	Title:	Kenson Quality Policy / Quality Manual	Number:	KPQPM
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	Signature:	*Signature on File*	Revision Edition:	*G*

1.0 SCOPE

1.1 GENERAL

1.1.1 Kenson Plastics Inc. (Kenson Plastics) top management is committed to adopting, implementing, and supporting a Quality Management System (QMS) to improve its overall performance and provide a sound basis for sustainable development initiatives. This manual serves to define and communicate a general overview of the Kenson QMS as well as provide the references to applicable procedures, its quality policy, and the relevant objectives of the company.

1.1.2 The Kenson organization utilizes their QMS as a vehicle to:

1.1.2.1 consistently provide products that meet customer and applicable statutory and regulatory requirements;

1.1.2.2 to enhance stakeholder satisfaction through the effective application of the system;

1.1.2.3 address risks and opportunities associated with its context and objectives;

1.1.2.4 demonstrate conformity to customer and applicable statutory and regulatory requirements;

1.1.2.5 continually improve the QMS system, its products, and its processes;

1.1.2.6 empower employees to enrich their work experience as well as their work environment.

1.2 JUSTIFIED EXCLUSIONS

1.2.1 Design and development Reference AS9100™ clause 8.3 requirements are excluded from the Kenson Plastics Inc. Quality Management System as it does not design / develop products or services. Justification: Kenson Plastics Inc. manufactures articles and completes assemblies solely through customer intellectual data (i.e. Engineering drawings and CAD models). While Kenson does not complete design activities, it incorporates support mechanisms to assist customers with their design and development processes by providing relevant feedback when solicited.

1.2.2 Post-Delivery Activities Reference AS9100™ 8.5.5 - All clauses except the last sentence. Justification: There are no current customer requirements to perform post-delivery activities. Clauses a, d, e are addressed under the Sales / Order Entry process. Nonconforming returned parts are replaced and if deemed significant entered into the corrective action system.

2.0 REFERENCES

AS9100™: Quality Management Systems-Requirements for Aviation, Space, & Defense Organizations [Latest Revision]

AS9102: Aerospace First Article Inspection Requirements [Latest Revision]

ISO 9000:2015 Quality Management Systems – Fundamentals and Vocabulary

ISO 9001:2015: Quality Management Systems - Requirements

ISO10007: Quality Management Systems- Guidelines for Configuration Management

3.0 TERMS AND DEFINITIONS

3.1 CONTEXT OF THE ORGANIZATION: refers to the business environment of the organization which can be considered a combination of internal and external factors and conditions that can have an effect on an organization's approach to its products, services, investments and interested parties.

3.2 COUNTERFEIT PART: An article misrepresented as a specified genuine item, from an authorized manufacturer; or a previously used material or a part which has been modified and is knowingly, recklessly, or negligently misrepresented as new without disclosure to the customer that it has been previously used.

3.3 CRITICAL ITEMS: Those items (e.g. functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products/services provided. Critical items require specific actions to ensure they are adequately managed. Kenson Plastics considers critical items to be those identified as Key Characteristics.

3.4 KEY CHARACTERISTICS: 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. Kenson Plastics considers attributes which affect the fit form, function, safety, and cosmetic application of the product to be key characteristics.

3.5 PRODUCT SAFETY: The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property. Kenson Plastics manufactures to customer design which includes utilizing the customer specifications regarding the materials from which the products are created. When applicable, Kenson Plastics will apply customer as well as statutory and regulatory safety requirements to all products it manufactures. Kenson demonstration of compliance can include but is not limited to flammability certificates; breaking sharp edges; RoHS, REACH, Proposition 65 certificates as well as conformance to International Standards for Phytosanitary Measures (Reference: ISPM 15) of pallets.

3.6 SPECIAL REQUIREMENTS: Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process.

4.0 CONTEXT OF THE ORGANIZATION

4.1 OVERVIEW

4.1.1 Kenson Plastics Inc. is a premier manufacturer of precision pressure-formed and vacuum-formed plastics since 1972, specializing in engineered plastic components and enclosures primarily for the medical, electronic, and transportation industries. Cost-effective solutions combine thermoforming, complex machining and unsurpassed fabrication work to meet the most exacting engineering and aesthetic requirements.

4.1.2 Kenson Plastics top leadership has determined relevant external and internal issues and their impact to achieve the intended results of their QMS. These issues are monitored, and the data is reviewed through various vehicles to include but not limited to Management Review Meetings; Key Performance Indicators (On Time Shipments, Parts Per Million, etc.); Continuous Improvement Measurables (i.e. Corrective Actions, etc.); Stakeholder Feedback (i.e. scorecards, surveys, complaints, etc.); and other quality and safety team activities and their results.

4.1.3 The Kenson Plastics mission is to become a market leader in providing high quality custom pressure formed products through innovative and collaborative implementation of customer designs; via a thorough understanding of customer's finish and functionality requirements, and the commitment to providing quality

and defect free products on time, every time by leveraging a fully documented quality management system.

4.1.4 The Kenson Plastics campus consists of a manufacturing facility which is comprised of departments that house the product realization capacity to include Thermoforming; Machining; Fabrication; Assembly; Packing / Shipping; Warehouse / Receiving; and support functions which include QA / Engineering and Inspection Tech Center; Offices; and Personnel facilities. REF: Facility Blueprint.

4.2 STAKEHOLDERS / INTERESTED PARTIES

4.2.1 Top Leadership has identified the interested parties who are relevant to the Kenson QMS as well as their requirements and monitors these items at least annually REF: ORG-007 Kenson External and Internal Environment (QMS).

4.2.2 Kenson Plastics is dedicated to providing their customers with a unique combination of old-world craftsmanship and state-of-the-art capabilities. Kenson's highly trained and experienced technicians are experts in producing world-class models and prototypes, as well as in fabricating production parts and subassemblies to the most exacting specifications. Kenson strives to supply their customers with the highest level of quality and product service.

