| QUALITY SYSTEMS MANUAL | | | |
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| **Approved By** | Management Representative | **Revision** | 14 |

# QUALITY SYSTEMS MANUAL

## Revision History

| Rev. | Reason for Change | Approved By | Effective |
|---|---|---|---|
| 14 | Change in scope of registration, change in core values, | Emma Sebeey | 03/31/2020 |
| 13 | Reviewed and revised in preparation for ISO 9001 system upgrade | Emma Sebeey | 06/13/2017 |
| 12 | Remove references to EMCO from Document and updates | Emma Sebeey | 06/24/2016 |
| 11 | Reformatted and added traceable table of content | Emma Sebeey | 03/15/2015 |
| 10 | Need to change President to Lorraine, also review the other signatures and organization chart | Lorraine Wiseman | 04/14/2014 |
| 9 | PED Module "D1" to "H" to reflect upgrade of PED scope. Other minor changes to reflect Longmont location versus LONGMONT Flow Systems, add full scope to section 1.0 to reflect scope on certificate. | Pat A Tillisch | 01/01/2012 |

This document is available on the Quality site of Spirax Sarco Inc. iShare page. A single hard copy will be printed upon request in order to maintain and manage this controlled document.

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# Introduction

Spirax Sarco, Inc. developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of Spirax Sarco, Inc. customers, and improve the overall management of the company.

This manual describes the Quality Management System, delineates authorities, inter relationships, and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality System to ensure compliance to the necessary requirement of the most recent ISO 9001 International Standard.

This manual is used internally to guide Spirax Sarco, Inc. employees through the various requirements of the ISO 9001 International Standard that must be met and maintained in order to ensure customer satisfaction, ensure regulatory compliance, support continuous improvement, and provide the necessary instructions that create an empowered workforce.

This manual is used externally to introduce Spirax Sarco, Inc. Quality System to our Customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality System is maintained in accordance to regulatory requirements and focused on customer satisfaction and continuous improvement.

As the Top Management (SLT), we are committed to support the continuous improvement of the Spirax Sarco, Inc. ISO 9001 Quality System set forth in this manual.

# Company Background

Spirax Sarco, Inc. is the USA's leading provider of steam system solutions. For over 100 years, the company has been committed to servicing steam users and is the recognized industry standard for steam specialties. We are dedicated to providing knowledge, service, and products for the control and efficient use of steam and other industrial fluids.

The existing and potential applications for steam, water, and gases are virtually unlimited. Beginning with steam generation, through distribution, utilization, and ultimately returning condensate to the boiler, Spirax Sarco, Inc. provides solutions to optimize steam systems and increase productivity to save valuable time and money. The company's vast knowledge of steam applications in conjunction with its wide product range has become an integral part in energy conservation in industry as well as commercial applications throughout the world.

In the USA, Spirax Sarco, Inc. is headquartered in Blythewood, South Carolina. Our manufacturing plant, Sales and administrative functions are centered there. In addition, we have our own field sales team and distributors. Spirax Sarco, Inc. operates five training centers with locations in Chicago IL, Houston TX, Allentown, PA and Blythewood, SC.

Today the Spirax Sarco PLC employs over 4000 people in more than 60 countries. Worldwide, the group employs about 1200 specialist engineers and has 12 manufacturing plants.

## PURPOSE STATEMENT

**Spirax Sarco, Inc. exists to consistently provide an acceptable return on our stockholders' investments, while providing mutually beneficial prosperity and sustainability for our customers, employees, business partners and communities.**

## MISSION STATEMENT

**We provide expertise and solutions that help our customers meet their sustainability goals based on our quality and performance. We will fulfill our mission through our organizational values of:**


Spirax-Sarco Engineering plc

## VISION STATEMENT

**To be first in solutions for steam and related fluids**

# STATEMENT OF AUTHORITY

This manual has been constructed to reflect the Quality Principles for Spirax Sarco, Inc.

