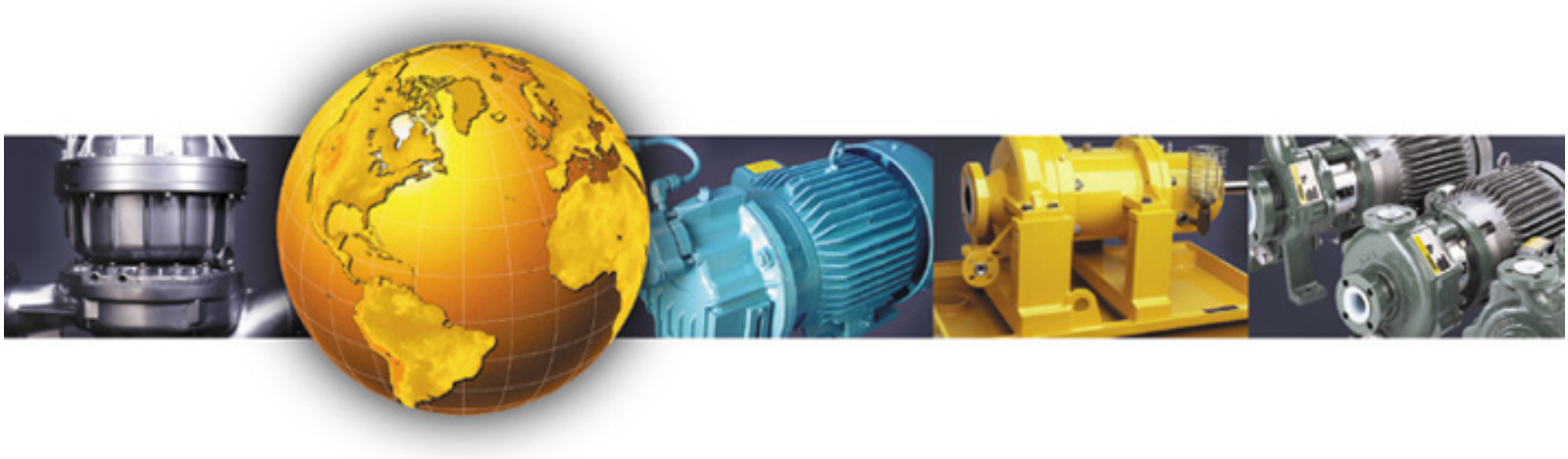
Sundyne LLC

QUALITY MANUAL



Sundyne

TABLE OF CONTENTS

Appendices

1.0 INTRODUCTION

1.1 General

Sundyne has implemented a Quality Management System (QMS) to:

- better understand and meet customer requirements,
- provide a mechanism for company personnel and customers to clearly understand the company's policies and procedures, and
- promote continual evaluation and improvement of business and quality processes in the ongoing pursuit of organizational and operational excellence.

Sundyne recognizes that successful implementation of a QMS will lead to improved discipline and clarity of day-to-day job functions for staff members, reduced waste and scrap, improved customer satisfaction, and increased company profitability.

The QMS implemented by Sundyne as outlined in this manual is available to all company personnel and customers as a single-source document regarding the company's policies and procedures for assuring control of processes and quality of products and services. This manual reflects and enables Sundyne's relentless commitment to total customer satisfaction and continual improvement.

1.2 Company Information and History

Sundyne LLC is a wholly owned subsidiary of parent company *Accudyne LLC*, a joint venture between The *Carlyle Group* and *BC Partners*. Sundyne is the company's common name and one of the company's brand names for its products and services.

1.2.1 What We Do

Sundyne designs and manufactures reliable industrial pumps and compressors.

Sundyne pumps are manufactured to meet industry standards including ISO 13709, API-685, API-610, ANSI, & ISO. Pump types OH1, OH2, OH5, OH6, ANSI, BB1, BB2, BB3, VS2, & VS4, centrifugal, close-coupled, gear driven, single stage, multi-stage, sealless magnetic drive non-metallic/metallic, displacement, high-pressure, in-line, vertical, and vertically suspended. Legacy pump brands in the Sundyne family include Ansimag®, Sunflo®, HMD/Kontro® and Marelli®. The Sundyne family of centrifugal pumps are used in process industries including refining, petrochemical, fertilizer production, pharmaceutical processing, steel, silicon development, chemical processing, power generation, pulp and paper, pipeline, beverage production, food processing including hot oils, municipal water, agricultural water, osmosis, waste water, wash water, and fire suppression.

Sundyne centrifugal integrally geared compressors are engineered to run continuously for 7 years under API-617 and API-614 standards. The high-speed, high-pressure compressors are available in both single and multi-stage configurations. Specialty engineered skid-packages are available to meet work in the harshest environments including refineries and off-shore platforms. Markets for Sundyne compressors include refining, petrochemical, gas processing, LNG, sulfur specialty gases, silicon manufacturing, chemical processing, power generation, oil and gas production, pipeline, and refrigeration.

Sundyne aftermarket services include Sundyne Genuine® spare parts, overhaul and repair, packaging, specialized engineering and technical support.

1.2.2 Sundyne Headquarters

Arvada, Colorado (12 miles northwest of Denver, CO)

1.2.3 Manufacturing Facilities

- Arvada, Colorado
- Dijon, France
- Eastbourne, England
- Illescas, Toledo-Spain

1.2.4 Sundyne Employees

More than 900 – approximately 400 located outside of the US.

1.2.5 Core Values

1.2.6 Customers

More than 2,000 customer sites in 117 countries.

1.2.7 Sundyne Product Brands

- Sundyne centrifugal integrally geared low flow - high head ISO 13709/API-610 standard pumps
- Sundyne centrifugal integrally geared high-speed compressors API-614/617 standards
- Sunflo medium-duty centrifugal integrally geared non-API pumps especially suited for high pressure water applications
- ANISIMAG centrifugal seal-less magnetic drive ANSI standard lined pumps

- HMD and Kontro centrifugal seal-less magnetic drive pumps including standard API-685
- Marelli Bombas centrifugal multi-stage pumps that meet ISO 13709/API-610 standards
- Pressure Products Industries (PPI) diaphragm compressors

1.2.8 Patents

Sundyne owns 40 patents.

