Business Management System

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ISO 9001:2008

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REVISION HISTORY

REV:	DATE:	DESCRIPTION OF CHANGE:
1	April 2009	Initial Issue
1A	7/6/2011	Changed General Manger Approval from Jean Perez to Stan Diniz, 3.1 to add process 1,8, and 9; 3.5 to rewrite bullet 3 and add bullet 4 and 5
2	8/23/2011	Major re-write
3	12/10/2012	Change to the Org. Chart.

DOCUMENT APPROVAL

Written by:	Al Shapouri / VP of Quality
APPROVED BY:	**TITLE:**
Vincent Lucas	President/CEO
Stan Diniz	General Manager

Table of Contents

Introduction

This Business System Manual outlines PIERCAN USA INC's Business Management System. These policies are designed to meet the requirements of International Standard ISO 9001:2008 and additional requirements determined by PIERCAN USA INC. Processes required to support these policies are identified within this Business System Manual. Maintenance of this manual is the responsibility of PIERCAN USA. Executive Management.

Company History

PIERCAN SAS was founded in Paris in 1948. The company originally produced natural rubber baby pants. In 1962, the production activities were relocated to the Normandy region of France with the head office remaining in Paris. At this time, the company started manufacturing glovebox gloves. In 1979, the factory was re-located in the Industrial Zone of Port en Bessin, France continuing with glovebox gloves and technical pieces made of natural rubber and neoprene material.

In 1985, the company developed a dissolution manufacturing production line in order to supply our customers with new, better performing materials such as butyl, viton, polyurethane, hypalon. The company has continued to invest in better materials and equipment and has recently introduced a "state of the art" robotic dipping machine.

In 1995, the mother company set-up a subsidiary in the United States named Latex Technology, Inc. located in Vista, California to dip natural rubber technical pieces mainly for the golf industry. In 2002, ownership decided to add dissolution glove dipping capacity and re-located the company to San Marcos, California. The company changed it's name to Piercan USA to better represent the diversity in the product line.

In 2011, the company purchased a 20,000 sq-ft building to allow for future expansion. Piercan USA currently has two dissolution glove dipping machines and one emulsion technical product dipping machine. Piercan USA is responsible for both manufacturing and selling product manufactured internally and acquired from a third party for sale in the nuclear, pharmaceutical, electronics, energy, aerospace, leisure, and defense markets. Piercan USA is responsible for sales in North America, South America, most of Asia, and Australia.

Quality Policy

PIERCAN USA INC. is fully committed to achieving the highest level of customer satisfaction through continual process improvement, quality, competitive pricing and timely service**.**

Quality Policy is promoted through all levels of the organization.

Quality Objectives

Quality objectives are established at all levels of the organization and are based on:

- Customer satisfaction
- Conformance to product requirements
- Continual process improvement and product performance

The top management takes responsibility and ensures that the quality policy is relevant to the organization and provides structure for the development and review of these quality objectives.

Section 1 – Scope

Scope

This Business Management System describes and addresses the activities related to the fabrication of latex and polymer products.

Exclusions

This Business Management System includes all requirements of the ISO 9001:2008 except

- Clause 7.3, Design and development: PIERCAN USA INC. does not take responsibility for the design and development of product
- Clause 7.5, Service provision: PIERCAN USA INC. does not provide field service

Section 2 - References

Reference Documents

PIERCAN USA INC. Business Management System is based on the International Standard ISO 9001:2008

A list of documents is located on page 24.

Section 3 - Definitions

Business Management System

Management System is designed to direct and control the organization

Quality

Degree to which a set of inherent characteristics fulfills the requirements

Customer Satisfaction

Customer's perception of the degree to which their requirements have been fulfilled

Process

Set of interrelated or interacting activities which transforms inputs into outputs

Continual Improvement

Recurring activity to increase the ability to fulfill requirements

Preventive Action

Action taken to eliminate the cause of potential nonconformity or undesirable outcome

Corrective Action

Action taken to eliminate the cause of detected nonconformity or undesirable outcome

Section 4 – Business Management System

General Requirements

PIERCAN USA INC. has developed, documented, implemented and maintains a Business Management System and is committed to continually improve its effectiveness in accordance with the requirements of the ISO 9001:2008

Development and maintenance of the Business Management System includes

1) Identification of the processes needed for the Business Management System and their application throughout the organization
2) Determination of the sequence and interaction of these processes,
3) Determination of the criteria and methods required to ensure that both the operation and the control of these processes are effective,
4) Provision of resources and information necessary to support the operation and monitoring of these processes,
5) Monitoring, measurement and analysis of these processes, and
6) Implementation of necessary actions to achieve the planned results and to ensure continual improvement of these processes.

