

# **Quality Manual**







This Quality Manual complies with the Requirements of ISO 9001:2008.

Prepared By: Phyllis Olsen Release Date: 06/19/12



# DNV BUSINESS ASSURANCE

# Management System Certificate

Certificate No. CERT-08776-2006-AQ-HOU-RvA

This is to certify that

# **Alabama Specialty Products Inc.**

at

152 Metal Samples Road, Munford, AL 36268 USA

has been found to conform to the Management System Standard:

ISO 9001:2008

*This Certificate is valid for the following product or service ranges:* 

Design and Manufacture of Corrosion Monitoring Equipment, Instrumentation and Supplies, and Specialty Manufactured Products.

Initial Certification date:

June 11, 1997

This Certificate is valid until:

August 31, 2015

The audit has been performed under the supervision of

Lead Auditor



Place and date:

Houston, Texas, August 17, 2012

for the Accredited Unit:

DNV CERTIFICATION B.V., THE NETHERLANDS

John Stefan

Management Representative

Lack of fulfillment of conditions as set out in the Certification Agreement may render this Certificate invalid.



# Alabama Specialty Products, Inc.

# **Quality Policy & Objectives**

Alabama Specialty Products, Inc.'s quality policy is to achieve sustained, profitable growth by providing products and services which consistently satisfy the needs and expectations of its customers

This level of quality is achieved through implementation of a system of documented procedures that provide guidance to our employees and reflect the competence of the Company to existing customers, potential customers and independent auditing authorities.

Achievement of this policy involves all staff, who are individually responsible for the quality of their work, resulting in a continually improving working environment for all. This policy is provided and explained to each employee by the Quality Assurance Department.

To achieve and maintain the required level of assurance the Management Representative retains responsibility for the Quality Management System with routine operations controlled by the Quality Managers.

The objectives of the Quality Management System are:

- To maintain an effective Quality Management System complying with International Standard ISO 9001.
- To achieve and maintain a level of quality which enhances the Company's reputation with customers.
- To ensure compliance with relevant statutory and regulatory requirements.
- To endeavor, at all times to maximize customer satisfaction with the products and services provided by Alabama Specialty Products, Inc.

NOTE: Executive Management is ultimately responsible for making balanced judgements, assessing the significance of variations in our processes and making decisions. In arriving at such decisions, the quality and personal integrity of staff are of fundamental importance. In this context, every effort is made to ensure that each person in the company understands that quality assurance is important to their future, that they know how they can assist in the achievement of adequate quality and that they are encouraged to do so.

**Excerpt from Quality Manual Dated 03/19/09** 



Table of ContentsPage: 1 of 19ISO 9001:2008Revision: -1-

# **TABLE OF CONTENTS**

POLICY	CONTENTS	PAGE	PROCEDURE	PROCESS
	Table of contents	1		
	Approvals	2		
	Manual distribution	3		
	Page revision status	4		
	Introduction	5		
1.0	Activities, scope and			
	Permissible exclusions	6		
2.0	Normative reference	7		
3.0	Terms and definitions	8		
4.0	Quality management system	_		
4.1	General requirements	9		FC 4.1-1
4.2	Documentation requirements	9	QP 4.2-1	FC 4.2-1
5.0	Management responsibility	_		
5.1	Management commitment	10		
5.2	Customer Focus	10		
5.3	Quality Policy	10		
5.4	Planning	10, 11		PC 5.4-1
5.5	Responsibility, authority and	,		
	communication	11, 12		
5.6	Management review	12		PC 5.6-1
6.0	Resource management			
6.1	Provision of resources	13		PC 6.1-1
6.2	Human resources	13	QP 6.2-1	PC 6.1-1
6.3	Infrastructure	13		PC 6.1-1
6.4	Work environment	13		PC 6.1-1
7.0	Product realization			
7.1	Planning of product realization	14		PC 7.1-1
7.2	Customer-related processes	14, 15		PC 7.2-1
7.3.	Design and development	15, 16	QP 7.3-1	FC 7.2.2
7.4	Purchasing	16		FC 7.4-2
7.5	Production and service provision	17	QP 7.5-1	PC 7.5-1
			QP 7.5.2	
7.6	Control of monitoring			
	and measuring devices	17		PC 7.6-1
8.0	Measurement, analysis			
	and improvement			
8.1	General	18	QP 8.1-1	
8.2	Monitoring and measurement	18, 19	QP 8.1-1	
8.3	Control of non-conforming			
	Product	19	QP 8.3-1	
8.4	Analysis of data	19	QP 8.3-1	
8.5	Improvement	19	QP 8.3-1	



