fit, function, performance, service life and producibility that requires specific actions for the purpose of controlling variation.

4.0 Quality Management System

4.1 General Requirements

The quality management system has been established, documented, implemented, maintained and is continually improved in accordance with the requirements of ISO 9001:2000 and AS 9100. To implement the system, the Leadership Team has completed the following activities:

- Identification of the processes needed for the quality management system and their application throughout the organization. Processes include activities that receive inputs from internal and/or external suppliers and deliver products to internal and/or external customers.
- Determination of the sequence and interaction of the processes- see QPlan 4.1 Organization Process Map for the pictorial display of the interaction of the processes.
- Determination of the criteria and methods needed to ensure that both the operation and control of these processes are effective. This involves management review, customer needs, and appropriate planning.
- Allocation of the resources and information necessary to support the operation and monitoring of these processes. Resource planning and allocation evolve from day-to-day and management review activities.
- Monitoring, measurement, and analysis of these processes. The Leadership Team uses customer satisfaction information, internal audit results, inspection results, data analysis, and improvement activities to monitor measure, and analyze the processes.

- Implementation actions necessary to achieve planned results and continual improvement of these processes- the continual improvement, corrective action, and preventive action processes are the tools used to determine if the implementation activities have met their targets.

Control is ensured over any outsourced processes, and control of such applicable processes is identified within the quality management system. Purchasing (see section 7.4) controls all outsourcing activity.

4.2 Document Requirements

4.2.1 General

The quality management system documentation includes:

- Documented statements of a Quality Policy (reference QP 5.3) and Quality Objectives (reference QP 5.4.1).
- A Quality Manual - all of the sections of the current manual meet this documentation requirement.
- Documented procedures required by ISO 9001 and AS9100. The titles of these procedures are included in the **Related and Support Documentation** of each section of the Quality Manual and are listed in QL 4.2.3-1, List of Controlled Program Documents.
- Documents needed by the organization to ensure the effective planning, operation and control of processes. Other documents include work instructions in the format of text work instructions, and blank forms.
- Quality records required by ISO 9001 and AS9100. These include, at a minimum, all required records indicated in the standards by the parenthetical note "(see 4.2.4)."
- Quality system requirements imposed by the applicable regulatory authorities.

Personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or regulatory authorities' representatives have access to quality management system documentation.

4.2.2 Quality Manual

This Quality Manual has been established and shall be maintained. It includes:

- The scope of the quality management system, including details of and justification for any permissible exclusion is contained in Section 1.0 of this manual.

- References to the documented procedures established for the quality management system are contained in the “Related and Support Documents” of each section of the Quality Manual – as applicable. See the AS9100 Quality Management System Procedures for the text of each referenced procedure. When referencing the procedures, the relationship between AS 9100 and the procedures are clearly shown by their numbering, titles and texts.
- A description of the interaction between the processes of the quality management system is contained in Section 1.0 of this manual. See QPlan 4.1, Organization Process Map for a pictorial display.

4.2.3 Control of Documents

Documents and quality records required by the quality management system are controlled.

A documented procedure (QAP 4.2.3, Control of Quality Management System Documents) has been established to define the controls needed to:

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

4.2.4 Control of Records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

Records are legible, readily identifiable and retrievable.

A documented procedure (QAP 4.2.4, Control of Records) has been established to define the controls needed for the records relating to:

- Identification;
- Storage;
- Protection;

- Retrieval;
- Retention time;
- Disposition;
- Method for controlling records that are created by and/or retained by suppliers;
- Availability of records for review by customer and regulatory authorities in accordance with contract or regulatory requirements.

4.3 Configuration Management

A documented procedure (QAP 4.3, Configuration Management) has been established to define the configuration management process appropriate to the scope of activities conducted by Karas Engineering.