These processes are managed by the organization in accordance with the requirements of the ISO 9001:2008. Any outsourced processes affecting product conformity are identified within the system and are controlled as part of the system.

Key Business Processes (KBP)

The following Key Business Processes have been identified:

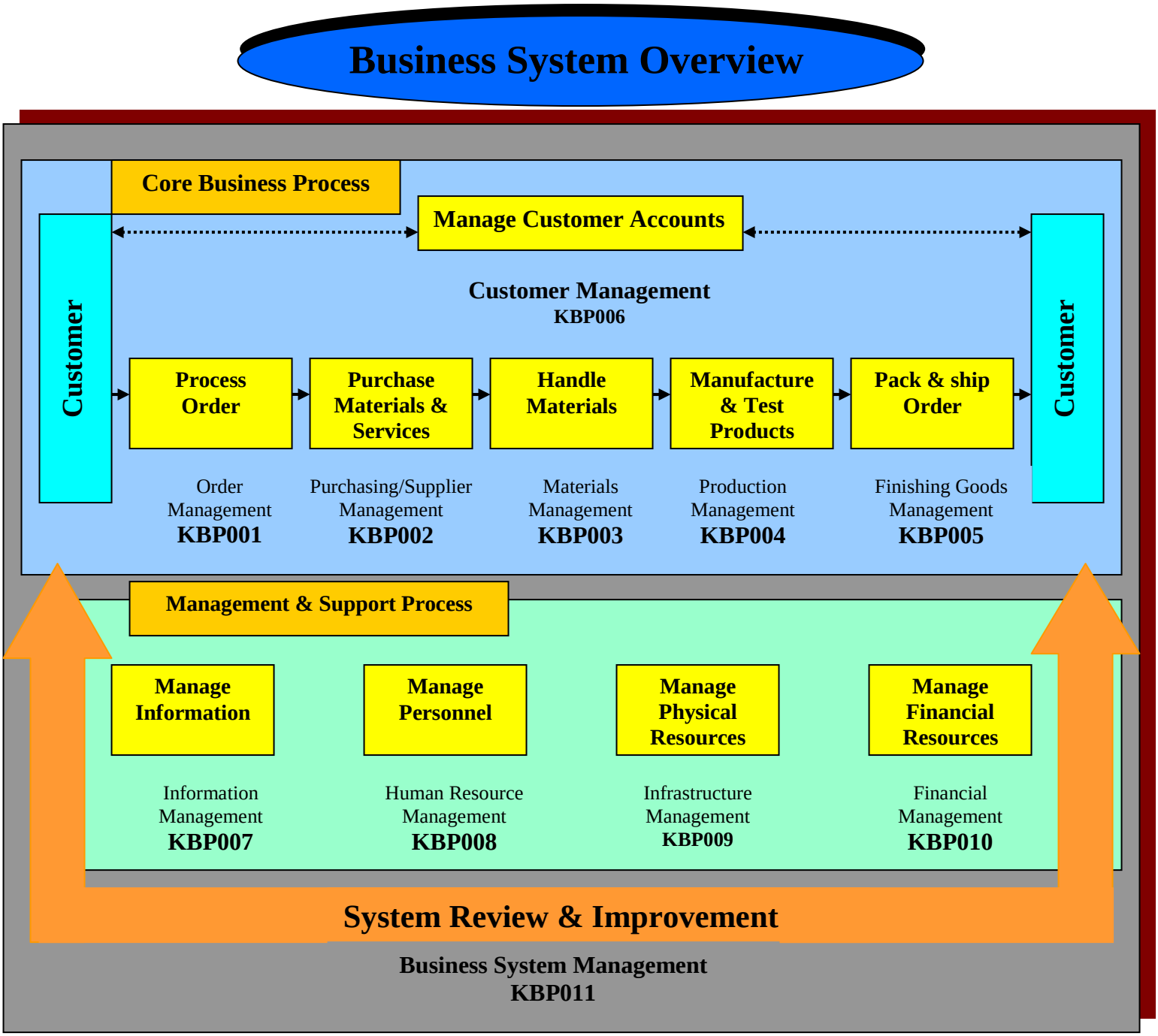
A) KBP001, Order Management
B) KBP002, Purchasing/Supplier Management
C) KBP003, Materials Management
D) KBP004, Production Management
E) KBP005, Finished Goods Management
F) KBP006, Customer Management
G) KBP007, Information Management
H) KBP008, Human Resource Management
I) KBP009, Infrastructure Management
J) KBP010, Financial Management
K) KBP011, Business System Management