Approvals Page: 2 of 19 Revision: -1-

Executive Management is ultimately responsible for making balanced judgements, assessing the significance of variations in our processes and making decisions. In arriving at such decisions, the quality and personal integrity of staff are of fundamental importance. In this context, every effort is made to ensure that each person in the company understands that quality assurance is important to their future, that they know how they can assist in the achievement of adequate quality and that they are encouraged to do so.

This quality manual and the quality policy are approved by the undersigned and are supported by all levels of management within the company.

Signature on Master File 06/18/12

Donald G. Johnson Date
Chief Executive Officer /President

Signature on Master File 06/18/12
Sai Mudiam Date
Vice-President ASPI

Signature on Master File 06/18/12

Matthew Johnson Date

Vice-President ASPI

Signature on Master File 06/19/12
Sam Patterson Date
Compliance Director

Signature on Master File 06/18/12

James P. Gray Date

President Metal Samples Co.



Manual DistributionPage: 3 of 19ISO 9001:2008Revision: -1-

# **MANUAL DISTRIBUTION**

ISSUE NO.	DATE OF ISSUE	ISSUED TO
Master Hard Copy File Hard Copy Electronic Copy Master Hard Copy Electronic Copy	03/19/09 03/27/09 04/03/09 06/19/12 06/19/12	Q.A. Administrative Assistant ISO 9000 Auditor Adobe Acrobat ISO Management Representative Adobe Acrobat
		7 10.000 7 10.0000



Page Revision Status ISO 9001:2008 Page: 4 of 19 Revision: -1-

**Page Revision Status** 

Page Revision Status							
PAGE	REVISION	DETAILS OF CHANGE	DATE	APPROVED BY			
1 - 19	- NEW-	INITIAL RELEASE	03/19/09	Don Johnson			
	4	Updated Executive Management on page 2. 5.5.2 Management Representative - "The CEO has appointed a Management Representative." Changed from "The Compliance Director has been appointed by the CEO as Management Representative."					
2, 11, & 12	- 1 -	Update Organizational Chart on page 11.	06/18/12	Don Johnson			



Introduction Page: 5 of 19 Revision: -1-

### Introduction

Alabama Specialty Products, Inc. developed and implemented a Quality Management System in order to document the company's basic policies and processes, to better satisfy the requirements and expectations of its customers and to continually improve quality through the use of the quality management system.

The Quality Management System of ASPI meets the requirements of the International Standard ISO 9001:2008. This system addresses the design and production of the company's products and services.

The manual is divided into eight sections that correlate to the Quality Management System elements of ISO 9001:2008. Each section begins with a policy statement expressing ASPI's obligation to implement the basic requirements of the referenced QMS elements. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

The manual describes the Quality Management System, defines authorities, interrelationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the QMS to ensure compliance to the necessary requirements of the ISO standard.

Internally the manual is used to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction and continuous improvement.

Externally the manual is used to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is also used to familiarize them with the controls that have been implemented and to assure them that the integrity of the QMS is maintained; thus demonstrating that the company is focused on customer satisfaction and continuous improvement.



Section 1 SCOPE Page: 6 of 19 Revision: -1-

# 1 ACTIVITIES, SCOPE AND PERMISSIBLE EXCLUSIONS

Alabama Specialty Products, Inc. is comprised of Metal Samples Co., Alabama Research and Development, and Alabama Laser, and is located in Munford, Alabama, USA.