Section Four Related and Support Documentation

QP 4.1 Organization Process Map
 QFile 4.2.1 Applicable Industry and Regulatory Requirements
 QAP 4.2.3 Control of Quality Management System Documents
 QL 4.2.3-1 Master List of Controlled Quality Management System Documents
 QFile 4.2.3-2 Controlled Customer Generated Documents
 QAP 4.2.4 Control of Quality Management System Records
 QFile 4.2.4 Master List of Quality Management System Records
 QAP 4.3, Configuration Management

5.0 Management Responsibility

5.1 Management Commitment

The Leadership Team has provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

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

5.2 Customer Focus

The Leadership Team has ensured that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction. (See Sections 7.2.1 and 8.2.1 of this manual).

5.3 Quality Policy

The Leadership Team has ensured that the quality policy is:

Appropriate to the purpose of the organization;

- Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- Provides a framework for establishing and reviewing quality objectives;
- Communicated and understood within the organization; and
- Reviewed for continuing suitability.

The quality policy is documented in QP 5.3, Quality Policy.

5.4 Planning

5.4.1 Quality Objectives

The Leadership Team has ensured that quality objectives, including those needed to meet requirements for product realization, are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

The quality objectives are defined in QP 5.4.1, Quality Objectives.

5.4.2 Quality Management System Planning

The Leadership Team has ensured that:

- The planning of the quality management system is carried out in order to meet the requirements of the general requirements of the international standard (Clause 4.1); and
- The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. Reference QAP 4.2.3 Control of Documents.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The Leadership Team has ensured that the responsibilities, authorities and their interrelation are defined and communicated within the organization. Reference QAP 5.5.1, Responsibility and Authority and QL 5.5.1, Organization Chart.

5.5.2 Management Representative

The President has appointed a qualified individual as the Management Representative – reference QP 5.5.1, Organizational chart. The Management Representative is responsible for establishing, implementing, and maintaining the Quality Management System, and for reporting on its performance at Management Review meetings, and irrespective to other duties is responsible and accountable for:

- Ensuring that processes needed for the quality management system are established, implemented and maintained;
- Reporting to the Leadership Team on the performance of the quality management system and any need for improvement;
- Ensuring the promotion of awareness of customer requirements throughout the organization;
- The organizational freedom to resolve matters pertaining to quality; and
- Acting as liaison with external parties on matters relating to the quality system as appropriate

5.5.3 Internal Communication

The Leadership Team has ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. Reference QAP 5.5.3, Internal Communication.

5.6 Management Review

5.6.1 General

The Leadership Team reviews the quality management system as a minimum once per year to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records of management reviews are maintained.

5.6.2 Review Input

Input to Management Review includes, as minimum, information on:

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

5.6.3 Review Output

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

- Improvement of the effectiveness of quality management system and its processes;
- Improvement of product related to customer requirements; and,
- Resource needs.

The Management Review process is described in QAP 5.6 Management Review.

Section Five Related and Support Documentation

QP 5.3, Quality Policy

QP 5.4.1, Quality Objectives

QF 5.4.1, Monthly Metrics Scorecard

QAP 5.5.1, Responsibility and Authority

QP 5.5.1, Organization Chart

QAP 5.5.3, Internal Communication

QF 5.5.3, Employee Meeting Agenda/Minutes

QAP 5.6, Management Review

QF 5.6, Record of Management Review Meeting

6.0 Resource Management

6.1 Provision of Resources

Resources have been determined and provided to:

- Implement and maintain the quality management system and continually improve its effectiveness; and
- Enhance customer satisfaction by meeting customer requirements.

Resources are reviewed and provided as necessary as part of management review process. The management review process is described in QAP 5.6 Management Review.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Training and Awareness

The Leadership Team has:

- Determined the necessary competence for personnel performing work affecting product quality;
- Provided training or taken other action to satisfy these needs;
- Evaluated the effectiveness of the actions taken;
- Ensured 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,
- Maintained appropriate records of education, training, skills and experience.

Competence, awareness, and training processes are described in QAP 6.2 Competence, Training and Awareness.

6.3 Infrastructure

The infrastructure needed to achieve conformity to product requirements has been determined, provided and maintained.