This manual resides on the company intranet on iShare where it is maintained on a controlled copy basis. All employees are aware to always retrieve the most up to date version from the intranet. This Manual contains Spirax Sarco, Inc. proprietary information and is not to be reproduced or distributed without written permission of Quality Assurance.

The Quality Procedures Program is administered by the President, with responsibility through the Management Representative for maintenance, distribution, interpretation and compliance of the written quality system manual.

In order to consistently and uniformly meet these requirements, it is mandatory that all duties and tasks delegated through the various organizational functions be implemented in accordance with this written quality system manual, latest edition. Preparation, planning, and commitment by the Management Representative will prevent most implementation obstacles. The Management Representative has the authority to stop production at any time until corrective action has been made; but in the unlikely event of conflict the ultimate decision regarding priorities, schedules and/or resources shall be resolved by the President of SSI.

Management Representative will conduct a review of this manual every year. Revisions to any part of the established procedures shall require approval by the Department Manager affected and the Management Representative.

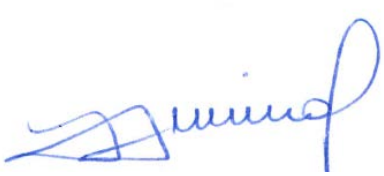
Javier Jimena
President and General Manager

# QUALITY POLICY STATEMENT

***We are committed to providing products and services that meet or exceed our customers' expectations for availability, safety, environmental stewardship, functionality, reliability and value.***

***We support our commitment to the quality processes that continually improve our performance by:***

- **Establishing measurable objectives for the business and communicating them to our people;**
- **Providing training and learning opportunities for stakeholders, channel partners and all customers;**
- **Seeking Customer input and measuring our performance;**
- **Addressing non-conformities and pursuing continuous improvement in all parts of our business, and**
- **Operating safely and in regulatory compliance.**



**Javier Jimena**
**President and General Manager**

# 1.0 Scope

The scope of the Spirax Sarco, Inc. Quality Management System includes: Design, Manufacture, Distribution and Servicing of Boiler Controls, Flow Meters, Controls and Regulators, Steam Trapping, Condensate Recovery, Strainers, Liquid Drain Traps, Pipeline Auxiliaries, Valves, Steam Technology Training Center and Engineered Systems such as Thermal Energy Management Solutions and Pump Packages.

## 1.1 General

Spirax Sarco, Inc. recognizes its responsibility as a provider of quality products/services. To this end Spirax Sarco, Inc. has developed and documented a quality management system. The quality system complies with the statutory and regulatory requirements of ISO 9001:2015, Pressure Equipment Directive 2014/68/EU Annex III Module H Quality Management Systems and Canadian Standards Association (B51-03) Boiler, Pressure Vessel and Pressure Piping Code – Requirements, American Society of Mechanical Engineers (ASME), The National Board of Boiler & Pressure Vessel Inspectors (NB) and ISO 10012 International Standard. This manual provides all customers, suppliers, and employees with comprehensive information detailing what specific controls are implemented to ensure that these statutory and regulatory requirements are applied to product/service quality.

## 1.2 Application

This manual is a controlled document, applicable to all activities at the Spirax Sarco, Inc. facilities at Northpoint and Carolina Pines in Blythewood, South Carolina including the Training Center in Blythewood SC. The major functions summarized herein are intended, as general guidelines for control of elements deemed critical to the quality of the products/services offered to our customers. These functions are documented where necessary and incorporated as a part of the Spirax Sarco, Inc. quality system and the guidelines will be followed by all personnel.

Documented information will be reviewed periodically to assure day-to-day business needs are satisfied. Recommendations for change may be submitted by any user. Each will be reviewed to evaluate the benefits. All changes must be approved by Spirax Sarco, Inc. management or designated management representative prior to incorporation. Following implementation, the change will be monitored to assure the desired result is obtained.

