

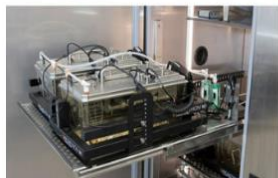



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**QMS-001M-01:**  
**SABLE SYSTEMS QUALITY MANUAL**

**Date of Issue: 01/30/2024**


**Area of Responsibility: Quality Department**



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## **Section 1: Introduction**

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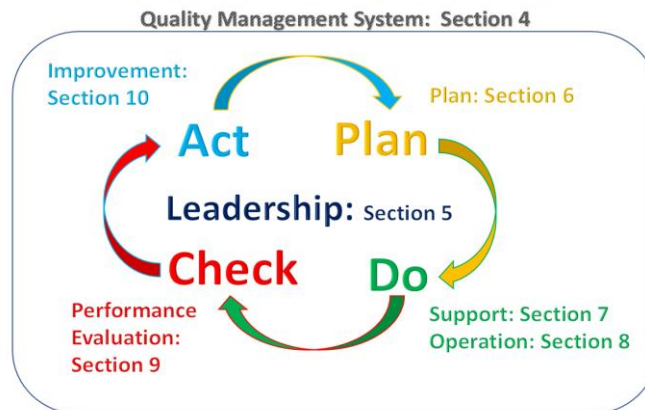
### 1.1. Overview

This manual was developed to illustrate full compliance with all aspects of the requirements as defined in ISO9001:2015.

The Sable Systems Quality Manual provides the necessary supplemental information for Sable Systems International, Inc. and Sable Systems Europe GmbH) to illustrate full compliance with all aspects of the requirements defined in ISO9001. Also herein, Sable Systems International, Inc. and Sable Systems Europe (GmbH) will be referred to as “Sable Systems” within this document. Sable Systems Europe (GmbH) is an independent entity, but a wholly owned subsidiary of Sable Systems International.

The Sable Systems Quality Management System has established practices that shall consistently produce and continuously improve the innovative and high-quality products and services offered to Sable Systems’ Customers. The products and services offered shall meet or exceed the needs and expectations of Customers all the while Sable Systems continuously seeks opportunities to enhance Customer satisfaction. Risks and opportunities associated with Sable Systems shall be addressed in order to achieve all intended results.


## ISO9001 PDCA CYCLE



Sable Systems is committed to the continual improvement of its Quality Management System and has implemented the “Plan-Do-Check-Act” (PDCA) cycle, as referenced in the image above, and risk-based thinking to the highest degree possible. The PDCA cycle is used for continuous control and improvement of products, services, and processes. Risk-based thinking is a practice in which Sable Systems evaluates risks, that may be positive or negative, when making decisions and establishing processes and improvements throughout its Quality Management System. The purpose of risk-based thinking is to ensure risks are properly identified, considered, and controlled in the context of the Quality Management System.

The Sable Systems Quality Management System is comprised of fourteen (14) Tier 2 QMS procedures that follow the same structure as the ISO9001 standard and the PDCA Cycle described above.

**Quality Management System:** Section 4

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**Leadership:** Section 5:

- Context of the Organization, Leadership, Planning and Management Review (QMS-010P-XX)

**NOTE:** A portion of this document also pertains to Section 6.

**Plan:** Section 6:

- Context of the Organization, Leadership, Planning and Management Review (QMS-010P-XX)

**NOTE:** A portion of this document also pertains to Section 5.

**Do- Support:** Section 7:

- Organizational Knowledge (QMS-020P-XX)
- Monitoring and Measuring Resources (QMS-030P-XX)
- Control of Documented Information (QMS-040P-XX)

**Do- Operation:** Section 8:

- Operational Planning and Control (QMS-050P-XX)
  - Production
  - Surface Mount Technology
- Requirements for Products and Services (QMS-060P-XX)
- Design and Development of Products and Services (QMS-070P-XX)
- Externally Provided Processes, Products, and Services (QMS-080P-XX)
- Identification, Traceability, Including Property Belonging to Customers or External Providers (QMS-090P-XX)
- Preservation and Post-Delivery Activities (QMS-100P-XX)
- Release of Products and Services (QMS-110P-XX)