4.2.3 Top Leadership is focused to ensure Kenson Employees have a safe, healthful, productive work environment with opportunities for advancement; and are empowered, challenged and motivated to continually improving products and processes through various venues to include but not limited to the following:

- Kenson Training Program REF: KPP-6.2-1 Training Program;
- Kenson Continuous Small Improvement Program REF: QMS-020 CSI - PAR Form;
- Kenson Safety Committee;
- Kenson Quality Improvement Team;
- Kenson Internal Audit Team;
- The Agreement between Kenson Plastics Inc. and the United Electrical, Radio and Machine Workers of America (UE) and Local 690, United Electrical, Radio and Machine Workers of America (UE).

4.3 SCOPE OF THE KENSON QUALITY MANAGEMENT SYSTEM

4.3.1 Kenson demonstrates conformance to the AS9100™ standard through the application of the relevant requirements as determined and documented by top leadership REF: Kenson QMS Processes ORG-010 and KPQPM Section 1.2 Justified Exclusions.

4.3.2 Through its Engineering Processes, Kenson Plastics is committed to supporting their customers but does not create / manufacture designs of their own. REF: KPP-7.3-1 Support of Customer Design.

4.4 QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES

4.4.1 Kenson Plastics Inc. has established and implemented a Quality Management System developed in accordance with AS9100™ and through its various continuous improvement processes maintains this system to achieve their intended results.

4.4.1.1 Kenson Plastics Inc. recognizes and addresses interested parties and their applicable requirements to include but not limited to customer, employees, bargaining unit, regulatory bodies and suppliers. REF: KPP-5.1-2 Quality System.

4.4.1.2 Kenson Top Leadership has determined the processes for the QMS and their application throughout the organization as well as:

a) inputs required and the outputs expected from these processes
b) sequence and interaction of these processes;
c) criteria and methods required to ensure effective operation and control of these processes;
d) monitoring and measuring techniques where applicable and analysis of the processes;
e) resources needed for these processes and ensure their availability;
f) assignment of the responsibilities and authorities for these processes;
g) methods and plans to addressing the risks and opportunities;
h) evaluation of these processes and the implementation of changes required to ensure these processes achieve their intended results;
i) improvement of the processes and the overall QMS.

4.4.2 Kenson Plastics Inc. maintains necessary documented information to provide:

4.4.2.1 support its processes;

4.4.2.2 evidence that the processes are carried out as planned REF: QMS-022 Quality Records Retention Index;

4.4.2.3 general descriptions of interested parties REF: ORG-007 Kenson External and Internal Environment (QMS);

4.4.2.4 the scope of the QMS to include its applicability REF: Section 4.3;

4.4.2.5 a description of the processes required for the QMS and their applications REF: ORG-010 Kenson QMS Processes;

4.4.2.6 the sequence and interaction of the processes REF: ORG-010 Kenson QMS Processes;

4.4.2.7 the assignment of responsibilities and authorities of the processes REF: ORG-010 QMS Processes.

4.4.3 The Kenson Plastics Inc. quality management system (QMS) consists of four levels of documentation:

Level I Quality Policy Manual (Defines Organizational Policies / Objectives)

Level II Procedures (Defines Who? What? When? Responsibilities, Procedures)

Level III Operating Instructions (Work / Task Specific Instructions);

Level IV Supporting Documentation (Forms, Labels, Drawings, Records, Data);

Reference: KPP-5.1-2, Quality System procedure; QMS-007 QMS Documentation Index

5.0 LEADERSHIP

5.1 LEADERSHIP AND COMMITMENT

5.1.1 Kenson Top Leadership is committed to ensuring the development and implementation of the QMS and continual improvement of its effectiveness and demonstrates such actions through various functions, roles, communications, analysis, measurements, meetings, and support.

5.1.2 Kenson Top Leadership demonstrates leadership and commitment regarding customer focus by ensuring the following:

5.1.2.1 Customer and applicable statutory / regulatory requirements are determined, understood and consistently met with the aim of enhancing customer satisfaction through various forays to include but not limited to new product introductions new process introductions;

contract / purchase order reviews as well as customer satisfaction monitoring.

5.1.2.2 Risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed.

5.1.2.3 That focus on customer satisfaction is communicated and maintained.

5.1.2.4 Product / service conformity and on-time delivery performance are measured, and appropriate action is taken if planned results are not or will not be achieved.

Reference: KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-7.3-1 Support of Customer Design; KWI-3.1-1-1 Change Management; KPP-7.2-1 Receiving and Scheduling Customer Orders; KWI-5.1-2-1 Customer Focus; KWI-5.1-2-2 QMS Risk Assessment; ORG-005 Quality Policy; KWI-5.1-2-1 Customer Focus.

5.2 QUALITY POLICY

5.2.1 Top Kenson Leadership has established, implemented, and maintains a quality policy (REF: ORG-005) which:

- Is appropriate to the purpose and context of the organization and supports its strategic direction;
- Provides a framework for setting quality objectives and goals;
- Includes a commitment to satisfy applicable requirements;
- Includes a commitment to continual improvement of the QMS.

5.2.2 Top Kenson Leadership ensures that the Kenson Quality Policy is:

- Readily available and maintained in documented format (REF: ORG-005);
- Communicated, understood, and applied throughout the organization (REF: TRN-001 Training Matrix - Orientation All Employees);
- Is available to interested parties as appropriate (REF: www.kensonplastics.com)

5.3 ORGANIZATIONAL ROLES, RESPONSIBILITIES, AND AUTHORITIES.

5.3.1 Top Leadership ensures the responsibilities, authorities and duties for relevant roles within the Kenson Plastics organization have been assigned, communicated and understood (REF: KWI-5.3-1 Management Duties and Responsibilities). These assignments include but are not limited to the following:

- Ensuring the QMS conforms to the requirements of the International Standard;
- Ensuring that the processes are delivering their intended outputs;
- Reporting on the performance of the QMS and opportunities for improvement;
- Ensuring customer focus throughout the organization;
- Ensuring the integrity of the QMS is maintained when changes are planned and implemented.