# 2.0 Definitions

- **Customer Owned Property -** Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
- **Customer Supplied Product –** Any type of service or material supplied to be utilized in manufacture, modification or repair of customer owned property.
- **Product/Service –** The end item result of meeting all contract terms and conditions. (e.g. manufactured goods, merchandise, services, training etc.)
- **Supplier –** The party to whom an order has been placed by the organization for the purchase of supplies, or the execution of a specific part of a particular order.
- **Customer –** The external or internal recipient of a product or service.
- **Organization –** Spirax Sarco, Inc.
- **Top Management –** The Strategic Leadership Team (SLT) consisting of the President, Vice Presidents and Directors of major business department of the organization.
- **Management Team –** The Management Team has responsibility for the major departments of the

organization and includes Top Management.

# 3.0 Quality Management System

## 3.1 General Requirements

The organization's Management has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2015, Pressure Equipment Directive 2014/68/EU Annex III Module H Quality Management Systems and Canadian Standards Association (B51-03) Boiler, Pressure Vessel and Pressure Piping Code – Requirements, American Society of Mechanical Engineers (ASME), The National Board of Boiler & Pressure Vessel Inspectors (NB) and ISO 10012 International Standard. .

To design and implement the QMS within its organizational environment and considering the associated risks, the organization has:

- Identified the main processes throughout the organization,
- Determined the sequence and interaction of these processes, as illustrated in Appendix A,
- Determined particular objectives, criteria and methods needed to ensure that operations and control of processes it employs are effective and documented through quality plans, procedures and management reviews, and
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes and products it provides.

The organization maintains control over and responsibility for all processes that affect product/service conformance to requirements, regardless of whether the process is completed internally or by an external supplier.

## 3.2 Documentation Requirements

### 3.2.1 General

The QMS documentation includes:

- Documented information required in ISO 9001 International Standard such as the quality policy,
- Policies and procedures required by the organization to ensure the effective planning, operation and control of its processes.

### 3.2.2 Quality Manual

This Quality Manual has been prepared to describe the organization's QMS. The scope and permissible exclusions of the QMS are described in ***Section 1.0*** of this manual. Each applicable section of this manual references documented QMS procedures and processes relating and/or supporting the requirements outlined in that section. The Process based illustration in Appendix A, outlines the end to end business processes within the QMS.

### 3.2.3 Control of Documents

All QMS documents are controlled according to documented procedure that defines the process for:

- Approving documents for adequacy prior to issue,
- Reviewing and updating as necessary and re-approving documents,

- Ensuring that changes and current revision status of documents are identified,
- Ensuring that relevant versions of applicable documents are available at points of use,
- Ensuring that documents remain legible and readily identifiable,
- Ensuring that documents of external origin determined by the organization to be necessary are identified and their distribution controlled, and
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

### 3.2.4 Control of Quality Records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. Records are maintained according to documented procedure for controlling all aspects of quality records in use. Records are to be legible, permanent and non-erasable. Records shall be maintained in a manner that they are readily retrievable and contained in a suitable environment to prevent damage or deterioration.

# 4.0 Management Responsibility

## 4.1 Management Commitment

Top Management is actively involved in implementing the QMS by taking accountability for the effective implementation of the QMS, and establishing a robust quality policy and quality objectives which align with the strategic direction of the organization.
Management continues to provide leadership and show commitment to the improvement of the QMS by:

- Integrating the QMS requirements into the business processes,
- Communicating the importance of consistently meeting customer, statutory, and regulatory requirements,
- Establishing quality objectives and plans as necessary and ensuring the QMS achieves it intended results,
- Clearly defining the roles and responsibilities of all functions affecting quality and ensuring that resources needed to the QMS are available,
- Establishing a quality policy, which is understood and implemented at all levels of the organization,
- Conducting management reviews at defined intervals sufficient to ensure the effectiveness of QMS,
- Addressing risks and opportunities identified within the business and promoting the process approach,
- Ensuring provisions for the necessary resources and personnel needed to maintain the QMS.

