SURVEILLANCE CHECKLIST
ISO 9001:2008

Organization : Precision Associates .

CA Number : US 1611
Company: Precision Associates
Name of responsible person: Paul Kadue
Name of responsible person: Richard Kadue

4. Quality Management System

4.1 General Requirements

Processes critical to product quality identified
Outsourced processes that affect quality identified and controlled

General Quality Awareness is excellent

4.2 Documentation Requirements

4.2.2 Quality Manual

Exclusions identified and justified
Design is limited to formulations

4.2.3 Control of Documents

Master register available
Documents issue controlled
Amendments recorded
Distribution recorded
4.2.3 Control of Records

Records available and controlled  Yes
Records legible and easily retrievable  Yes
Storage facilities satisfactory to prevent loss or deterioration  Yes

Comments

Documents are held electronically. Appx system has been extensively updated by the President to provide additional functions.

ISO 9001:2008 amendments have been done – one or two additions suggested in the audit should be completed – OBSERVATION

Latest update needs to be shown in the Amendment Record - OBSERVATION

Daily back up of records and weekly copies taken off-site

5 Management Responsibility

5.1 Management Commitment

Commitment by management to meeting customers' requirements  Yes

5.2 Customer Focus

Customer requirements clearly understood and met or exceeded  Yes

5.3 Quality Policy

Manual signed as authorised  Yes
Quality Policy signed  Yes
Objectives established and monitored  Yes
Commitment to continual improvement  Yes

5.4 Planning

Plans reviewed and updated  Yes
5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Responsibilities and authorities defined  Yes
Organization chart correct  Yes
Quality Representative and Auditors identified  Yes

5.5.2 Management Representative

Management Representative appointed  Yes
System performance reported at Management Review  Yes

5.6 Management Review

Management Review Meeting held  Yes
Minutes kept and available  Yes
All agenda items reviewed including improvement  Yes

Comments

Management reviews are held quarterly – checked over notes for quarter 2 and 3. Most metrics are stable or improving, but some recent concerns to be addressed.

6 Resources Management

6.1 Provision of Resources

Adequate resources and skills to maintain and improve the quality management system  Yes
6.2 Human Resources
Training/competence needs identified Yes
Training records available for all employees Yes
Training effectiveness and records reviewed Yes

6.3 Infrastructure
Workplace, equipment, etc satisfactory Yes

6.4 Work Environment
Housekeeping, Health and Safety etc satisfactory Yes

Comments
Very comprehensive computerized training record system, with list of topics for each job role and records of completion.
Annual review process includes training requirements. There is a monitoring system to ensure these are completed.
Training on weighing of ingredients (July 09) has yet to be fully recorded for those who did it – OBSERVATION

7 Product Realization
7.1 Planning of Product Realization
Production and validation process adequately planned Yes

7.2 Customer Related Processes
Customer requirements documented and understood Yes
Positive record of Contract Review Yes
Effective communication with the customer Yes

Comments
Monica Benson demonstrated entry of an order, new customer set up and system for recording customer communications – all very impressive.
Also noted re-order process, customer classification for revision level checking and generation of NAFTA certificate.
7.3 Design and Development

Briefly reviewed – retain in the scope as formulations are sometimes created to meet customer needs,

7.4 Purchasing

Current Approved Suppliers List Yes
Record of Supplier Evaluation Yes
Written purchase orders Yes - sent electronically usually
Purchase order system adequate Yes
Purchase orders/goods checked against advice note Yes on receipt of goods
Suppliers made aware of special requirements Yes

Comments

All done through Appx. There is a monthly review of selected vendors. Reviewed Lakeside as an example.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Production process adequately planned Yes
Characteristics identified by instructions, drawings Yes route cards etc
Measuring/monitoring requirements defined Yes
Appropriate equipment (including measuring equipment) Yes
Instructions where required Yes

Comments

Observed Bobby pick the order generated by Monica, - weighing for number count through to packing and labeling.

Also reviewed milling process and sampling. Noted Kan-Ban usage.

Instruction 60-04 is displayed as Rev B, Rev C is latest - OBSERVATION
7.5.2 Validation of Processes for Production and Service Provision

Additional controls in place where faults only become apparent after delivery or use. Not applicable.

7.5.3 Identification and Traceability

Product and component identification adequate Yes
Traceability requirements defined and in use Yes

Comments
Clear identification using compound numbers and bar codes at key points.
History of batch 47403 and traceability to lot numbers and suppliers demonstrated on the computer system.

7.5.4 Customer Property

Customer supplied product or material identified Yes

Comments
3700-10 part has rubber supplied by customer.

7.5.5 Preservation of Product

Goods stored in designated areas under adequate control Yes
Handling procedures to prevent damage Yes
Goods packaged to prevent damage Yes
Delivery notes raised to control delivery Yes
Product identified as required for delivery Yes

Comments
Observed completion of order and placing for UPS – including certification.
7.6 Control of Monitoring and Measuring Equipment

Equipment for calibration identified   Yes
Accuracy/tolerances identified   Yes
Calibration status identified   Yes
Calibration records kept   Yes
Suitable storage area for calibration equipment   Yes

Comments

Excellent computerized records with scanned in certificates from external calibration agencies.