The success and reputation of the company may be measured by the high standing maintained with our customers. A policy of continuous self-appraisal and attention to detail has ensured the expansion of our customer base.

The company has implemented a quality management system to demonstrate its ability to provide consistent products that meets customer and applicable statutory and regulatory requirements.

This enables the company to address and achieve customer satisfaction through the effective application of the system, including processes for continual improvement and the prevention of nonconformity.

The scope of the quality management system applies to:

- a complete line of corrosion engineering and monitoring equipment and supplies;
- medical laboratory equipment, and engineering, research and development services;
- industrial laser beam delivery components, and industrial laser cutting and welding equipment, and;
- complete custom product manufacturing/fabrication capabilities.

At this time, ASPI has no exclusion to the ISO 9001:2008 Standard.



Section 2 Normative Reference ISO 9001:2008 Element 2

Page: **7 of 19** Revision: **-1-**

### 2 NORMATIVE REFERENCE

This quality manual defines the policies and principles applied against each of the requirements of ISO 9001:2008 and relates to all activities carried out in the company that determine quality, and lays down guidelines within which the company can operate.

Each section of the manual is related to an identified element of ISO 9001:2008.

#### Distribution

The ISO 9000 Management Representative (Management Representative) is responsible for the controlled internal distribution of this manual, and changes thereto. Outside organizations and personnel have access to the latest revision of our Quality Manual through the company website: www.alspi.com.

### **Uncontrolled Manuals**

Any uncontrolled hard copy manuals are up-to-date at issue and are only issued to outside organizations, customers, etc. Such uncontrolled manuals will be clearly marked "For information only, not subject to automatic update".



Section 3 Terms and Definitions ISO 9001:2008 Element 3

Page: 8 of 19 Revision: -1-

## **3 TERMS AND DEFINITIONS**

The following terms and definitions are provided to assure a uniform understanding of selected terms as they are used in these requirements.

COMPANY Alabama Specialty Products, Inc. and its Divisions

SUPPLIER The party to whom an order has been placed by the company for the

purchase of raw materials, equipment, supplies, or the performance of outside

services for a particular order.

CUSTOMER Firm or person having a contractual agreement with, or the recipient of a

product or service from the company.

PRODUCT The result of a process, or series of processes, which is the combination of

some, or all of the four generic product categories, hardware, software,

services and processed materials.

SERVICE Product installation and prove-out, or maintenance/repair other than routine

preventive maintenance, routine replacement of consumables, or replacement

of out of warranty broken and/or worn components of our products.



Section 4

Quality Management System Requirements ISO 9001:2008 Element 4

Page 9 of 19 Revision - 1 -

# **4 Quality Management System**

### **4.1 General Requirements**

See Process Flow Chart FC 4.1-1

Alabama Specialty Products, Inc. has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of the ISO 9001:2008 Standard, it is not a stand-alone system, but is integrated within ASPI's operating discipline which encompasses the policies, requirements, and work processes of Environment, Health, Safety, Manufacturing, Human Resources and Quality.

Developed and endorsed by company management the QMS ensures that customers' receive quality, reliability and integrity in the products and services ASPI provides them and that customers' needs and requirements are met. The QMS calls for precise adherence to specifications, as well as legal and quality requirements.

Product quality is maintained through systems of standardization and process control. Service quality covers all aspects of customer transactions and is ensured by the function that is providing the service.

# 4.2 Documentation Requirements

#### 4.2.1 General

The QMS documentation includes:

- A documented Quality Policy and objectives
- A Quality Manual, (requirements for the quality manual are contained in section 4.2.2)
- Documented procedures required by ISO 9001:2008 (i.e., sections 4.2.3, 4.2.4, 8.2.2, 8.3, 8.5.2 and 8.5.3)
- Documents (information and its supporting medium) needed by the organization to ensure the effective planning, operation and control of its processes
- Records required by ISO 9001:2008, (stating results achieved or providing evidence of activities performed)

### 4.2.2 Quality Manual

This Quality Manual has been prepared to describe Alabama Specialty Products, Inc. QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The Process Flow Chart, FC 4.1-1, provides a description of the interaction between the processes of the QMS system.