The sequence and interaction of these processes are identified on page 8.
Criteria for ensuring the effective operation and control of these processes are identified by the process owners and are an integral part of the quality objectives program. Supporting documentation and records are developed for each process as required. (Table on page 23)

Section 4 – Business Management System, continued

Interaction of the Key Processes

The Business System Diagram demonstrates the Key Business Processes of the organization and how they interact within the Business Management System.



Section 4 – Business Management System, continued

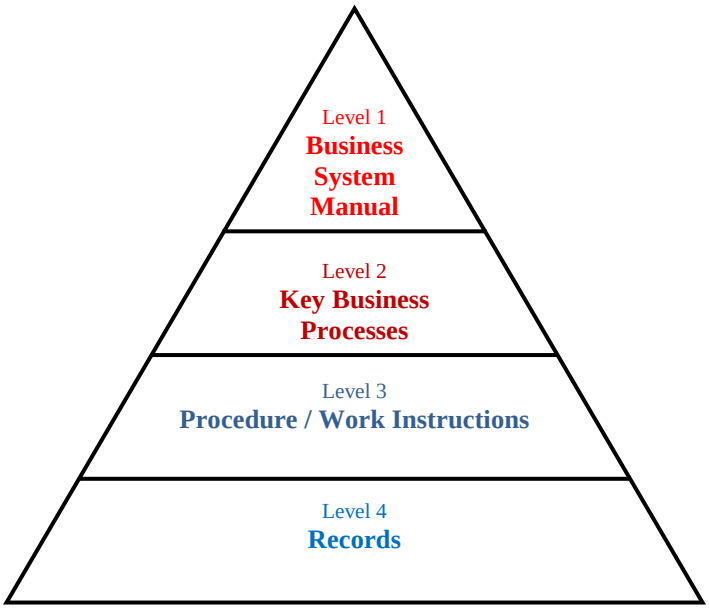
Documentation Requirements

The Business management System documentation includes

1) documented statements of a quality policy and quality objectives
2) a business system manual
3) documented procedures
4) documents needed to ensure the effective planning, operation and control of processes including work instructions and forms
5) records required to provide evidence of conformity to requirements and the effective operation of the Business Management System

Documentation Structure

The structure of the documented system is as follows



The **Business System Manual** (Level 1) defines the policies for the BMS and references the **Key Business Processes** (Level 2) for the organization. The Key Business Processes define the processes of the organization and references the **Procedures/Work Instructions** (Level 3) and other Supporting documents needed for effective operation and control of the processes. Work instructions reference the **Records** (Level 4) needed to provide evidence of conformance to requirements and of the effective operation of the system.

Section 4 – Business Management System, continued

Control of Documents

All documents required by the Business Management System are controlled. All records required are controlled according to the requirements listed under "Control of Records".

Document control procedures define the controls needed to:

1) Approve documents for adequacy prior to issue
2) Review, update and re-approve as necessary
3) Ensure that changes and the current revision status of documents are identified
4) Ensure that the relevant versions of applicable documents are available at all points of use
5) Ensure that documents remain legible and readily identifiable
6) Ensure that external originated documents are identified and their distribution is controlled
7) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

Control of Records

All required records are established and maintained to provide evidence of conformity to requirements and of effectiveness of operation of the Business Management System. Records must remain legible, readily identifiable and retrievable. Record control procedures define the responsibility and controls needed for the identification, storage, protection, retrieval, retention and disposition of records

Section 5 - Management Responsibility

Management Commitment

Top management is responsible and provides evidence of its commitment to the development and implementation of the system and continually improving its effectiveness by :

