ALABAMA SPECIALTY PRODUCTS, INC.

Quality Manual

ALABAMA RESEARCH AND DEVELOPMENT

Metal Samples®

ALABAMA LASER TECHNOLOGIES

Alabama LASER

This Quality Manual complies with the Requirements of ISO 9001:2015 and
EN ISO/IEC 80079-34, ATEX Directive 2014/34/EU

Prepared By: Phyllis Olsen

Release Date: 12/18/18

Rev. -2- December 18, 2018

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
CERT-08776-2006-AQ-HOU-ANAB

Initial certification date:
11 June, 1997

Valid:
31 August, 2018 - 31 August, 2021

This is to certify that the management system of

Alabama Specialty Products, Inc.
Also Doing Business As: Metal Samples Company, Alabama Laser Technologies, Alabama Laser Systems, Alabama Laser, Alabama Research and Development

152 Metal Samples Road, Munford, AL, 36268, USA

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:
Design and Manufacture of Corrosion Monitoring Equipment, Instrumentation and Supplies, and Specialty Manufactured Products.

Place and date:
Katy, TX, 02 August, 2018

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

For the issuing office:
DNV GL – Business Assurance
1400 Ravello Drive, Katy, TX, 77449-5164, USA

David Hilbert
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
ACCREDITED UNIT: DNV GL Business Assurance USA, Inc., 1400 Ravello Drive, Katy, TX 77449 USA. TEL:281-396-1000. dnvglcert.com

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Approvals

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 File **09/13/17**

Donald G. Johnson **Date**
Chief Executive Officer /President

Signature on File **09/08/17**

James P. Gray **Date**
Vice-President ALSPI

Signature on File **09/13/17**

Tim Johnson **Date**
Vice-President ALSPI

Signature on File **09/08/17**

Sam Patterson **Date**
Compliance Director

Signature on File **10/17/17**

Sai Mudiam **Date**
Vice-President ALSPI

Quality System Manual Revision Index

PAGE	REVISION	DETAILS OF CHANGE	DATE	APPROVED BY
1-38	- NEW-	INITIAL RELEASE	01/25/18	Don Johnson
16-38	- 1-	Moved the Ex Representative from under Division VP to VP of ALSPI.	11/26/18	Don Johnson
26	- 2-	Added “The person identified in clause 5.3 shall approve any changes that could compromise Ex compliance.”	12/18/18	Don Johnson
28	- 2-	Added: “The person identified in clause 5.3 shall be involved any changes that could affect Ex compliance.”	12/18/18	Don Johnson
29	-2-	Added latest requirements of 80079-34, Annex C to Clause 8.4.2 Type & Extent of Control.	12/18/18	Don Johnson
36	-2-	Referenced timescale between audits and audits to be performed on both ISO9001:2015 and EN/ISO80079-34, ATEX Directive 2014/34/EU.	12/18/18	Don Johnson

MANUAL DISTRIBUTION

ISSUE NAME	ISSUE DATE	ISSUED TO
ELECTRONIC HARD COPY	01/25/18	Adobe Acrobat
ELECTRONIC HARD COPY	08/15/18	www.alspi.com
ELECTRONIC HARD COPY	11/26/18	Adobe Acrobat
ELECTRONIC HARD COPY	11/26/18	www.alspi.com
ELECTRONIC HARD COPY	12/18/18	www.alspi.com

Introduction

Alabama Specialty Products, Inc. (ALSPI) is a materials processing firm that meets the needs of its customers around the world. Combining the resources of its company divisions: Metal Samples Company, Alabama Research and Development, Alabama Laser Technologies and Alabama Laser. ALSPI offers a wide variety of products and services.

The purpose of the Quality Manual is to document the quality system and policies and to inform ALSPI's customers of the controls implemented to assure product quality. The Quality Manual provides for a quality management system to:

- Consistently provide products and services that meet customer and applicable regulatory requirements.
- Address risks and opportunities associated with its context and objectives.
- Enhance customer satisfaction through effective application of the quality system, including processes for continual improvement of the system and assurance of conformity to customer and applicable regulatory requirements.

The Quality Management System of ALSPI meets the requirements of the ISO 9001:2015 and EN ISO/IEC 80079-34, ATEX Directive 2014/34/EU and employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. Quality Management principles described in the ISO9000 Standard are applied. This system addresses the design and production of the company's products and services.

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.

Internally the manual is used to guide the company's employees through the various requirements of the ISO 9001:2015 and EN ISO/IEC 80079-34, ATEX Directive 2014/34/EU, 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.

1 SCOPE

Scope and Exclusions

Alabama Specialty Products, Inc. is comprised of Metal Samples Co., Alabama Research and Development, Alabama Laser Technologies and Alabama Laser, 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.

This Quality Manual establishes compliance with **ISO9001:2015 and EN ISO/IEC 80079-34, ATEX Directive 2014/34/EU.** It applies to all of our business activities including research and development where applicable, production, sales, marketing and service activities.

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 quality management system applies to:

- A complete line of corrosion monitoring equipment and supplies
- Medical laboratory equipment, and engineering, research and development services
- Industrial laser cutting and welding equipment
- Complete custom product manufacturing/fabrication capabilities.

In addition, Alabama Specialty Products, Inc. provides product to the following EU Directive:

- *Equipment intended for use in Potentially Explosive Atmospheres (ATEX) Directive 2014/34/EU*

At this time, ALSPI has **no Non-applicable requirements** to the ISO 9001:2015 Standard.

NOTE: Italicized words and statements in this document pertain to the EN ISO/IEC 80079-34, ATEX Directive 2014/34/EU.

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 9001:2015.

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”.

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.
RISK	Effect of uncertainty.