## 4.2 Customer Focus

The organization continues to focus on our customers and ensures that all customer and applicable statutory and regulatory requirements are determined, understood and consistently achieved. The risks and opportunities that can affect conformity of product and services and the ability to enhance customer satisfaction are continually evaluated and addressed. Top Management ensures that customer requirements are clearly understood and communicated and the appropriate processes are developed, implemented and continually improved to meet and exceed customer requirements.

## 4.3 Quality Policy

Top management lead by the President and General Manager is responsible for ensuring that the Quality Policy Statement is communicated, understood, implemented, and maintained at all levels of the organization. The quality policy is posted in prominent places throughout the organization. The policy is available as a controlled document in the document management system. The President, Management Representative, and Top Management reviews the quality policy at least annually at management review meetings to determine the policy's continuing suitability for the organization.

## 4.4 Planning

### 4.4.1 QMS & Quality Objectives Planning

Quality objectives are established at relevant functions, levels and processes to support Quality Policy and any applicable requirements. Top Management continuously reviews the Business objectives and ensures there is alignment with the defined Quality Objectives. These objectives are maintained as documented information and are relevant to product conformity and customer satisfaction, consistently monitored, measured and communicated through Key Performance Indicators (KPIs). The objectives are communicated via different media identified by the organization such as emails, meetings, bulletin postings and memos; to be the most suitable and effective at reaching each and every employee.

When planning to achieve quality objectives, the organization agrees on what to measure, identifies the owner of each KPI and resources needed to support the owner, target dates to achieve results.

### 4.4.2 Planning for Change

When a need for significant change in the QMS arises, these changes are carried out in a planned manner. These changes are review with Top Management during the Management Review meeting and take into consideration the purpose for change, its consequences, impact to QMS, resource availability and the allocation or reallocation of responsibilities and authorities. All other business process changes are handled through the Management of Change (MOC) Process.

### 4.4.3 Addressing Risk and Opportunities

Top management continually review issues, both internal and external, that could potentially affect the organization's ability to achieve strategic objectives or impact customer satisfaction. These strategic objectives are aligned with the Quality Objectives and are monitored continuously. Each department is required to assess the risk associated with its activities that effect the company's quality objectives.

A risk and opportunities register exist and is reviewed annually by senior management. A high level "interested parties" register is maintained to support the QMS.

## 4.5 Responsibility, Authority and Communication

### 4.5.1 Responsibility and Authority

An Organizational Chart has been established to show the interrelation of personnel who manage, and are directly responsible for affecting quality. A business Organization Chart is maintained on the company intranet. Personnel are made aware of their responsibility, authority and to whom they report during orientation, job descriptions and training.

### 4.5.2 Management Representative

The Quality Group Leader has been appointed by the President as the Management Representative with the

authority and responsibility for the development, overall implementation, conformity and maintenance of the QMS together with the control and issue of all quality documentation.

#### 4.5.3 Internal Communication

Top Management is to promote awareness of the quality policy, disseminate progress on quality performance and customer satisfaction and changes in the QMS. This promotion may include activities such as thorough management review meetings, management meetings, orientation, training, internal audit closing meetings, announcements, posting, access to quality documentation, and other routine business communication.

### 4.6 Management Review

#### 4.6.1 General

The Quality Group Leader facilitates the Management Review Meetings in accordance with procedural documentation with Top Management at intervals of at least once a year. This review assesses the continuing effectiveness of the QMS and identifies opportunities for improvement and needed changes. Management Review records are maintained as outlined in the procedure document.

Management review inputs and outputs are planned to meet the requirements in ISO 9001 International Standard.

During management review meetings decisions are made. Required actions are assigned to appropriate Top Management personnel and are recorded in the minutes of management review.