A) Communicating to the organization the importance of meeting customer and the statutory and regulatory requirements
B) Establishing the quality policy
C) Ensuring that all quality objectives are established
D) Conducting management reviews
E) Ensuring the availability of the required resources

Customer Focus

Top management ensures that all customer requirements are determined and are met with the aim of enhancing customer satisfaction. All customer requirements are identified as part of the entire Product Realization Process (see Section 7), and customer satisfaction data is collected and analyzed as part of the continual improvement activities (see Section 8)

Quality Policy

Top management ensures that the quality Policy

A) Is appropriate to the purpose of the organization
B) Includes a commitment to the company with requirements and continually improves the effectiveness of the system
C) Provides a framework for establishing and reviewing quality objectives
D) Is communicated and understood within the organization
E) Is reviewed for continuing suitability

Quality Objectives

Top management ensures that the quality objectives, including those needed to meet requirements for product are established at the relevant functions and levels within the organization. The quality objectives are measured and consistent with the quality policy.

BMS Planning

Top management ensures that

A) The planning of the BMS is carried out in order to meet BMS requirements, as well as the quality objectives
B) The integrity of the BMS is maintained when changes to the system are planned and implemented

Section 5 - Management Responsibility, continued

Responsibility and Authority

Top management ensures that responsibilities and authorities are identified, defined and communicated within the organization through the development and application of the organization chart, job descriptions and other BMS documents (see org. chart Page 13)

Management Representative

The president and CEO is the Management Representative for the organization and therefore have responsibility and authority for

A) Ensuring that all processes needed for the BMS are established, implemented and maintained
B) Reporting on the performance of the BMS and any needed improvements
C) Ensuring the promotion of awareness of customer requirements throughout the organization

Internal Communication

Top management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the BMS

Management Review

Top management reviews the BMS at least quarterly to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the BMS, including the quality policy and the quality objectives.

Input to the Management Review includes information on

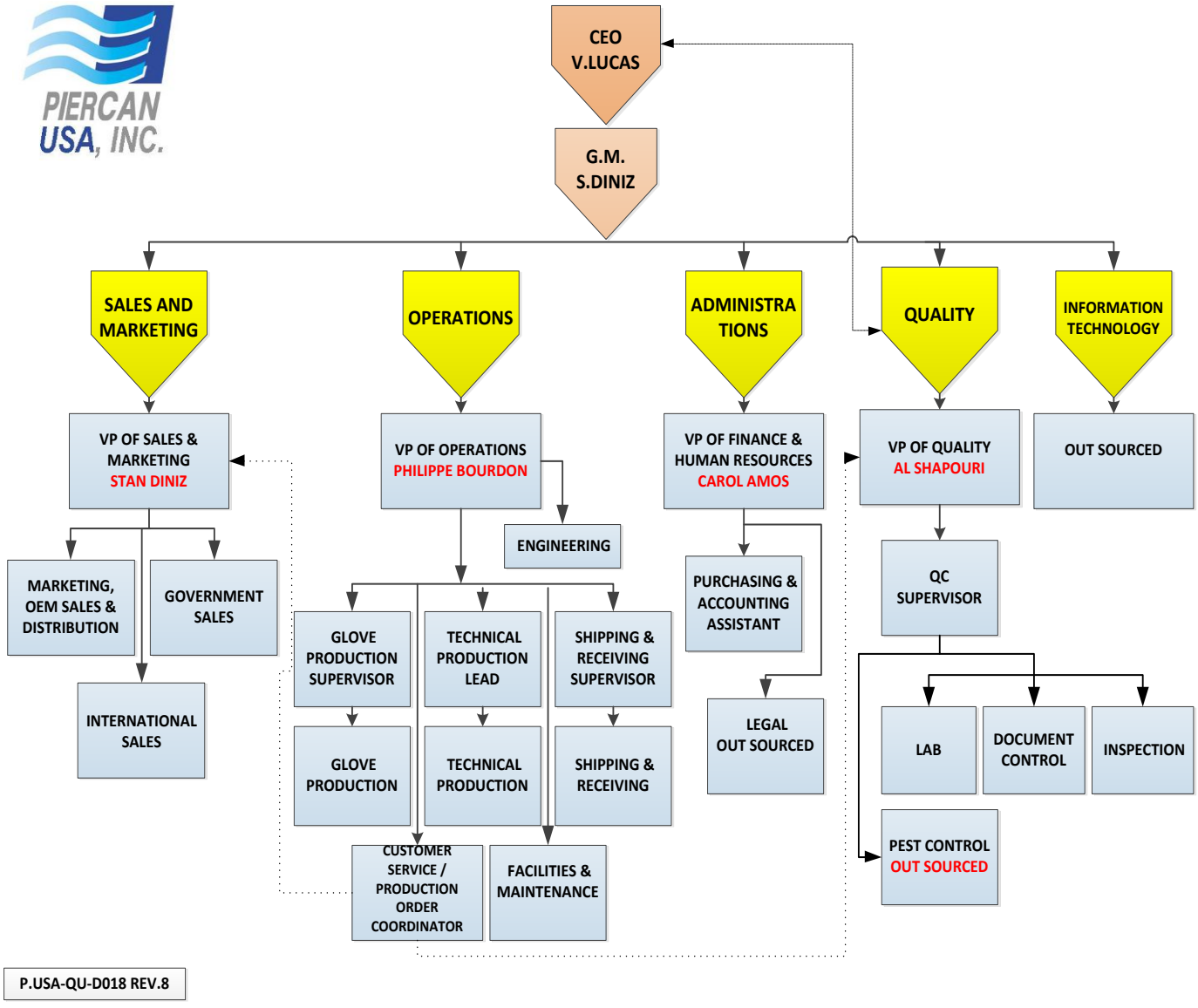
A) Results of internal audits
B) Customer feedback
C) Process performance and product conformity
D) Status of corrective and preventative actions
E) Follow-up actions from previous management reviews
F) Changes that could affect the BMS
G) Recommendations for improvement