**Check- Performance Evaluation:** Section 9:

- Measurement, Analysis, Evaluation, and Improvement (QMS-120P-XX)

**NOTE:** A portion of this document also pertains to Section 10.

- Internal Audit (QMS-130P-XX)

**Act- Improvement:** Section 10:

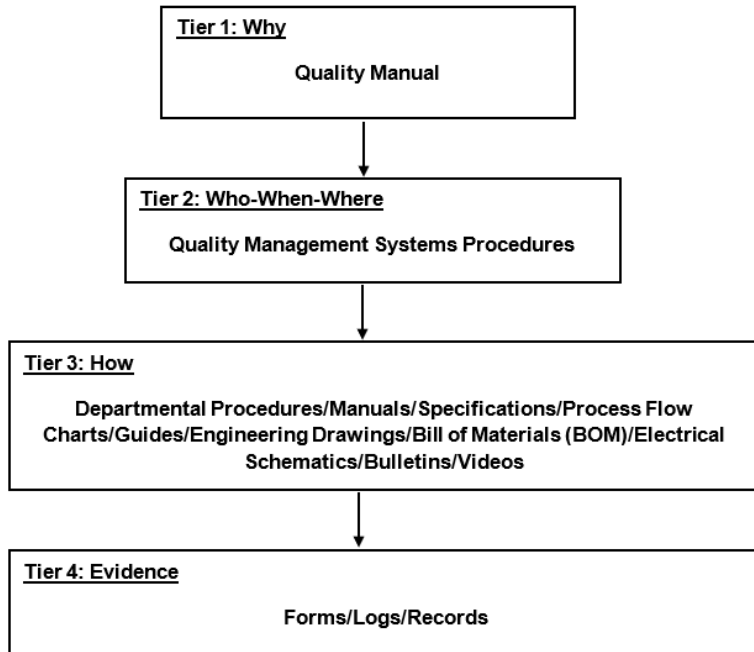
- Nonconformity and Corrective Action (QMS-140P-XX)
- Measurement, Analysis, Evaluation, and Improvement (QMS-120P-XX)

**NOTE:** A portion of this document also pertains to Section 9.

The tiers of the Quality Management System documented information are outlined below.



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The Executive Team at Sable Systems supports the principle that each Team Member is responsible for the quality of products and services that they have generated. It is Sable Systems' intent to design and develop products and services of the highest quality and thereby maintain a position of leadership in the metabolic research community. Therefore, the Executive and Management Teams are committed to leadership by creating an environment where Team Members can apply their strengths and to grow and develop their skillset professionally. The Executive Team has delegated that the Chief Operating Officer has the organizational freedom and unrestricted access to the Executive Team to resolve any and all Quality Management Systems issues at Sable Systems. The Chief Operating Officer is accountable for the development, implementation, maintenance, and effectiveness of the Sable Systems Quality Management System.

## 1.2. About Sable Systems

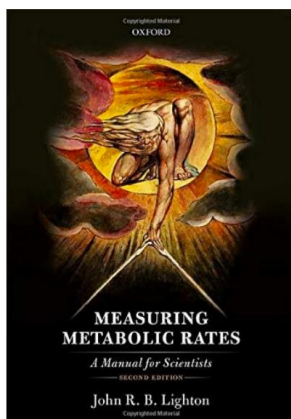
Sable Systems designs and manufactures innovative, high-quality gas, metabolic and behavioral measurement systems for calorimetry, respirometry, metabolic/behavioral phenotyping, and gas analysis. These products enable the highest precision and resolution, optimized workflows, and reliable performance – giving scientists the utmost confidence in their results. Scientists, researchers and technicians world-wide rely on Sable Systems technology for their research needs in physiological, biomedical, environmental, process control and gas analysis applications.

