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 D. 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 5.2) and has identified Quality Objectives (reference QAP 6.2) 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 ensures the promotion of customer requirements throughout the organization. He has the authority to limit processing or stop work as required. He has the organizational freedom including sufficient independence from cost and schedule considerations with unlimited access to top management to resolve quality management issues. He 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
Revision B – Updated to comply with AS9100, Revision C – 1/01/2012
Revision C – Updated to add references to new documents; editorial changes – 04/30/2014
Revision D – Updated to add references to Karas Enterprise Management System (KEMS) – 10/27/2015
Revision E – Updated to comply with AS9100, revision D – 12/01/2017
Revision F – Updated Sections 1.0 Scope, 5.1 Customer Focus & 8.3 D&D
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 9001:2015 standard and AS 9100 Revision D standard. The scope of the quality system is defined below:

Karas Engineering manufactures and machines product in accordance with customer design drawings; therefore, Section 8.3, Design and Development is not applicable to the organization. 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.

2.0 Normative References

AS 9102, Aerospace First Article Inspection Requirement
AS9103, Variation Management of Key Characteristics
3.0 Terms and Definitions

3.1 Counterfeit Product: A fraudulent product (e.g., material, part, component) that has been confirmed to be a copy, imitation or substitute that has been represented, identified, or marked as genuine, and/or altered by a source without legal right with intent to mislead, deceive or defraud.

3.2 Critical Items: Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

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

NOTE Special requirements (3.5) and critical items (3.2), along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 8.2.2 and 8.2.3). Special requirements can require the identification of critical items. Design output (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

3.4 Product Safety: The ability of a product to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5 Risk-based Thinking: Risk is the effect of uncertainty. Risk-based thinking is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in AS9100 including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of AS9100, the organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

3.6 Special Requirements: Those requirements identified by the customer, or determined by the organization, which have high risks to 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 limit of the industry’s capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

3.7 Traceability: Traceability requirements can include:

- the 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;
- for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable

4.0 Context of the organization

4.1 Understanding the Organization and its Context

The organization determines external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

Issues can include positive and negative factors or conditions for consideration. Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional or local. Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

The organization monitors and reviews information about these external and internal issues and documents this review during its periodic management review meetings.

Reference QAP 9.3, Management Review
4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on the organization’s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization determines:

a) the interested parties that are relevant to the quality management system;

b) the requirements of these interested parties that are relevant to the quality management system.

The organization monitors and reviews information about these interested parties and their relevant requirements and documents this review during its periodic management review meetings. (Note: green shading denotes internal and yellow shading denotes external interested parties.)

<table>
<thead>
<tr>
<th>Interested Party</th>
<th>Need</th>
<th>Karas Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employees</td>
<td>Opportunity to earn/enjoy adequate standard of living for family; fulfilling employment opportunity</td>
<td>Provision of stable, successful and fulfilling employment opportunity</td>
</tr>
<tr>
<td>Owner</td>
<td>Return on investment of time and money</td>
<td>Implement quality management system and sound business practices</td>
</tr>
<tr>
<td>Customers</td>
<td>Reference Management Review for current List</td>
<td></td>
</tr>
<tr>
<td>Regulators</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSHA</td>
<td>Safe work environment</td>
<td>Compliance with all OSHA workplace safety requirements</td>
</tr>
<tr>
<td>Department of Defense</td>
<td>Safeguarding controlled technical data for defense weapons systems</td>
<td>Compliance with export control procedures (ITAR)</td>
</tr>
<tr>
<td>State Department</td>
<td>Management of manufacturers of components for weapon systems</td>
<td>Registration as recipient of department of defense technical data</td>
</tr>
<tr>
<td>Department of Labor</td>
<td>Fair workplace environment for employees</td>
<td>Compliance with all labor laws</td>
</tr>
<tr>
<td>EPA</td>
<td>Safe environmental conditions</td>
<td>Proper disposal of hazardous waste</td>
</tr>
</tbody>
</table>

Reference QAP 9.3, Management Review
4.3 Determining the Scope of the Quality Management System

The organization has determined the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization has considered:

a) the external and internal issues referred to in 4.1;

b) the requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization.

The organization has applied all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization’s quality management system is available and maintained as documented information. Section 1.0, Scope, states the types of products and services covered by the quality management, and provides justification for any requirement of this International Standard that the organization has determined is not applicable to the scope of its quality management system.

The quality management system documentation includes:

- Documented statements of a Quality Policy (reference QP 5.2) and Quality Objectives (reference QAP 6.2).
- A Quality Manual - all of the sections of the current manual meet this documentation requirement.
- Documented procedures required by the quality management system. 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 7.5, Master List of Controlled Quality Management system Documents.
- Documents needed by the organization to ensure the effective planning, operation and control of processes. Other documents include work instructions, quality logs, quality lists, databases and blank forms.
- Quality records required by the quality management system. These include, at a minimum, all required records indicated in the quality assurance procedures.
- 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 and changes to this documentation.