Checked Rheometer, Tensometer, Scales 100, 320, 322, 125, Fluke digital thermometer 112 and standard weights used for internal calibration. All OK.

8 Measurement, Analysis and Improvement

8.1 General

Conformity of product addressed   Yes
Conformity/improvement to QMS addressed   Yes

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer satisfaction measured   Yes

Comments

Monthly visits to key customers to check on their perception of performance and discuss On Time, quality etc.
8.2.2 Internal Audit

Audit program prepared  Yes
Quality audits undertaken  Yes
Quality audit reports prepared  Yes
Corrective action determined by authorized personnel  Yes
Preventative action determined by authorized personnel  Yes
Corrective and preventative action implemented  Yes
Employees responsible for the area audited informed of results  Yes

Comments

Observations used as well as ACARs. Noted that ACAR 1 (due 23 May) still outstanding - OBSERVATION

8.2.3 Monitoring and Measurement of Processes

Process effectiveness monitored  Yes

8.2.4 Monitoring and Measurement of Product

Testing procedure operated  Yes
Record of inspection results  Yes
Quality specifications available  Yes

Comments

All records held on Appx system. This links to POs and to certifications.

8.3 Control of Nonconforming Product

Status of non conforming product clearly identified  Yes
Authority to deal with non-conforming product defined  Yes
Non conforming work stored in quarantine area  Yes
Comments

Hold area for rubber and for parts. Somewhat informal system but this works OK.

8.4 Analysis of Data

Data used effectively to measure the effectiveness of the system Yes

8.5 Improvement

8.5.1 Continual Improvement

Information collected used to improve the system Yes

8.5.2 Corrective Action

Customer complaints recorded Yes
Internal/Supplier non-conformances recorded Yes
Corrective action implemented, reviewed and effective Yes
All non-conformances reviewed Yes

8.5.3 Preventive Action

Potential nonconformities identified Yes
Preventative action implemented, reviewed and effective Yes

Comments

Resolved complaints are reviewed each week to gain learning. Client noted one or two resolved that needed more work - OBSERVATION

As no major non-conformances have been identified, I can recommend that QAS International retains the organization on its register of Quality Approved Companies operating to the ISO 9001:2008 series of standards.

Signed Date 3 December 2009

Auditor:

Tony Maynard
### ISO 9001:2008 – Non-Compliance Report

**Organization:** PAI  
**Date:** 3 Dec 2009  
**Assessor:** Tony Maynard  
**CA No:** US 1611

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<tr>
<th>Ref.</th>
<th>Description</th>
<th>Action Required</th>
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<tbody>
<tr>
<td>4</td>
<td>General &amp; Documentation</td>
<td>Complete identified changes to manuals for ISO 9001:2008 Update amendment record</td>
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<td>5.1</td>
<td>Management Commitment</td>
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<td>Provision of Resources</td>
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<td>6.2</td>
<td>Human Resources</td>
<td>Complete training records identified in audit</td>
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<td>Measuring &amp; Monitoring Equipment</td>
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<td>8.1/8.2.1</td>
<td>Planning/Customer Satisfaction</td>
<td>Overdue corrective action (ACAR 1 – 05/23/09)</td>
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<td>Internal Audit</td>
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<td>Control of Non-Conformity</td>
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<td>Analysis of Data</td>
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<td>Improvement/CAPA</td>
<td>Fully resolve complaints identified during the audit</td>
<td>OBS</td>
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Your Company’s quality management systems have been audited and checked against the ISO 9001:2008 Standard. However, there are certain of the Company’s activities which will need to be addressed in order to maintain the validity of your ISO 9001:2008 certification. These have been specified above. Please sign in the space provided below whenever these non-compliances have been corrected and send this form to QAS International, The Gig House, Oxford Street, Malmesbury, Wiltshire SN16 9AX.

Signed: -               
Signed: -

For the Company Date:- For QAS Date:- 3 December 2009

I can confirm that the above non-compliances have now been corrected.

Signed:- Date:-

NO RESPONSE REQUIRED
Company **Precision Associates inc.**

Acting on behalf of QAS International, I have today undertaken a surveillance visit to the above named Company with a view to conducting a systematic and independent examination of the Company’s quality activities. The purpose of this visit was to determine whether these arrangements are controlled and in keeping with the requirements of the current ISO 9001:2008 Quality and Procedures manuals in their possession.

During the course of the inspection I have met and been afforded the full co-operation of: -

**Paul Kadue**

**Richard Kadue**

As no major non-conformances (i.e. those that will affect the system) have been identified, I can confirm that QAS International Limited will be able to maintain:-

**Precision Associates Inc.**

in its register of Quality Approved Companies operating to the BS EN ISO 9000:2008 series of standards for a further year to **18 November 2010**

Attached – Schedule of Non-conformances and Observations

Signed

For & on behalf of
QAS International