1.2.9 Technology and Business Milestones

- 1905 – The Rockford Milling Machine Company, owned by Edwin Cedarleaf and brothers Oscar and David Sundstrand, begins operations.
- 1926 – The Sundstrand Machine Tool Company is formed through the merger of the Rockford Tool Company and the Rockford Milling Machine Company.
- 1933 – The Sundstrand Machine Tool Company sells the first oil burner pump. Hydraulic pumps, motors and valves are also developed.
- 1957 – Sundstrand develops the first water injection pump for the commercial jet aircraft industry. The pump is designed to boost engine thrust during takeoff.
- 1962 – Sundstrand develops the first Sundyne high-speed centrifugal pump and sells it to Shell Chemical.
- 1965 – Sundstrand develops a high-speed process gas compressor and sells it to Union Carbide.
- 1970 – Sundstrand Fluid Handling Division is established in Denver, Colorado. Nikkiso-Sundstrand Fluid Handling Joint Venture is established in Japan and Sundstrand Fluid Handling opens manufacturing plan in Dijon, France. New division manufactures industrial pumps and compressors and other engineered packaging for the hydrocarbon and chemical processing industries.
- 1994 – Sundstrand Fluid Handling acquires Kontro, HMD Seal-less Ltd., and SINE Pump.
- 1998 – Sundstrand Fluid Handling acquires ANSIMAG Inc.
- 1999 – United Technologies Corporation acquires Sundstrand Corporation and merges it with its Hamilton Standard division. The new company, Hamilton-Sundstrand, is headquartered in Windsor Locks, Connecticut. Sundstrand Fluid Handling changes its name and logo to Sundyne Corporation under the Hamilton-Sundstrand Industrial Division.
- 2008 – Sundyne acquires Marelli Bombas in Illescas, Toledo-Spain.
- 2009 – Sundyne sells the MASO/Sine division in Ilsfeld, Germany to Watson-Marlow.
- 2010 – Sundyne purchases 100% of the joint venture from NIKKISO bringing an end to the partnership.
- 2012 – Sundyne, Sullair, and Milton Roy are sold by United Technologies to a joint venture owned by the Carlyle Group and BC Partners.
- 2013 – The Carlyle Group and BC Partners form Accudyne Industries, the parent company of Sundyne, Sullair, and Milton Roy.

- 2014 – Sundyne transitions manufacturing of Pressure Products Industries (PPI) diaphragm compressors from Milton Roy's Warminster, PA location to Arvada.