5.3.2 A Kenson Management Representative is assigned and shall have responsibility and authority for the oversight of the requirements stated in 5.3.1 (REF: TRN-113 Quality / Safety Manager) and is supported by Top Leadership.

- The Management Representative has organizational freedom and unrestricted access to Top Leadership to resolve QMS matters and can liaison with external parties as necessary.

- Kenson Ownership is responsible to supply adequate resources for the proper implementation, maintenance and auditing of the QMS.
- The VP of Sales and Marketing is responsible for communicating the importance of meeting customer as well as statutory requirements.
- The VP of Operations and VP of Business Development are responsible to provide adequate, appropriate, and effective training has been completed for shop laborers and shop supervision.
- Kenson Employees throughout the company are responsible for completing their job responsibilities, participating in appropriate training and supporting continuous improvement activities for the QMS as applicable to their individual job requirements.

6.0 PLANNING

6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

6.1.1 Top Leadership shall consider the context of the organization and the concerns, issues and expected outcomes of the interested parties when planning, implementing and evolving the Kenson QMS. (REF: KWI-5.1-2-2 Risk Assessment and ORG-007 External and Internal Environment.) Concepts that are addressed shall include but not be limited to the following:

6.1.1.1 Assurance that the QMS can achieve its intended results;

6.1.1.2 Enhance desirable effects;

6.1.1.3 Prevent / reduce undesired effects;

6.1.1.4 Achieve improvement.

6.1.2 Top Leadership plan actions to address identified risks and opportunities as well as how to integrate and implement the actions into the QMS processes and how to evaluate the effectiveness of these actions. (REF: KWI-5.1-2-2 Risk Assessment.)

6.2 DETERMINATION AND ACHIEVEMENT OF QUALITY OBJECTIVES

6.2.1 Kenson Plastics Inc. has established quality objectives at relevant functions, levels, and processes for the QMS and has determined Key Performance Indicators to serve as a dashboard for monitoring and communication. Top Leadership ensures that these objectives / key performance indicators are:

6.2.1.1 consistent with the Quality Policy;

6.2.1.2 measurable;

6.2.1.3 relevant to applicable requirements;

6.2.1.4 relevant to conformity of products and services and to enhancement of customer satisfaction;

6.2.1.5 monitored;

6.2.1.6 communicated;

6.2.1.7 updated when appropriate;

6.2.1.8 maintained as documented information (REF: ORG-005 Quality Policy).

6.2.2 Top Leadership plans how to achieve its Quality Objectives and its associated key performance indicators and determines the following:

6.2.2.1 what will be done;

6.2.2.2 what resources will be required;

6.2.2.3 who will be responsible;

6.2.2.4 when the due date is;

Reference: KPP-5.1-1 Leadership Commitment and Management Responsibility.

6.3 CHANGES TO THE QMS are carried out in a planned manner. Considerations included but not limited to the following:

6.3.1 Purpose;

6.3.2 Potential consequences;

6.3.3 Impact to the integrity of the QMS;

6.3.4 Resource availability;

6.3.5 Allocation or reallocation of responsibilities and authorities;

Reference: KPP-5.1-1 Leadership Commitment and Management Responsibility; KWI-5.1-2-2 Risk Assessment; ORG-007 External and Internal Environment; KWI-3.1-1-1 Change Management.

7.0 SUPPORT

7.1 RESOURCES

7.1.1 General:

7.1.1.1 Kenson Plastics determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS through various forums such as meetings, forecasts, and key performance indicators.

7.1.1.2 Considerations include but are not limited to the following: the capabilities of, and constraints on, existing internal resources and what needs are to be obtained from external providers.

Reference: ORG-007 External and Internal Environment; KWI-3.1-1-1 Change Management; KWI-5.1-2-2 Risk Assessment; KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-7.2-1 Receiving and Scheduling Customer Orders

7.1.2 Personnel: Kenson Plastics determines and provides the staff necessary for the effective implementation of its QMS and for the operation and control of its processes.

Reference: ORG-007 External and Internal Environment; KPP-6.2-1 Training Program; The Agreement between Kenson Plastics Inc. and the United Electrical, Radio and Machine Workers of America (UE) and Local 690, United Electrical, Radio and Machine Workers of America (UE).

7.1.3 Infrastructure: Kenson Plastics determines, provides, and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. (REF: KPP-5.1-1 Leadership Commitment and Management Responsibility). Considerations included but not limited to the following: buildings and associated utilities; equipment, including hardware and software; transportation resources; information and communication technology.

7.1.4 Environment for the Operation of Processes

7.1.4.1 Kenson Plastics Inc. determines, provides, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. Top Leadership recognizes that a suitable environment can be a combination of human and physical factors.

7.1.4.2 Top Leadership:

a) Is committed to ensuring a safe, clean, healthful and productive workplace as well as meeting its legal obligations as dictated by current occupational health and safety standards. (REF: KPSMM Safety Management System Manual and its associated procedures.)

b) Prohibits harassment and discrimination activities in the workplace, at work sites and in other work-related activities, such as business trips and business-related meetings and business sponsored events. (REF: KPP-6.2-2 Kenson Employee Guidelines Manual; KPP-6.2-3 Code of Conduct.)

c) Supports a structured atmosphere to development employees within the guidelines as provided by Agreement between Kenson Plastics Inc. and the United Electrical, Radio and Machine Workers of America (UE) and Local 690, United Electrical, Radio and Machine Workers of America (UE).

d) Provides resources necessary to the well being of the personnel. (REF: Employee Assistance Program – UPMC.)

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General: Kenson Plastics Inc. 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. Top Leadership 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;

c) Are captured in the appropriate retained documented information as evidence of the fitness for the monitoring and measurement resources.

7.1.5.2 Measurement Traceability: When required by customer or regulatory standard and / or when considered to be an essential part of providing confidence in the validity of measurement results, Kenson Plastics Inc. shall

a) Ensure the calibration and / or verification of measuring devices at specified intervals, or prior to initial use, against measurement standards traceable to international or national measurements standards. When no such standards exist, the basis used for calibration or verification is retained as documented information.
b) Ensure measuring devices are identified to determine their status.
c) Ensure measuring devices are safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results.
d) Ensures calibration / verification of monitoring and measurement equipment is carried out under suitable environmental conditions.