Infrastructure examples may include, but not be limited to:

- Buildings, workspace and associated utilities;
- Process equipment, both hardware and software; and,
- Supporting services such as transport or communication.

The Leadership Team has identified and maintains the required infrastructure to achieve product conformity. Reference QL 6.3, Facilities List.

6.4 Work Environment

The work environment needed to achieve conformity to product requirements has been determined and managed.

Factors affecting conformity of the product include temperature, humidity, lighting, cleanliness, and protection, etc. as deemed appropriate by the Leadership Team. Reference QAP 6.4, Work Environment.

Section Six Related and Support Documentation

QAP 6.2, Competence, Training and Awareness

QL 6.2-1, Requirements Applicability Table

QL 6.2-2, List of Qualified Personnel

QF 6.2-1, Record of Training – Reading List

QF 6.2-2, Record of Training – Attendance Sheet

QF 6.2-3, Record of Personnel Qualification

QF 6.2-4, Annual Employee Performance Review

QL 6.3 Facilities List

QAP 6.4 Work Environment

QF 6.4-1, Request for Addition to Infrastructure

QF 6.4-2, 5S Checklist

7.0 Product Realization

7.1 Planning of Product Realization

The processes needed for product realization are planned and developed, and are consistent with the requirements of the other processes of the quality management system. In planning product realization, the following has been determined, as appropriate:

- Quality objectives and requirements for the product;
- The need to establish processes, documents, and provide resources specific to the product;
- Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- Records needed to provide evidence that the realization processes and resulting product fulfill requirements;
- Planning output is in a suitable form for methods of operation; and,
- Identification of resources to support operation and maintenance of the product.

Reference QP 7.1, Standard Quality Plan, for the product realization process activity sequence.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to Product

Requirements related to the product have been determined, including:

- Requirements specified by the customer, including the requirements for delivery and post-delivery activity;
- Requirements not stated by the customer but necessary for specified use or known and intended use;
- Statutory and regulatory requirements related to the product; and,
- Determination of any additional requirements.

7.2.2 Review of Requirements Related to Product

Requirements related to the product are reviewed. This review is conducted prior to committing to supply a product to customers, and ensures that:

- Product requirements are defined;
- Contract or order requirements differing from those previously expressed are resolved;

- The organization has the ability to meet the defined requirements; and
- Risks associated with new technology, short delivery time scales, etc. have been evaluated.

Records of the results of review and actions arising from this review are maintained.

Where the customer provides no documented statement of requirements, customer requirements are confirmed before acceptance.

Where product requirements are changed, it is ensured that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

Reference QAP 7.2.2, Customer Requirements Review and Order Entry

Reference QDB 7.2.2-1, Approach Estimating Worksheet

Reference QDB 7.2.2-2, EstiTrack Quote Module

Reference QF 7.2.2-1, Quote Sheet

Reference QLog 7.2.2-2, Record of Customer Contract Review.

Reference QDB 7.2.2-3, EstiTrack Sales Order Module

7.2.3 Customer Communication

Effective arrangements for communication with customers relating to the following are determined and implemented:

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

Reference QDB 7.2.3-1, Customer Complaint & Returned Product

7.3 Design and Development

Karas Engineering provides precision machining services in compliance with customer supplied design drawings and is not a product design and development organization. Therefore, Karas Engineering takes a permissible exception to the requirements of this section.

7.4 Purchasing

7.4.1 Purchasing Process

Purchasing processes are controlled to ensure purchased product conforms to specified purchase requirements. The type and extent of control is applied to suppliers and purchased product is

dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization is responsible for the quality of all products purchased from suppliers, including any customer-designated sources.

Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements. Criteria for selection, evaluation and re-evaluation and any necessary actions arising from the evaluation are maintained.

The organization:

- Maintains a register of approved suppliers that includes scope of approval;
- Periodically reviews supplier performance, records these reviews and uses them as a basis for establishing the levels of controls to be implemented;
- Defines the necessary actions to take when dealing with suppliers that do not meet requirements;
- Ensures where required that both the organization and all suppliers use customer-approved special process sources; and,
- Ensures that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.