## 5.0 Resource Management

### 5.1 Provision of Resources

Top Management has the responsibility to ensure that the resources, essential to the achievement of the organization's objectives, including implementing, maintaining and improving the QMS, and enhancing Customer satisfaction are identified during the quality planning. Resource requirements are usually planned during the budgeting process and adjusted during the year in response to sales growth, profit plans, capacity constraints, changing customer requirements, and other internal needs. Top Management is to review the adequacy of resources and adjustments that are to be made based on identified business needs.

### 5.2 Human Resources

#### 5.2.1 General

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

#### 5.2.2 Competence, Awareness and Training

Qualifications are reviewed during recruiting, when an employee changes positions and/or the requirements for a position change. Human Resource maintains records of employee qualifications. If any differences between the employee's qualifications and the requirements for the assigned job are found, training or other action is taken to provide the employee with the necessary competence for the job assignment. The results, where applicable, are evaluated to determine the necessary competence. The company deploys performance management systems to

compliment managing on the job competence and ensuring employee continuous suitability for the jobs.

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

### 5.2.3 Organizational Knowledge

Appropriate business processes have been put in place to identify areas where tacit knowledge exist and implements programs to safeguard the organization from loss of that knowledge. These programs foster learning from experienced employees, mentoring, as well as documenting processes and procedures. Where applicable, knowledge is maintained as seen fit by the company. The people managers are responsible for identifying positions that are at risk for organizational knowledge and put in place development plans to mitigate.

## 5.3 Infrastructure & Work Environment

The organization has determined the infrastructure needed to achieve conformity to quality objectives and product/service requirements. The infrastructure has been provided and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented in quality plans through the management of change processes for the respective areas.

Facilities, including workstations and associated equipment are maintained in a state of order, cleanliness, and repair appropriate to the product(s) manufactured or to the service being provided. All work areas must comply with established safety, regulatory and environmental standards and codes. Existing infrastructure are maintained to ensure product/service conformity.

Maintenance requirements are documented through scheduled maintenance activities or planned preventive maintenance activities.

A robust safety program is in place to ensure the continued assessment of all risk related to employee safety and contributing factors to those risks. Consideration and feedback from employees is critical within this program.

# 6.0 Operation

## 6.1 Operation Planning and Control

The organization has determined all the requirements necessary to plan, implement, and control processes to meet product/service standards. All associated risk to each process has been reviewed and actions determined to ensure a consistent output including the definition of acceptance criteria - as required in the ISO 9001 International Standard.

## 6.2 Product and Service Requirements

### 6.2.1 Determination of Requirements Related to Products and Services

The organization determines customer requirements in accordance with procedural/process documents before acceptance of an order. Customer requirement include those:

- Requested by the customer,
- Required for delivery and post-delivery activities, (i.e. warranty, contractual etc.)
- Not stated by the customer, but necessary for specified use or known intended use,

- Statutory and regulatory requirements applicable to the product, and
- Additional requirements considered necessary by the organization.

### 6.2.2 Review of Requirements Related to Products and Services

The organization determines the process for reviewing requirements related to the product/service in accordance with procedural/process documents. The review is conducted before the order is accepted to ensure that:

- Product/service requirements are defined,
- Contract or order requirements differing from those previously expressed are resolved,
- The organization has the ability to meet the defined requirement,
- Records are maintained showing the results of the review and any actions arising from the review,
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance, and
- When product/service requirements are changed, the organization communicates changes to relevant personnel and amends relevant documents its associated processes.

### 6.2.3 Customer Communication

The organization has determined and implemented procedural/process documents for communicating with customers in relation to:

- Product information,
- Inquiries, contracts and order handling, including amendments,
- Customer feedback, including customer complaints,
- Handling or controlling customer property,
- Establishing specific requirements for contingency actions when relevant.

## 6.3 Design and Development

### 6.3.1 Design and Development Planning

The organization's process for design and development is carried out in accordance with procedural/process documents. Engineering/Drafting receives new design and development planning through the Sales and Marketing team as well as feedback from customers through warranty returns for product improvements. The design planning process is developed to meet the requirement of ISO 9001 International Standard through a stage gate process.