Sable Systems International and Sable Systems Europe (GmbH) are committed to being the industry leader in metabolic research.

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### 1.3. History

In 1987, Dr. John Lighton founded Sable Systems International to provide scientists with integrated, lab- and field-tested metabolic measurement systems designed specifically for their use. Sable Systems quickly grew into the leading metabolic measurement company for researchers demanding quality instrumentation, system configuration expertise, study design know-how, and world class Customer support. In 2008, Dr. Lighton wrote “Measuring Metabolic Rates – A Manual for Scientists” (published by Oxford University Press), which is ranked as the most widely-read and referenced work on metabolic measurement. A second revised edition was released in 2019,



### 1.4. Classic Line and Promethion Line (including Promethion Core®)

Classic Line instruments are designed for benchtop and field use and provide the ultimate combination of ruggedness, performance, and flexibility. They are used in the measurement and control of gases, gas flow rate, humidity, temperature, and barometric pressure. Sable Systems offers a broad range of Classic Line devices that can be configured as a system or used in a stand-alone capacity. Classic Line instruments include:

- Full systems, such as the FMS (Field Metabolic System),
- Flow meters and controllers, such as the Flowbar-8 Mass Flow Meter System,
- Gas analyzers, such as the CA-10 Carbon Dioxide Analyzer,
- Gas controllers, such as the ROXY-1 Universal Regulator/Controller,
- Gas flow switchers, such as the CBL-2 Baseline System,
- Humidity measurement and control devices, such as the DG-4 Dewpoint Generator
- Sample dryers, such as the ND-2 Gas Dryer, and
- Temperature controllers, such as the Pelt-5 Temperature Controller.

Promethion Line systems capture synchronized metabolic and behavioral information, yielding a highly resolved and uniquely rich data stream. These multiplexed systems offer multiple cages that share a gas analyzer chain. Promethion Core® is the only metabolic and behavioral



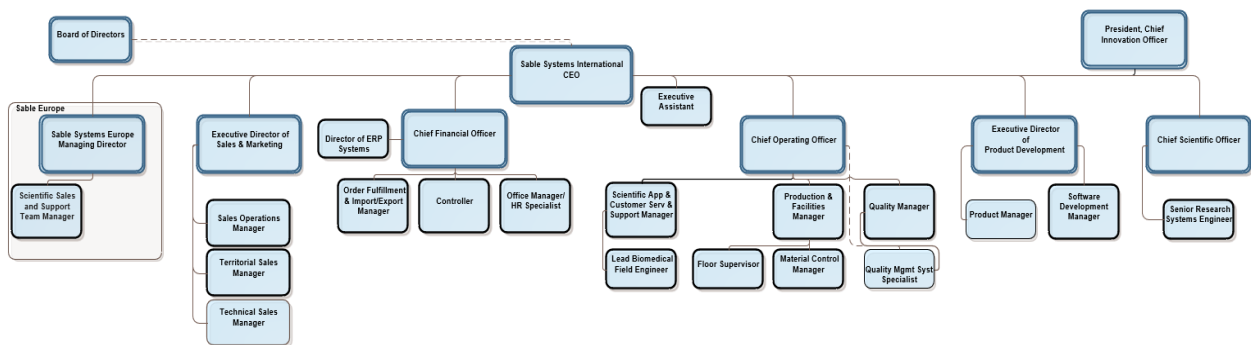
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phenotyping system that enables tight synchronization of metabolic data with behavioral events. This includes the Promethion Core® CGF (Multiplexed Gas and Flow) system, which is typically comprised of 8 to 16 rat or mouse cages, independent mass flow controllers, analyzers, pumps, and Promethion Live software, which allows for real-time experiment evaluation.