Reference QAP 7.4.1, Purchasing Process

Reference QDB 7.4.1, Approved Suppliers (Approach)

7.4.2 Purchasing Information

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

Requirements for approval of product, procedures, processes, and equipment;

Requirements for qualification of personnel;

Quality management system requirements;

- The name or other positive identification and applicable issues of specifications, drawings process requirements, inspection instructions and other relevant technical data;
- Requirements for design, test, examination inspection and related instructions for acceptance by the organization;
- Requirements for test specimens for design approval, inspection, investigation or auditing;
- Requirements relative to supplier notification to the organization of nonconforming product and any arrangements for the organization approval of supplier nonconforming material;
- Requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain the organization's approval;

- Right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records; and,
- Requirements for supplier flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

The adequacy of specified purchasing requirements prior to their communication to suppliers is ensured.

Reference QL 7.4.2, Quality Procurement Requirements

Reference QF 7.4.2-1, Request for Quote

Reference QLog 7.4.2, Purchase Order Numbers

Reference QDB 7.4.2, EstiTrack Purchase Order Module

Reference QF 7.4.2-2, Purchase Order

Reference QF 7.4.2-3, Supplier Waiver/Deviation Request

7.4.3 Verification of Purchased Product

Inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements are established and implemented.

Verification activities may include:

- Obtaining objective evidence of the quality of the product from suppliers;
- Inspection and audit at supplier's premises;
- Review of the required documentation;
- Inspection of products upon receipt; and
- Delegation of verification to the supplier, or supplier certification.

Purchased product is not to be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

Where the organization utilizes test reports to verify purchased product, the data in those reports is accepted per applicable specifications. The organization periodically validates test reports for raw material.

When the organization delegate's verification activities to the supplier, the requirements for delegation are defined and a register of delegations is maintained.

Where verification of purchased product is intended at suppliers' premises, including customer verification of such product, the verification activity and the method of product release are stated in the purchasing information.

Where specified in the contract, the customer or the customer's representative is afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conform to specified requirements.

Verification by the customer is not used by the organization as evidence of effective control of quality by the supplier and does not absolve the organization of the responsibility to provide acceptable product, nor does it preclude subsequent rejection by the customer.

Reference QAP 7.4.3, Verification of Purchased Product

Reference QF 7.4.3-1, Record of Source Inspection/Release Form

Reference QF 7.4.3-2, Record of Receipt Inspection

Reference QDB 7.4.3-3, Job Card Entry

Reference QLog 7.4.3-4, Record of Raw Material Test Results

Reference QDB 7.4.3-5, EstiTrack Receiving Module

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Planning shall consider, as applicable or as required by the customer, the:

- Establishment of process controls and development of control plans where key characteristics have been identified (See Section 1.0 of the Quality Manual);
- Identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization;
- Design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics; and,
- Special processes.

Production and service operations are planned and carried out under controlled conditions, including, as applicable, the:

- Availability of information that describes the characteristics of the product;
- Availability of work instructions;
- Use of suitable equipment;
- Availability and use of monitoring and measuring devices;
- Implementation of monitoring and measurement;
- Implementation of release, delivery and post-delivery activities;
- Accountability for all products during manufacture (parts quantities, split orders, nonconforming product);

- Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized;
- Provision for the prevention, detection, and removal of foreign objects;
- Monitoring and control of utilities and supplies such as water, compressed air; electricity and chemical products to the extent they affect product quality; and
- Criteria for workmanship, which stipulates in the clearest practical manner what is acceptable.

Reference QAP 7.5.1, Control of Production and Service Provision.

7.5.1.1 Production Process Verification

Production operations are carried out in accordance with approved data. This data contains as necessary:

- Drawings, parts lists, process flow charts including inspection operations, production documents, and inspection documents; and,
- A list of specific or non-specific tools and numeric control machine programs required and any specific instructions associated with their use.