### 6.3.2 Design and Development Inputs, Controls & Outputs

Design inputs from Product Management relating to product requirements are determined in accordance with procedural/process documents. Inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs/outputs with those responsible for imposing these requirements.

The design plan specifies suitable stages of the project to conduct design and development review. These controls

are carried out in accordance with procedural/process documents. Records of design review activities and resulting actions are maintained in accordance with procedural documents.

Outputs of design and development are documented in accordance with procedural/process documents. Design outputs are expressed in terms that can be verified and validated against design inputs, and are approved prior to release. Design inputs, controls and outputs meet the requirements of ISO 9001 International Standard as well as any statutory and regulatory requirements.

### 6.3.3 Design and Development Verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Design verification results and/or any necessary actions are maintained in accordance with procedural/process documents.

### 6.3.4 Design and Development Validation

Design and development validation is performed according to the design plan to ensure compliance with the product specification and/or known intended use or application. Validation is completed prior to delivery whenever practicable. When necessary, actual testing may be performed at other qualified test facilities, but shall be under the coordination and approval of Engineering/Drafting receiving the initial test request. Records of validation activities are maintained in accordance with procedural documents.

### 6.3.5 Control of Design and Development Changes

Design and development changes are identified, documented, reviewed, validated, and approved in accordance with procedural/process documents by authorized personnel prior to delivery and/or implementation. The review of design and development changes includes an evaluation to ensure that the changes do not adversely affect product quality, performance, and/or reliability. Records of changes during the development process are maintained.

## 6.4 Purchasing

### 6.4.1 Purchasing Process

Procedural documents controlling all aspects of purchasing functions are implemented to ensure that purchased product/service conforms to specified purchase requirements. These documented procedures outline the extent of control required for suppliers. Suppliers of production material, components and assemblies, as well as services suppliers that could impact product quality or delivery are to be evaluated, selected, and/or re-evaluated in accordance with procedural documents prior to classifications as an approved supplier. The supplier excellence manual provides guidelines on the intended approach to managing suppliers to conform to business requirements. In this manual, the organization makes clear the quality expectation of processes, products and services to be provided, the approval of products and services, methods and processes, and criteria for release of products and services. Where necessary, competence of personnel is specified. Supplier KPIs are monitored by the organization, where necessary verification and validation activities can be performed at supplier premises. Records of the results of evaluations and any necessary actions resulting from supplier evaluations are maintained in the business systems designed by the Purchasing group of the organization.

### 6.4.2 Purchasing Information

Purchasing information describes the product to be purchased. Where appropriate, this includes:

- Purchase Orders (PO) placed with suppliers is to define the product, the revision level and any additional quality system requirements.
- Authorization for Expenditures (AFE) placed with suppliers is to define the product, the project number/date and any additional quality system requirements.

Purchasing documents are reviewed by qualified personnel to ensure the adequacy of requirements before orders are placed with the supplier.

### 6.4.3 Verification of Purchased Product

Procedural documents describing the processes are used to verify that purchased product meets specified purchase requirements. This is outlined in the process for Receiving Inspections for product. If the organization or the customer performs verification at the supplier's premises; the verification arrangements and method of product release are documented in the purchasing information.

## 6.5 Production and Service Provision

### 6.5.1 Control of Production and Service Provision

Identification and planning of production and service processes that directly affect quality are carried out under controlled conditions, which include, as applicable:

- The availability of information that describes the characteristics of the product and results to be achieved,
- The availability of work instructions,
- The use of suitable equipment, the availability, implementation and use of monitoring and measuring equipment to verify criteria for control of processes or outputs and ensuring acceptance criteria is met,
- The appointment of competent personnel and periodic verification to achieve planned results and the implementation of product release, delivery and post-delivery activities.

### 6.5.2 Validation of Processes for Production and Service Provision

The organization 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 and as a consequence 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, which includes the following:

- Defined criteria for review and approval of the processes,
- Approval of equipment and qualification of personnel,
- Use of specific methods and procedures,
- Requirements for records, and
- Revalidation if necessary.