- 2017 – Sullair divested from Accudyne Industries

Figure 1: Sundyne Headquarters in Arvada, Colorado, USA

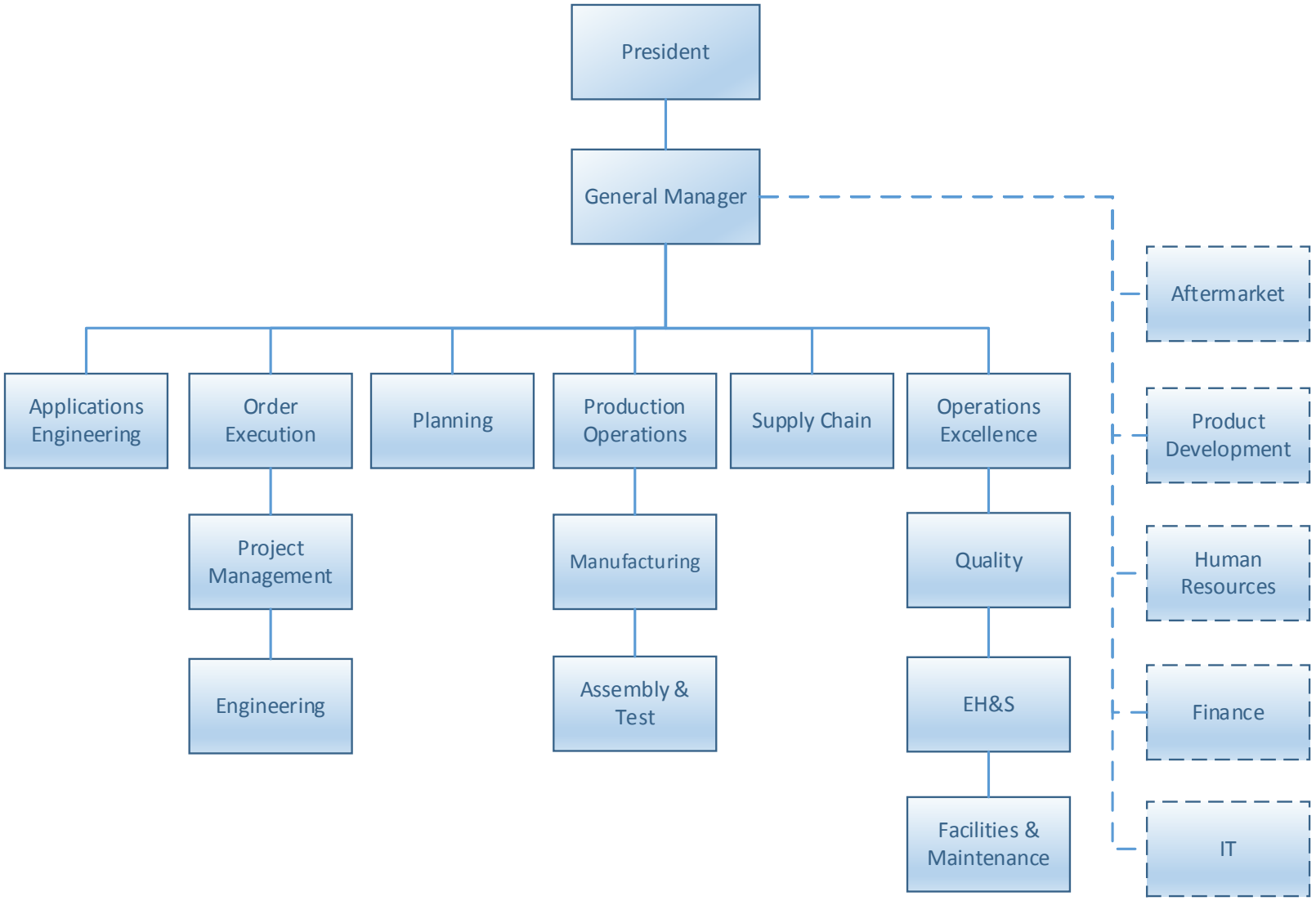


Figure 2: Sundyne – Arvada Organizational Structure

2.0 QUALITY POLICY, PERFORMANCE OBJECTIVES, AND CONTINUOUS IMPROVEMENT

2.1 Quality Policy

Sundyne is committed to delivering world-class engineering, products and services, and strives to exceed customer and stakeholder expectations. To achieve this, Sundyne will:

- Establish Performance Objectives aligned with customer satisfaction and world-class performance;
- Implement and comply with the ISO9001 certified Quality Management System;
- Employ a highly trained and skilled staff, maintain modern facilities and equipment, and utilize standardized processes, tools and methods; and
- Utilize the Sundyne Continuous Improvement Program to improve the effectiveness of the Quality Management System in delivering customer and stakeholder value.

Quality is engrained in the Sundyne culture and is achieved through the personal empowerment and commitment from every employee.

2.2 Performance Objectives

Sundyne's Performance Objectives are aligned with customer requirements and strategic business objectives.

- Safety (TRIR) $\leq$ 0.8
- Cost of Poor Quality $\leq$ 2.0% Cost of Sales
- Delivery (On-Time Units) $\geq$ 90%
- Delivery (On-Time Aftermarket) $\geq$ 95%
- Cash Flow $\geq$ 100% to Plan
- EBITDA $\geq$ 100% to Plan
- PPV $\geq$ 100% to Plan

2.3 Process-Based Quality Management System (QMS)

To implement its Quality Policy and achieve its Performance Objectives Sundyne utilizes a *process* approach to develop, implement, and improve its Quality Management System (QMS). Utilizing a process approach enables Sundyne to link together individual departments, functions, and processes into a complete value stream, thus allowing management to fully understand the potential effects of changes in customer requirements or changes in upstream processes on downstream outputs.

This is process-based QMS approach is accomplished by identifying the

Supplier – **I**nput – **P**rocess – **O**utput – **C**ustomer (**SIPOC**)

interactions that exist within all processes and business activities. Figure 3 illustrates this approach, and Appendix A1 illustrates how the Sundyne value stream and QMS are linked via this model.

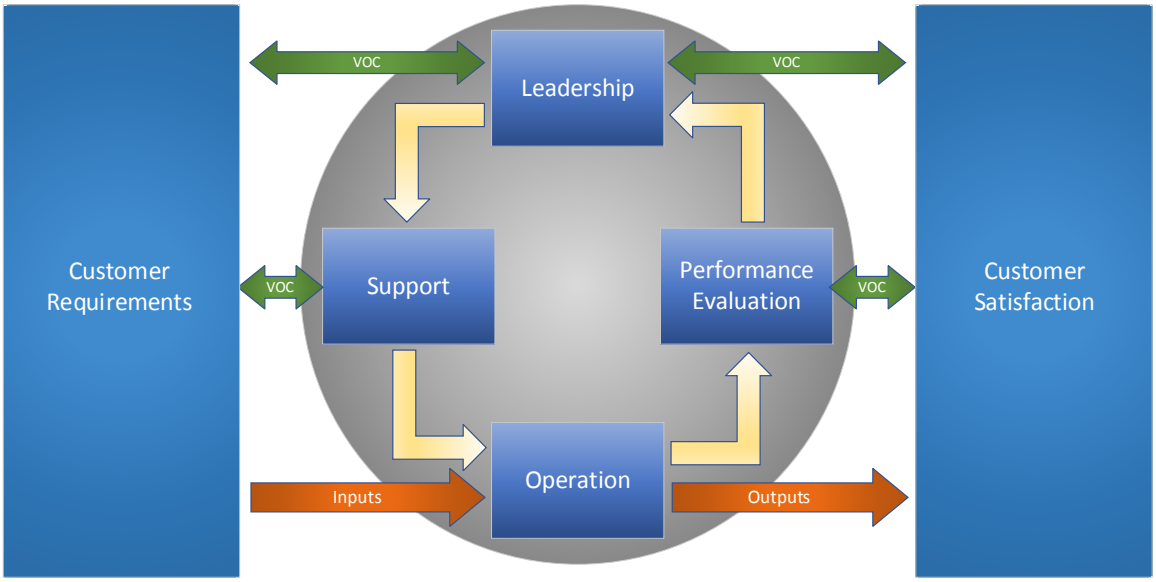


Figure 3: Process-Based QMS

2.4 Continuous Improvement Program

Results-driven continuous improvement involves all employees – leaders and associates alike – and it touches all our manufacturing, engineering, business and supporting processes that create and deliver customer and stakeholder value.

Sundyne's Continuous Improvement Program stands on four pillars:

- A system founded on internationally recognized principles of ISO9001, ISO9004, Lean and Six Sigma,
- Continuous Improvement strategies and leadership that are aligned with delivering unmatched value to our customers and stakeholders,
- Application of proven, industry-standard tools for improving our processes by eliminating waste and reducing variation, and
- Competence, commitment, engagement, and accountability of the entire organization.

2.5 Quality Manual Distribution

The Sundyne Quality Manual and all QMS documentation are available to company personnel via the company network. The Sundyne Quality Manual is available to all customers, suppliers, and regulatory agencies on request.