7.1.5.3 Kenson Plastics Inc has established, implemented, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.

7.1.5.4 A register of the monitoring and measuring equipment is maintained and includes at minimum the following:

a) Equipment type;
b) Unique identification;

c) Location / assignment;
d) Calibration or verification method;
e) Frequency of calibration / verification
f) Acceptance criteria.

7.1.5.5 If the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, action is taken by Top Leadership.

Reference: KPP-4.2-1 Document and Data Control; KPP-7.6-1 Calibration and Verification; MTN-001 Preventive Maintenance Schedule; Calibration Records / Certificates; KWI-8.5-1-1 Quality Escapes Program.

7.1.6 Organizational Knowledge: Kenson Plastics determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge is maintained and made available to the extent necessary.

References: KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-5.1-2 Quality System; KPP-6.2-1 Training Program; KPP-6.3-1 Business Continuity and Disaster Recovery Contingency Plan

7.2 COMPETENCE

7.2.1 Kenson Plastics determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS.

7.2.2 It is ensured that those persons are competent based on appropriate education, training, and / or experience.

7.2.3 Where applicable, actions are taken to acquire the necessary competence, and evaluate the effectiveness of actions taken.

7.2.4 Appropriate documented information is retained as evidence of competence.

7.2.5 Periodic reviews of employee performance and / or training needs are conducted.

References: KPP-6.2-1 Training Program; Kenson Form TRN-001 Training Matrix; Kenson Form TRN-100 through 199 Completed Job Descriptions; Training Attendance Rosters; Personnel files (i.e. certificates, degrees, etc.).

7.3 AWARENESS

Kenson Plastics ensures that persons doing work under their control are aware of:

7.3.1 the Quality Policy;

7.3.2 relevant Quality Objectives;

7.3.4 their contribution to the effectiveness of the QMS, including the benefits of improved performance;

7.3.5 the implications of not conforming with the QMS requirements;

7.3.6 relevant QMS documented information and changes thereto;

7.3.7 their contribution to product or service conformity;

7.3.8 their contribution to product safety;

7.3.9 the importance of ethical behavior;

Reference: TRN-001 Training Matrix; ORG-005 Quality Policy; ORG-006: Safety Policy; KPP-6.2-1 Training; KPP-5.1-2 Quality System; KPP-6.2-2 Employee Guidelines Manual; KPP-6.2-3 Code of Conduct

7.4 COMMUNICATION

7.4.1 Kenson Plastics determines and provides internal and external communication and feedback relevant to the QMS, to include what is communicated, when it is communicated, with whom to communicate, how it is communicated, and who communicates the information.

7.4.2 Kenson Plastics Top Leadership is committed to an environment which promotes communication between its various levels and functions.

Reference: KPP-5.1-1 Leadership Commitment and Management Responsibility; Customer Satisfaction Survey (results); KPP-7.4-1 Purchasing; Employee meetings and training sessions; Internal memos and email communications; Bulletin board postings; Quality Alerts.

7.5 DOCUMENTED INFORMATION

7.5.1 General: The Kenson Quality Management System includes:

7.5.1.1 documented information required by the AS9100™ Standard [latest revision];

7.5.1.2 documented information determined by Kenson Plastics as being necessary for the effectiveness of the QMS.

7.5.2 When creating and updating documented information, Kenson Plastics ensures appropriate:

7.5.2.1 identification and description (e.g. title, date, author, or reference number);

7.5.2.2 format and media (e.g. paper, electronic);

7.5.2.3 review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the Kenson Quality Management System and by the AS9100™ Standard [latest revision] 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 following activities are addressed, 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

f) documented information of external origin determined by Kenson Plastics to be necessary for the planning and operation of the QMS is identified as appropriate and controlled.

g) documented information retained as evidence of conformity is protected from unintended alterations.

Reference: KPP-4.2-1 Document and Data Control; KPP-4.2-2 Control of Quality Records

8.0 OPERATION

8.1 OPERATION PLANNING AND CONTROL: Kenson Plastics plans, implements, and controls the QMS processes needed to meet the requirements for the provision of products and services, and to implement the actions determined via Planning by

8.1.1 determining the requirements for the products and services, which may include but is not limited to the following:

8.1.1.1 personal and product safety;

8.1.1.2 producibility and inspectability;

8.1.1.3 reliability, availability, and maintainability;

8.1.1.4 suitability of parts and materials used in the product;

8.1.1.5 selection and development of embedded software;

8.1.1.6 product obsolescence;

8.1.1.7 prevention, detection, and removal of foreign objects;

8.1.1.8 handling, packaging, and preservation;

8.1.1.9 recycling or final disposal of the product at the end of its life.

8.1.2 establishing the criteria for:

8.1.2.1 the processes;

8.1.2.2 the acceptance of products and services;

8.1.2.3 any statistical techniques which could be used to support verifications, process controls, process capabilities, failure mode effects and critical analysis, etc.

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

8.1.4 implementing control of the processes in accordance with the criteria;

8.1.5 determining, maintaining, and retaining documented information to the extent necessary:

8.1.5.1 to have confidence that he processes have been carried out as planned;

8.1.5.2 to demonstrate the conformity of products and services to their requirements;

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

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

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

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

8.1.10 establishing the controls needed to prevent the delivery of nonconforming products and services to the customer;

8.1.11 controls planned changes and reviews the consequences of unintended changes, acting to mitigate any adverse effects, as necessary;

8.1.12 ensures that outsourced processes are controlled.

8.1.13 plans and controls the temporary or permanent transfer of work to ensure the continuing conformity of the work to requirements, ensuring that work transfer impacts and risks are managed.

Reference: KPP-7.5-1 Process Control; KPP-7.5-2 Product Identification, Traceability, and Inspection - Test Status; KPP-7.5-4 Handling, Storage and Delivery; KWI-7.1-3-2 PPAP Documentation Submissions; KWI-7.5-2-1 Validation Plan.