Records from management reviews are maintained, including any decisions and actions related to

a) Improvement of the effectiveness of the BMS and its processes
b) Improvement of the product related to customer requirements
c) Resources needed

Section 5 - Management Responsibility, continued

Organizational Functional Chart



Section 6 – Resource Management

Provision of resources

All required resources are identified and provided to

A) Implement and maintain the Business Management System and to continually improve its effectiveness

B) Enhance customer satisfaction by meeting customer requirements

Human Resources

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

Processes are established to

A) Determine the necessary competence for personnel performing work affecting product quality

B) Provide training or take other actions to satisfy those needed

C) Evaluate the effectiveness of the actions taken

D) Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives

E) Maintain appropriate records of educations, training, skills and experience.

Infrastructure

All necessary resources are allocated to determine, provide and maintain the infrastructure needed to achieve conformity to product requirements, including as applicable

A) Buildings, workspace and associated utilities

B) Process equipment (both hardware and software)

C) Supporting services (such as transport or communication)

Work Environment

Resources are identified and allocated to determine and manage the work environment (such as safety, humidity, temperature and lighting) needed to achieve conformity to product requirements

Section 7 – Product Realization

Planning of Product Realization

All required processes needed for product realization are planned and developed as necessary. Planning of product realization is consistent with the requirements of the other processes of the Business Management System.

Planning for product realization includes the determination of

A) Quality objectives and requirements for the product
B) The need to establish required processes, documents and provide necessary resources specific to the product
C) Required verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance
D) Records needed to provide evidence that the realization processes and resulting product meet requirements

The output of this planning may be in various forms, including Traveler/Process Sheets, checklist sheets and programs.

Customer Related Processes

Determination of product requirements include

A) Requirements specified by the customer, including the requirements for delivery and post-delivery activities
B) Requirements not stated by the customer but necessary for specified or intended use where known
C) Statutory and regulatory requirements related to the product
D) Any additional requirements related to the product
E) Any additional requirements that may be determined

Review of requirements is conducted prior to quoting or order acceptance, in order to ensure that

A) Product requirements are defined
B) Contract or order requirements differing from those previously expressed are resolved
C) PIERCAN USA MFG. has the ability to meet the defined requirements

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

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

Where product requirements are changed, relevant documents are revised and relevant personnel are notified and made aware of the changed requirements.

Section 7 – Product Realization, continued

Customer Related Processes, cont.