3.0 SCOPE

3.1 General

This Quality Manual outlines the requirements of the Sundyne QMS and the supporting procedures developed to meet those requirements. The system is structured to comply with conditions and requirements defined in ISO9001:2015

The QMS requirements and the company policies and procedures by which those requirements are met are complimentary to contractual, statutory and regulatory requirements. If a conflict exists between this manual and contractual, statutory, or regulatory requirements, the latter shall take precedence.

3.2 Application

The Sundyne QMS complies with all requirements of ISO9001:2015. All aspects of the QMS are administered from and applicable to all operations of the Sundyne facility located at 14845 West 64th Avenue, Arvada, Colorado 80007.

No requirements of ISO9001:2015 are excluded from the Sundyne QMS, however, due to the nature of their product lines and business models, some company-specific procedures may not apply to the Sunflo, Ansimag or PPI product lines for a given product model or sales order. Applicability or exclusion of company-specific procedures to these product lines shall be noted in the procedure-level documents of the QMS.

Sundyne currently does not control regulatory compliance items such as OSHA, Import/Export Control, Sarbanes-Oxley or Generally Accepted Accounting Practices (GAAP) within the QMS. Assurance of compliance of Sundyne practices to local, state and federal regulations is managed outside the QMS by the responsible Executive Staff members.

Sundyne may choose to control compliance to such regulatory requirements within the QMS at a future date.

3.3 Normative References

The following documents were used as reference during the development of the Sundyne QMS and in preparation of this Quality Manual:

- ISO9001:2015 – Quality Management Systems – Requirements
- ISO9000:2015 – Quality Management Systems – Vocabulary
- ISO9004:2009 – Managing for the Sustained Success of an Organization – A Quality Management Approach

3.4 Terms and Definitions

For the purposes of this manual and all QMS supporting documents, the following apply:

- The words “will”, “shall”, and “must” indicate a requirement.
- The words “may” and “should” indicate a recommended practice.

4.0 CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and its Context

Sundyne will determine the internal and external issues that: (a) are relevant to Sundyne's purpose and strategic direction, and (b) affect its ability to provide products and services meeting the requirements of customers and other interested parties.

Sundyne will monitor and review the internal and external issues to assure the QMS remains relevant as changes take place. Sundyne Leadership will be responsible for determining relevant external and internal issues based on assessment of the requirements of interested parties.

Sundyne will identify relevant external issues by considering local, regional, national, and international arising issues from technological, competitive, market, and economic environments. Sundyne will identify key internal issues by considering values, organizational culture, current process performance, and operating results.

Sundyne will determine when new activities, products, services, and facilities lead to changes in the ranking of these issues and ensure that these are reviewed and factored into the re-assessment of relevant quality-impacting issues.

Management will regularly review current issues and identify new issues and monitor the evolution of issues and their potential impact on management system performance.

4.2 Understanding the Needs and Expectations of Interested Parties

Through strategic planning activities, Sundyne will consider and evaluate the needs and expectations of interested parties regarding their potential impact on the QMS and its ability to deliver products and services consistently meet customer requirements. Interested parties to be considered will include internal and external entities such as: External Providers (Suppliers), Channel Partners, Customers, Employees, Local Government, Community, Regulators, and Corporate Owners.

4.3 Determining the Scope of the Quality Management System

Sundyne shall continually monitor and consider changes to the organization, organizational structure, and the needs of interested parties in determining the boundaries and applicability of the QMS.

Functional departments that will are assessed for conformity and compliance to industry standards outside of the scope of ISO9001 may be omitted from the QMS (e.g., Compliance, EH&S, Finance).

If Sundyne chooses to outsource any processes that may affect product conformity, Sundyne will ensure control over those processes and will define the type and extent of control to be exercised within the QMS.

4.4 Quality Management System and its Processes

In defining and deploying the QMS, Sundyne will:

- Determine the processes needed for the QMS and their application throughout the organization,
- Determine the most efficient sequence of these processes and how they are linked and interact,
- Determine the inputs, outputs, and methods necessary to ensure controlled and effective operation of these processes,

- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- Monitor, measure, and analyze, where applicable and not cost-prohibitive, the inputs and outputs of these processes,
- Implement procedures and work controls to achieve the planned results,
- Implement actions necessary to ensure continual improvement of these processes and the QMS, and
- Accommodate contractual, statutory, and regulatory requirements.

Related Documents:

EX-04-01-00, Quality Manual

QA-04-02-00, Document Control

QA-04-03-00, Records Control

SC-04-04-00, Supplier Quality Manual

5.0 LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

Sundyne leadership is actively involved in the implementation and operation of the QMS. To continue to provide leadership and show commitment to the continual improvement of the QMS, management will:

- Establish the Sundyne Quality Policy,
- Establish company Quality Objectives or Metrics,
- Communicate the importance of meeting customer, statutory, and regulatory requirements,
- Conduct management reviews of the effectiveness of the QMS, and
- Ensure the availability of resources for the proper and effective operation of the QMS.

5.1.2 Customer Focus

Sundyne management recognizes that customer satisfaction is a key indicator of organizational and operational excellence and of the effectiveness of the QMS. In support of its commitment to meeting or exceeding customer requirements and expectations, Sundyne management will:

- Ensure that customer requirements are determined and reviewed in accordance with this manual with the intent of enhancing customer satisfaction and
- Ensure that product and service quality, on-time delivery, and customer satisfaction are measured and/or reviewed, and that appropriate action is taken if customer requirements will not be (or have not been) met.

5.2 Policy

5.2.1 Establishing the Quality Policy

Sundyne management shall establish and regularly review the company Quality Policy in accordance with Section 9.3 to ensure that it:

- Is aligned to the purpose, ethics, and morals of Sundyne and its parent companies, and
- Demonstrates the company's commitment to the QMS.

5.2.2 Communicating the Quality Policy

Is communicated to and understood by all company personnel via new-hire orientation and on-going Sundyne QMS training sessions.