4 CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and Its Context

Alabama Specialty Products, Inc. (ALSPI) is a materials processing company that meets the needs of its customers around the world. Combining the resources of its company divisions, Metal Samples, Alabama Laser Technologies, Alabama Laser and Alabama Research and Development, ALSPI offers a wide variety of products and services. The supply of products and services include but are not limited to: manufacturing of corrosion monitoring and materials evaluation products, coupons, probes, instrumentation, high pressure access fittings, injection systems, reference assortment kits and electrodes. The company designs and develops tissue slicer products, such as tissue slicers, thickness gauges, coring presses and tools, embedding and incubation units. In addition, Alabama Specialty Products offers services, including laser cutting, welding, tube cutting, etching, cladding, heat- treating, metal disposition and precision machining, bending and forming, punching, wire EDM, CNC milling, water jet and plasma cutting, material folding, CNC screw machining, powder coating, wet paint, and grinding.

Further, the company provides services such as CAD and engineering, prototype fabrication, custom laser system services, laser research and new product development. It serves aerospace, auto racing, transportation, industrial equipment, medical, defense/government, construction equipment, furniture, agricultural, lawn/garden equipment, automotive, oil and gas, water treating, chemical, and recreational vehicle industries. The company is committed to superior quality, quick delivery, fair pricing, and excellent service. With a rapidly expanding physical plant, state-of-the-art equipment, ever broadening product lines, dedicated research, and a highly skilled work force, it stands ready to meet customer's specific manufacturing needs.

External factors exist outside the boundaries of the company and have significant influences on our growth and survival. We have little or no control over these issues, but constantly monitor and adapt to any necessary changes. Not all elements impact the day to day operations and thus are weighted differently. Common external factors that influence the company include: Related Industries - when developing business philosophies and products we use our strength in quality, production, customer service and/or operational efficiencies to build competitive advantages that benefit our customers. Customer Preferences - economic factors relate to the values, attitudes and concerns of our target customers and their economic abilities to afford our products. Technology - we continually embrace the science and technology required for production, the Internet, social networks, and advances in communication technologies have revolutionized how we operate. New Laws and Regulations - are constantly added due to political or social changes. Compliance - can result in additional cost, development of new technology, additional taxes or legal fees. Finances - provide operational support, which may include savings or available cash, and credit lines to fund new ventures. Raw Materials - ALSPI uses a large amount of raw materials. A sizeable variety of alloys is stored on the premises, but any disruption in supply and/or changes in cost of materials could have an adverse effect.

4 CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and Its Context

Skilled Employees - the availability of adequately skilled employees at various levels is challenging. Formal and in-plant training for critical skills exists. Progression of the trainee is based on specified levels of demonstrated performance on the job. New trainees are phased into the work force where skill shortages occur. Demographics - play a crucial role in the success of businesses, as learning consumer characteristics helps to determine what products and services to create and how to market them. Future shifts in demographics also determine what necessary adjustments we must make to our strategies. Due to the increasingly broad world economy the Global context is becoming more important to observe by means of assessing the business environment in other countries, including economic, financial, structure, business practices, and regulatory systems.

4.2 Understanding the needs and expectations of interested parties

Interested parties are individuals and other entities that add value to the organization. Meeting the needs and expectations of interested parties contributes to the achievement of sustained success by the company. The needs and expectations of interested parties can take a wide variety of forms, including collaboration, cooperation, negotiation, and outsourcing or terminating an activity.

a. Interested Party	b. Needs and Expectations
Customers	Quality, Price & Delivery of Products and Services
Owners/Share Holders	Sustained Profitability and Transparency
Employees	Good Work Environment, Job security, Recognition and Reward
Suppliers & partners	Mutual Benefit and Continuity
Community	Environmental Protection, Ethical Behavior, Compliance with Statutory and Regulatory Requirements.

4. 3 Determining the Scope of the Quality Management System

This Quality Manual has been prepared to describe Alabama Specialty Products, Inc. The scope and permissible exclusions of the QMS are expressed in section one of this manual.

4.4 Quality Management System and Its Processes

Alabama Specialty Products, Inc., has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of the ISO 9001:2015 Standard. It is not a stand-alone system, but is integrated within ALSPI's operating discipline which encompasses the policies, requirements, and work processes of Environment, Health, Safety, Manufacturing, Human Resources and Quality.

It is recognized that defining, implementing and documenting our quality management system is only the first step towards fully implementing its requirements. The effectiveness of each process and its subsequent output is measured and evaluated through regular internal audits, quality inspections and data analysis. Performance indicators are linked to our objectives to control and monitor our processes, as well as assessments to determine the risks and opportunities inherent to each process. We use trends and indicators relating to nonconformities, objectives and corrective action, as well as, monitoring and measurement results, audit results and customer satisfaction data, process performance and the conformity of our products.

Process Flow Chart, FC 4.4-1, provides a description of the interaction between the processes of the QMS system.

5 LEADERSHIP

5.1 Leadership and 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.

5.1.1 General

Executive Management of ALSPI clearly demonstrates its commitment by:

- QMS effectiveness is measured, and management is involved in assessing this.
- The Quality Policy and objectives are in place per management direction, communicated in the organization, and tracked for progress.
- The QMS is part of the business processes, not a side project.
- Resource needs are reviewed and addressed by management.
- Continual improvement is promoted and supported by management.
- There is a way to ensure customer, statutory and regulatory requirements are understood and met, and people understand why this is important.
- There is a management focus on customer satisfaction.
- Organizational roles, responsibilities, and authorities are assigned, understood by the person who is assigned, and known to those employees who need to assess a person in a certain role.

Management review is the significant method of feedback to top management on the maintenance of the Quality Management System. This process continues to have a central role in demonstrating top management's commitment to the QMS.