Effective arrangements have been determined and implemented for communicating with customers in relation to

A) Product information
B) Inquires, contracts or other handling , including changes
C) Customer feedback, including customer complaints

Purchasing

Purchasing Process

PIERCAN USA INC. ensures that purchasing product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on the final product

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

Purchasing Information

Purchase orders describe the product to be purchased, including where appropriate

A) Requirements for approval of product, procedures, processes and equipments
B) Requirements for qualification of the personnel
C) Business Management System requirements

The adequacy of the specified purchase requirements is verified prior to their communication to the supplier

Verification of purchased products

Incoming inspection and other activities have been established to ensure that purchased products meets specified purchase requirements.

If verification is conducted by PIERCAN USA INC. or its customers at the supplier's premises, the intended verification arrangements and the method of product release is stated in the accompanying order or by other appropriate means.

Section 7 – Product Realization, continued

Production

Control of production

Production of PIERCAN USA INC. product is carried out under controlled conditions. Controlled conditions include as applicable

A) Availability of information describing the characteristics of the product
B) Availability of the work instructions when required
C) Use of appropriate equipment
D) Availability and use of monitoring and measuring equipment
E) Implementation of monitoring and measurement and traceability
F) Implementation of release, delivery and post-delivery activities

Validation of Process

If any production processes are implemented where subsequent monitoring or measurement cannot verify the resulting output, validation is conducted to demonstrate the ability of these processes to achieve planned results.

Where necessary, processes are controlled by means of

A) Defined criteria for review and approval of the processes
B) Approval of equipment and qualification of personnel
C) Use of specified methods and procedures
D) Requirements for records
E) Revalidation

Identification and Traceability

Product is clearly identified throughout product realization wherever required

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

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

Customer Property

Care of customer property is exercised while it is under the PIERCAN USA INC's control or being used by PIERCAN USA INC. Customer property provided for use or incorporated into the product is identified, verified, protected and safeguarded. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer and records are maintained. Customer property may include intellectual property.

Section 7 – Product Realization, continued

Production

Preservation of Products

The Quality and conformity of products is preserved during all stage of the product realization which includes, identification/traceability, handling, processing, storage, packaging and delivery

Control of Monitoring and measurement equipment

The necessary monitoring and measurements activities are determined, including the monitoring and measuring equipment needed to provide evidence of product conformity to determined requirements.

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

Where necessary to ensure valid results, measuring equipment is

A) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded
B) Adjusted re-adjusted as necessary
C) Identified to enable the calibration status to be determined
D) Safeguarded from adjustments that would invalidate measurement results
E) Protected from damage and deterioration during handling, maintenance and storage

When equipment is found not to conform to requirements, the validity of previous measuring results is assessed and recorded. Appropriate actions taken on the equipment and any products affected.

Records of calibration and verification results are maintained

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

Section 8 – Measurement, Analysis and Improvement

General

Processes for measurement, analysis and improvement are planned and implemented to

A) Demonstrate conformity of the product
B) Ensure conformity of the Business Management System
C) Continually improve the effectiveness of the system

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

Customer Satisfaction

Information is monitored relating to customer perception as to whether PIERCAN USA INC. has met and satisfied customer requirements. Processes are established for obtaining and using information relating to customer satisfaction. Monitoring of customer satisfaction includes review of

A) Customer survey feedback
B) Customer awards and recognition
C) Customer complaints
D) Customer returns
E) Customer audit results

Internal Audits

Internal audits are conducted at least once a quarter to determine whether the Business Management System

A) Conforms to planned arrangements, to the requirements of the ISO 9001-2008 and to Business Management System requirements
B) Is effectively implemented and maintained

Audits are planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined in audit plans and procedures. Auditors are selected on their ability to conduct objective and impartial audits. Auditors do not audit their own work.

Internal audit procedures define responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records.

Section 8 – Measurement, Analysis and Improvement, continued

Internal Audits continued.

Managers in audited areas ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities include verification of the actions taken and reporting of verification results.

Monitoring and Measurement of Processes

Monitoring and measurement of processes is applied using appropriate statistical methods to create metrics for specified processes. Metrics are created and reviewed to demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of the product.

Monitoring and Measurement of Product

Product characteristics are monitored and measured to verify that product requirements have been met. Such activities are planned and carried out at appropriate stages of the product realization and may include in-process inspection and testing, final inspection and testing and other activities as appropriate.