5.3 Organizational Roles, Responsibilities and Authorities

The Sundyne organizational structure has been established to show the interrelation of personnel and departments within the organization. Additionally, job descriptions have been created to define the responsibilities and authorities of the various positions in the company. These job descriptions are reviewed and approved by management for accuracy and suitability and are made available to all company personnel for review.

It is the responsibility of the entire leadership team to ensure that the QMS includes those processes that are critical and necessary in meeting the needs of interested parties, that those processes are delivering their intended results and to drive improvements or corrections if the intended results are not achieved.

In support of the entire leadership team's efforts to deploy and drive the QMS throughout the organization, Sundyne management shall appoint a member of management who shall have the following responsibilities and authorities in the deployment and administration of the QMS, irrespective of other job responsibilities:

- Ensure the QMS conforms to the requirements and intent of ISO9001:2015.
- Report to leadership on the performance and effectiveness of the QMS and note needed improvements.
- Drive awareness and focus of the customer throughout the organization.
- Champion the integrity of the QMS to ensure changes are planned, implemented and monitored to verify effectiveness.

6.0 PLANNING

6.1 Actions to Address Risks and Opportunities

6.1.1 Determining Risks and Opportunities to be Addressed

Sundyne will use industry-standard risk assessment practices to determine which risks and opportunities identified in Section 4.2 will be addressed and how these will be managed. High severity and consequence risks will be prioritized and actively managed. Key opportunities may be selected for continual improvement initiatives.

6.1.2 Planning to Address Risks and Opportunities

Sundyne will proactively address high-severity and consequence risks while lower consequence risks may be managed in a graded approach which may include: risk mitigation, transfer, acceptance, and continual improvement initiatives.

6.2 Quality Objectives and Planning to Achieve Them

Sundyne shall incorporate Performance (Quality) Objectives listed in Section 2.2 into strategic and annual planning activities to ensure changes or improvements in the QMS deployment and monitoring necessary to achieve the objectives are undertaken and managed.

The leadership team shall review performance of the organization against planned objectives at regular, planned intervals in the site QMS Management Review (see Section 9.3).

6.3 Planning of Changes

When Sundyne determines that changes to the QMS are needed to meet new or emerging issues or requirements, it will evaluate required changes and effectively plan and manage the scope and impact of changes on responsibilities, resources and integrity of the QMS.

Related Documents:

ISO2555, Management Review of QMS

7.0 SUPPORT

7.1 *Resources*

7.1.1 General

Sundyne management shall determine and provide, in a timely manner, the resources needed to:

- Implement, maintain, and continually improve the QMS, and
- To enhance customer satisfaction by meeting customer requirements.

When determining these resources, consideration shall be given to:

- Current business opportunities and constraints,
- Mechanisms that will encourage innovative continual improvement

7.1.2 People

When determining resources, consideration shall be given to:

- Methods to enhance existing competency, and
- Future resource requirements.

7.1.3 Infrastructure

Sundyne has determined the infrastructure needed to meet quality objectives and product requirements. The infrastructure provided includes buildings, workspace, utilities, necessary process equipment, adequate environmental conditions, and supporting services. Infrastructure is maintained in accordance with *MT-06-02-00, Preventive Maintenance* to ensure operational continuity and achieve conformity of products and services.

7.1.4 Environment for the Operation of Processes

To achieve product conformity, Sundyne shall manage both the human and physical factors which affect the work environment as defined below:

- Sundyne actively promotes and encourages employee participation, creativity, and new ideas to improve the work environment, especially as they relate to improved product quality.
- Safety rules and guidance are provided to all company personnel, including the use of personal protective equipment.
- The heat, lighting, humidity, noise level, cleanliness, and proper air flow of all office and shop facilities shall be controlled to ensure conditions support product quality and to optimize personnel performance.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

Sundyne controls, calibrates, and recalls calibrated measurement and test equipment / tooling used for product acceptance in accordance with *QA-07-13-00, Control of Monitoring and Measuring Equipment*.

Software and NC programs used in the manufacture of production parts and used in place of product measurements will have their ability to satisfy requirements confirmed, be controlled to ensure intended use, and be reconfirmed as necessary.

7.1.5.2 Measurement Traceability

Sundyne ensures that all calibrated equipment and tools are done so using standards traceable to NIST or to other company-defined standards. Sundyne does not allow personally owned equipment or tools to be used for product acceptance.

All records of calibration and certification are maintained in accordance with Section 7.5.3.

7.1.6 Organizational Knowledge

Sundyne uses its extensive operational experience together with industry-standard practices to determine the organizational knowledge needed to ensure continuity of operations and optimize performance of the QMS. Sundyne maintains and manages organizational knowledge using standard general-employee training, trade progression, advanced practical qualification by recognized external providers, and operator certification and re-certification. Sundyne may also sponsor professional-development training provided by approved professional organizations to improve the competency of its personnel resources.

7.2 Competence

All Sundyne personnel who perform work affecting product quality or who may indirectly affect product quality by performing tasks in support of the QMS shall be competent based on appropriate education, training, skills and experience.

Sundyne shall:

- Determine necessary skills and competence for employees who perform work that directly affects product quality and for employees who may indirectly affect product quality by performing tasks in support of the QMS,
- Where applicable, provide training or take other actions to achieve the necessary competence, and
- Evaluate the effectiveness of the actions taken.
- Maintain appropriate records of education, training, skills, and experience (see Section 7.5.3).

7.3 Awareness

Sundyne shall:

- Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

All competence, training, and awareness initiatives deployed by Sundyne shall be done so in accordance with *HR-06-01-00, Competence, Training and Awareness*.

7.4 Communication

Sundyne management shall utilize department and management meetings, circulation of minutes of management reviews, Internal Audit results, site and local communication boards, all-hands meetings, and other common business communication methods to share and disseminate information including the effectiveness of the QMS.

7.5 Documented Information

7.5.1 General

Sundyne's QMS documentation shall include:

- Documented Quality Policy and Quality Objectives / Metrics,
- This manual, *EX-04-01-00, Quality Manual*,
- The supplier quality manual, *SC-04-04-00, Supplier Quality Manual*,
- Documented procedures and standard work required to meet the requirements of this manual and ISO9001:2015,
- Quality records,
- Records required by customers and regulatory agencies, and
- Other documents and records deemed necessary to ensure the proper and efficient planning, operation, and control of processes which support the QMS.