5.1.2 Customer Focus

ALSPI views its product and service quality as being defined by its customers. We continually look for ways to interact directly with our customers to ensure that we focus on their unique needs and expectations. This close working relationship helps ALSPI better meet its customers' 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.

Customer complaints and other customer feedback are continually monitored to identify opportunities for improvement.

5 LEADERSHIP

5.2 Policy

The quality policy of Alabama Specialty Products, Inc.'s 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 and *EN ISO/IEC 80079-34, ATEX Directive 2014/34/EU.*

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- 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

5 LEADERSHIP

5.2.1 Developing the Quality Policy

Executive Management ensures that the Quality Policy:

- Is appropriate to the purpose of ALSPI.
- Includes a commitment to comply with requirements and continually improve the effectiveness of the QMS.
- Provides the framework for establishing and reviewing quality objectives.
- Is communicated, understood and promoted throughout the organization, and
- Is reviewed during the annual QMS review for continuing suitability.

5.2.2 Communicating the Quality Policy

Executive Management ensures that the quality policy is communicated internally to all employees. It is included in the new employee orientation and training, day-to-day operations and general awareness. It is conveyed and reinforced during employee performance reviews. Externally it is provided on our website for review by interested parties.

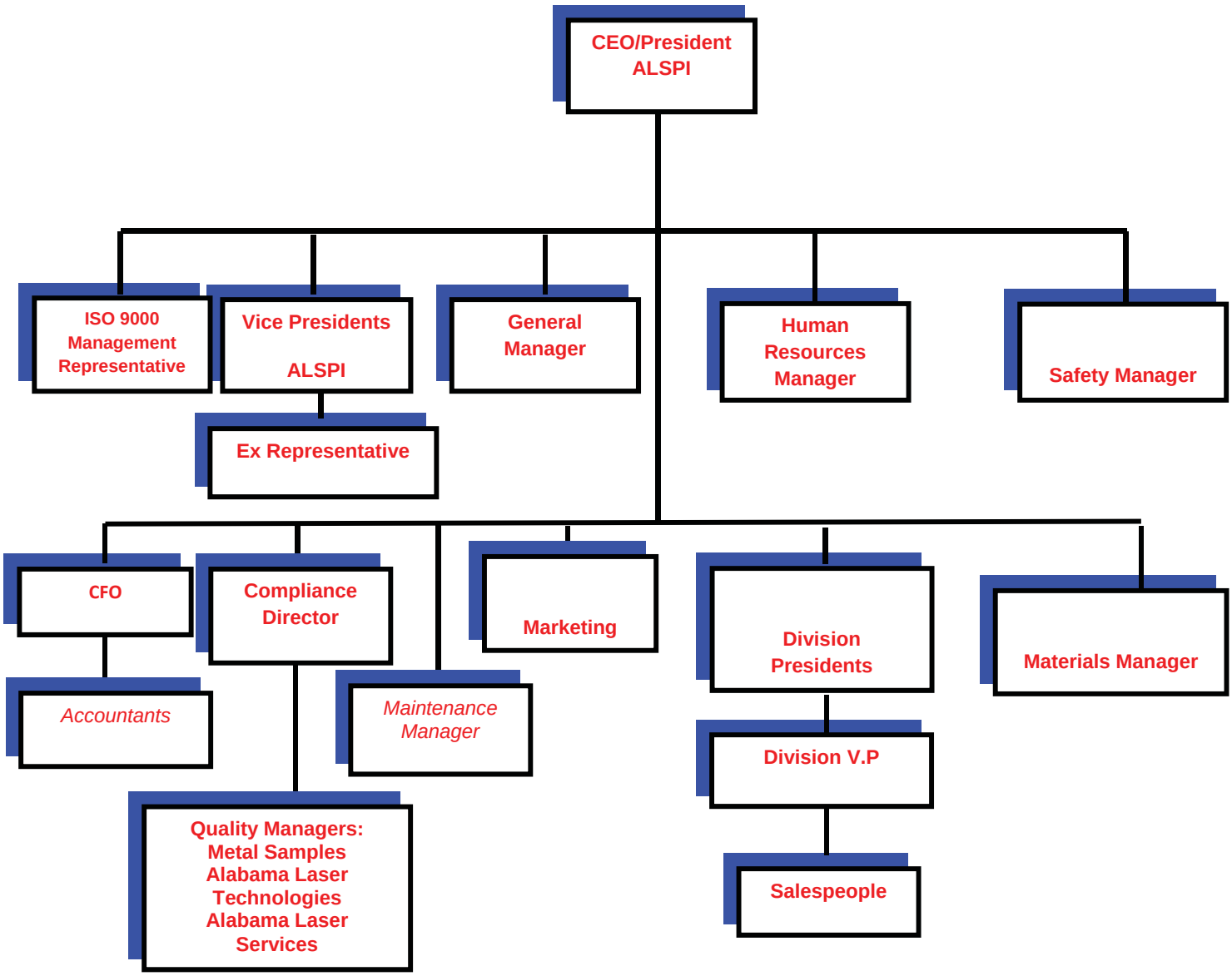
5.3 Organizational Roles, Responsibilities and Authorities

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 on page (16).**

- *Senior Electrical Engineer serves as the Ex Representative and is responsible for the activities associated with products intended for use in explosive atmospheres, and is under the direction of the President of Metal Samples and V.P. of Engineering.*
- *These activities include interfacing with the approval organization for Ex certificates when changes in design require changes in the related drawings.*
- *The appointed Management Representative is responsible for interfacing with the approval organization for changes in the Quality system.*
- *The Senior Electrical Engineer and V.P. of Engineering are responsible for initial approval and changes to related drawing where appropriate.*
- *The Senior Electrical Engineer and V.P. of Engineering are responsible for any necessary concessions. For changes that impact the explosion proof design there are no concessions.*
- *The Senior Electrical Engineer is responsible for informing customers of any applicable special conditions for safe use and any limitations. If the sign "X" is placed after the certification number, it indicates that the equipment or protective system is subject to special conditions for safe use specified in the schedule to this certificate.*
- *The Electronics Lab Supervisor is responsible for receiving inspection of Ex product/services, reviewing Ex certificates and technical documentation and identifying any changes that effect product compliance with the certificate. The Ex Representative is responsible for annually checking the validity of all Ex related certificates, standards, regulations and other external specifications.*

5 LEADERSHIP

ALABAMA SPECIALTY PRODUCTS, INC.
ORGANIZATIONAL CHART



5 LEADERSHIP

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.