### 1.5. About the Sable Systems Quality Manual

This Quality Manual defines and outlines the Sable Systems International and Sable Systems Europe (GmbH) Quality Management System (QMS), hereinafter referred to as Sable Systems, Quality Management System, and the ways in which it aligns with and complies with the ISO9001 international standard.

### Section 2: Organizational Chart




The Executive Team, used interchangeably with the term “Top Management” within the Quality Management System, includes the following positions and their scopes:

**Chief Executive Officer:** The CEO position encompasses, and is accountable for the continued development, communication, implementation, and definitive execution of Sable’s overall business strategy and corporate vision. Also serves the company as Co-Director of Sable Systems Europe (GmbH).

**President & Chief Innovation Officer:** Research, development, and advanced data analysis. World expert in the measurement of metabolism. Role also includes classroom technical instruction, escalated technical Customer support and analysis. Provides Customer feedback for Sable’s Product Development Process.

**Chief Financial Officer:** Managing profitability, financial planning and strategy, corporate accounting and finance, strategic planning, promoting process improvement, financial forecasting, budget development, and dealing with complexity. Also addresses fiscal responsibility for corporate policies and procedures.

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**Chief Operating Officer:** Oversees Quality Assurance/Quality Control, Manufacturing, and Material Control departments. This position is the first line of contact with regulatory agencies and ensures compliance in accordance with the established ISO9001 Quality Management System.

**Chief Scientific Officer:** Research and business development. Drives innovative solutions in product offerings that are both relevant to the markets served by the company and also bring a return on the company’s extensive investment in design, development, and technical support.

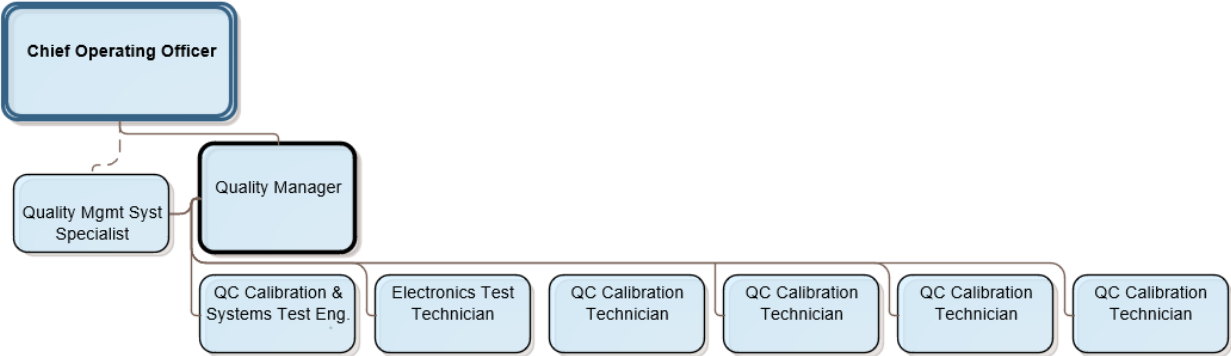
**Executive Director of Product Development:** Responsible for managing the Product Engineering and Product Management teams including directing and implementing the company’s strategies, policies, objectives, and initiatives. Projects include novel or original product design and development and/or iterative improvement of the company’s products.

**Executive Director of Sales and Marketing:** Leads the Sales and Marketing departments to set goals and to develop and execute the plans to achieve department goals. Conveys sales and marketing information to the Executive Team and the CEO.

**Managing Director, Sable Systems Europe GmbH:** Director of the Commissionaire, Sable Systems Europe (GmbH). Responsible for achieving sales revenues of Sable Systems products and services in the European Union and other nearby territory as mutually agreed with Sable Systems International.

