KENSON
Precision Pressure Formed Plastic

Form:	Vendor Audit Survey	Number:	PUR-002
Approved by:	Christopher O'Leary	Issued:	2014 FEB 21
Signature:	Signature On File	Revised:	2014 FEB 21

Company Name

Survey Completed By ..... Date .....

Mailing Address .....

.....

.....

Telephone ..... Fax .....

Web Address

Organization Information and Contacts:

Please list the following with name and actual title:

	Name:	Title:	Phone	Email:
Executive Management				
Sales Management				
Purchasing Agent				
Customer Service Agent				
Quality Management				
Engineering Management				
Production / Service Management:				

Total Number of Employees ..... Number in Manufacturing ..... Number in Engineering ..... Number in Quality .....

Year Established ..... Facility Size .....

Type of Vendor:

Manufacturer ☐ Calibration Service ☐ Distributor ☐

Service Provider ☐ Special Processes ☐ Other:

Quality Management System Certification

	Yes	No	N/A
Does your company have a Quality System?	☐	☐	☐
If yes, is it certified by a third party registrar?	☐	☐	☐
If yes, what standard is it registered to? ISO9001 ☐ AS9100 ☐ Other ☐ Describe:			
Procedures to ensure the effective planning, operation and control of these processes? (4.2.1c,d)	☐	☐	☐
If you are a calibration service are you certified to ISO 17025 or other recognized standard?	☐	☐	☐

For those companies who are third party certified, please provide a copy of the current certificate and the company Quality Manual, if available. The following questions are not mandatory to complete if you are third party certified and in good standing order with your registrar.

Quality Management System…Is there:		Yes	No	N/A
1	an active Quality Management System? (4.1)	☐	☐	☐
2	a quality policy and quality objectives / goals? (4.2.1a)	☐	☐	☐
3	a quality manual? (4.2.1b) If yes, record revision and date here:	☐	☐	☐
4	Procedures to ensure the effective planning, operation and control of these processes? (4.2.1c,d)	☐	☐	☐

Control of Documents and Records…Is /are there:		Yes	No	N/A
5	a documented procedure to define the control of documents required by the QMS? (4.2.3)	☐	☐	☐
6	a document change control system? (4.2.3b)	☐	☐	☐
7	a procedure to ensure that changes and revision status are identified? (4.2.3c)	☐	☐	☐
8	a protocol to ensure that only current documents are used? (4.2.3g)	☐	☐	☐
9	records in place and maintained showing evidence of conformity to requirements? (4.2.4)	☐	☐	☐
10	a documented procedure to define the controls needed for the identification, storage, protection, retrieval and disposition of records? (4.2.4)	☐	☐	☐
11	record retention procedure of listing? (4.2.4)	☐	☐	☐
12	retained records available for review by the customer or their representative? (4.2.4)	☐	☐	☐

Responsibility and Authority		Yes	No	N/A
13	Has someone been appointed who has responsibility, authority and freedom to resolve matters pertaining to quality? (5.5.2d)	☐	☐	☐
14	Does management review the quality management system at planned intervals? (5.6.1)	☐	☐	☐
15	Are records from management reviews maintained? (5.6.1)	☐	☐	☐

Human Resources		Yes	No	N/A
16	Does the organization determine the necessary competence for personnel performing work affecting product quality? (6.2.2a)	☐	☐	☐
17	Are appropriate records of education, training, skills and experience maintained? (6.2.2e)	☐	☐	☐

Product Realization		Yes	No	N/A
18	Have product realization (production) processes been planned and developed? (7.1)	☐	☐	☐
19	Are the records available to provide evidence that the processes and product meet the requirements? (7.1d)	☐	☐	☐
20	Prior to commitment does the organization ensure that product requirements are defined; differences resolved and the organization has the ability to meet the requirements? (7.2.2a,b,c)	☐	☐	☐
21	Are customer requirements confirmed prior to acceptance of a purchase order? (7.2.2)	☐	☐	☐
22	Are customer changes to the product requirements reviewed and approved? (7.2.2)	☐	☐	☐

Design and Development…If applicable:		Yes	No	N/A
23	Are the design / development responsibilities / authorities assigned to qualified personnel? (7.3.1c)	☐	☐	☐
24	Are the assigned personnel provided with adequate resources? (7.3.1)	☐	☐	☐
25	Does the organization manage the interfaces between the different groups involved in design and development to ensure effective communication and clear assignment of responsibilities? (7.3.1)	☐	☐	☐
26	Are the design tasks defined according to functional objectives in accordance with customer and/or regulatory requirements? (7.3.1)	☐	☐	☐
27	Are inputs relating to product requirements determined and are records maintained? (7.3.2)	☐	☐	☐
28	Are the design and development inputs reviewed for adequacy? (7.3.2)	☐	☐	☐
29	Are the design / development input requirements complete / do not contradict each other? (7.3.2)	☐	☐	☐
30	Are the design outputs verified against the inputs and approved prior to release? (7.3.3)	☐	☐	☐
31	Do the design outputs: a) meet the input requirements? (7.3.3a) b) provide appropriate information for purchasing, production and for service provisions? (7.3.3b) c) contain or reference product acceptance criteria? (7.3.3c) d) specify the characteristics of the product that are essential to it's safe and proper use? (7.3.3d)	☐	☐	☐
32	Are design and development reviews performed as planned to evaluate the ability of the results to meet requirements? (7.3.4a); identify any problems and propose necessary actions? (7.3.4b); to authorize progression to the next stage? (7.3.4c)	☐	☐	☐