Ex Representative

Authorized person to deal with product manufactured to the requirements of an "Ex" type directive (e.g. ATEX or IECEx). The Ex Representative has the following responsibilities and authority:

- *Ensure the implementation of approved (by Notified Body) documents, verifies validity of Ex certifications, standards and regulations (ATEX/IECEx), etc., annually.*
- *Maintain approved documents.*
- *Influence training activities.*
- *Evaluate non-conformances.*
- *Perform audits in regards to Explosive Atmospheres procedures.*

5.4 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 9001:2015 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 4.4-1 represents an overview of the ALSPI 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 9001:2015 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 8.6-A.

6 PLANNING

6.1 Action to Address Risk and Opportunities

While planning the QMS, ALSPI considers the context of the organization, needs and expectations of interested parties, and the scope of the QMS. The CEO and executive management determine risks and opportunities related to the ability to give assurance that the QMS can achieve intended results, enhance desirable results, prevent or reduce undesired effects, is compatible with the context of the organization, and can achieve continual improvement.

Executive management is responsible for incorporating risk based thinking in to our organization's culture. Risk and opportunity management is undertaken as part of ALSPI's day-to-day operations and is captured in the following categories: Budgets and profitability (Strategic level), Performance and efficiency (Programmer level), Resources and targets (Department Level), and Evaluation and assurance (Process level). This ensures that each category for capturing risk and opportunity is managed at the most appropriate level.

ALSPI has planned actions to address the risks and opportunities and has initiated appropriate procedures to integrate and implement appropriate actions into our QMS including the evaluation of the effectiveness our QMS processes. The company also applies quality planning to all work resources and considers the implementation of the contents of this quality manual to meet ISO 9001:2015 requirements. (Quality Plans for individual jobs are documented through individual job routings and Inspection and Test Reports).

6.2 Quality Objectives and Planning to Achieve Them

Executive management at ALSPI ensures that quality objectives are established throughout the quality management system at relevant functions, levels and processes. The quality objectives meet the following requirements:

- Consistent with the Quality Policy.
- Measurable.
- Take into consideration the applicable requirements.
- Relevant to conformity of products and services and enhancement of customer satisfaction.
- Monitored.
- Communicated.
- Updated as appropriate.

The objective results are regularly reviewed by the management in order to monitor realization and to include new or modified situations during regular production and management review meetings.

6.3 Planning of Changes

When the organization determines a need for changes to the Quality Management System, the Management Representative takes responsibility to carry them out in a planned manner. Executive management plans changes to the QMS considering the purpose of the changes & potential consequences, integrity of the QMS and allocation or relocation of responsibilities & authorities.

The quality system ensures that product conforms to the type described in the Ex certificate. All the elements, requirements and provisions adopted by ALSPI are documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation permits a consistent interpretation of quality programs, plans, manual and records.

7 SUPPORT

7.1 Resources

ALSPI determines and provides resources needed for establishment, implementation; maintenance, and continual improvement of the Quality Management System. We are committed to preserving and communicating organizational knowledge.

7.1.1 General

Resources include:

- People.
- Machines and materials.
- Software and hardware.
- Tools.
- Environment.
- Monitoring and measuring instruments.
- Safety equipment.

7.1.2 People

ALSPI provides the necessary staff with the needed knowledge and skills, organization infrastructure, and financial resources for establishing, implementing, maintaining and improving the QMS.

7.1.3 Infrastructure

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, 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.

7.1.4 Environment for the Operation of Processes

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, etc. ALSPI is committed to maintain its facilities in a safe and healthy manner and establish and provide an infrastructure that is needed to comply with product requirements.

7 SUPPORT

7.1.5 Monitoring and Measuring Resources

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. ALSPI takes appropriate action on the equipment and any product affected.

7.1.5.1 General

Suitable equipment is used. Monitoring and measuring activities are implemented. Product release, delivery and post - delivery activities are implemented.

ALSPI provides procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the product with the type described in the Ex certificates.

7.1.5.2 Measuring Traceability

Records of the results of calibration and verification are maintained. Ref: PC 7.1.5, Control of Measuring and Monitoring Devices.

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.

7.1.6 Organization Knowledge

The Organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. Organizational knowledge is the specific knowledge that the company has gained by experience, which is used and shared to achieve the objectives of the company. This comes from internally, such as intellectual property, lessons learned from failure and successes, or the results of improvements; or externally from conferences, customer knowledge, or supplier knowledge. Knowledge is a resource needed for the company to support the quality management system processes and to ensure conformity of its products and services.