**4.4 Quality Management System and its Processes**

4.4.1 The organization has established, implemented, maintains and continually improves its quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization’s quality management system addresses customer and applicable statutory and regulatory quality management system requirements.

The organization has determined the processes needed for the quality management system and their application throughout the organization, and has:

a) determined the inputs required and the outputs expected from these processes;

b) determined the sequence and interaction of these processes;

c) determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d) determined the resources needed for these processes and ensures their availability;

e) assigned the responsibilities and authorities for these processes;

f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1;

g) evaluated these processes and implement any changes needed to ensure that these processes achieve their intended results;

h) committed to continually improve the processes and the quality management system.

4.4.2 To the extent necessary, the organization:

a) maintains documented information to support the operation of its processes;

b) retains documented information to have confidence that the processes are being carried out as planned.

The organization has established and maintains documented information in the form of a Quality Management System Manual (this document) that includes:

- a general description of relevant interested parties (see 4.2 a);
- the scope of the quality management system, including boundaries and applicability (see 4.3);
- a description of the processes needed for the quality management system and their application throughout the organization;
- the sequence and interaction of these processes;
- assignment of the responsibilities and authorities for these processes;
the documented information established for the quality management system, or reference to it.

Section Four Related and Support Documentation

QP 4.1 Organization Process Map
QP 5.2 Quality Policy
QAP 7.5-1 Control of Quality Management System Documents
QL 7.5 Master List of Controlled Quality Management System Documents
QAP 9.3 Management Review

5.0 Leadership

5.1 Leadership and Commitment

5.1.1 General

The organization’s leadership team demonstrates leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system;
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirements into the organization’s business processes;
d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

The organization’s leadership team demonstrates leadership and commitment with respect to customer focus by ensuring that:
a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
c) the focus on enhancing customer satisfaction is maintained;
d) product and service conformity and on-time delivery performance are measured and appropriate action is taken if intended results are not, or will not be, achieved.

Reference QAP 6.2, Quality Objectives
Reference QAP 8.2.3, Customer Requirements Review and Order Entry
Reference QAP 9.3, Management Review

5.2 Policy

5.2.1 Developing the Quality Policy

The organization’s leadership team has established, implements and maintains a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;
b) provides a framework for setting quality objectives;
c) includes a commitment to satisfy applicable requirements;
d) includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy

The quality policy is:

a) available and maintained as documented information;
b) communicated, understood and applied within the organization;
c) available to relevant interested parties, as appropriate.

Reference QP 5.2, Quality Policy

5.3 Organizational Roles, Responsibilities and Authorities

The organization’s leadership team ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

The organization’s leadership team has assigned the responsibility and authority for:
a) ensuring that the quality management system conforms to the requirements of this International Standard;
b) ensuring that the processes are delivering their intended outputs;
c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to The organization’s leadership team;
d) ensuring the promotion of customer focus throughout the organization;
e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

The organization’s leadership team has appointed a specific member of the organization’s management, identified as the management representative, who has the responsibility and authority for oversight of the above requirements.

Persons having these assigned responsibilities have the organizational freedom and unrestricted access to the organization’s leadership team to resolve quality management issues.

Reference QAP 5.3, Responsibilities and Authorities

Section Five Related and Support Documentation

QP 5.2, Quality Policy
QAP 5.3, Responsibility and Authority
QP 5.3, Organization Chart
QAP 6.2, Quality Objectives
QF 6.2-1, Monthly Metrics Scorecard
QF 6.2-2, Organizational Scorecard
QAP 8.2.3, Customer Requirements Review and Order Entry
QAP 9.3, Management Review
QF 9.3, Record of Management Review Meeting

6 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, the organization considers the issues referred to in 4.1 and the requirements referred to in 4.2 and determines the risks and opportunities that need to be addressed to:
a) give assurance that the quality management system can achieve its intended result(s);
b) enhance desirable effects;
c) prevent, or reduce, undesired effects;
d) achieve improvement.
6.1.2 The organization plans:

a) actions to address these risks and opportunities;

b) how to:
   1) integrate and implement the actions into its quality management system processes (see 4.4);
   2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services. Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization’s or its customers’ needs.

Reference QAP 8.1.1, Risk Management

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 The organization establishes quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives are:

a) consistent with the quality policy;

b) measurable;

c) relatable to applicable requirements;

d) relevant to conformity of products and services and to enhancement of customer satisfaction;

e) monitored;

f) communicated;

g) updated as appropriate.

The organization maintains documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization determines:

a) what will be done;

b) what resources will be required;
c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

Reference QAP 6.2, Quality Objectives

6.3 Planning of Changes

When the organization determines the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4).