Reference QF 7.5.1-1, Shop Order

Reference QF 7.5.1-2, Shop Floor Routing

Reference QDB 7.5.1-3, Process Control Plan

Reference QF 7.5.1-4, Process Control Chart

Reference QF 7.5.1-5, Release of Finished Goods for Shipment

Reference QFile 7.5.1-6, Completed First Article Inspection Reports

7.5.1.2 Control of Production Process Changes

Persons authorized to approve changes to production process are identified.

The organization identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with regulatory or contract requirements.

Changes affecting processes, production equipment, tools and programs are documented. Procedures are available to control their implementation.

The results of changes to production processes are assessed to confirm that the desired effect is achieved without adverse effects to the product quality.

Reference QAP 7.5.1.2, Production Process Change Control

Reference QF 7.5.1.2, Production Process Change Authorization

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and programs are validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use includes verification of the first article produced to the design data/specification as determined necessary.

Storage requirements, including periodic preservation/condition checks, are established for production equipment and tooling in storage.

Reference QFile 7.5.1.3-1, CNC Programs – Released Directory

Reference QLog 7.5.1.3-2, Tooling

7.5.1.4 Control of Work Transferred, On a Temporary Basis, Outside of the Organization's Facility

When planning to temporarily transfer work to a location outside the organization's facilities, the organization defines the process to control and validate the quality of work in a project quality management system plan appropriate for the scope of work transferred. **Note:** Scope of work normally subcontracted is handled under the provision of Section 7.4, Purchasing and is not to be considered as a temporary transfer outside of the Karas Engineering facility.

7.5.1.5 Control of Service Operations:

Where servicing is a specified contract requirement, service operation processes will provide for:

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

Note: Karas Engineering's current scope of work does not contain requirements for post delivery servicing of product. Processes for handling customer complaints and returned defective product are described in QF 7.2.3-1, Record of Customer Complaint and QF 7.2.3-2, record of Customer Returned Product.

7.5.2 Validation of Processes for Production and Service Provision

Processes for production where the resulting output cannot be verified by subsequent monitoring or measurement are validated. This includes any processes where deficiencies become apparent only after the product is in use and has been delivered. Validation demonstrates the ability of these processes to achieve planned results. Arrangements are established for these processes including, as applicable:

- Defined criteria for review and approval of the processes, including qualification and approval of special processes prior to use;
- Approval of equipment and qualification of personnel;
- Use of specific methods and procedures including control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto;
- Requirements for records; and,
- Revalidation.

Reference QAP 7.5.2, Validation of Hidden and Special Processes

7.5.3 Identification and Traceability

Product is identified by suitable means throughout production realization.

The organization maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

The status of the product is identified with respect to measurement and monitoring requirements.

When acceptance authority media is used (stamps, etc.) the organization establishes and documents controls for the media.

Where traceability is a requirement, the unique identification of product is controlled and recorded.

According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system provides for:

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

- For an assembly, the identity of its components and those of the next higher assembly to be traced; and,
- For given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

Reference QAP 7.5.3, Identification and Traceability

Reference QL 7.5.3, Raw Material Inventory Codes

7.5.4 Customer Property

Care is exercised with customer property while it is under control or being used. Customer property provided for use or incorporation into product is identified, verified, protected and safeguarded. Any customer property that is lost, damaged or otherwise found to be unsuitable for use is recorded and reported to customers.

Customer property includes intellectual property, including customer furnished data used for design, production, and/or inspection.

Reference QLog 7.5.4, Customer Furnished Property

7.5.5 Preservation of Product

Conformity of product during internal processing and delivery to the intended destination is preserved. This includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

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

- Cleaning;
- Prevention, detection and removal of foreign objects;
- Special handling for sensitive products;
- Markings and labeling including safety warnings;
- Shelf life control and stock rotation; and,
- Special handling for hazardous materials.