7 SUPPORT

ALSPI captures necessary knowledge in a number of ways including but not limited to:

- Work Instructions
- Processes
- Product Knowledge
- Work Experience
- Technologies and Infrastructures
- Checklist
- Training Classes, Seminars and etc.
- On-The-Job-Training
- Conferences and Networking
- Knowledge Databases
- Legal Requirements and Limitations
- Logistics Requirements
- Customer Requirements and Expectations
- Business & Market Knowledge

Documents for maintaining knowledge and providing evidence of compliance include but not limited to:

- Contract Reviews – clause 8.2.3.2
- Operations of processes – clause 4.4.2
- Monitoring & measuring resources, fitness for use – clause 7.1.5.1
- Planning & control processes – clause 8.1
- Design & Development records – clauses 8.3.3. – 8.3.6
- Change control records – clause 8.5.6
- Supplier evaluations – clause 8.4.1
- Personnel competency records – clause 7.2
- Product non-conformity records – 8.7.2
- Corrective action records – 10.2.2
-

ALSPI's Organizational Knowledge is continually improved upon through company practices, behaviors, decisions and performance. Our focus is on knowledge processes, creation, acquisition, refinement, storage, transfer, sharing and utilization. These processes support organizational innovation, individual learning, collective learning and collaborative decision making. The outcomes are improved organizational behaviors, decisions, products, services, processes and relationships that enable the company to improve its overall performance.

7.2 Competence

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.

7 SUPPORT

Appropriate qualifications, along with required training, provide the competencies required for each position. Human Resources maintain appropriate records of education, training, skills and experience.

ALSPI ensures that all personnel having an impact on Ex compliance receive appropriate training

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.

ALSPI ensures that all personnel having an impact on Ex compliance receive appropriate training.

7.3 Awareness

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

7.4 Communication

Executive management shall ensure that appropriate internal and external communication processes are established within the organization and that communication takes place. Executive management is able to communicate within the organization at all levels. Communication is one of our support processes necessary to make the QMS work and to stimulate continuous improvement. It is the link between requirements and the people who must fulfill them. The methods and nature of ALSPI communications include, but are not limited to the following:

- Changes in work instructions
- Revisions to customer specifications
- Project status
- Training
- Process deviations
- Segregation of material
- Signatures
- E-mails
- Meetings
- ECN's
- Internal audits
- Memos
- Bulletin Boards
- Computer terminals
- Records

7 SUPPORT

Internal and external communications relating to Ex product shall be controlled. These communications may include but not limited to, manufacturer documentation, technical documentation, Ex certificates, and non-conform products placed on the market. External communication could be communicated to clients, certification body, providers, distributors, authorities and etc.

7.5 Documented Information

7.5.1 General

The QMS documentation includes:

- The documented Quality Policy and Quality Objectives.
- The Quality Procedures established to meet quality, customer and regulatory requirements. The documented processes and workflows are implemented and maintained.
- All such documents (including work instructions and forms) that ALSPI needs to ensure the effective planning, operation and control of its processes.
- All records that are required by quality, customer and regulatory requirements to provide objective evidence of policy, product and/or process compliance.
- *All documentation required by the ISO 9001:2015 and EN ISO/IEC 80079-34, ATEX Directive 2014/34/EU.*

7.5.2 Creating and Updating

ALSPI has established, documented, implemented and maintains a Quality Procedure for the control of documents and records. This procedure defines how all documents and records that are required by the QMS are controlled. (Ref: QP 7.5.3)
They provide evidence of conformity to requirements and the effective operation of our Quality Management System.
All such records are kept legible, readily identifiable and retrievable.

Records are considered a type of document; records are controlled according to the requirements of QP 7.5.3.

a) The company maintains quality records in order to provide evidence of conformance to requirements as well as to provide evidence of effective operation of the QMS. (Ref: QP 7.5.3, Control of Documents and Quality Records.)

b) ALSPI's procedures ensure that information contained within ALSPI's documentations is compatible with the technical documentation. ALSPI shall not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings.

c) ALSPI's quality system ensures that no factor (type, characteristic, etc.) defined within the Ex Certificate and technical documentation (e.g. schedule drawings) is modified.

d) ALSPI has a documented system that refers all related drawings to the relevant schedule drawings, Where there are common schedule drawings associated with more than one Ex certificate, ALSPI has a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings.

7 SUPPORT

e) Where ALSPI also has drawings for equipment not intended for use in explosive atmospheres, ALSPI has a system that enables both the related drawings and schedule drawings to be clearly identified,

f) Intertek is the notified body responsible for the quality system of each Ex certificate.

g) Ethical business practices are applied. We believe it would not be in the company's best interest to send technical documents that were misleading.

h) ALSPI has a documented procedure to annually check the validity of all Ex related certificates, standards, regulations and other external specifications. (Ref: QP 7.5.3, Control of Documented Information and EXDOC-000011, EX Standards Compliance Checklist.)

7.5.3 Control of Documented Information

REF: QP 7.5.3, Control of Documented Information.

As a minimum, the list of documents requiring control and retention, as far as applicable, shall be: those arising from regulatory requirements, all documents regulated by external certifying bodies, customer orders, contract review, training records, part specifications, drawings, bill of materials and inspection and test data (per batch), calibration data, sub-contractor evaluations, delivery data (customer, delivery date and quantity, including serial numbers where available).

Documented information is retained indefinitely in the company business management software to provide evidence of conformity to the requirements specified by ISO standard 9001:2015, *ATEX/IECEX*, and customer requirements and of the effective operations of our management system. All management system documents are controlled according to QP 7.5.3, Control of Documented Information.

8 OPERATION

8.1 Operational Planning and Control

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 4.4-1 which addresses the requirements and interactive needs. These are further delineated in each of the appropriate paragraphs of Section 8.

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.

8.2 Requirements for Products and Services

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.

8.2.1 Customer Communication

ALSPI 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.

- ALSPI produces hard copy product and services catalogues and catalogues for its divisions.
- ALSPI maintains a comprehensive website.
- Customers can contact ALSPI via phone, e-mail, fax and mail.
- Customer complaints are handled through the Sales Department.
- Customer Satisfaction Surveys are used to monitor customer satisfaction.