7.5.2 Creating and updating

Sundyne shall control all documented information required for the support and deployment of the QMS in accordance with *QA-04-02-00, Document Control*.

7.5.3 Control of documented information

Sundyne ensures that all personnel are aware of relevant procedures and work controlling documents and have access to the QMS documentation. QMS documented information is made available as change-protected electronic files and/or version-controlled hardcopies. Access to QMS documentation is also provided to customers, auditors, and regulatory agencies when requested or required.

Sundyne shall control all records which provide evidence of conformity to requirements and of the proper and effective operation of the QMS in accordance with *QA-04-03-00, Records Control*.

<u>Related Documents:</u>

HR-06-01-00, Competence, Training and Awareness

MT-06-02-00, Preventive Maintenance

QA-04-02-00, Document Control

QA-04-03-00, Records Control

QA-07-13-00, Control of Monitoring and Measuring Equipment.

SC-04-04-00, Supplier Quality Manual

8.0 OPERATION

8.1 Operational Planning and Control

Based on the size and complexity of the service or product to be provided, Sundyne shall utilize appropriate planning and management of the product realization process, in a structured and controlled manner, to ensure customer requirements are met. Design planning will occur in accordance with *PM-07-01-00, Quoting and Order Reviews*. Considerations shall be given to the determination of the following;

- Quality objectives and requirements for the product,
- The need to establish processes, procedures, standard work, and resources specific to the product,
- Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the acceptance criteria, and
- Records required providing evidence that the realization process and resulting product meet requirements.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Sundyne shall communicate with customers as required or requested to provide information relating to status or progress of products and services. Additionally, Sundyne shall maintain open communication with customers in order to coordinate contract and order inquiries, contract and order amendments, and customer satisfaction feedback.

8.2.2 Determination of Requirements for Products & Services

In accordance with *PM-07-01-00, Quoting and Order Reviews* Sundyne shall determine:

- Requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- Requirements not stated by the customer but deemed necessary by Sundyne for the specified or intended use,
- Statutory and regulatory requirements applicable to the product, and
- Any additional requirements deemed necessary by Sundyne.

8.2.3 Review of Requirements for Product & Services

8.2.3.1 In accordance with *PM-07-01-00, Quoting and Order Reviews* Sundyne shall review product requirements to ensure:

- Product requirements are clearly defined,
- Any contract or sales order requirements that differ from those previously defined or expressed are resolved,
- Sundyne possesses the resource and process capabilities to meet the requirements, and
- Any special requirements that fall outside the normal Sundyne QMS are determined

This review shall be conducted prior to Sundyne's commitment to supply a service or product to the customer. Where the customer provides no documented statement of requirements, Sundyne shall confirm the requirements prior to acceptance.

8.2.3.2 Records of the review, including resulting actions, shall be maintained in accordance with Section 7.5.3.

8.2.4 Changes to Requirements for Products & Services

Sundyne will amend relevant documented information for its products and services whenever requirements change. Updated documented information will be promulgated to assure operational awareness.

8.3 Design and Development of Products and Services

8.3.1 General

All products and services provided by Sundyne shall be suitable and commensurate with health, safety, and environmental considerations of the users. Product safety shall be assured through a systematic application of sound engineering and management principles in the conception, design, development, manufacture, testing, sales and servicing of all products. All projects that involve new or engineered product design or analysis shall be managed to the extent defined in *PM-07-14-00, Design Control*.

8.3.2 Design and Development Planning

In accordance with *PM-07-14-00, Design Control* and *PM-07-02-00, Design and Release* Sundyne shall plan and control the design and development of product. During the design and development planning, the organization shall determine:

- The design and development stages appropriate for the level of complexity of the project,
- The review, verification, and validation that are appropriate to each design and development stage,
- The responsibilities and authorities for design and development, and
- The requirement for the application of the Passport process.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.

8.3.3 Design and Development Inputs

In accordance with *PM-07-14-00, Design Control* and *PM-07-02-00, Design and Release*, inputs to the product development plan shall be determined and include the following:

- Customer defined functional and performance requirements,
- Applicable statutory and regulatory requirements,
- Where applicable, information derived from previous similar designs and
- Other requirements deemed necessary or essential for the product design and development.

Records of the design inputs shall be maintained in accordance with Section 7.5.3.

8.3.4 Design and Development Controls

In accordance with *PM-07-14-00, Design Control* and *PM-07-02-00, Design and Release* at suitable stages of the project, systematic reviews of design and development shall be performed. Design reviews shall:

- Evaluate the results of design and development activities and determine if they fulfill requirements,
- Identify any risks to not meeting the product requirements and propose necessary actions and
- Include representatives of functions concerned with the design and development stage being reviewed for the authorization of progression to the next stage of the product development process.
- Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.
- Design and development validation shall be performed in accordance with *PM-07-05-00, Product Validation* to ensure that the resulting product can meet the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product.
- Records of the design validation, including resulting actions, shall be maintained in accordance with Section 7.5.3.

8.3.5 Design and Development Outputs

In accordance with *PM-07-14-00, Design Control* and *PM-07-02-00, Design and Release* outputs of the product development plan must be approved prior to release. Design and development outputs shall:

- Be verifiable against the product development inputs,
- Meet the input requirements,
- Provide appropriate and necessary information required for purchasing, production, and service,
- Contain or reference product acceptance criteria, and
- Identify key product or process characteristics that are essential for safe and proper use.

8.3.6 Design and Development Changes

Design and development changes shall be identified, and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation in accordance with *PM-07-06-00, Configuration Control*. The review of design and development changes shall include evaluation of the effect of the changes on product safety and on parts in stock, WIP, and in service.

Records of the Configuration Control process, including resulting actions, shall be maintained in accordance with Section 7.5.3.