The Quality Department, which encompasses Quality Assurance, Quality Control and Quality Systems Test, includes the following positions:

**Sable Systems Quality Department Organization Chart**



**Section 3: Document Approvals and Revision History:**

**Approval Record:**

**DOCUMENT APPROVAL AND CIRCULATION IS CONTROLLED THROUGH MICROSOFT TEAMS®.**



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Title	Approver Name	Date
Chief Executive Officer	Robbin Turner	01/30/2024
Chief Operating Officer/ /Author	Taffi Servenack	01/30/2024

**Revision History:**

Revision	Name	Description of Change	Date
00	Maria Namiatov	Creation of Document	06/23/2022
01	Taffi Servenack	<ul style="list-style-type: none"> <li>• Changed title from Executive Director of Quality and Operations to Chief Operating Officer throughout the document.</li> <li>• Updated Organizational Chart in Section 2.</li> <li>• Updated Quality Department Organizational Chart in Section 2.</li> <li>• Updated Purpose in Section 4.1.</li> <li>• Updated the Needs and Expectations of Interested Parties table in Section 4.2.</li> <li>• Updated the Quality Policy in Section 5.2.1.</li> <li>• Updated Appendix 1: Example of Sable Systems Key Process SIPOC (QMS-050P-XX)</li> <li>• Updated Appendix 2: Core Values</li> </ul>	01/30/2024



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## **Section 4: Context of the Organization**

### **Section 4.1: Understanding the Organization and its Context**

The purpose of Sable Systems is to:



Sable Systems International, Inc. is located at 3840 N. Commerce Street, North Las Vegas, NV 89032, USA. Sable Systems Europe (GmbH), an independent entity, but a wholly owned subsidiary of Sable Systems International, is located at Ostendstr. 25, D-12459 Berlin, Germany.

The North Las Vegas facility designs, develops, and manufactures tools for metabolic measurement, neurophysiology, and environmental science (e.g., metabolic and behavior measurement systems for calorimetry, respirometry, metabolic/behavioral phenotyping, and gas analysis). These instruments are installed around the world and are supported by the appropriate Sable Systems Team Members (US and Europe).

Sable Systems has determined both internal and external issues that are relevant to its purpose, strategic direction, and that affect its ability to achieve the intended result(s) of the Quality Management System. These issues, as outlined in the QMS-010P-XX: Context of the Organization, Leadership, Planning and Management Review, are monitored, updated as appropriate and discussed as part of the Executive Meetings and Management Review Meetings.





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## Section 4.2: Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on Sable Systems' ability to consistently provide products that meet Customer and applicable statutory/regulatory requirements, the following internal and external interested parties are considered relevant for the effective implementation of this Quality Management System.


<b>Relevant Interested Parties</b>	<b>Needs, Expectations, and Requirements</b>	<b>Monitoring Method and Review</b>
Owners/Shareholders& Board of Directors	<ul style="list-style-type: none"> <li>-Sound financial management</li> <li>-Robust Business performance (e.g., Cash Management)</li> <li>-Innovation for continued growth</li> <li>-Educational development opportunities</li> </ul>	<ul style="list-style-type: none"> <li>-Legal and financial compliance with zero fines or penalties</li> <li>-Legal and regulatory adherence</li> <li>-Bi-annual analysis of Quality Objectives (e.g., Annual Goals may include Quarterly Rocks, and/or Departmental Priorities)</li> <li>-Return on investment to shareholders and stakeholders</li> </ul>
Banks & Equity Partners	<ul style="list-style-type: none"> <li>-Sound financial management-</li> <li>Robust Business performance (e.g., Cash Management)</li> </ul>	<ul style="list-style-type: none"> <li>-Legal and financial compliance with zero fines or penalties</li> <li>-Financial statements</li> <li>-Return of the invested capital</li> </ul>
Executive Team	<ul style="list-style-type: none"> <li>-Innovation for continued growth &amp; profit to fund it.</li> <li>-Safe work environment</li> <li>-Work-life balance</li> <li>-Development &amp; training opportunities</li> <li>-Strategic direction</li> <li>-A resilient and rewarding culture of continual learning and outreach</li> </ul>	<ul style="list-style-type: none"> <li>-Executive Team Meetings (daily-weekly-monthly-quarterly)</li> <li>-Legal and financial compliance with zero fines or penalties</li> <li>-Legal and regulatory adherence</li> <li>-Analysis of Quality Objectives (e.g., Annual Goals, Year over Year performance, Quarterly Rocks, and/or Departmental Priorities)</li> </ul>
Management Team	<ul style="list-style-type: none"> <li>-Recognition and reward</li> <li>-Safe work environment</li> <li>-Work-life balance</li> <li>-Development &amp; training opportunities</li> <li>-Revenue generation</li> <li>-Operational excellence (e.g., materials supply supportive of demand, production efficiencies, work in progress tracking, and efficiencies).</li> </ul>	<ul style="list-style-type: none"> <li>-Performance appraisal feedback through AF-099F-XX: Team Member Performance Appraisal SMART Goal Setting Template Form, AF-100F-XX: Team Member Performance Appraisal SMART Goal Outcomes Template Form, and AF-101F-XX: Team Member Performance Appraisal Annual Review Template Form</li> <li>- Management Review Meetings (at planned intervals)</li> </ul>
Sable Team Members	<ul style="list-style-type: none"> <li>-Recognition and reward</li> <li>-Safe work environment</li> <li>-Work-life balance</li> </ul>	<ul style="list-style-type: none"> <li>-Performance appraisal feedback through AF-099F-XX: Team Member Performance Appraisal SMART Goal Setting Template</li> </ul>