The organization considers:

a) the purpose of the changes and their potential consequences;

b) the integrity of the quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

Reference QAP 7.5-1, Control of Quality Management System Documents

Section Six Related and Support Documentation

QAP 6.2, Quality Objectives
QAP 7.5-1, Control of Quality Management System Documents
QAP 8.1.1, Risk Management

7 Support

7.1 Resources

7.1.1 General

The organization determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization considers:

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers.
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 the periodic management review process. The management review process is described in QAP 9.3 Management Review.

7.1.2 People

The organization determines and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

The infrastructure necessary for the operation of its processes and 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, communication or information systems.

The Leadership Team has identified and maintains the required infrastructure to achieve product conformity. Reference QL 7.1.3-1, Facilities List.

7.1.4 Environment for the Operation of Processes

The work environment necessary for the operation of its processes and to achieve conformity of products and services been determined and maintained.

A suitable environment can be a combination of human and physical factors, such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.
NOTE: Consideration of human factors is the understanding of the interactions between people, machines, and each other and their impact on human performance (e.g., physical fitness, physiological characteristics, personality, stress, fatigue, distraction, communication and attitude).

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

Reference QAP 7.1.3, Infrastructure and Work Environment

7.1.5 Monitoring and Measuring resources

7.1.5.1 General

The organization determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization ensures that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;

b) are maintained to ensure their continuing fitness for their purpose.

The organization retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

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. When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

d) Protected from damage and deterioration during handling, maintenance and storage;

The organization has established, implemented and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.
The organization maintains a register of the monitoring and measuring equipment. The register includes the equipment type, unique identification, location, and the verification or calibration method, frequency, and acceptance criteria. Monitoring and measuring equipment may also include personally owned and customer supplied equipment used to provide evidence of product conformity.

Verification or calibration is carried out under suitable environmental conditions (see 7.1.4).

The organization determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

Reference QAP 7.1.5, Control of Monitoring & Measuring Devices
Reference QDB 7.1.5, Measuring and Monitoring Equipment
Reference QF 7.1.5, Out-of-Tolerance Report

7.1.6 Organizational Knowledge

The organization determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and is made available to the extent necessary.

When addressing changing needs and trends, the organization considers its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

The organization has established the following repositories of organizational knowledge on the network:

QFile 7.1.6-1 Completed First Article Inspection Report
QFile 7.1.6-2 CNC Programs
QFile 7.1.6-3 Controlled Customer Generated Documents
QFile 7.1.6-4 Quality Management System Records
QFile 8.2.2 Applicable Industry and Regulatory Requirements

7.2 Competence

The organization:

a) determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b) ensures that these persons are competent on the basis of appropriate education, training, or experience;
c) where applicable, takes actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
d) retains appropriate documented information as evidence of competence.

The Leadership Team has:

- Determined the necessary competence for personnel performing work affecting conformity to product requirements;
- Where applicable, provided training or taken other action to achieve the necessary competence;
- 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.

The organization understands that product conformity can be affected directly or indirectly by personnel performing any task within the quality management system.

7.3 Awareness

The organization ensures that persons doing work under the organization’s control are aware of:

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d) the implications of not conforming with the quality management system requirements;
e) relevant quality management system documented information and changes thereto;
f) their contribution to compliance and product safety;
g) the importance of ethical behavior.

Reference QAP 7.2 Competence, Training and Awareness
Reference QL 7.2-1 QMS Requirements Applicability
Reference QL 7.2-2 List of Certified Personnel
Reference QF 7.2-1 Employee Training – Reading List
Reference QF 7.2-2 Employee Training – Attendance Sheet
Reference QF 7.2-3 Personnel Qualification Form
Reference QF 7.2-4 Periodic Employee Performance Review
7.4 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. The organization determines the internal and external communications relevant to the quality management system, including:

a) on what it will communicate;
b) when to communicate;
c) with whom to communicate;
d) how to communicate;
e) who communicates.

Reference QAP 7.4, Organizational Communication.

7.5 Documented information

7.5.1 General

The organization’s quality management system includes:

a) documented information required by the AS9100/ISO 9001 International Standard;
b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and Updating

When creating and updating documented information the organization ensures appropriate:

a) identification and description (e.g. a title, date, author, or reference number);
b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
c) review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the quality management system and by this International Standard is controlled to ensure:

a) it is available and suitable for use, where and when it is needed;
b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization has addressed the following activities, as applicable:
a) distribution, access, retrieval and use;
b) storage and preservation, including preservation of legibility;
c) control of changes (e.g. version control);
d) retention and disposition;
e) prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system is identified as appropriate, and controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

When documented information is managed electronically, back-up processes are defined. Electronic documented information is protected from corruption.

A documented procedure (QAP 7.5-1, 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 determined by the organization to be necessary for the planning and operation of the quality management system 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.