#### 4.2.3 Control of Documents

All the QMS documents are controlled according to the Document Control Procedure, QP 4.2-1.

#### 4.2.4 Control of Quality Records

Quality Records are maintained to provide evidence of conformity to requirements and the effective operation of the QMS. The records are maintained according to the Control of Documents and Quality Records, QP 4.2-1.



Section 5

Management Responsibility ISO 9001:2008 Element 5

Page **10 of 19** Revision - **1** -

# **5 Management Responsibility**

## **5.1 Management Commitment**

Executive Management takes a visible and leading role in creating and sustaining core values, policies, strategies, directions, performance expectations and customer focus. Executive Management approves and leads the implementation of the quality management system that promotes excellence. Leadership from all levels of the company plays an active role in verifying the effectiveness and efficiency of the QMS and ensuring that resulting actions lead to continuous improvement.

#### **5.2 Customer Focus**

ASPI views its product and service quality as being defined by its customers. ASPI works closely with its customers to understand their businesses and their expectations. This close working relationship helps ASPI better meet its customer's expectations today and to anticipate and meet their needs in the future.

Executive Management ensures that not only are customer requirements understood, but they are determined and met with the aim of enhancing customer satisfaction. Customer requirements are determined, converted into internal requirements and communicated to the appropriate people within the organization through documented processes and work instructions.

## **5.3 Quality Policy**

Executive Management ensures that the quality policy is communicated to all employees. It is included in the new employee orientation and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within the organization.

Executive Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for the organization. The Quality Policy is documented on page 3 of the Quality Manual.

### 5.4 Planning

## 5.4.1 Quality Objectives

Ref: Process Chart, PC 5.4-1

Quality objectives are established to support the organization's commitment and efforts in achieving our quality policy and reviewed annually for suitability. Objectives have been established for the following:

- To maintain an effective Quality Management System complying with International Standard ISO 9001.
- To achieve and maintain a level of quality which enhances the Company's reputation with customers.
- To ensure compliance with relevant statutory and regulatory requirements.
- To endeavor, at all times to maximize customer satisfaction with the products and services provided by Alabama Specialty Products, Inc.

The quality objectives are measurable and reviewed against performance goals at each management review meeting.



Section 5 Management Responsibility ISO 9001:2008 Element 5

Page **11 of 19** Revision - **1** -

# 5.4.2 Quality Management System Planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001:2008 standard. The CEO and executive management have identified, planned and provided the resources needed to achieve the quality objectives and ensure the continual improvement of the system. Process Flow Chart, FC 4.1-1 represents an overview of the ASPI Quality Plan.

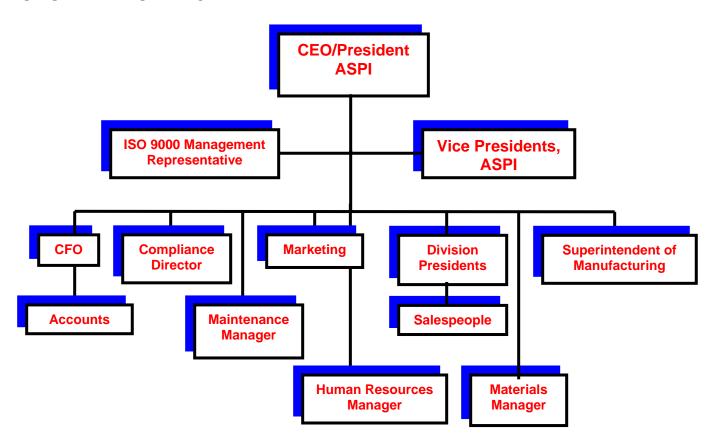
The company also applies quality planning to all work resources and considers the implementation of the contents of this quality manual to meet ISO 9001:2008 requirements and to be their primary quality plan. Quality Plans for individual jobs are documented through individual job routings and Inspection and Test Reports, QF 8.2.4-A.