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	-Development & training opportunities	Form, AF-100F-XX: Team Member Performance Appraisal SMART Goal Outcomes Template Form, and AF-101F-XX: Team Member Performance Appraisal Annual Review Template Form -Safety record data
External Providers	-Beneficial relationship (e.g., supply, demand, communications) -Timely communications -Payments made on time	-Quality data
Society/Community	-Compliance with statutory & regulatory requirements (e.g., environmental & safety protocols) - -Export assistance and training, human resource, manufacturing, and marketing advisors.	-Zero complaints filed -Zero fines issued
<u>Customers</u>	-Innovation -Continuous improvement of existing products -Quality Products that meet Customer expectations -Customer Support - <u>Feedback on and for quality products</u>	-Sales data -Nonconformance data -Customer Survey data

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-010-XX: Context of the Organization, Leadership, Planning, and Management Review Procedure.

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### Section 4.3: Determining the Scope of the Quality Management System

Sable Systems has determined the boundaries and applicability of the Quality Management System to comply with applicable standard requirements (e.g., ISO9001). While determining the scope, Sable Systems has considered external and internal issues, requirements of relevant interested parties, the products manufactured, and services offered. Therefore, Sable Systems has the following Scope:




The Quality Management System applies to all of the processes, products, services, and activities as Sable Systems does not claim any nonapplicable sections (e.g., exclusions) to the ISO9001 standard.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-010-XX: Context of the Organization, Leadership, Planning and Management Review Procedure.

### Section 4.4: Quality Management System and its Processes

The processes performed at Sable Systems have been identified as either Key or Support processes. The processes, as well as the applicable Quality Management Systems procedure, are shown below:

- **Key Processes:**
  - Operational Planning and Control (QMS-050P-XX)
    - Production
    - Surface Mount Technology
  - Requirements for Products and Services (QMS-060P-XX)
  - Design and Development of Products and Services (QMS-070P-XX)
  - Externally Provided Processes, Products, and Services (QMS-080P-XX)
  - Preservation and Post-Delivery Activities (QMS-100P-XX)
- **Support Processes:**

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- Context of the Organization, Leadership, Planning and Management Review (QMS-010P-XX)
- Organizational Knowledge (QMS-020P-XX)
- Monitoring and Measuring Resources (QMS-030P-XX)
- Control of Documented Information (QMS-040P-XX)
- Identification, Traceability, Including Property Belonging to Customers or External Providers (QMS-090P-XX)
- Release of Products and Services (QMS-110P-XX)
- Measurement, Analysis, Evaluation, and Improvement (QMS-120P-XX)
- Internal Audit (QMS-130P-XX)
- Nonconformity and Corrective Action (QMS-140P-XX)