**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 7.5-2, 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.

Section Seven Related and Support Documentation

QAP 7.1.3, Infrastructure and Work Environment
QL 7.1.3-1, Facilities List
QL 7.1.3-2 Equipment Responsibility List
QF 7.1.3, Request for Addition to Infrastructure
QF 7.1.4, 5S Checklist
QAP 7.1.5, Control of Monitoring & Measuring Devices
QDB 7.1.5, Measuring and Monitoring Equipment
QF 7.1.5, Out-of-Tolerance Report
QFile 7.1.6-1 Completed First Article Inspection Report
QFile 7.1.6-2 CNC Programs
QFile 7.1.6-3 Controlled Customer Generated Documents
QFile 7.1.6-4 Quality Management System Records
QFile 8.2.2 Applicable Industry and Regulatory Requirements
QAP 7.2, Competence, Training and Awareness
QL 7.2-1, Requirements Applicability Table
QL 7.2-2, List of Qualified Personnel
QF 7.2-1, Record of Training – Reading List
QF 7.2-2, Record of Training – Attendance Sheet
QF 7.2-3, Record of Personnel Qualification
QF 7.2-4, Annual Employee Performance Review
QAP 7.4, Organizational Communication
QAP 7.5-1, Control of Quality Management System Documents
QAP 7.5-2, Control of Records

8 Operation

8.1 Operational Planning and Control

The organization plans, implements and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:
a) determining the requirements for the products and services;

Determination of requirements for the products and services includes consideration of:

- personal and product safety;
- producibility and inspectability;
- reliability, availability and maintainability;
- suitability of parts and materials used in the product;
- selection and development of embedded software;
- product obsolescence;
- prevention, detection, and removal of foreign objects;
- handling, packaging and preservation;
- recycling or final disposal of the product at the end of its life.

b) establishing criteria for:

1) the processes;
2) the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;

d) implementing control of the processes in accordance with the criteria;

e) determining and keeping documented information to the extent necessary:

1) to have confidence that the processes have been carried out as planned;
2) to demonstrate the conformity of products and services to their requirements;

f) determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;

g) engaging representatives of affected organization functions for operational planning and control;

h) determining the process and resources to support the use and maintenance of the products and services;

i) determining the products and services to be obtained from external providers;

j) establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

Reference QPlan 8.1, Standard Quality Plan

The organization plans and manages product and service provision in a structured and controlled manner including timed events performed in the appropriate sequence to meet requirements at acceptable risk, with resource and schedule constraints.
Reference QAP 8.1-1, Project Management

The output of this planning is suitable for the organization's operations.

Reference QP 8.1, Specialized Project Plan

The organization controls planned changes and reviews the consequences of unintended changes, taking action to mitigate adverse effects, as necessary.

The organization ensures that outsourced processes are controlled (see 8.4).

**Control of Work Transfers**

The organization has established, implemented and maintains a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process ensures that work transfer impacts and risks are managed.

[Reference QAP 8.1-2, Control of Work Transfers]

**8.1.1 Operation Risk Management**

The organization plans, implements and controls a process for managing operation risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services:

a) assignment of responsibilities for risk management;

b) definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);

c) identification, assessment and communication of risks throughout operations;

d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

e) acceptance of risks remaining after implementation of mitigating actions.

The organization plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints, as appropriate to the organization and the product.

Reference QAP 8.1.1 Risk Management
Reference QAP 10.3-2, Preventive Action
8.1.2 Configuration Management

The organization plans, implements and controls a process for configuration management as appropriate to the organization and product in order to ensure the visibility and control of physical and functional attributes throughout the product lifecycle. This process:

a) controls product identity and traceability to requirements, including the implementation of identified changes;

b) ensures that the documented information (e.g., requirements, design, test, and acceptance documentation) is accurate and consistent with the actual attributes of the products and services.

Reference QAP 8.1.2, Configuration Management

8.1.3 Product Safety

The organization plans, implements and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product. The organization identifies all product safety considerations including characteristics designated by the design authority as “flight safety” or “safety critical” during the customer requirements review process.

Reference QAP 8.2.3 Customer Requirements Review and Order Entry

8.1.4 Prevention of Counterfeit Product

The organization plans, implements and controls a process, appropriate to the product, that prevents the use of counterfeit or suspect counterfeit product and their inclusion in product(s) delivered to the customer.

The organization’s counterfeit product prevention process considers, as applicable:

- training of appropriate persons in the awareness and prevention of counterfeit product;
- application of a parts obsolescence monitoring program;
- procurement requirements for assuring traceability of parts and components to their original authorized manufacturers;
- verification and test methodologies to detect counterfeit product;
- monitoring of counterfeit product reporting from external sources; quarantine and reporting of suspect or detected counterfeit product.