# 5.5 Responsibility, Authority and Communication

# 5.5.1 Responsibility and Authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by executive management for adequacy. These documents are available in Human Resources.

## ORGANIZATIONAL CHART





Section 5 Management Responsibility ISO 9001:2008 Element 5

Page **12 of 19** Revision - **1** -

## 5.5.2 Management Representative

The CEO has appointed a Management Representative. As management representative, he or she has the following responsibilities and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to executive management on the performance of the quality management system and note any needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

### 5.6 Management Review

#### 5.6.1 General

Executive Management reviews the QMS annually at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

### 5.6.2 Review Input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Status of corrective and preventive actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the QMS and
- · Recommendations for improvement

### 5.6.3 Review Output

- During these review meetings, management will identify appropriate actions to be taken regarding the following issues:
- Improvement of the QMS and its processes;
- Improvement of product related to customer requirements, and;
- Resource needs

Responsibilities for required actions are assigned to members of the management review group. Any decisions made during the meeting, assigned actions and their due dates are recorded in the minutes of management review.



Section 6 Resource Management ISO 9001:2008 Element 6

Page **13 of 19** Revision - **1** -

# **6 Resource Management**

#### 6.1 Provision of Resources

See Process Chart PC 6.1-1

Executive Management ensures that resources essential to the implementation; maintenance and improvement of the quality management system are identified and made available.

## 6.2 Human Resources

**6.2.1 General** See Process Chart PC 6.1-1

To ensure the competence of personnel, job descriptions have been prepared identifying the qualifications required for each position that affects conformity to product requirements. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competencies required for each position.

### 6.2.2 Competence, Training and Awareness

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human Resources maintain records of employee qualifications. If any differences between the employee's qualification and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure See Process Chart PC 7.1-1

ASPI Executive Management is committed to providing and maintaining suitable facilities that are necessary to implement the Quality Management System that will achieve conformity of product. The required infrastructure and resources are identified, as applicable this includes: building facilities, necessary work space, associated facilities, process equipment, information systems, communication media and transportation.

An electronic maintenance program specifies the type and the frequency of needed maintenance, the methods for maintenance and the verification of its completion.

Executive Management ensures the timely availability of identified and approved resources.

#### 6.4 Work Environment

Executive Management ensures that the appropriate human and physical factors of the work environment are considered and provided, including such factors as noise, temperature, lighting and etc. ASPI is committed to maintain its facilities in a safe and healthy manner, establish and provide an infrastructure that is needed to comply with product requirements.



**Section 7** 

Product Realization ISO 9001:2008 Element 7 Page: **14 of 19** Revision: **-1-**

#### 7 Product Realization

## 7.1 Planning of Product Realization

See Process Chart PC 7.1-1

Quality planning is required before new products or processes are implemented. Quality plans for product realization have been prepared in the form of collaborative processes involving many functions and departments. These are outlined in Process Flow Chart FC 4.1-1 which addresses the requirements and interactive needs. These are further delineated in each of the appropriate paragraphs of Section 7.

The quality planning elements specifically determine quality objectives for products; the need for processes, facilities, documentation and resources specific to product realization; product verification and validation, monitoring, inspection and test activities; criteria for product acceptability and the records to demonstrate product and process conformance.

#### 7.2 Customer-related Processes

#### 7.2.1 Determination of Requirements Related to the Product

See Flow Chart FC 7.2-2

Alabama Specialty Products, Inc. has documented procedures that provide for the determination/identification of customer requirements, to include those that are not specified, but are necessary for intended use or compliance with statutory and regulatory requirements applicable to the product.

Reviews of customer specifications are performed when received and any requirements documented for implementation as applicable. These may take the form of quality assurance instructions, standard comments for specific customer orders, instructions for design implementation or the use of industry standards for design, product fabrication, validation and/or verification processes.