### 6.5.3 Identification and Traceability

Where appropriate the organization identifies the product/service by suitable means throughout product realization, identifying the product/service status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization controls the unique identification of the product/service and maintains records.

### 6.5.4 Customer Property

Procedural documents for the control of identification, verification, protection, and safeguarding of customer property, while under the organization's control, has been established and maintained. Any such product that is either lost, damaged, or is otherwise unsuitable for use, is reported to the customer and records maintained.

### 6.5.5 Preservation of Product

Procedural documents are established and maintained for handling, storing, packaging, preserving, and delivering product in order to maintain conformity to requirements. Product is maintained and stored in such a way that first goods in are consumed/sold

Designated distribution warehouse storage areas and/or general warehouse storage areas are utilized to prevent damage or deterioration of product - pending use or delivery.

## 6.6 Control of Monitoring and Measuring Equipment

The organization has established processes to ensure that business processes are capable of consistently producing the required output through effective adoption and implementation of measurement systems.

Measuring equipment (where necessary) will be managed using the company designated Calibration Management System. The designated system will meet ISO 9001 International Standard as well as any required statutory and regulatory requirements.

In addition, a process has been established that assesses the validity of previous inspections and test results when measuring equipment are found to be out of calibration. Customer notification/ product recall is considered if suspect product was shipped. Suspect product still in inventory will be quarantined, and evaluated using the non-conforming product process and corrective action report requests raised if needed. Records of this assessment are maintained as deemed required.

# 7.0 Monitoring, Measurement, Analysis and Improvement

## 7.1 General

The organization plans and implements the monitoring, measuring, analyzing, evaluating and improving processes as needed:

- Processes shall have sufficient controls, at all stages, to ensure that only acceptable products are delivered to internal operations and/or to the external customer. Records are maintained,
- To ensure conformity of the QMS and strategic goals, and
- To continually improve the effectiveness of the QMS.

These processes are identified and include determination of applicable methods, including statistical techniques, and the extent of their use.

## 7.2 Monitoring and Measurement

### 7.2.1 Customer Satisfaction

The organization has established documented process for determining customer satisfaction, including frequency of determination, and how objectivity and validity are assured. Trends in customer satisfaction and key indicators of customer dissatisfactions are documented and supported by objective information. Customer satisfaction data is received in a variety of methods, including but not limited to:

- Feedback received in response to answer to customer complaints,
- Dialogue between the customer and Field Sales and/or Product Management,
- Lost business,
- Supplier evaluation, and
- Meeting with customers

### 7.2.2 Internal Audit

Quality System audits are conducted at least annually by the organization registrar and internal audits to verify compliance with planned arrangements, effectiveness, and suitability to meet objectives to organization QMS.

The organization conducts internal audits of the QMS in accordance with procedural document at regular intervals based on status and importance of the activity. Internal audits of the QMS are carried out by personnel selected to ensure objectivity and impartiality of the area being audited.

The Management, of the area being audited, have the responsibility for ensuring that actions are taken without undo delay to eliminate detected nonconformities and their causes. Follow-up audit activities are verified and record the implementation and effectiveness of the corrective action taken.

### 7.2.3 Monitoring and Measurement of Processes

The organization applies suitable methods for monitoring and, where applicable, measuring of the QMS.

Results of audits of the QMS, coupled with the assessment of Customer satisfaction and dissatisfaction are indicators of the effectiveness of the defined QMS. When audits determine an inadequacy in the implementation of the QMS, appropriate corrective action shall be taken in accordance with this business procedure.

### 7.2.4 Monitoring and Measurement of Product

Product characteristics are measured and monitored at appropriate stages (as deemed appropriate throughout the manufacturing process) to ensure that the product meets the established requirements.

Evidence of conformity with the acceptance criteria is maintained and records identify the individual(s) completing the activities.