Reference QAP 8.4.1 Purchasing Process
Reference QAP 8.4.2 Verification of Purchased Product
8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customers includes:

a) providing information relating to products and services;
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

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 9.1, Customer Complaint & Returned Product

8.2.2 Determining the Requirements Related to Products and Services

When determining the requirements for the products and services to be offered to customers, the organization ensures that:

a) the requirements for the products and services are defined, including:
   1) any applicable statutory and regulatory requirements;
   2) those considered necessary by the organization;
b) the organization can meet the claims for the products and services it offers;
c) special requirements of the products and services are determined;
d) operation risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

8.2.3 Review of Requirements Related to Products and Services

8.2.3.1 The organization ensures that it has the ability to meet the requirements for products and services to be offered to customers. The organization conducts a review before committing to supply products and services to the customer, to include:
a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer, but necessary for the specified or intended use, when known;

c) requirements specified by the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

This review is coordinated with applicable functions of the organization.

If upon review the organization determines that some customer requirements cannot be met or can only partially be met, the organization negotiates a mutually acceptable requirement with the customer.

The organization ensures that contract or order requirements differing from those previously defined are resolved.

The customer requirements are confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 The organization retains documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services

The organization ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

Reference QAP 8.2.3 Customer Requirements Review and Order Entry

8.3 Design and development of products and services

Karas Engineering provides precision machining services in compliance with customer supplied design drawings and is not a product design and development organization.

Therefore, the requirements of Section 8.3 do not apply to the Karas Engineering scope
8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

The organization ensures that externally provided processes, products, and services conform to requirements.

The organization is responsible for the conformity of all externally provided processes, products and services, including from sources defined by the customer.

The organization ensures, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

The organization identifies and manages the risks associated to the external provision of processes, products and services, as well as the selection and use of external providers (e.g., direct and sub-tier external providers and sources identified by the customer).

The organization requires their external providers to apply appropriate controls to their sub-tier providers, to ensure that requirements are met.

The organization determines the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization’s own products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1 The organization:

a) defines the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of external providers depending on their approval status;

b) maintains a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);
c) periodically reviews external provider performance including product and service conformity and on time delivery performance;

d) defines the necessary actions to take when dealing with external providers that do not meet requirements;

e) defines the process for controlling documented information created by and/or retained by external providers.

Reference QAP 8.4.1 Purchasing Process
Reference QDB 4.1.1 Approved Suppliers

8.4.2 Type and Extent of Control

The organization ensures that externally provided processes, products and services do not adversely affect the organization’s ability to consistently deliver conforming products and services to its customers.

The organization:

a) ensures that externally provided processes remain within the control of its quality management system;

b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) takes into consideration:

1) the potential impact of the externally provided processes, products and services on the organization’s ability to consistently meet customer and applicable statutory and regulatory requirements;

2) the effectiveness of the controls applied by the external provider;

3) the results of the periodic review of external provider performance (see 8.4.1.1 c);

d) determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements (see 8.4.2.1).

Reference QAP 8.4.1 Purchasing Process

8.4.2.1 Verification of Externally Provided Processes, Products and Services

Verification activities of externally provided products and services are performed according to the risks identified. These activities include inspection or periodic testing, as applicable, when there is high risk of nonconformities or counterfeit product.

Verification activities include, as applicable:
review of objective evidence of the conformity of the processes, products and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);

- inspection and audit at the external provider’s premises;
- review of the required documentation;
- review of production part approval process implementation;
- inspection of products or verification of services upon receipt;
- review of delegations of product verification to the external provider.

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

When the organization delegates verification activities to the external provider, the scope and requirements for delegation are defined and a register of delegations is maintained. The organization periodically monitors the external provider’s delegated verification activities.

When external provider test reports are utilized to verify externally provided products, the organization has a process to evaluate the data in the test reports to confirm that the product meets requirements. When raw material is used in critical item applications, the organization has a process to validate the accuracy of test reports.

Reference QAP 8.4.2 Verification of Purchased Product

### 8.4.3 Information for External Providers

The organization ensures the adequacy of requirements prior to their communication to the external provider.

The organization communicates to external providers its requirements for:

a) the processes, products and services to be provided including the identification of specifications, drawings, process requirements, instructions and other relevant technical data;

b) the approval of:
   1) products and services;
   2) methods, processes and equipment;
   3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers’ interactions with the organization;
e) control and monitoring of the external providers’ performance to be applied by the organization;

f) verification or validation activities that the organization, or its customer, intends to perform at the external providers’ premises;

g) design and development control;

h) critical items, including key characteristics;

i) test, inspection and verification (including production process verification);

j) the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;

k) the need to:
   - implement a quality management system;
   - use customer-designated or approved external providers, including process sources (e.g., special processes);
   - notify the organization of nonconforming processes, products or services and obtain approval for their disposition;
   - prevent the use of counterfeit products (see 8.1.4);
   - notify the organization of changes to processes, products or services, including changes of external providers or location of manufacture, and obtain their approval;
   - flow down to their external providers the applicable requirements including customer requirements;
   - provide test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing;
   - retain documented information, including retention periods and disposition requirements;

l) the right of access by the organization, their customer and regulatory authorities to the applicable areas of facilities and to applicable documented information;

m) ensuring persons are aware of their contribution to compliance and product safety and of the importance of ethical behavior.