The organization ensures that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

Reference QAP 7.5.5, Preservation of Product

QF 7.5.5-1, Packing List

QF 7.5.5-2, Certificate of Conformance

7.6 Control of Measuring and Monitoring Equipment

The organization determines the monitoring and measurements to be undertaken, and the monitoring and measuring devices needed to assure conformity of product to determined requirements.

The organization maintains a register of monitoring and measuring devices, and defines the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Monitoring and measuring devices may include, but is not limited to, test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It may also include personally owned and customer supplied equipment used to provide evidence of product conformity.

Processes are established to ensure that monitoring and measurement can be carried out and are carried out in a manner consistent with the monitoring and measurement requirements.

The organization ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Where necessary to ensure valid results, measuring equipment is:

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

The validity of the previous measuring results are assessed and recorded when the equipment is found not to conform to requirements. Appropriate action is taken on the equipment and any product affected. Records of the results of calibration and verification are maintained.

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

The control of monitoring and measuring devices process is described in QAP 7.6 Control of Monitoring and Measurement Devices.

Reference QDB 7.6-1, Measuring and Monitoring Equipment

Reference QF 7.6-2, Out-of-Tolerance Report

Section Seven Related and Support Documentation

QP 7.1, Standard Quality Plan

QAP 7.2.2, Customer Requirements Review and Order Entry

QDB 7.2.2-1, Approach Estimating Worksheet

QDB 7.2.2-2, EstiTrack Quote Module

QF 7.2.2-1, Quote Sheet

QLog 7.2.2-2, Record of Customer Contract Review

QDB 7.2.2.-3, EstiTrack Sales Order Module

QDB 7.2.3, Customer Complaint & Returned Product

QAP 7.4.1, Purchasing Process

QDB 7.4.1, Approved Suppliers (Approach)

QL 7.4.2, Quality Procurement Requirements

QF 7.4.2-1, Request for Quote

QLog 7.4.2, Purchase Order Numbers

QDB 7.4.2, EstiTrack Purchase order Module

QF 7.4.2-2, Purchase Order

QF 7.4.2-3, Supplier Waiver/Deviation Request

QAP 7.4.3, Verification of Purchased Product

QF 7.4.3-1, Record of Source Inspection/Release Form

QF 7.4.3-2, Record of Receipt Inspection

QDB 7.4.3-3, Job Card Entry

QLog 7.4.3-4, Record of Raw Material Test Results

QDB 7.4.3-5, EstiTrack Receiving Module

QAP 7.5.1, Control of Production and Service Provision

QDB 7.5.1-1, EstiTrack Shop Order Module

QF 7.5.1-2, Shop Floor Routing

QDB 7.5.1-3, Process Control Plan

QF 7.5.1-4, Process Control Chart

QF 7.5.1-5, Release of Finished Goods for Shipment

QFile 7.5.1-6, First Article Inspection Reports

QAP 7.5.1.2, Production Process Change Control

QF 7.5.1.2, Production Process Change Authorization

QFile 7.5.1.3-1, CNC Programs – Released Directory

QLog 7.5.1.3-2, Tooling

QAP 7.5.2, Validation of Special Processes
QAP 7.5.3, Identification and Traceability
QL 7.5.3, Raw Material Inventory Codes
QLog 7.5.4, Customer Furnished Property
QAP 7.5.5, Preservation of Product
QF 7.5.5-1, Packing List
QF 7.5.5-2, Certificate of Conformance
QAP 7.6 Control of Monitoring and Measurement Devices
QDB 7.6-1, Measuring and Monitoring Equipment
QF 7.6-2, Out-of-Tolerance Report

8.0 Measurement, Analysis and Improvement

8.1 General

The Leadership Team has planned and implemented the monitoring, measurement, analysis and improvement procedures needed to:

- Demonstrate conformity of the product;
- Ensure conformity of the quality management system; and
- Continually improve the effectiveness of the quality management system.