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

Sundyne shall ensure that all purchased product, including materials, parts, assemblies and services, conforms to the specified requirements.

Sundyne shall evaluate and select suppliers based on their ability to supply conforming product in accordance with *SC-07-07-00, Supply Chain Management*.

8.4.2 Type and Extent of Control

Supplier Quality and Development activities will be administered and managed via *SC-04-04-00, Supplier Quality Manual*.

Sundyne shall establish criteria for the selection, evaluation, and re-evaluation of suppliers. Records of the results of supplier evaluations, including resulting actions, shall be maintained in accordance with Section 7.5.3.

Sundyne shall verify the conformity of purchased goods in accordance with *QA-07-08-00, Receiving Inspection*.

If Sundyne requires a source or delegated verification of conformity, that activity will be managed in accordance with explicit procurement document requirements.

8.4.3 Information for External Providers

All Sundyne procurement documents must be reviewed and approved prior to distribution to suppliers and must include the following information, where appropriate:

- The part number and revision, or other clear identification such as description of the product, specifications, drawings, process documents, and other relevant technical data,
- Requirements for approval of product, procedures, processes, and equipment,
- Requirements for qualification of personnel, and
- QMS requirements

Amended procurement documents are subject to the above requirements and must also reference the original procurement document number.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

8.5.1.1 Sundyne plans and carries out production under controlled conditions in accordance with *AT-07-10-00, Production Control-Assembly & Test, MF-07-10-00, Production Control-Manufacturing, and AN-07-10-00, Production Control-Ansimag*, and plans and carries out post-delivery service under controlled conditions in accordance with *SA-07-11-00, Service Control*.

Master production scheduling is planned and carried out in accordance with *RS-07-04-00, Production Scheduling* to ensure customer delivery requirements are met while providing a level production load for Operations.

Specific customer quality, inspection, and test requirements are planned and carried out in accordance with *RS-07-03-00, Unit Manufacturing Engineering* to ensure all customer requirements are clearly defined, controlled and executed during the production process.

Inventory control and material handling is planned and carried out in accordance with *MH-07-09-00, Material Handling* to ensure proper and timely availability/delivery of materials and parts necessary for production.

In planning of the production environment, the following are considered on a case-by-case basis:

- The establishment of process controls and the development of control plans, where necessary, to meeting customer requirements or where beneficial to reducing waste and scrap,
- The identification of in-process inspection points when adequate verification of product conformance cannot be performed at a later stage of production,
- The identification of in-process inspection points to reduce waste and scrap,
- The design, manufacture, and use of tooling to ensure process control and capability, and
- Special processes that may be required (see Section 8.5.1.2)

For all production work, Sundyne controls production conditions using approved procedures and standard work which address the following:

- Control of work orders to initiate production and release completed product,
- Readily available product information including work orders, drawings, part numbers, bills of materials, and process specifications,
- Standard work, process notes, and process sketches,
- The use of suitable manufacturing equipment, tools, fixtures, and NC machining programs,
- Proper use and control of monitoring and measuring equipment,
- Clearly defined product acceptance criteria, and
- Evidence that all manufacturing and inspection tasks have been completed as planned.

8.5.1.2 Sundyne shall validate any processes for production and service where the resulting output cannot be verified by subsequent monitoring or measurement and, consequently, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. Sundyne shall establish arrangements for these processes including, as applicable,

- 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
- Re-validation where necessary

8.5.2 Identification and Traceability

Materials, parts, and assemblies produced by Sundyne shall be marked or identified in accordance with *MF-07-12-00, Identification and Traceability* to provide traceability and to provide product status throughout production (and throughout the service life of the material, part or assembly if required by customer or regulatory agency requirements).

8.5.3 Property belonging to customers or external providers

Sundyne shall exercise care with customer property while it is under the organization's control or being used by Sundyne. Sundyne shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, Sundyne shall report this to the customer and maintain records in accordance with Section 7.5.3.

8.5.4 Preservation

Sundyne shall preserve the conformity of product during internal processing and delivery to the intended destination. As applicable to the product being provided, preservation may include the following, in accordance with Sundyne procedures and derivative work controls, and customer or regulatory agency requirements:

- Identification, marking, and labeling,
- Cleaning,
- Handling,
- Packaging,
- Storage and protection,
- Segregation.

8.5.5 Post-delivery activities

For all post-delivery service, Sundyne controls service using approved procedures and standard work which addresses the following:

- Commissioning a unit,
- Aftermarket sales,
- Overhaul and repair services,
- Field Service, and
- Processing warranty claims

8.5.6 Control of Changes

Design and development changes shall be identified, and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation in accordance with *PM-07-06-00, Configuration Control*. The review of design and development changes shall include evaluation of the effect of the changes on product safety and on parts in stock, WIP, and in service.

Records of the Configuration Control process, including resulting actions, shall be maintained in accordance with Section 7.5.3.

8.6 Release of Products and Services

Sundyne shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out in accordance with *QA-08-03-00, Product Measurements* at appropriate stages of the product realization process in accordance with the planned arrangements of Section 8.1.

Evidence of conformance to the acceptance criteria shall be maintained.

Records indicating the person(s) authorizing release of product to the subsequent manufacturing/assembly process or for delivery to the customer shall be maintained in accordance with Section 7.5.3.

- No products may be allowed to progress to the next manufacturing or assembly sequence until the required inspections have been completed, unless otherwise approved by Sundyne management or the customer, where required,

- No products may be delivered to the customer until all inspection requirements are shown to conform to the requirements and any nonconforming product characteristics are dispositioned and approved in accordance with Section 8.3.

8.7 Control of Nonconforming Outputs

8.7.1 Identification and control

Sundyne shall ensure that product which does not conform to customer requirements is identified and controlled to prevent its unintended use or delivery in accordance with *QA-08-04-00, Control and Disposition of Nonconforming Product*.

When nonconforming product is corrected (reworked or repaired) it shall be subject to re-verification to demonstrate conformity to the requirements.