8.1.14 Operational Risk Management: Kenson Plastics plans, implements, and controls a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate:

8.1.14.1 assignment of responsibilities for operational risk management;

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

8.1.14.3 identification, assessment, and communication of risks throughout operations;

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

8.1.14.5 acceptance of risks remaining after implementation of mitigating actions.

Reference: KWI-5.1-2-2 Risk Assessment

8.1.15 Configuration Management: Kenson Plastics plans, implements, and controls a process for configuration management as appropriate in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process:

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

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

Reference: KWI-7.1-3-1 Configuration Management Plan

8.1.16 Product Safety: Kenson Plastics plans, implements, and controls the processes needed to assure product safety during the entire product lifecycle. Considerations may include:

8.1.16.1 assessment of hazards and management of associated risks;

8.1.16.2 management of safety critical items;

8.1.16.3 analysis and reporting of occurred events affecting safety;

8.1.16.4 communication of these events and training of persons.

Reference: KWI-5.1-2-2 Risk Assessment; WI-8.2-2-8 Deburring and Breaking Sharp Edges.

8.1.17 Prevention of Counterfeit Parts: Kenson Plastics plans, implements, and controls processes as appropriate for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer. Counterfeit part prevention processes consider the following:

8.1.17.1 Training of appropriate personnel;

8.1.17.2 Application of parts obsolescence monitoring;

8.1.17.3 Controls for acquiring externally provided product from original / authorized / approved sources;

8.1.17.4 Traceability requirements;

8.1.17.5 Verification / test methods to detect counterfeit parts;

8.1.17.6 Monitoring counterfeit parts reporting from external sources;

8.1.17.7 Quarantine and reporting of suspect or detected counterfeit parts.

Reference: KWI-7.5-1-4 Counterfeit Parts Prevention Program

8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES

8.2.1 Customer Communication: Kenson Top Leadership acts as primary point of contact for customers regarding the communications which includes but is not limited to the following:

8.2.1.1 providing information relating to products and services;

8.2.1.2 handling enquiries, contracts, or orders, including changes;

8.2.1.3 obtaining customer feedback relating to products and services, including customer complaints;

8.2.1.4 handling or controlling customer property;

8.2.1.5 establishing specific requirements for contingency actions, when relevant

8.2.2 Determining the Requirements for Products and Services: when determining the requirements for products and services to be offered to customers, Kenson Plastics ensures that:

8.2.2.1 the requirements for the products and services are defined, including:

a) any applicable statutory and regulatory requirements;

b) those considered necessary by Kenson Plastics.

8.2.2.2 it can meet the claims for the products and services it offers

8.2.2.3 special requirements of the products and services are determined

8.2.2.4 operational risks (e.g. new technology, ability and capacity to provide, short delivery time frame) have been identified

8.2.3 Review of the Requirements for Products and services

8.2.3.1 Kenson Plastics ensures that it can meet the requirements for products and services to be offered to customers. An order review is conducted before committing to supply products and services to the customer, which includes but is not limited to the following:

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, if known

c) requirements specified by Kenson Plastics;

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

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

f) Reviews are coordinated with applicable organizational functions, as needed.

g) If upon review Kenson Plastics determines that some customer requirements cannot be met or can only partially be met, Kenson Plastics shall negotiate a mutually acceptable requirement with the customer.

h) Kenson ensures that contract or order requirements differing from those previously defined are resolved.

i) Customer requirements are confirmed by Kenson Plastics before acceptance when the customer does not provide a documented statement of their requirements.

8.2.3.2 Kenson maintains documented information as deemed applicable or necessary:

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

8.2.4.1 Kenson Plastics 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 have changed.

Reference: KPP-7.2-1 Receiving and Scheduling Customer Orders; KPP-7.3-1 Support of Customer Design; KPP-7.3-7 Engineering Change Notices

8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

8.3.1 Kenson Plastics establishes, implements, and maintains support processes for customer design and development as appropriate to ensure the subsequent provision of products.

8.3.2 Kenson Plastics builds to customer designs and does not design or develop products of its own for commercial use.

Reference: KPP-7.2-1 Receiving and Scheduling Customer Orders; KPP-7.3-1 Support of Customer Design; KPP-7.3-7 Engineering Change Notices.

8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS, AND SERVICES

8.4.1 General:

8.4.1.1 Kenson ensures that externally provided processes, products, and services conform to requirements which may include but is not limited to:

a) Sources defined by the customer;

b) Customer designated or approved external providers are utilized;

c) Risks associated with the provision and selection of external providers;

d) Application of appropriate controls to Kenson's direct and sub-tier external providers.

8.4.1.2 Kenson Plastics determines the controls to be applied to externally provided process, products, and services when:

a) products and services from external providers are intended for incorporation into Kenson's products;

b) products and services are provided directly to the customer(s) by external providers on behalf of Kenson Plastics (e.g. drop shipment);

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

8.4.1.3 Kenson Plastics 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.

8.4.1.4 Kenson Plastics retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.5 Kenson Plastics Inc.:

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).

c) periodically reviews external provider performance including processes, 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 requirements for controlling documented information created by and/or retained by external providers.

8.4.2 Type and Extent of Control

8.4.2.1 Kenson Plastics ensures that externally provided processes, products, and services do not adversely affect its ability to consistently deliver conforming products and services to its customers.

a) Kenson ensures externally provided processes remain within control of its QMS;

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

8.4.2.2 Kenson takes into consideration:

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

b) the effectiveness of the controls applied to the external provider;

c) the results of the periodic review of external provider performance.

8.4.2.3 Kenson determines the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

8.4.2.4 Verification activities of externally provided processes, products, and services are performed according to the risks identified by Kenson Plastics.

a) Included is inspection or periodic testing, as applicable, when there is a high risk of nonconformities, including counterfeit parts.