Reference QL 8.4.3 Quality Procurement Requirements

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

The organization implements production and service provision under controlled conditions.

Controlled conditions include, as applicable:
a) the availability of documented information that defines:
   1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
   2) the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

   1) ensuring that documented information for monitoring and measurement activity for product acceptance includes:
      □ criteria for acceptance and rejection;
      □ where in the sequence verification operations are to be performed;
      □ measurement results to be retained (at a minimum an indication of acceptance or rejection);
      □ any specific monitoring and measurement equipment required and instructions associated with their use;

   2) ensuring that when sampling is used as a means of product acceptance, the sampling plan is 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).

d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities;

i) accountability for all product during production (e.g., parts quantities, split orders, nonconforming product);

j) control and monitoring of identified critical items, including key characteristics, in accordance with established processes;

k) determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);

l) identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages;
having evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;

n) provision for the prevention, detection and removal of foreign objects;

o) control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);

p) establishing criteria for workmanship (e.g., written standards, representative samples, illustrations).

Reference QAP 8.5.1 Control of Production and Service Provision

8.5.1.1 Control of Production Equipment, Tools and Software Programs

Equipment, tools and software programs used to automate, control, monitor or measure production processes are validated prior to final release for production and shall be maintained.

Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

Reference QLog 8.5.1.1 Tooling

8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization establishes arrangements for these processes including, as applicable:

a) definition of criteria for the review and approval of the processes;

b) determination of conditions to maintain the approval;

c) approval of facilities and qualification of persons;

d) use of specific methods and procedures for implementation and monitoring the processes;

e) requirements for documented information to be retained.

QAP 8.5.1.2 Validation of Hidden and Special Processes

8.5.1.3 Production Process Verification

The organization implements production process verification activities to ensure the production process is capable of producing products that consistently meet requirements.

Reference QDB 8.5.1-2 Process Control Plan
The organization uses 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 activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).

Reference QAP 8.5.1.3 First Article Inspection

The organization retains documented information on the results of production process verification.

Reference QF 8.5.1.3 First Article Inspection Report

8.5.2 Identification and Traceability

The organization uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

The organization identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization establishes appropriate controls for the media.

The organization controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

Reference 8.5.2 Identification and Traceability

8.5.3 Property Belonging to Customers or External Providers

The organization exercises care with property belonging to customers or external providers while it is under the organization’s control or being used by the organization.

The organization identifies, verifies, protects and safeguards customers’ or external providers’ property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization reports this to the customer or external provider and retains documented information on what has occurred.

Reference QLog 8.5.3 Customer Furnished Property
8.5.4 Preservation

The organization preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Preservation of outputs includes, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

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

Reference QAP 8.5.4 Preservation of Product

8.5.5 Post-delivery Activities

The organization meets the requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization considers:

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback;
f) collection and analysis of in-service data (e.g., performance, reliability, lessons learned);
g) control, updating, and provision of technical documentation relating to product use, maintenance, repair and overhaul;
h) controls required for work undertaken external to the organization (e.g., off-site work);
i) product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).
When problems are detected after delivery, the organization takes appropriate action including investigation and reporting.

Reference QDB 9.1 Customer Complaints and Returned Product

8.5.6 Control of Changes

The organization reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes are identified.

The organization retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Reference QAP 8.5.6 Production Process Change Control

8.6 Release of products and services

The organization implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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

The release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization retains documented information on the release of products and services. The documented information includes:

a) evidence of conformity with the acceptance criteria;

b) traceability to the person(s) authorizing the release.

When required to demonstrate product qualification, the organization ensures that retained documented information provides evidence that the products and services meet the defined requirements.

The organization ensures that all documented information required to accompany the products and services are present at delivery.
8.7 Control of Nonconforming Outputs

8.7.1 The organization ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The term “nonconforming outputs” includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.

The organization takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This action also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization’s nonconformance control process is maintained as documented information including the provisions for:

- defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- taking actions necessary to contain the effect of the nonconformity on other processes, products or services;
- timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).

The organization deals with nonconforming outputs in one or more of the following ways:

a) correction;
b) segregation, containment, return or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products is only implemented:

- after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;
after authorization by the customer, if 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.

Counterfeit, or suspect counterfeit, product is not returned to the external provider and shall be controlled to prevent reentry into the supply chain.

Conformity to the requirements are verified when nonconforming outputs are corrected.

8.7.2 The organization retains documented information that:

a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity.