8.2.2 Determination of Requirements Related to Products and Services

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.

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.

8 OPERATION

8.2.3 Review of Requirements Related to Products and Services

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.
- ALSPI has the resources to meet the defined requirements.

The review ensures that any stated customer requirement is compatible with the Ex certificate e.g. equipment group, temperature class, type of protection, EPL and ambient temperature range.

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

8.2.4 Changes to Requirements for Products and Services

In cases in which product or service requirements are changed, ALSPI ensures that relevant documents are amended and relevant personnel are made aware of the changed requirements.

- 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 ALSPI and that relevant documentation is revised.
- *The person identified in clause 5.3 shall approve any changes that could compromise Ex compliance.*

8.3 Design and Development of Products and Services

Vice President of Engineering appoints persons responsible for planning, realization and management of product design and development and project management according to QP 8.3.1 Design or Development Project Creation.

8.3.1 General

The Design and Development procedures outline the processes for controlling the Design and Development process.

8.3.2 Design and Development Planning

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, ALSPI consistently exercises its organizational interfaces. Planning is maintained to its most current status, as appropriate, as design activities progress.

8 OPERATION

8.3.3 Design and Development Inputs

ALSPI 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.

Inputs are reviewed for adequacy, and ensures that all requirements are complete, unambiguous and not in conflict with each other. Records are maintained in compliance with section 7.5.3, Control of Documented Information.

8.3.4 Design and Development Controls

ALSPI performs systematic reviews of design and development at suitable stages in accordance with our design and development plan (Ref: 8.3.2). These reviews:

- evaluate if the results of design and development are able to meet requirements.
- identify any problems and propose necessary actions.

Representatives of those functions concerned with the design and development stage under review are participants in the reviews.

Records of the results of the reviews and any necessary actions are maintained. (Ref: 7.5.3)

The design control procedure assures that at appropriate stages of design, design verification is conducted in accordance with planned arrangements (Ref: 8.3.2) to assure the design stage output meets the design stage input requirements. Records of design verification and any necessary actions are maintained.

The design control procedure assures that design validation is performed in accordance with planned arrangements (Ref: 8.3.2) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practical, validation is completed prior to the delivery of implementation of the product. Records of the results of validation and any necessary actions are maintained.

8.3.5 Design and Development Outputs

ALSPI 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 outputs are 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.

8 OPERATION

8.3.6 Design and Development Changes

All design changes either initiated by ALSPI 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.

The person identified in 5.3 shall be involved in any changes that could affect Ex product compliance.

8.4 Control of Externally provided Processes, Products and Services

Alabama Specialty Products, Inc. has established, documented and implemented a Quality Management System (QMS), in accordance with the requirements of the ISO 9001:2015 and EN ISO/IEC 80079-34 Standards. It is not a stand-alone system, but is integrated within ALSPI'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 ALSPI provides them and that customers' needs and requirements are met. *The QMS ensures that product conforms to the type described in the Ex certificate and technical documentation.* 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.

8.4.1 General

Where ALSPI chooses to outsource any process that affects how our products meet requirements, ALSPI ensures control over such processes and maintains responsibility for meeting customer requirements. The QMS identified the type and extent of control over such outsourced processes.
while manufacture, testing and final inspection may be sub-contracted, the responsibility for ensuring conformance with the Ex certificate shall not be sub- contracted, suppliers that provide a product, process or service that can affect the product's compliance with the Ex certificate, shall only be selected after an evaluation has demonstrated that they have the capability of ensuring compliance with all specified requirements.

- *documented objective evidence that the supplier can provide a product, process, or service that is fit for its purpose shall be made by one or more of the following methods:*
    - *the supplier has an acceptable Ex quality system,*
    - *the supplier has a quality system certificate in accordance to the appropriate standard and with an acceptable scope,*
    - *a documented site assessment to ensure that all relevant controls are available, documented, understood and effective.*
- *suppliers providing calibration services (including verification on measuring devices by comparisons with calibrated equipment) shall be evaluated on their ability to meet stated requirements, in addition to 7.1.5.*

8.4.1 General

- *where the features affecting the type of protection cannot be verified at a later stage, e.g. encapsulated intrinsically safe circuits, then the product, process or service shall only be accepted by one of the following methods:*
    - *ALSPI can demonstrate that the control process implemented by the subcontractor ensures Ex compliance,*
    - *the body responsible for the verification of the quality system performs periodic audits at the sub-contractors.*

Suppliers not used for a period exceeding 1 year shall be re-evaluated in accordance with FC 8.4.2.

- *8.4.1, prior to the placing of a contract or a purchase order;*
- *requirements b) and c) are not mandatory for products, processes or services where ALSPI verifies conformance in accordance with 8.4.2;*
- *the ongoing ability of the supplier to provide conforming product, process or service shall be reviewed at periods not exceeding one year;*
- *ALSPI shall facilitate an arrangement whereby the body responsible for the verification of the Ex quality system may also verify aspects of any supplier's operation that affects the type of protection.*

8.4.2 Type and Extent of Control

A documented process, FC 8.4.2, Purchasing, 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. *Receipt or acceptance of a Declaration of Conformity according to Annex C does not absolve the manufacturer from responsibility to ensure conformity. It shall be confirmed that one of the following processes is used to verify the continued conformity of the materials critical to the applied type of protection, used in the production of the Ex equipment:*

- *Review of the Declaration of Conformity from the material supplier with in the supply chain that may impact the material characteristics; as applicable; to demonstrate that the material used in the production of the Ex equipment is in accordance with schedule drawings.*
- *Review of the manufacturer's confirmation that the material maintains the particular material property of concern; e.g. flammability, CTI, RTI, or UV resistance, chemical composition, physical properties.*
- *Review of the manufacturer's process and data for the validation of material characteristics.*
- *Confirmation that equipment testing necessary to confirm that the material is in accordance with the Ex certificate or schedule drawings is repeated as required.*

Alternative processes may be utilized if it can be demonstrated that they provide the same level of conformity. Records of the evaluation and necessary actions are maintained as quality records.