33	Do design review participants include representatives of functions concerned with the design phase being reviewed? (7.3.4)	☐	☐	☐
34	Are records of the results of reviews maintained? (7.3.4)	☐	☐	☐
35	Is design and development verification performed in accordance with planned arrangements to ensure the outputs have meet the input requirements? (7.3.5)	☐	☐	☐
36	Are records of the results of verifications maintained? (7.3.5)	☐	☐	☐
37	Is design and development verification performed in accordance with planned arrangements to ensure the resulting product is capable of meeting the requirements for the specific application or intended use? (7.3.6)	☐	☐	☐
38	Are records of the results of validation maintained? (7.3.6)	☐	☐	☐
39	Are design and development changes reviewed, verified, validated and approved before implementation? (7.3.7)	☐	☐	☐
40	Does the change control process provide for customer and/or regulatory approval when required? (7.3.7)	☐	☐	☐

Purchasing		Yes	No	N/A
41	Has the type / extent of control applied to the supplier, and the purchased product been defined? (7.4.1)	☐	☐	☐
42	Are suppliers evaluated and selected on the basis of their ability to meet requirements? (7.4.1)	☐	☐	☐
43	Are the criteria for selection, evaluation and re-evaluation established? (7.4.1)	☐	☐	☐
44	Are records of supplier evaluations and necessary actions maintained? (7.4.1)	☐	☐	☐
45	Does purchasing information clearly describe the requirements for the product being purchased? (7.4.2a)	☐	☐	☐
46	Does the verification of purchased product include inspection or other objective evidence of the quality of the product upon receipt (e.g., documentation, certificate of conformity, test reports)? (7.4.3a,d)	☐	☐	☐

Production Operations		Yes	No	N/A
47	Does the organization plan and carry out production under controlled conditions? (7.5.1)	☐	☐	☐
48	Do controlled conditions include, as applicable: a) the availability of information that describes the characteristics of the product? (7.5.1a) b) the availability and use of monitoring and measuring devices? (7.5.1d)	☐	☐	☐
49	Is there evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized? (7.5.2h)	☐	☐	☐
50	Is workmanship criteria stipulated in the clearest possible manner? (7.5.1k)	☐	☐	☐

Servicing		Yes	No	N/A
51	When servicing is a specified requirement is there a method of collecting and analyzing in-service data? (7.5.1.5a)	☐	☐	☐
52	Does the servicing process provide for actions to be taken where problems are identified after delivery; and for acting on service information consistent with contractual and/or regulatory requirements? (7.5.1.5b)	☐	☐	☐

Validation of Processes		Yes	No	N/A
53	Are there established arrangements for the qualification and approval of special processes prior to use? (7.5.2a)	☐	☐	☐
54	Are there documented specifications and/or certifications for special processes? (7.5.2e)	☐	☐	☐

Identification and Traceability		Yes	No	N/A
55	When required, is a system in place for maintaining, controlling and recording the identity and traceability of product throughout product realization? (7.5.3)	☐	☐	☐
56	Is a sequential record of production (manufacturing, assembly, inspection) maintained? (7.5.3d)	☐	☐	☐

Customer Property		Yes	No	N/A
57	Does the organization identify, verify, protect and safeguard customer property? (7.5.4)	☐	☐	☐
58	Is any product that is lost, damaged, or unsuitable for use recorded and reported to the customer? (7.5.4)	☐	☐	☐

Preservation of Product		Yes	No	N/A
59	Does preservation of product include identification, handling, packaging, storage and protection? (7.5.5)	☐	☐	☐
60	Does preservation of product also include, where applicable, provisions for: a) cleaning (7.5.5a) b) special handling for sensitive products (7.5.5c) c) marking and labeling including safety warnings (7.5.5d) d) shelf life control and stock rotation (7.5.5e) e) special handling for hazardous materials (7.5.5f)	☐	☐	☐
61	Are the documents required for the product, present at delivery and are they protected against loss and deterioration? (7.5.5)	☐	☐	☐

Control of Monitoring and Measuring Devices		Yes	No	N/A
62	Has the organization determined the monitoring and measurement required, and the devices needed to provide evidence of conformity? (7.6)	☐	☐	☐
63	Is a register of monitoring and measurement devices maintained that includes equipment type, method of calibration, unique identification, location, frequency of calibration and criteria? (7.6)	☐	☐	☐
64	Are environmental conditions suitable for calibrations, inspections, measurements and test? (7.6)	☐	☐	☐
65	Is measuring equipment verified to international or national standards (SI, NIST etc.)? (7.6a)	☐	☐	☐
66	Is measuring equipment identified to enable the calibration status to be determined? (7.6c)	☐	☐	☐
67	Can measuring equipment be recalled to a defined method when requiring calibration? (7.6f)	☐	☐	☐
68	Are records of the result of calibration and verification maintained? (7.6)	☐	☐	☐