Reference QAP 8.7 Control of Nonconforming Material

Section Eight Support and Related Documents

QPlan 8.1, Standard Quality Plan
QAP 8.1-1, Project Management
QP 8.1, Specialized Project Plan
QAP 8.1-2, Control of Work Transfers
QAP 8.1.1, Risk Management
QAP 8.1.2, Configuration Management
QDB 8.2.2 KEMS Risk Assessment Module
QAP 8.2.3, Customer Requirements Review and Order Entry
QDB 8.2.3-1, KEMS Quote Module
QF 8.2.3, Quote Sheet
QLog 8.2.3, Record of Customer Contract Review.
QDB 8.2.3-2, KEMS Sales Order Module
QAP 8.4.1, Purchasing Process
QDB 8.4.1.1, Approved Suppliers
QF 8.4.2, Supplier Waiver/Deviation Request
QAP 8.4.2, Verification of Purchased Product
QF 8.4.2-1, Source Inspection/Release Form
QF 8.4.2-2, Receipt Inspection Form
QDB 8.4.2-1, Job Card Entry
QLog 8.4.2, Record of Raw Material Test Results
QDB 8.4.2-2, KEMS Receiving Module
QDB 8.4.3, KEMS Purchasing Module
QL 8.4.3, Quality Procurement Requirements
QLog 8.4.3, Purchase Order Numbers
QF 8.4.3-1, Request for Quote
QF 8.4.3-2, Purchase Order
QAP 8.5.1, Control of Production and Service Provision
QDB 5.5.1-1, KEMS Shop Order Module
QF 8.5.1-1, Shop Floor Routing
QDB 8.5.1-2, Process Control Plan
QF 8.5.1-2, Process Control Chart
QF 8.5.1-3, Release of Finished Goods for Shipment
QF 8.5.1.1 Preset Summary Report
QLog 8.5.1.1, Tooling
QAP 8.5.1.2, Validation of Hidden and Special Processes
QAP 8.5.1.3, First Article Inspection
QF 8.5.1.3, First Article Inspection Report
QAP 8.5.2, Identification and Traceability
QL 8.5.2 Raw Material Inventory Codes
QLog 8.5.3, Customer Furnished Property
QAP 8.5.4, Preservation of Product
QAP 8.5.6, Production Process Change Control
QF 8.5.6, Production Process Change Authorization
QF 8.6-1, Packing List
QF 8.6-2, Certificate of Conformance
QAP 8.6-1, Sampling Plans
QAP 8.6-2, Measurement of Product
QT 8.6-1, Acceptance Tag
QT 8.6-2, Reject Tag
QT 8.6-3, MRB Hold Tag
QF 8.6-3, Record of Production Inspection
QF 8.6-4, Record of Final Inspection
QAP 8.7, Control of Nonconforming Material
QLog 8.7, Nonconforming Material Report Log
QF 8.7-1, Nonconforming Material Report (NCR)
QF 8.7-2, Quality Alert
QF 8.7-3, Nonconforming Material Containment Checklist
QDB 9.1, Customer Complaint & Returned Product
9 Performance evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

The organization determines:

a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) when the monitoring and measuring shall be performed;
d) when the results from monitoring and measurement shall be analyzed and evaluated.

The organization evaluates the performance and the effectiveness of the quality management system.

The organization retains appropriate documented information as evidence of the results.

Reference QF 6.2-1 Monthly Metrics Scorecard
Reference QF 6.2-2 Organizational Scorecard

9.1.2 Customer Satisfaction

The organization monitors customers’ perceptions of the degree to which their needs and expectations have been fulfilled. The organization determines the methods for obtaining, monitoring and reviewing this information.

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product and service conformity, on-time delivery performance, customer complaints and corrective action requests. The organization develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

Karas Engineering periodically sends out a customer satisfaction survey to all active customers. The methods for obtaining and using this information are determined and documented in QF 9.1, Customer Survey. The organization also monitors customer on-time delivery, customer complaints, returned product and customer corrective actions - reference QAP 6.2, Quality Objectives, for specific customer satisfaction metrics.

The organization implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assesses the effectiveness of the results.
9.1.3 Analysis and Evaluation

The organization analyses and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.

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

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;
- Determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or product and,
- Identify and control any nonconforming product in accordance with QAP 8.3, Control of
Nonconforming Product.

**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.

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;
- Required records of measurement results (at a minimum a record of acceptance/rejection);
- Any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics have been identified or are required by the customer’s contract, the organization ensures that they are monitored and controlled in accordance with the established process.

When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical valid principles and appropriate for use – for example, matching the sampling plan to the criticality of the product and to the process capability. The plan precludes the acceptance of lots whose samples have known nonconformance. When required, the plan is submitted for customer approval. Reference QAP 8.6-1, Sampling Plans

Where product is released for production use pending completion of all required measurement and monitoring activities it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements. Reference QF 8.6-1, Acceptance Tag and QF 8.6-2, Reject Tag and QF 8.6-3, MRB Hold Tag

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

When required to demonstrate product qualification, test records provide evidence that the product meets the defined requirements.