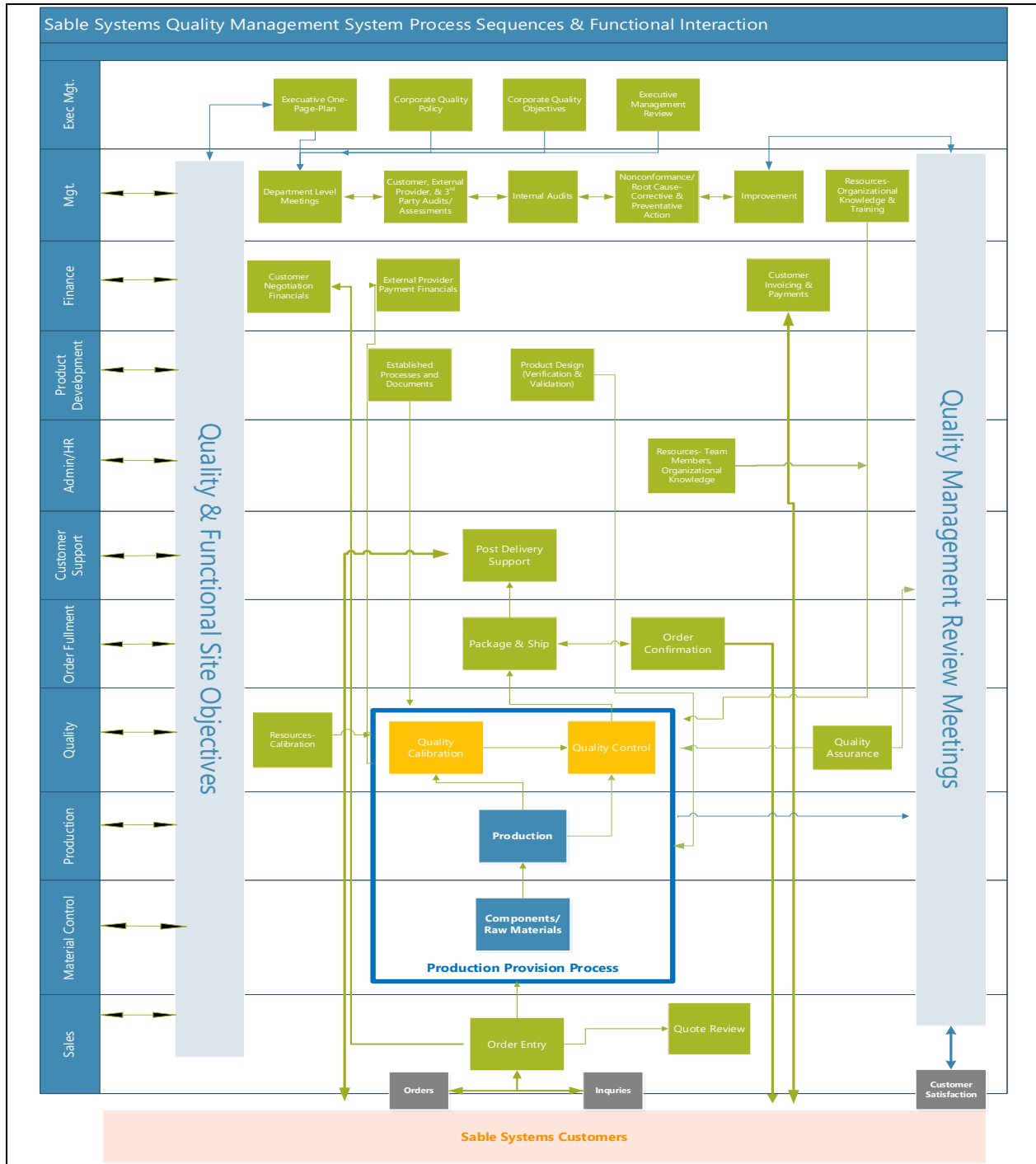
[Figure 1](#) below illustrates the Sable Systems Quality Management Systems Process Sequences & Function Interaction Process Flow Diagram, which shows the sequences/flow of the processes and their interactions (e.g., inputs and outputs) that are needed for the effective maintenance of the Quality Management System. The Sable Systems Process SIPOCs, an abbreviation for Suppliers (e.g., internal or External Provider), Inputs, Processes, Outputs, Customers, can be found in the QMS-010P-XX: Context of the Organization, Leadership, Planning and Management Review Procedure. The SIPOCs detail the elements involved in the processes that are necessary for the effective maintenance and improvement of the Quality Management System. An example of a SIPOC, the Operational and Control for the manufacturing process, can be found in [Appendix 1](#).