#### 7.2.2 Review of Requirements Related to the Product

See Flow Chart FC 7.2-2

In order to establish and maintain customer satisfaction, a formal system is in place and maintained to ensure that each commitment to supply a product is formally reviewed and controlled. The review is conducted prior to the commitment to supply a product and ensures that:

- The requirements are adequately defined and documented.
- Where the customer provides no written statement of requirements, the order requirements are confirmed verbally before acceptance;
- That ASPI has the resources to meet the defined requirements, and that;
- Any differences between the contract and the tendered quotation are resolved to the mutual satisfaction of the involved parties before formal acceptance of the contract.
- In the event of product/contract requirement amendments, appropriate notification is given to affected departments within ASPI and that relevant documentation is revised.

Record requirements from these reviews are shown on the quote, e-mails, and/or the order acknowledgement.



Section 7 Product Realization
ISO 9001:2008 Element 7

See Process Chart PC 7.2-1

Page: 15 of 19

Revision: -1-

#### 7.2.3 Customer Communication

ASPI recognizes the necessity for customer communication and feedback as a major contributing element of customer satisfaction and has implemented an effective process for communicating with customers.

- ASPI produces hard copy product and services catalogues and catalogues on CD's for each of it's three divisions
- ASPI maintains a comprehensive website
- Customers can contact ASPI via phone, e-mail, fax and mail
- Customer complaints are handled through the Sales Department
- Customer Satisfaction Surveys are used to monitor customer satisfaction

## 7.3 Design and Development

### 7.3.1 Design and Development Planning

See Quality Procedure QP 7.3-1

The company reviews and evaluates design requirements to ensure that the products it designs and/or develops meet or exceed customer specifications. In the course of addressing technical, logistical and financial concerns that impact the design process activities, ASPI consistently exercises its organizational interfaces. Planning is maintained to its most current status, as appropriate, as design activities progress.

## 7.3.2 Design and Development Inputs

See Quality Procedure QP 7.3-1

ASPI identifies design and development inputs and any applicable statutory or regulatory requirements during contract review and/or customer meetings. Ambiguous, conflicting, changing and unclear/incomplete requirements are clarified by reviews of the design at various stages of the designing process. Design requirements are amended to accurately capture all pertinent design input information. Design and development inputs, where applicable, are derived from previous similar designs and other requirements essential for design and development.

#### 7.3.3 Design and Development Outputs

See Quality Procedure QP 7.3-1

ASPI captures design and development outputs in design review minutes and customer reviews as needed. The reviews are performed specifically to verify that design output meets or exceeds design input requirements, contains or references acceptance criteria, and identifies characteristics of the design crucial to the safe and proper functioning of the product. It also assures design output is reviewed and approved prior to release. Design and development outputs provide appropriate information for purchasing, production and for service provision. The design control procedure assures that all pertinent data required for the product to be identified, manufactured, inspected, used and maintained is defined.

#### 7.3.4 Design and Development Review

See Quality Procedure QP 7.3-1

The design control procedure assures that the appropriate stages of design, formal or rotating documented design reviews are planned and conducted in accordance with planned arrangements (ref: 7.3.1) and include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel as required. Records of such reviews and any necessary actions are maintained (ref: 4.2.4). The design control procedure assures that consideration to the validity of design in relation to the objectives of the design stage, actions to be taken in the event of any identified deviation and decisions necessary for progression to the next phase.



Section 7

Product Realization ISO 9001:2008 Element 7

See Quality Procedure QP 7.3-1

Page: 16 of 19

Revision: -1-

# 7.3.5 Design and Development Verification

The design control procedure assures that at appropriate stages of design, design verification is conducted in accordance with planned arrangements (ref: 7.3.1) to assure the design stage output meets the design stage input requirements. Records of design verification and any necessary actions are maintained.

#### 7.3.6 Design and Development Validation

See Quality Procedure QP 7.3-1

The design control procedure assures that design validation is performed in accordance with planned arrangements (ref: 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery of implementation of the product. Records of the results of validation and any necessary actions are maintained.

#### 7.3.7 Control of Design and Development Changes

See Quality Procedure QP 7.3-1

All design changes either initiated by ASPI or requested by the customer are reviewed and approved before implementation. Changes that impact parts or product form, fit or function will have applicable verification and/or validation performed.