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

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

- Process control;
- Selection and inspection of key characteristics;
- Process capability measurements;
- Design of experiments;
- Matching sampling rate to the criticality of the product and process capability; and,
- Failure mode and effect analysis.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality system, the organization monitors information relating to customer perception as to whether customer requirements have been fulfilled.

Karas Engineering sends out a customer satisfaction survey to all active customers at least once per calendar year. The methods for obtaining and using this information are determined and documented in QF 8.2.1, Customer Survey. Also, reference QP 5.4.1, Quality Objectives, for specific customer satisfaction metrics.

8.2.2 Internal Audit

Periodic internal audits are conducted at planned intervals to determine whether the quality management system:

- Conforms to the planned arrangements, to the requirements of the standard, and to the quality management system requirements established by the organization; and,
- Is effectively implemented and maintained.

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

Reference Internal Audit Schedule QF 8.2.2-1

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, are defined in a documented procedure QAP 8.2.2, Internal Audits.

The management responsible for the audited area ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Detailed tools and techniques are developed to support the audit of the quality management system requirements. They include, but are not limited to, checklists, flowcharts, audit reports, and audit schedules with assigned auditors. The acceptability of the selected tools is measured against the effectiveness of the internal audit procedure and overall organizational performance.

Internal audits also meet contract and/or regulatory requirements.

8.2.3 Monitoring and Measurement of Processes

Suitable methods are applied for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the product.

In the event of procedure nonconformity, the organization shall:

- Take appropriate action to correct the nonconforming procedure;
- Evaluate whether the procedure nonconformity has resulted in product nonconformity; and,
- Identify and control the nonconforming product in accordance with the Control of

Nonconforming Product Procedure QAP 8.3.

8.2.4 Monitoring and Measurement of Product

The characteristics of the product are monitored and measured to verify that product requirements are fulfilled. This is completed at appropriate stages of the product realization procedure in accordance with planned arrangements.

When key characteristics have been identified or are required by the customer's contract, they are monitored and controlled.

When the organization uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan precludes the acceptance of lots whose samples have known nonconformance. When required, the plan is submitted for customer approval. Reference QAP 8.2.4, Sampling Plans

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive recall procedures pending completion of all required measurement and monitoring activities. Reference QF 8.2.4-1, Acceptance Tag and QF 8.2.4-2, Reject Tag and QF 8.2.4-3, MRB Hold Tag

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing the release of product.

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

8.2.4.1 Inspection Documentation

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

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

Test records show actual test results data when required by specification or acceptance test plan. When required to demonstrate product qualification, test records provide evidence that the product meets the defined requirements.

Reference QF 8.2.4.1-1, Record of Production Inspection.

Reference QF 8.2.4.1-2, Record of Final Inspection

8.2.4.2 First Article Inspection

The organization's system provides a procedure for the inspection, verification, and documentation of a representative item from the first production run of a new part or following any subsequent change that invalidates the previous first article inspection result.

Karas Engineering performs first article inspection in accordance with AS9102. The methods are described in QAP 8.2.4.2, First Article Inspection and QF 8.2.4-1, First Article Inspection Report.

8.3 Control of Nonconforming Material

Product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in a documented procedure QAP 8.3, Control of Nonconforming Product Procedure.

The term "nonconforming product" also includes nonconforming product returned from a customer. The organization's documented procedure defines responsibility for review and authority for the disposition of nonconforming product and the procedure for approving personnel making such decisions.

Karas Engineering effectively deals with nonconforming product, as appropriate, by:

- Taking action to eliminate the detected nonconformity;
- Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; and/or
- Taking action to preclude its original intended use or application.

The organization does not use dispositions of 'use-as-is' or 'repair' unless specifically authorized by the customer, if:

The product is produced to customer design; or

The nonconformity results in a departure from the contract requirements.

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

When nonconforming product is corrected, it is subject to reverification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, actions are taken appropriate to the effects, or potential effects, of the nonconformity.

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

Parties requiring notification of nonconforming product may include suppliers, internal departments, customers, distributors, and regulatory authorities.