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

8.4.2.5 When Kenson Plastics delegates verification activities to the external provider, the scope and requirements for delegation are defined, and a register of delegations is maintained.

a) Kenson Plastics shall periodically monitor the external provider's delegated verification activities.

b) When external provider test reports are utilized to verify externally provided products, Kenson Plastics shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements.

8.4.2.6 When a customer or organization has identified raw material as a significant operational risk (e.g. critical items) Kenson Plastics shall implement a process to validate the accuracy of test reports as appropriate to the customer requirements and expectations.

8.4.3 Information for External Providers

8.4.3.1 Kenson Plastics ensures the adequacy of requirements prior to their communication to the external provider.

8.4.3.2 Kenson Plastics communicates to external providers requirements for:

a) the processes, products, and services to be provided including the identification of relevant technical data (e.g. specifications, drawings, process requirements, work instructions).

b) the approval of products and services; methods processes and equipment; the release of products and services.

c) competence, including any required qualification of persons.

d) the external provider's interactions with Kenson Plastics.

e) control and monitoring of the external provider's performance to be applied by Kenson Plastics.

f) verification or validation activities that Kenson Plastics, or its customer, intends to perform at the external provider's premises.

g) support of design and development control.

h) special requirements, critical items, or 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 Kenson Plastics.

k) ensuring that persons are aware of: their contribution to product or service conformity; their contribution to product safety; the importance of ethical behavior.

8.4.3.3 When applicable, Kenson Plastics communicates to external providers the need to:

a) implement a quality management system;

b) use customer-designated or approved eternal providers, including process sources (e.g. special processes);

c) notify Kenson Plastics of nonconforming processes, products, or services, and obtain approval for their disposition;

d) prevent the use of counterfeit parts;

e) notify Kenson Plastics of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain Kenson Plastics approval;

f) flow down to external providers applicable requirements, including customer requirements;

g) provide test specimens for design approval, inspection/verification, investigation, or auditing;

retain documented information, including retention periods and disposition requirements.

8.4.3.4 Kenson Plastics communicates to external providers the requirement for the right of access by Kenson Plastics, its customer(s), and regulatory authorities to the applicable areas of facilities, and to applicable documented information at any level of the supply chain.

Reference: KPP-7.4-1 Purchasing; KPP-4.2-1 Document and Data Control; KPP-7.2-1 Receiving and Scheduling Customer Orders; KPP-7.5-3 Customer Owned Property; KPP-8.5-1 Corrective and Preventive Actions; KWI-7.4-3-1 Receipt of Critical Incoming Products; KWI-7.4-1-6 Procurement Procedures; KWI-7.5-1-4 Counterfeit Parts Prevention Program; PUR-003 Approved Supplier Listing; PUR-014 Quality Clauses for Purchase Orders

8.5.1 Control of Production and Service Provision

8.5.1.1 Kenson Plastics implements production under controlled conditions which 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 of verification operations are to be performed
- measurement results to be maintained (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 based on 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 or processes;

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

f) the validation, and periodic re-validation, 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. Note: This is commonly referred to as ‘special processes’;

g) the implementation of actions to prevent human error;

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

i) the establishment of criteria for workmanship (e.g. written standards, representative sample, illustrations);

j) the accountability for all products during production (e.g. part quantities, split orders, nonconforming product);

k) the control and monitoring of identified critical items, including key characteristics, in accordance with establish processes;

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

m) the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at a later stage;

n) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;

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

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

q) the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it’s later found that the product does not meet requirements.

Reference: Engineering / Customer Intellectual Data such as drawings and CAD models; Traveler Documentation; KPP-7.5-2 Product Identification, Traceability, and Inspection - Test Status; KPP-7.5-1 Process Control

8.5.1.2 Control of 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 are maintained.
- Storage requirements are defined for production equipment or tooling in storage, including any necessary periodic preservation or condition checks.

Reference: KPP-7.6-1 Calibration and Verification; KWI-7.5-1-1 Preventive Maintenance

8.5.1.3 Validation and Control of Special Processes: When applicable, Kenson Plastics shall establish arrangements for special processes;

those where the resulting output cannot be verified by subsequent monitoring or measurement. Arrangements shall include:

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 equipment

d) qualification of persons

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

f) requirements for documented information to be retained

Reference: KWI-7.5-1-8 Special Processes Plan

8.5.1.4 Production Process Verification

a) Kenson Plastics implements production process verification activities to ensure the production process can produce parts that meet requirements.

b) In accomplishing production process verification, Kenson Plastics uses a representative item from the first production run of a new part or assembly to verify the production processes, production documentation, and tooling can produce parts and assemblies that meet requirements.

c) This activity is repeated when changes occur that invalidate the original results (e.g. engineering changes, production process changes, tooling changes).

d) Kenson Plastics retains documented information on the results of production process verification.

Reference: KWI-7.5-2-2 First Article Inspection Protocol

8.5.2 Identification and Traceability

8.5.2.1 Kenson Plastics uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

8.5.2.2 Kenson Plastics maintains the identification of the configuration of the products in order to identify any differences between the actual configuration and the required configuration.

8.5.2.3 Kenson Plastics identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

8.5.2.4 When acceptance authority media are used (e.g. stamps, electronic signatures, passwords) Kenson Plastics establishes control for the media.

8.5.2.5 Kenson Plastics controls the unique identification of the outputs when traceability is a requirement, and retains documented information necessary to ensure traceability

Reference: KPP-7.5-2 Product Identification, Traceability, and Inspection - Test Status; KWI-7.1-3-1 Configuration Management Plan

8.5.3 Property Belonging to Customers or External Providers

8.5.3.1 Kenson Plastics exercises care with property belonging to customers or external providers while it is under Kenson Plastics' control or is being used by Kenson Plastics.

8.5.3.2 Kenson Plastics identifies, verifies, protects, and safeguards customers' or external providers' property provided for use or incorporation into the products.

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

Reference: KPP-7.5-3 Customer - External Provider Property

8.5.4 Preservation

8.5.4.1 Kenson Plastics preserves the outputs during production and service provision to the extent necessary to ensure conformity to requirements.