### 7.4 Purchasing

### 7.4.1 Purchasing Process

See Flow Chart FC 7.4-2

A documented process (FC 7.4-2) is followed to ensure that purchased product conforms to the specified purchase requirements. The process outlines the extent of control required for suppliers. Suppliers are evaluated, selected and re-evaluated based on their ability to supply product in accordance with requirements as outlined in the process. Records of the evaluation and necessary actions are maintained as quality records.

## 7.4.2 Purchasing Information

Purchasing information describes the product or the service to be purchased, including where appropriate:

- Requirements for approval of product, processes, procedures, services and equipment
- Requirements for qualification of personnel
- Quality management system requirements

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

#### 7.4.3 Verification of Purchased Product

The verification of purchased product is performed in accordance with work instruction WI 7.4.3-1, Receiving Inspection. Where the company or its customer proposes to perform verification activities at the supplier's premises, the intended verification arrangements and the methods of product or service release are specified in the purchasing documentation. Verification by the customer neither releases the company of responsibility to provide products or services, which are acceptable to the customer, nor does it preclude subsequent rejection by the customer.

#### 7.5 Production and Service Provision

See Process Chart PC 7.5-1 Ref: WI 7.5.1-1

#### 7.5.1 Control of Production and Service Provision

ASPI plans and carries out the production and service provision under controlled conditions according to documented procedures, processes and work instructions where applicable.



Section 7

Product Realization ISO 9001:2008 Element 7

See Process Chart PC 7.5-1

Page: 17 of 19

Revision: -1-

# 7.5.2 Validation of Processes for Production and Service Provision

See Process Chart PC 7.5-7 Ref: QP 7.5-2

ASPI validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

# 7.5.3 Identification and Traceability

See Process Chart PC 7.5-1

ASPI identifies the product throughout the product realization, identifying the product status with respect to monitoring and measurement requirements. ASPI controls and records the unique identification of the product where ever traceability is a specified requirement.

### 7.5.4 Customer Property

See Work Instruction WI 7.5.4-1

ASPI exercises care with customer property while it is under the company's control or being used. A work instruction, WI 7.5.4-4, Processing Customer Supplied Material outlines the identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records are maintained (Ref: WI 7.5.4-3).

#### 7.5.5 Preservation of Product

See Work Instruction WI 7.5.5-4 Ref: Process Chart PC 7.5-1

The methods used for handling, storing, packaging, preserving and delivery of products to ensure they are not damaged and that they're maintained in an acceptable condition are documented in various processes and procedures These also apply to any constituent parts. Damaged or nonconforming products are controlled and dispositioned according to procedures described in QP 8.3.1, Control of Nonconforming Product.

#### 7.6 Control of Monitoring and Measuring Equipment

See Process Chart PC 7.6-1

The monitoring and measurement to be undertaken is identified and the monitoring and measuring equipment needed to provide evidence of conformity of product to specified requirements is determined.

Measuring and monitoring equipment is used and controlled to ensure that measurement capability is consistent with monitoring and measurement requirements.

In addition, Quality Control reviews and records the validity of the previous measuring results when the equipment is found not to conform to requirements. ASPI takes appropriate action on the equipment and any product affected.

Records of the results of calibration and verification are maintained. (Ref: 4.2.4)

The capability of computer software to satisfy the intended application is established prior to initial use and reconfirmed as necessary, when used in the monitoring and measurement of specified requirements.



Section 8

**Measurement Analysis and Improvement** 

ISO 9001:2008 Element 8

Page: 18 of 19 Revision: -1-

# 8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General See Quality Procedure QP 8.1-1

The company plans and implements the monitoring, measurement, analysis and improvement processes needed to:

- demonstrate conformity to product requirements;
- ensure conformity of the quality management system, and;
- continually improve the effectiveness of the quality management system.