Reference QLog 8.3-1, Nonconforming Material Report Log

8.4 Analysis of Data

The determination of, collection, and analysis of appropriate data is completed to demonstrate the suitability and effectiveness of the quality management system, and to evaluate where continual improvement of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

Forums for the analysis of such data are:

- Management Review Meeting(s) of the Quality System;
- Monthly review of Quality Objectives measures, QP 5.4.1

The analysis of data provides information relating to:

- Customer satisfaction;
- Conformance to product requirements;
- Characteristics and trends of procedures and products including opportunities for preventive action; and,
- Suppliers.

Sources of appropriate data include:

- Customer Satisfaction Surveys
- Customer On-time Delivery measures
- Customer Returned Product measures
- Supplier On-time Delivery measures
- Supplier Product Quality measures
- Shop Floor Process Control Statistical measures
- Product Inspection Results
- Internal Audit Findings and Process measures
- Corrective and Preventive Action measures

8.5 Improvement

8.5.1 Continual Improvement

The effectiveness of the quality management system is continually improved through the use of the following:

- Quality policy;
- Quality objectives;
- Audit results;
- Analysis of data;
- Corrective and preventive actions; and,
- Management review.

Reference QAP 8.5.1 for Continual Improvement process procedure.

8.5.2 Corrective Action

Corrective action is taken to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the impact of the problems encountered.

A documented procedure for corrective action is established defining requirements for:

- Reviewing nonconformities (including customer complaints);
- Determining the causes of nonconformities;
- Evaluating the need for action to ensure that nonconformities do not recur;
- Determining and implementing action needed;
- Records of the results of actions taken;
- Reviewing corrective action taken;

- Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause; and,
- Specific actions where timely and/or effective corrective actions are not achieved.

Reference QAP 8.5.2 for Corrective Action process procedure.

8.5.3 Preventive Action

Preventive action is determined to eliminate the causes of potential nonconformities in order to prevent occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure for preventive action is established defining requirements for:

- Determining potential nonconformities and their causes;
- Evaluating the need for action to prevent occurrence of nonconformities;
- Determining and implementing action needed;
- Records of results of action taken; and,
- Reviewing preventive action taken.

Reference QAP 8.5.3 for Preventive Action process procedure.

Reference QF 8.5.3-1, Record of Preventive Action

Reference QF 8.5.3-2, Failure Mode and Effects Analysis (FMEA)

Reference QF 8.5.3-3, Record of Total Productive Maintenance (TPM)

Section Eight Related and Support Documentation

QF 8.2.1, Customer Satisfaction Survey

QAP 8.2.2, Internal Audit

QF 8.2.2-1, Internal Audit Schedule

QF 8.2.2-2, Internal Audit Report

QAP 8.2.4, Sampling Plans

QT 8.2.4-1, Acceptance Tag

QT 8.2.4-2, Reject Tag

QT 8.2.4-3, MRB Hold Tag

QF 8.2.4.1-1, Record of Production Inspection

QF 8.2.4.1-2, Record of Final Inspection

QAP 8.2.4.2, First Article Inspection

QF 8.2.4.2, First Article Inspection Report (FAIR)

QAP 8.3, Control of Nonconforming Material

QLog 8.3-1, Nonconforming Material Report Log

QF 8.3-2, Nonconforming Material Report (NCR)
QF 8.3-3, Quality Alert
QF 8.3-4, Nonconforming Material Containment Checklist
QAP 8.5.1, Continual Improvement
QF 8.5.1, Record of Continuous Improvement Project
QAP 8.5.2, Corrective Action
QLog 8.5.2-1, Corrective/Preventive Action Request Log
QF 8.5.2-2, Corrective Action Request
QAP 8.5.3, Preventive Action
QF 8.5.3-1, Record of Preventive Action
QF 8.5.3-2, Failure Mode and Effects Analysis (FMEA)
QF 8.5.3-3, Record of Total Productive Maintenance