8 OPERATION

8.4.3 Information for External Providers

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

- Requirements for approval of product, processes, procedures, services and equipment.

- *Purchasing documents shall clearly describe the specific requirements pertaining to subcontracted product set out in the Ex certificate and the equipment documents (e.g. for process control, testing or inspection).*
- *for items where conformance cannot be verified after manufacture (e.g. encapsulated intrinsically safe circuits), the purchasing information shall set out the specific quality procedures, resources and sequence of activities relevant to the particular item.*
- *ALSPI shall define the method by which documents, e.g. technical specifications, stated in a particular purchase order remain traceable to the order.*
- *Where ALSPI does not provide such documents with subsequent orders, then ALSPI shall have procedures for ensuring that suppliers have current copies of documents and that their integrity is maintained.*
- *Requirements for qualification of personnel.*
- *Quality management system requirements.*

In cases where ALSPI intends to have verification and/or validation performed at the supplier's premises, arrangements and methods of product release are submitted in the purchase order information. This includes materials used in the Ex equipment is in accordance with scheduled drawings, material maintains the particular material properties (CRT, RTI, or UV resistance), chemical composition, physical properties, and necessary

testing to confirm that the material is in accordance with the Ex certificate or schedule drawings is repeated as required.

Prior to communicating the purchase information to the supplier, ALSPI ensures that the purchase requirements are adequate.

The verification of purchased product is performed in accordance with work instruction WI 8.4.2-1, 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.

8.5 Production and Service Provision

ALSPI 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.

8 OPERATION

8.5.1 Control of Production and Service Provision

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

- Quality control checks are performed;
- Evidence of completed inspections;
- Detailed process work instructions and specifications for all products;
- Criterial for workmanship and competence;
- Defining qualification criteria and approval of special processes prior to use;
- Approval of equipment and qualification of personnel;
- Requirements for records;
- Revalidation

ALSPI provides procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the product with type as described in the Ex certificate.

8.5.2 Identification and Traceability

ALSPI identifies the product throughout the product realization, identifying the product status with respect to monitoring and measurement requirements. ALSPI controls and records the unique identification of the product wherever traceability is a specified requirement. *ALSPI establishes and maintains procedures for product identification during all stages of production, testing, final inspection and placing on the market. Traceability is required with respect to the final product and its significant parts. Traceability can be achieved using serial number, batch or other acceptable methods.*

8.5.3 Property Belonging to Customers or External Providers

ALSPI exercises care with customer property while it is under the company's control or being used. A work instruction, WI 8.5.3-4, 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 in ERP System.

***No customer-supplied products/materials are used in the manufacturing of Ex products*.**

8.5.4 Preservation

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.

The manufacturer shall provide customers with instructions prepared in accordance with the relevant standards or statutory and regulatory requirements.

8 OPERATION

8.5.5 Post-Delivery Activities

Post-delivery support is usually contractual or regulatory, but not always, and may include but is not limited to:

- Engagement with customer to determine if the products or services were to their satisfaction.
- On-site installation of equipment.
- Contractual arrangements such as warranties or technical support.
- Frequently asked questions.
- Authentication of the products.

8.5.6 Control of Changes

ALSPI identifies any design and development changes and maintains records. Changes that impact parts or product form, fit or function will have applicable verification and validation performed and approvals prior to their implementation including, if applicable, approval by the customer, statutory or regulator authority. The review of design and development changes includes an evaluation on the effect of the changes on constituent parts and product already delivered. Ref: WI 8.5.6-1, Origination and Use of ECR/ECN.

8.6 Release of Products and Services

The verification of purchased product is performed in accordance with work instruction WI 8.4.2-1, 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.

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. 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. The following applies to Ex products:

- *Purchased products that can compromise the type of protection ALSPI shall determine and implement verification arrangements which demonstrate the product's compliance with the Ex certificate, taking into account the nature of the product and the nature of the supplier.*
- *When deciding what type of verification is required for a particular purchased product, ALSPI shall consider the nature of the purchased product, the supplier and how critical it is to the type of protection.*
- *Where the supplier has been evaluated, and documented objective evidence has been obtained to demonstrate that the supplier is fully capable of producing and verifying the product or service, no*

further verification of the product or service is required, provided a declaration of conformity according to ISO/IEC 17050-1 is supplied with each batch or product.

- *Where the Ex certificate specifies routine tests or inspections, these shall be carried out on each product, unless specifically permitted by the Ex certificate and the technical documentation, statistical methods shall not be used. They may be carried out by either the supplier or ALSPI. When carried out by the supplier, this shall be specified on the purchasing documents, e.g. by a quality plan, and confirmed by the supplier, e.g. by a declaration of conformity according to ISO/IEC 17050-1 including test results, if required.*
- *Where verification of a purchased product cannot be carried out after manufacture, e.g. the internal parts of encapsulated intrinsically safe circuits, then the product shall only be accepted if supplied with*
- *a declaration of conformity according to ISO/IEC 17050-1. This shall specifically state compliance to the purchase documents, e.g. a quality plan that lists the factors that together demonstrate conformity of the product*.
- *Where sample inspections or tests are permitted they shall be conducted in a manner which demonstrates conformity of the entire batch.*
- *Where either the supplier or ALSPI requires training or specialist skills or knowledge to carry out a verification, then the training material, specialist skill, knowledge or background shall be documented and training records maintained.*
- *Where ALSPI chooses not to carry out inspections and tests on their own premises, then inspections and tests shall be performed on the supplier's premises under the responsibility of ALSPI.*
- *Where a supplier provides product with evidence of conformity applicable to use in an explosive atmosphere (e.g. Ex certificate), then further verification is not required unless ALSPI considers it necessary.*
- *Where verification of a purchased product relates to the material (metals, alloys, nonmetallic parts, resins and similar), a specific analysis certificate or declaration shall be supplied.*