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

# 8.2 Monitoring and Measurement

#### 8.2.1 Customer Satisfaction

See Quality Procedure QP 8.1-1

As one of the measurements of the performance of the quality management system, information relating to customer perception as to whether the company has met customer requirements is monitored. The method's for obtaining and using this information are determined, and include review of Customer Return Reports, repeat customer order volume, and a customer satisfaction survey that is posted on our website.

#### 8.2.2 Internal Audit

See Quality Procedure QP 8.1-1

ASPI conducts internal audits to determine whether the quality managements system conforms to the requirements of ISO 9001:2008 and has been effectively implemented.

ASPI develops the audit plan annually, taking into consideration the status and importance of the activities and areas to be audited as well as the results of previous audits. The audit plan is revised after each audit and updated if needed. The audits criteria, scope, frequency, methods and responsibilities are defined.

Audits are conducted by personnel other than those who perform the activity being audited.

The documented procedure includes the responsibilities and requirements for planning, conducting audits, ensuring their independence, recording results and reporting to management.

The management accountable for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow up activities include the verification of the actions taken and the reporting of verification results.

#### 8.2.3 Monitoring and Measurement of Processes

See Quality Procedure QP 8.1-1

ASPI applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate to ensure conformity of the product requirements.

#### 8.2.4 Monitoring and Measurement of Product

See Quality Procedure QP 8.1-1

Documented procedures have been established and maintained to monitor and measure the characteristics of the product to verify that requirements for the product are met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.



**Section 8** 

**Measurement Analysis and Improvement** 

ISO 9001:2008 Element 8

Page: 19 of 19 Revision: -1-

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of the product for delivery to the customer. Product release and service delivery to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and where applicable by the customer.

### 8.3 Control of Nonconforming Product

See Quality Procedure QP 8.3-1

ASPI ensures that products which do not conform to requirements are identified and controlled to prevent unintended use for delivery. ASPI takes actions appropriate to the effects or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started. These activities and responsibilities are defined in documented quality procedure QP 8.3-1, Control of Nonconforming Product. Records of the nonconformities and actions taken are kept in accordance with QP 4.2-1, Control of Documents and Quality Records. Nonconforming products are corrected and subject to re-verification after correction to exhibit conformity to product requirements.

# 8.4 Analysis of Data

See Quality Procedure QP 8.3-1

ASPI determines, collects and analyzes appropriate data to determine the suitability and effectiveness of the quality management system and to identify improvements that can be made using QP 8.1-1, Measurement, Analysis and Improvement. This includes data generated by monitoring and measurement activities and other relevant sources.

- Customer satisfaction and/or dissatisfaction (Ref: 8.2.1)
- Conformity to product requirements (Ref: 8 .2.4)
- Characteristics of trends of processes and products/service including opportunities for preventive and corrective action ( Ref: 8.2.3 and 8.2.4)
- Suppliers (Ref: 7.4)

### 8.5 Improvement

#### 8.5.1 Continual Improvement

See Quality Procedure QP 8.3-1

Identification of continual improvement needs are determined by analyzing customer satisfaction information, product and process conformance data, supplier performance data, internal audit results and other data and information relevant to quality performance. Management review considers all relevant information and defines priorities for improving the quality system. The corrective action and/or auditing processes are used to formally identify, respond to, verify acceptability of actions and track the corrective action request or internal audit findings.

#### **8.5.2 Corrective Action**

See Quality Procedure QP 8.3-1

The process utilized by ASPI for the implementation of corrective action is as defined within quality form QF8.5.2-A, Corrective Action Request. The corrective action process provides for defining non-conformities, determining root causes, evaluating action to ensure non-recurrence, also includes the implementation, recording and reviewing the effectiveness of the actions taken

#### **8.5.3 Preventive Action**

See Quality Procedure QP 8.3-1

Implementation of preventive action measures are as defined within quality form, QF8.5.2-B, Preventive Action Request. The preventive action initiated is to be appropriate to the potential impact of the problem. Similar to the corrective action process, the process employed identifies potential nonconformities and there causes, determines and ensures implementation, reviews and records the effectiveness of the preventive actions taken.