8.7.2 Retention of documented information

All records pertaining to the control and disposition of nonconforming product, including any resulting actions (including customer approval), shall be maintained in accordance with Section 7.5.3.

Related Documents:

PM-07-01-00, Quoting and Contract Reviews

PM-07-02-00, Design and Release

RS-07-03-00, Unit Manufacturing Engineering

RS-07-04-00, Production Scheduling

PM-07-05-00, Product Validation

PM-07-06-00, Configuration Control

SC-07-07-00, Supply Chain Management

QA-07-08-00, Receiving Inspection

MH-07-09-00, Material Handling

AT-07-10-00, Production Control – Assembly & Test

MF-07-10-00, Production Control – Manufacturing

AN-07-10-00, Production Control – Ansimag

SA-07-11-00, Service Control

MF-07-12-00, Identification and Traceability

QA-07-13-00, Control of Monitoring and Measuring Equipment

PM-07-14-00, Design Control

QA-08-03-00, Product Measurements

QA-08-04-00, Control and Disposition of Nonconforming Product.

9.0 PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

Sundyne shall apply suitable methods for monitoring and, where applicable, measurement of the QMS processes in accordance with *QA-08-05-00, Continual Improvement*. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

Sundyne shall plan and implement processes needed to achieve the following:

- Demonstration of product and process conformity,
- Assurance of company conformity to the QMS,
- Continual improvement of the effectiveness of the QMS, and
- Assurance of customer satisfaction.

9.1.2 Customer Satisfaction

Sundyne recognizes the importance of customer satisfaction both as a key indicator of the effectiveness of the QMS and as a measure of organizational and operational excellence. As such, Sundyne will collect information regarding internal and external customer satisfaction in accordance with *QA-08-01-00, Customer Satisfaction*.

Information regarding product quality, on-time delivery, and customer satisfaction will be monitored. Customer satisfaction data may be collected in the form of interviews, questionnaires or other means deemed effective.

9.1.3 Analysis and evaluation

Sundyne will collect and analyze appropriate data to evaluate the effectiveness of the QMS and to identify where improvement of the QMS can be made. The analysis of data shall utilize industry standard tools such as Six Sigma or Lean Principles to provide information relating to:

- Performance relative to Quality Objectives
- Conformity to product requirements
- Characteristics and trends of processes and products and services, including opportunities for preventive action, and
- Supplier performance.

9.2 Internal Audit

9.2.1 Design of internal audit process

Sundyne will design its internal audit program using a process-based approach to ensure all aspects of the QMS are reviewed on a regular basis. The design strategy will also consider (a) identified nonconformances (b) adverse trends in quality objectives or other key quality indicators, (c) prior audit results indicating deterioration in its QMS and (d) areas identified as high or emerging risk resulting from strategic planning activities.

9.2.2 Planning, executing and documenting internal audits

Sundyne shall conduct internal audits in accordance with *QA-08-02-00, Internal Audits* to determine whether the QMS:

- Conforms to the planned arrangements, to the requirements ISO9001:2015 and to the QMS requirements established by the organization, and
- Is effectively implemented and maintained.

Records of the internal audits and their results, including any resulting corrective actions, shall be maintained in accordance with Section 7.5.3.

9.3 Management Review

9.3.1 General

At planned intervals during the year, Sundyne management shall review the QMS in accordance to ensure its continuing suitability, adequacy and effectiveness. These reviews shall include assessing opportunities for improvement and the need for changes to the QMS, including the Quality Policy and Quality Objectives.

Records of the management reviews shall be maintained in accordance with Section 7.5.3.

9.3.2 Management Review Inputs

Sundyne management reviews of the QMS will include data and information from the following sources:

- Results of internal, customer, and third-party audits,
- Customer feedback,
- Process performance and product conformity,
- Supplier performance,
- Status of preventive and corrective actions,
- Follow-up actions from previous management QMS reviews,
- Changes that could affect the QMS, and
- Recommendations for improvement

9.3.3 Management Review Outputs

Outputs from Sundyne management reviews of the QMS shall be documented and include decisions made and actions taken related to:

- The improvement of the effectiveness of the QMS and its processes,
- The improvement of services or products related to customer requirements, and
- Resources required to implement any actions deemed necessary

Related Documents:

QA-08-01-00, Customer Satisfaction

QA-08-02-00, Internal Audits

QA-08-05-00, Continual Improvement

ISO2555, Management Review of QMS

10.0 IMPROVEMENT

10.1 General

Sundyne shall continually improve the effectiveness of the QMS using the Quality Policy, Quality Objectives, audit results, analysis of data, corrective and preventive actions, risk assessment and management, and management reviews.

10.2 Nonconformity and Corrective Action

10.2.1 Corrective Action Process

Sundyne shall ensure that product which does not conform to customer requirements is identified and controlled to prevent its unintended use or delivery in accordance with *QA-08-04-00, Control and Disposition of Nonconforming Product*.

When nonconforming product is corrected (reworked or repaired) it shall be subject to re-verification to demonstrate conformity to the requirements.

Sundyne shall act to understand and eliminate the causes of measured nonconformities and prevent recurrence in accordance with *QA-08-05-00, Continual Improvement*.

Sundyne may assign a Supplier Corrective Action in accordance with *SC-04-04-00, Supplier Quality Manual* when it is determined that a nonconformity is the result supplier actions.

10.2.2 Retention of objective evidence

All records pertaining to the control and disposition of nonconforming product, including any resulting actions (including customer approval), shall be maintained in accordance with Section 7.5.3.

10.3 Continual Improvement

Sundyne shall determine and take actions to understand and eliminate the causes of potential nonconformities and prevent occurrence in accordance with *QA-08-05-00, Continual Improvement*.

Related Documents:

SC-04-04-00, Supplier Quality Manual

QA-08-04-00, Control and Disposition of Nonconforming Product

QA-08-05-00, Continual Improvement

Appendix A1: Link between Sundyne Value Stream and Process-Based QMS