The release of product and delivery of service to the customer 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.
The organization ensures that all documents required to accompany the product are present at delivery.

9.2 Internal audit

9.2.1 The organization conducts internal audits at planned intervals to provide information on whether the quality management system;

a) conforms to:
   1) the organization’s own requirements for its quality management system;
   2) the requirements of this International Standard;

b) is effectively implemented and maintained.

9.2.2 The organization:

a) plans, establishes, implements and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) defines the audit criteria and scope for each audit;

c) selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensures that the results of the audits are reported to relevant management;

e) takes appropriate correction and corrective actions without undue delay;

f) retains documented information as evidence of the implementation of the audit program and the audit results.

Reference QAP 9.2 Internal Audit
Reference QF 9.2-1 Internal Audit Schedule
Reference QF 9.2-2 Internal Audit Report

9.3 Management Review

9.3.1 General

The organization’s leadership team reviews the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.
9.3.2 Management Review Inputs

The management review is planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system;

c) information on the performance and effectiveness of the quality management system, including trends in:
   1) customer satisfaction and feedback from relevant interested parties;
   2) the extent to which quality objectives have been met;
   3) process performance and conformity of products and services;
   4) nonconformities and corrective actions;
   5) monitoring and measurement results;
   6) audit results;
   7) the performance of external providers;
   8) on-time delivery performance;

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities (see 6.1);

f) opportunities for improvement.

9.3.3 Management Review Outputs

The outputs of the management review include decisions and actions related to:

a) opportunities for improvement;

b) any need for changes to the quality management system;

b) any need for changes to the quality management system;

c) resource needs;

d) risks identified.

The organization retains documented information as evidence of the results of management reviews.

Reference QAP 9.3 Management Review
Reference QF 9.3 Management review Meeting Form
Section Nine Related and Support Documentation

QDB 9.1 Customer Complaint and Returned Product Database
QF 9.1 Customer Satisfaction Survey
QAP 9.2 Internal Audit
QF 9.2-1 Internal Audit Schedule
QF 9.2-2 Internal Audit Report
QAP 9.3 Management Review
QF 9.3 Management review Meeting Form
10 Improvement

10.1 General

The organization determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These actions include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

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.

The organization monitors the implementation of improvement activities and evaluates the effectiveness of the results. (Note: Continual improvement opportunities can result from lessons learned, problem resolution and the benchmarking of best practices).

Reference QAP 10.3 for Continual Improvement process procedure.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization:

a) reacts to the nonconformity and, as applicable:
   1) takes action to control and correct it;
   2) deals with the consequences;

b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   1) reviewing and analyzing the nonconformity;
   2) determining the causes of the nonconformity;
   3) determining if similar nonconformities exist, or could potentially occur;
c) implements any action needed;
d) reviews the effectiveness of any corrective action taken;
e) updates risk and opportunities determined during planning, if necessary;
f) makes changes to the quality management system, if necessary;
g) flows down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
h) takes specific actions when timely and effective corrective actions are not achieved;
i) evaluates the need for action based on human factors to ensure nonconformities do not recur.

Corrective actions are appropriate to the effects of the nonconformities encountered.

10.2.2 The organization retains documented information as evidence of:
a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.

**Corrective Action**

Corrective action is taken to eliminate the causes 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 the effectiveness of the corrective action taken;
- Flowing down corrective action requirement to a supplier, when it is determined that the supplier is responsible for the nonconformity;
- Specific actions where timely and/or effective corrective actions are not achieved, and
- Determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action where required.

Reference QAP 10.2 Corrective Action

**10.3 Continual Improvement**

The organization continually improves the suitability, adequacy and effectiveness of the quality management system.
The organization considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

The organization monitors the implementation of improvement activities and evaluate the effectiveness of the results.

**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 the effectiveness of the preventive action taken.

Note: Examples of preventive action opportunities include risk management, error-proofing, failure mode and effect analysis (FMEA), and information on product problems reported by external sources.

Reference QAP 10.3-2 Preventive Action
Reference QF 10.3-2, Record of Preventive Action
Reference QF 10.3-3, Failure Mode and Effects Analysis (FMEA)
Reference QF 10.3-4, Record of Total Productive Maintenance (TPM)

**Section Ten Related and Support Documentation**

QAP 10.2, Corrective Action
QLog 10.2, Corrective/Preventive Action Request Log
QF 10.2, Corrective Action Request
QAP 10.3, Continual Improvement
QF 10.3-1, Record of Continual Improvement Project
QLog 10-3-1, Continual Improvement Log
QAP 10.3-2, Preventive Action
QF 10.3-2, Record of Preventive Action
QF 10.3-3, Failure Mode and Effects Analysis (FMEA)
QF 10.3-4, Record of Total Productive Maintenance