## 7.3 Control of Nonconforming Product

The organization ensures that nonconforming or suspect nonconforming product is identified and controlled to prevent inadvertent further processing by storing in an area that is visually identified and segregated for this purpose.

Review and disposition of nonconforming or suspect nonconforming product is coordinated in accordance with procedural document.

## 7.4 Analysis and Evaluation of Data

The organization analyzes and evaluates appropriate data arising from monitoring and measurement. The results of the analysis is used to evaluate business process performance and foster continual improvement. Characteristics and trends of processes and products, including opportunities for preventive action.

## 7.5 Continual Improvement

The organization continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management reviews.

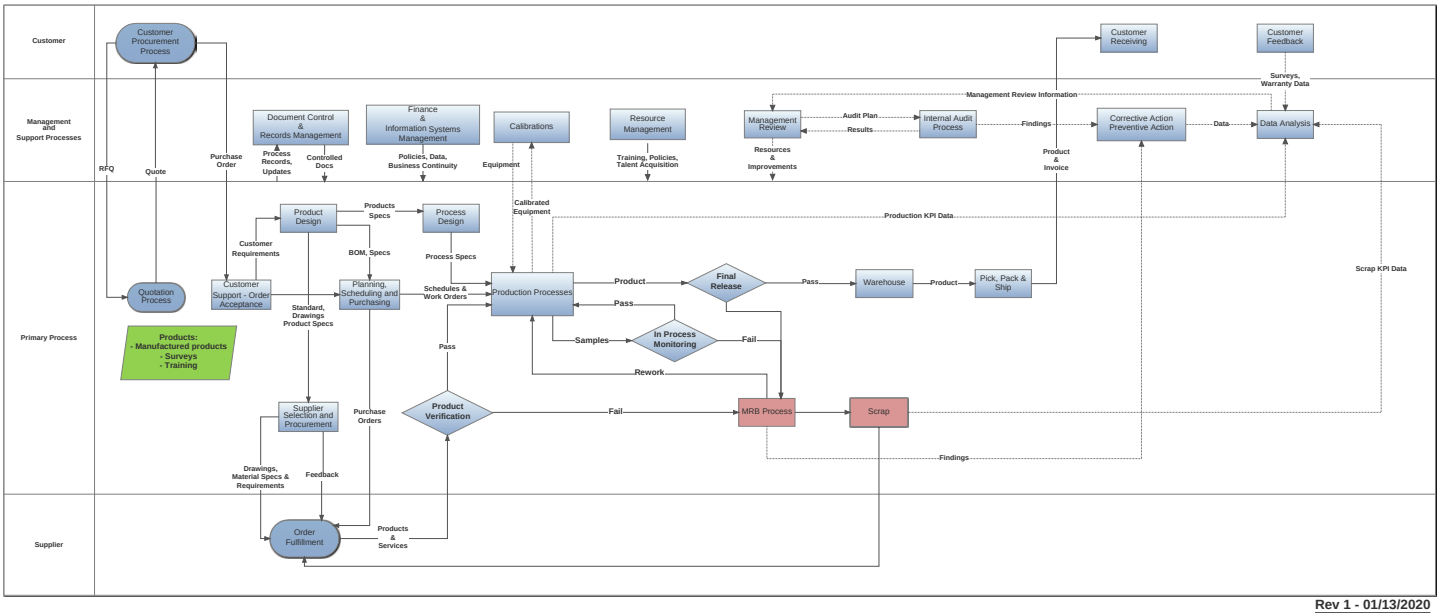
### 7.5.1 Corrective and Preventive Action

The organization takes appropriate action to eliminate the cause of nonconformities in order to prevent recurrence. When potential nonconformities are identified, the organization determines actions to prevent their occurrence. The business process document outlines the approach to addressing nonconformities with resulting follow up actions to prevent occurrence.

# 8.0 Appendix

## 8.1 Appendix A

SPIRAX SARCO "QMS" Business Process Map

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