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

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

Control of Non-Conforming Product

Product that does not conform to requirements is identified and controlled to prevent its unintended use or delivery. Procedures determine the controls and related responsibilities and authorities for dealing with nonconforming product.

Non-conforming product is dealt with by one or more of the following ways by

A) Taking action to eliminate the detected nonconformity (e.g. rework repair)
B) Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
C) Taking action to preclude its original intended use or application (e.g. Scrap)

Section 8 – Measurement, Analysis and Improvement, continued

Control of Non-Conforming Product, cont.

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

Any reworked or repaired nonconforming product is subject to re-verification to demonstrate conformity to requirements.

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

Analysis of Data

Appropriate data is collected and analyzed to demonstrate the suitability and effectiveness of the Business Management System and to evaluate where continual improvement can be made. This includes data generated as a result of monitoring, measurement and from other relevant sources.

Data provided for analysis includes information relating to

A) Customer satisfaction
B) Conformity to product requirements
C) Safety
D) Characteristics and trends of processes and products including opportunities for preventive action
E) Supplier performance

Continual Improvement

The effectiveness of the system is continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, lean manufacturing principles, and management review.

Corrective action

Action is taken to eliminate the cause of nonconformities in order to prevent their recurrence. Corrective actions taken are appropriate to the effects of the nonconformities found

Procedures for corrective action define requirements for

A) Reviewing nonconformities (including customer complaints)
B) Determining the root cause of the nonconformities

Section 8 – Measurement, Analysis and Improvement, continued

Corrective action, continued.

C) Evaluating the need for action to ensure that nonconformities do not recur
D) Determining and implementing action needed
E) Records of the results of action taken
F) Reviewing and verification of corrective action taken

Preventive Action

Action is taken to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions taken are appropriate to the effects of the potential problems.

Procedures for preventive action define requirements for

A) Determining potential nonconformities and their causes
B) Evaluating the need for action to prevent occurrence of nonconformities
C) Determining and implementing action needed
D) Recording of the results of action taken
E) Reviewing preventive action taken

DOC ID	Document Table Key Process/Procedure Title	ISO 9001:2008 Clauses
KBP001	Order Management	7
Various*	Sales, Contract review etc.	7.1, 7.2
"	Order processing work instructions	7.1
KBP002	Purchasing/Supplier Management	7.4
Various*	Purchasing work instructions	7.4.1
KBP003	Materials Management	7, 8
Various*	Material control	7.5.1.5, 7.5.3
"	Non-conformance control and reporting	8.3
"	Return of goods to suppliers	7.5.4
"	Receiving inspection	7.4.3
KBP004	Production Management	7, 8
Various*	Special process training	7.5.2
"	Production work instruction	7.5.2
"	Packaging work instruction	7.5.1
"	Marking work instruction	7.5.1
"	Machine operation work instruction	7.5.1.3
"	Material control	7.5.1, 7.5.3
"	Quality control	7.5.1
"	Non-conforming reporting	8.3
"	Workmanship standards	7.5.1, 8.1, .4
KBP005	Finished Goods Management	7, 8
Various*	Material control	7.5.1,.3, 8.2.4
"	Customer source inspection	7.4.3
KBP006	Customer Management	8
Various*	Customer satisfaction monitoring	8.2.1
"	Non-conforming/ Car procedures	8.5.2,.3, 8.2.4
KBP007	Information Management	4, 7
Various*	Document control	4.2.3, 4.2.4
"	Information system back up and IT	7.5.1
"	Stamp control	7.5.3
"	Quality planning / shop traveler	7.5.1.3
KBP008	Human Resources Management	6, 7
Various*	Special process training	7.5.2
EHB2011	Employee hand book	6.2.2
Various*	Training	6.2.2
KBP009	Infrastructure Management	6, 7
Various*	Preventive maintenance	6.3, 6.4
"	Control of test and measurement equipment	7.6
KBP010	Financial Management	7
Various*	Credit memo, concessions and waivers	7.2.3
KBP011	Business System Management	4, 5, 7, 8
P.USA-QU-DO16	Quality manual	4.2
P.USA-QU-D020	Business Manual System	4.1, 5.1
Various*	Internal Audit	8.2.2
"	Corrective and Preventive Action	8.2.3, 8.5.2,3
"	Management review	5.6.1, 5.1
"	Monthly Report	7.6