8.5.4.2 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: KWI-7.5-1-5 Shelf Life Program; KWI-7.5-1-3 FOD Program; KPP-7.5-4 Handling, Storage and Delivery; KWI-8.2-2-2 Cosmetic Quality Requirements for Plastics Parts, Painted Parts, and Parts with Artwork; KSI-6.4-14-1 HazCom Program

8.5.5 Post-Delivery Activities

8.5.5.1 Kenson Plastics meets requirements for post-delivery activities associated with the products it manufactures to the extent that post-delivery activities are required.

8.5.5.2 To determine the extent of post-delivery activities that is required of Kenson Plastics, Top Leadership considers the following:

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. Note: This item is not applicable to the scope of Kenson Plastics' QMS

h) controls required for work undertaken external to Kenson Plastics (e.g. off-site work). Note: Kenson Plastics only provides servicing in the manner of warranty work on its product returned / flagged as non-conforming by customers and work permitted by Kenson Plastics QMS.

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

8.5.5.3 When problems are detected after delivery, Kenson Plastics takes appropriate action to include containment, investigation and reporting activities.

Reference: KPP-7.3-1 Support of Customer Design; KPP-7.2-1 Receiving and Scheduling Customer Orders; KPP-8.3-1 Control of Nonconforming Product; KPP-8.5-1 Corrective and Preventive Actions.

8.5.6 Control of Changes

8.5.6.1 Kenson Plastics reviews and controls changes for production to the extent necessary to ensure continuing conformity with requirements.

8.5.6.2 Persons authorized to approve production changes are identified.

8.5.6.3 Documented information is retained describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Reference: KWI-7.1-3-1 Configuration Management Plan; KPP-7.5-1 Process Control; KPP-4.2-2 Control of Quality Records; KWI-3.1-1-1 Change Management; TRN-011 Training Roster

8.6 RELEASE OF PRODUCTS AND SERVICES

8.6.1 Kenson Plastics implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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

8.6.3 Kenson Plastics retains documented information on the release of products and services, to include:

8.6.3.1 evidence of conformity with the acceptance criteria;

8.6.3.2 traceability to the person(s) authoring the release.

8.6.4 When required to demonstrate product qualification, Kenson Plastics ensures that retained documented information provides evidence that the products meet the defined requirements.

8.6.7 Kenson Plastics ensures that all documented information required to accompany the products or services are present at delivery.

Reference: Kenson Business System and associated documentation; KWI-7.4-3-1 Receipt Inspection of Incoming Critical Products; KWI-7.5-5-1 Shipping Process Flow and Protocol; KWI-8.2-2-1 In Process and Final Inspection.

8.7 CONTROL OF NONCONFORMING OUTPUTS

8.7.1 Kenson Plastics ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

8.7.2 Nonconforming outputs include nonconforming product or service generated internally, received from an external provider, or identified by a customer.

8.7.3 Kenson Plastics takes appropriate actions based on the nature of the nonconformity and its effect on the conformity of products. This also applies to nonconforming products detected after delivery of products, and during or after the provision or services.

8.7.4 Kenson Plastics' nonconformity control process is maintained as documented information including provisions for:

8.7.4.1 defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;

8.7.4.2 taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;

8.7.4.3 timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties (i.e. external providers, internal organizations, customers, distributors, and regulatory authorities);

8.7.4.4 defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts.

8.7.5 Kenson Plastics deals with nonconforming outputs in one or more of the following ways:

8.7.5.1 correction;

8.7.5.2 segregation, containment, return, or suspension of provision of products and services;

8.7.5.3 informing the customer;

8.7.5.4 obtaining authorization for acceptance under concession by a relevant authority, and when applicable, by the customer.

8.7.6 Dispositions of use-as-is or rework for the acceptance of nonconforming products shall only be implemented:

8.7.6.1 after approval by a Kenson Plastics authorized representative for design or by persons having delegated authority from the design organization;

8.7.6.2 after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

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

8.7.8 Counterfeit, or suspect counterfeit, parts are controlled to prevent reentry into the supply chain.

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

8.7.10 Kenson Plastics retains documented information that:

8.7.10.1 describes the nonconformity;

8.7.10.2 describes the actions taken;

8.7.10.3 describes any concessions obtained;

8.7.10.4 identifies the authority deciding the action in respect to the nonconformity.

Reference: KPP-8.3-1 Control of Nonconforming Product; KWI-8.5-1-1 Quality Escapes Program; KWI-8.3-1-2 Material Review Board; KWI-8.3-1-3 Return Authorization Control; KWI-7.5-1-4 Counterfeit Parts Prevention Program; KPP-8.5-1 Corrective and Preventive Actions.

9.0 PERFORMANCE EVALUATION

9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

9.1.1 General

9.1.1.1 Kenson Plastics 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 the monitoring and measurement are analyzed and evaluated

9.1.1.2 Kenson Plastics evaluates the performance and the effectiveness of the QMS.

9.1.2.3 Appropriate documented information is retained as evidence of the results.

Reference: KPP-8.2-1 Internal Audits; KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-4.2-2 Control of Quality Records; KPP-7.5-2 Product Identification, Traceability, and Inspection - Test Status; KPP-8.5-1 Corrective and Preventive Actions.

9.1.2 Customer Satisfaction

9.1.2.1 Kenson Plastics monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. Determined are the methods for obtaining, monitoring, and reviewing this information.

9.1.2.2 Information to be monitored and used for the evaluation of customer satisfaction may include but is not limited to:

a) product and service conformity

b) on-time delivery performance

c) customer complaints

d) corrective action requests

9.1.2.3 Kenson Plastics develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assess the effectiveness of the results.

Reference: Kenson Plastics Customer Satisfaction Survey; Customer Scorecards and feedback; KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-8.5-1 Corrective and Preventive Actions.

9.1.3 Analysis and Evaluation

9.1.3.1 Kenson Plastics analyzes and evaluates appropriate data and information arising from monitoring and measurement. This may include information on production and service problems reported by external sources (e.g. government/industry alerts, advisories).