Internal Audits		Yes	No	N/A
69	Are internal audits conducted at planned intervals to determine conformance to international standards and the requirements established by the organization? (8.2.2a)	☐	☐	☐
70	Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process? (8.2.2)	☐	☐	☐
71	Is a documented procedure in place defining the responsibilities and requirements for conducting audits? (8.2.2)	☐	☐	☐
72	Does the procedure include requirements for reporting results and maintaining records? (8.2.2)	☐	☐	☐
73	Are tools and techniques such as check sheets, flowcharts etc. in place to support the audits? (8.2.2)	☐	☐	☐

Monitoring and Measurement of Processes and Product		Yes	No	N/A
74	Are methods in place to demonstrate the ability of processes to achieve planned results? (8.2.3)	☐	☐	☐
75	Is the monitoring and measurement of the product carried out at appropriate stages of the process in accordance with planned arrangements? (8.2.4)	☐	☐	☐
76	If sampling inspection is used as a means of product acceptance, is the plan statistically valid and appropriate for use? (8.2.4)	☐	☐	☐
77	When required is the sampling plan submitted for customer approval? (8.2.4)	☐	☐	☐
78	Do the processes ensure that product shall not be released or used until it has been inspected or otherwise verified as conforming to planned arrangements and specified requirements? (8.2.4)	☐	☐	☐
79	Do inspection records provide evidence of product conformity and the person authorizing the release of the product? (8.2.4)	☐	☐	☐
80	Does inspection documentation include the criteria for acceptance and/or rejection? (8.2.4.1a)	☐	☐	☐
81	Do test records show actual test result data when required by specification or test plan? (8.2.4.1)	☐	☐	☐

Control of Non-Conforming Product		Yes	No	N/A
82	Does the organization ensure that nonconforming product is identified and controlled to prevent its unintended use or delivery? (8.3)	☐	☐	☐
83	Is there a documented procedure that defines the responsibility for the review and disposition of nonconforming product? (8.3)	☐	☐	☐
84	Does the procedure include the process for approving the personnel disposition nonconforming product? (8.3)	☐	☐	☐
85	Are records of the nonconformities and any subsequent actions maintained? (8.3)	☐	☐	☐
86	When nonconforming product is corrected is it re-verified to the requirements? (8.3)	☐	☐	☐
87	When nonconforming product is detected after delivery or use, is the customer notified? (8.3)	☐	☐	☐

Corrective and Preventive Actions		Yes	No	N/A
88	Is a process in place that takes action to eliminate the cause of nonconformities in order to contain, correct and prevent recurrence? (8.5.2)	☐	☐	☐
89	Is a documented procedure established that defines the requirements for:	☐	☐	☐
	a) reviewing nonconformities (including customer complaints), (8.5.2a)	☐	☐	☐
	b) determining the causes of nonconformities, (8.5.2b)	☐	☐	☐
	c) evaluating the need for action to ensure nonconformities do not recur, (8.5.2c)	☐	☐	☐
	d) determining and implementing action needed, (8.5.2d)	☐	☐	☐
	e) records of the results of actions taken, (8.5.2e)	☐	☐	☐
	f) reviewing corrective action taken (8.5.2f)	☐	☐	☐
90	Is a process in place that determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence? (8.5.3)	☐	☐	☐
91	Is a documented procedure established that defines the requirements for:	☐	☐	☐
	a) determining potential nonconformities and their causes, (8.5.3a)	☐	☐	☐
	b) evaluating the need for action to prevent occurrences of nonconformities, (8.5.3b)	☐	☐	☐
	c) determining and implementing action needed, (8.5.3c)	☐	☐	☐
	d) records of the results of actions taken, (8.5.3d)	☐	☐	☐
	e) reviewing corrective action taken (8.5.3e)	☐	☐	☐

Kenson Plastics Inc. Use Only

Supplier Quality System Questionnaire Results	
Survey Type	☐Mail In ☐On-Site ☐ Initial ☐ Surveillance
Approved	☐ **Yes** ☐ **No**
Survey Evaluated by	

Supplier Evaluation / Risk Assessment			
Attribute	Low Risk	High Risk	Value
1. 3rd Party Registered / Approved	Approve=1	Not approved=5	
2. Critical to Quality Article or Service	Not critical=1	Very critical=5	
3. Historical record of supplier performance (on time deliveries / service; PO requirements fulfilled; documentation complete; etc.).	Excellent performance=1	Poor performance=5	
4. CAPA System in Place	Acceptable = 1	Nonexistent = 5	
5. Quality of supplier survey	Excellent Survey=1	Acceptable Survey=5	
6. Complexity of Article or Service	Simple =1	Complicated =5	
		Score	

Scoring:
22-30: May require on site or additional audits / evaluations dependent on the criticality of the service or products provided.
14-21: Requires Periodic Evaluations / Monitoring
6-13: Approved as Critical Supplier