8.7 Control of Nonconforming Outputs

ALSPI ensures that products which do not conform to requirements are identified and controlled to prevent unintended use for delivery. ALSPI 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 10.2, Non-Conformity and Corrective Action. Records of the nonconformities and actions taken are kept in accordance with QP 7.5.3, Control of Documents and Quality Records. Nonconforming products are corrected and subject to re-verification after correction to exhibit conformity to product requirements.
The following applies to the control of nonconforming outputs in regards to Ex products:

- *ALSPI shall maintain a system such that in the event of the product not complying with the Ex certificate, and having been supplied, then ALSPI's customer can be identified.*

8.7 Control of Nonconforming Outputs

- *ALSPI shall take action, appropriate to the degree of risk, where a nonconforming product has been supplied to a customer.*

- *Where an unsafe nonconforming product has been supplied to a customer, ALSPI shall inform the customer in writing as well as the body responsible for the verification of the quality system, and the issuer of the Ex Certificate.*
- *Where it is not possible to trace the unsafe, nonconforming product (e.g. product supplied via a distributor or for high volume products such as cable glands) then a notice shall be placed in appropriate publications providing recommended action to be taken.*

- *For all nonconforming products that have been supplied to a customer, ALSPI shall maintain, for a minimum period of 10 years, records of:*

    - *Serial numbers or identification of products supplied*
    - *The customer who received the product*
    - *Action taken to inform customers and the body responsible for the verification*
    - *The quality system in the case of unsafe nonconforming product*
    - *Action taken to implement corrective action and update risk and opportunities.*

Concessions for the product that take it outside the design, as defined in the Ex certificate and technical documentation, are not permitted.

9 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

The company plans and implements suitable methods for determining which aspects of the quality management system and its processes are to be monitored, measured and evaluated. The frequency and methods by which our processes are monitored, measured and evaluated is determined and informed by:

- Statutory and regulatory requirements
- Customer specifications requirements and feedback
- Processes and QMS requirements
- Process performance and audit results
- Non-conformities and corrective actions
- Critical for service

All monitoring, measuring and evaluation outputs are documented and analyzed to determine process effectiveness and to ensure their effectiveness in achieving in-tolerance results, and to identify opportunities for improvement.

9.1.2 Customer Satisfaction

Customer satisfaction is one of the key indicators of the performance of our Quality Management System. ALSPI, therefore, monitors information relating to our customers' perception as to whether ASLPI has met customer requirements.

ALSPI has determined and established the methods used to obtain and to use this information. These methods include review of Customer Return Reports, repeat customer order volume, and a customer satisfaction survey that is posted on our website.

9.1.3 Analysis and Evaluation

ALSPI 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 9.1, Monitoring, Measurement, Analysis and Improvement. This includes data generated by monitoring and measurement activities and other relevant sources.

- Customer satisfaction and perception data (Ref:8.2.1)
- Conformity to product, customer and legal requirements (Ref: 8 6)
- The effectiveness of actions taken to address risks and opportunities
- Suppliers and external providers (Ref 8.4)
- Improvement opportunities identified during internal audits and management review

9 Performance Evaluation

9.2 Internal Audit

ALSPI conducts two internal audits annually to determine whether the quality management system conforms to the requirements of ISO 9001:2015 (1), EN ISO/IEC 80079-34, ATEX Directive 2014/34/EU (2) and company requirements and have been effectively implemented. The maximum period between audits is normally 12 months and shall not exceed 14 months.

ALSPI develops the audit plans 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.

9.3 Management Review

9.3.1 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.

- *The maximum intervals between reviews should normally be 12 months and shall not exceed 14 months.*
- *Top management shall chair the review.*
- *Personnel responsible for the activities detailed in 5.3 shall participate in the review*.

9.3.2 Management 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 – External & Internal Issues
- Recommendations for improvement

The review includes the overall effectiveness of the quality management system with respect to products intended for use in potentially explosive atmospheres.

9 Performance Evaluation

9.3.3 Management 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
- 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.

10 Improvement

10.1 General

Identification of continual improvement needs are determined by analyzing customer satisfaction information, product and process conformance data, supplier performance data, relevant interested parties, internal audit results and other data and information relevant to quality performance. Management review considers all pertinent 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.

10.2 Nonconformity and Corrective Action

ALSPI handles nonconformities in order to control and correct them and deal with the consequences, according to procedure QP 10.2-1, Control of Non-conforming Product and WI 10.2-1, Issue and Handling of Corrective Action Request.

Concessions for the product that take it outside the design, as defined in the Ex certificate and technical documentation is not permitted.

10.3 Continual Improvement

ALSPI initiates actions to continually improve the suitability, adequacy and effectiveness of the QMS. Continual improvement techniques and processes are applied to areas of the business that have an impact on the quality of our products and services. We analyze customer satisfaction information, product and process conformance data, supplier performance data, internal audit results and other data and information relevant to quality performance. We take necessary actions on results of improvement projects as well as from the Management Review, which 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, and verify effectiveness of actions taken to address risks and opportunities for continual improvement.

The implementation of the “Process Approach” including the PDCA Cycle and Risks provides verifications that our QMS is solid, and the achievement of effective process performance.