9.1.3.2 The results of analysis are used to evaluate:

a) conformity of products;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the QMS;

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 QMS.

Reference: Kenson Plastics Customer Satisfaction Survey; Customer Scorecards and feedback; KPP-7.4-1 Purchasing; KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-8.5-1 Corrective and Preventive Actions.

9.2 INTERNAL AUDIT

9.2.1 Kenson Plastics conducts internal audits at planned intervals to provide information on whether the QMS:

9.2.1.1 conforms to:

a) Kenson Plastics' own requirements for its QMS

b) the requirements of the AS9100™ Standard

9.2.1.2 is effectively implemented and maintained.

9.2.2 Kenson Plastics:

9.2.2.1 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 Kenson Plastics, and the results of previous audits;

9.2.2.2 defines the audit criteria and scope for each audit;

9.2.2.3 selects auditors and conducts audits to ensure objectivity and the impartiality of the audit process;

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

9.2.2.5 takes appropriate correction and corrective actions without undue delay;

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

Reference: KPP-8.2-1 Internal Audits; KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-4.2-2 Control of Quality Records; KPP-8.5-1 Corrective and Preventive Actions.

9.3 MANAGEMENT REVIEW

9.3.1 General: Top Management reviews Kenson Plastics' QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness, and alignment with Kenson Plastics' strategic direction.

9.3.2 Management Review Inputs

9.3.2.1 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 QMS

c) information on the performance and effectiveness of the QMS, 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

f) opportunities for improvement

9.3.3 Management Review Outputs

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

a) opportunities for improvement

b) any need for changes to the QMS

c) resource needs

d) risks identified

9.3.4 Kenson Plastics retains documented information as evidence of the results of management reviews.

Reference: KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-4.2-2 Control of Quality Records; KPP-8.5-1 Corrective and Preventive Actions; Management Review Meeting Minutes.

10.0 IMPROVEMENT

10.1 GENERAL

10.1.1 Kenson Plastics determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction, to include:

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

10.1.1.2 correcting, preventing, or reducing undesired effects;

10.1.1.3 improving the performance and effectiveness of the QMS.

Reference: KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-4.2-2 Control of Quality Records; KPP-8.5-1 Corrective and Preventive Actions.

10.2 NONCONFORMITY AND CORRECTIVE ACTION

10.2.1 When a nonconformity occurs, including any arising for customer complaints, Kenson Plastics:

10.2.1.1 reacts to the nonconformity and, as applicable:

a) acts to control and correct it

b) deals with the consequences

10.2.1.2 evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere by:

a) reviewing and analyzing the nonconformity;

b) determining the cause(s) of the nonconformity, including as applicable, those related to human factors;

c) determining if similar nonconformities exist, or could potentially occur;

10.2.1.3 implements any action needed;

10.2.1.4 reviews the effectiveness of any corrective action taken;

10.2.1.5 updates risks and opportunities determined during planning, if necessary;

10.2.1.6 makes changes to the QMS, if necessary;

10.2.1.7 flows down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;

10.2.1.8 takes specific actions when timely and effective corrective actions are not achieved.

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

10.2.3 Kenson Plastics maintains documented information that defines the nonconformity and corrective action management processes.

10.2.4 Kenson Plastics retains documented information as evidence of:

10.2.4.1 the nature of the nonconformities and any subsequent actions taken

10.2.4.2 the results of any corrective action

Reference: KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-4.2-2 Control of Quality Records; KPP-8.5-1 Corrective and Preventive Actions.

10.3 CONTINUAL IMPROVEMENT

10.3.1 Kenson Plastics continually improves the suitability, adequacy, and effectiveness of the QMS.

10.3.2 Considered are the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that are to be addressed as part of continual improvement.

10.3.3 Kenson Plastics monitors the implementation of improvement activities and evaluates the effectiveness of the results.

Reference: KPP-5.1-1 Leadership Commitment and Management Responsibility; KPP-8.2-1 Internal Audits; KPP-4.2-2 Control of Quality Records; KPP-8.5-1 Corrective and Preventive Actions.

11.0 Revision History

REV.	DESCRIPTION	DATE	BY
New	Initial Release of Work Instruction.	2009 SEP 24	Bob Zimmer
A	Added references to ANSI/ISO/ASQ Q9001-2008, also added references to procedures	2010 JUN 09	Bob Zimmer
B	Added language to reference ISO requirements Closer, Per Auditors recommendations.	2010 SEP 20	Bob Zimmer
C	5.3 Reworded policy (added implementation of customer designs)	2010 DEC 20	Bob Zimmer
D	Section 5.6.2 Added review QPM for suitability, 7.1 Training requirements, 7.2.1 Referencing external standards, ISO standards, inspection and testing standards.	2011 OCT 10	Bob Zimmer
E	Annual review and update to include justified exclusions 1.2, clarify support of customer design (7.3) and to reflect new procedure numbers.	2013 OCT 24	Grace F Neyman
F	Complete revision to incorporate and reflect AS9100™ Standard elements / compliance; addition of Revision and Leadership Review Sections.	2017 NOV 04	Grace F Neyman
G	Added Exclusion 1.2.2: Post-Delivery Activities Reference AS9100™ 8.5.5 - All clauses except the last sentence.	*2019 JUN 27*	*Grace F Neyman*

12.0 Leadership Team Review:

BUSINESS DEVELOPMENT REVIEW

☒ Review Required

☐ Review not Required

REVIEWER: *Signature on File* *2019 JUN 27*

(signature) Patrick D O'Leary Date

SALES / MARKETING REVIEW

☒ Review Required

☐ Review not Required

REVIEWER: *Signature on File* *2019 JUN 27*

(signature) David J. O'Leary Date

QUALITY / SAFETY REVIEW

☒ Review Required

☐ Review not Required

REVIEWER: *Signature on File* *2019 JUN 27*

(signature) Grace F. Neyman Date

OPERATIONS REVIEW

☒ Review Required

☐ Review not Required

REVIEWER: *Signature on File* *2019 JUN 27*

(signature) Christopher B. O'Leary Date