This Process Flow Diagram is reviewed for accuracy and improvement opportunities during the internal audit process for the relevant Key or Support process area. The audit results are used to determine the inputs required/outputs expected from each process, criteria/methods for monitoring and measurement (e.g., conformances, nonconformances, and opportunities for improvement) to ensure the effective operation/control of processes, resource needs and their availability, responsibilities/authorities for the processes, risks/opportunities associated with the processes, and evaluation and improvement of the processes.


**Figure 1:** Sable Systems Quality Management Systems Process Sequences & Functional Interaction Process Flow Diagram



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**Section 5: Leadership**

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## Section 5.1: Leadership and Commitment

### Section 5.1.1: General

The Executive Team at Sable Systems demonstrates leadership and commitment in regard to the Quality management System by:

- Taking accountability and ensuring the effectiveness of the Quality Management System,
- Ensuring the Quality Policy and Quality Objectives (e.g., Annual Goals, Quarterly Rocks, and/or Quarterly Departmental Priorities) are established and are compatible with the context and strategic direction of Sable Systems,
- Promoting and supporting a process approach and risk-based thinking, which is performed daily throughout the entire business process,
- Ensuring resources, both tangible and intangible, are available to support the Quality Management System,
- Communicating the importance of conformance to the Sable Systems Quality Management System. This is accomplished through Team Member awareness training and during the monthly updates to all Team Members regarding the status of the Annual Goals, Quarterly Rocks, and/or Quarterly Departmental Priorities at the Company Standup Meetings.
- Ensuring the Quality Management System achieves the intended results. Intended results are assessed, as applicable, during the Executive Meetings and Management Review Meetings.
- Engaging, directing, and supporting Team Members to contribute to the effectiveness of the Quality Management System through a Team Member suggestion program and open exchange of ideas during daily/weekly departmental meetings.
- Promoting continual improvement,
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility through training and assessment (e.g., SMART® Goals documented on the Performance Appraisal Form) of Supervisory Team Member's competence.
  - A SMART® Goal (an assessment trademarked by Leadership Management International) is an abbreviation for a goal that is: Specific, Measurable, Attainable, Realistic, Timely. Original derivatives of this concept used by Sable Systems are copyrighted by Assured Strategies and by the Growth Institute.

### Section 5.1.2: Customer Focus

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The Executive Team at Sable Systems demonstrates leadership and commitment with respect to Customer focus by ensuring that:

- Customer and applicable statutory/regulatory requirements are determined, understood, and consistently met. For more information regarding how Sable Systems is committed to the Customer focus and meeting all requirements, refer to the QMS-060P-XX: Requirements for Products and Services Procedure (Customer Company Contract Review) for the sales portion of the process and the QMS-100P-XX: Preservation and Post-Delivery Activities Procedure for the Customer Support portion.
- The risks/opportunities that can affect the conformity of products and services and the ability to enhance and maintain Customer satisfaction are determined and addressed. For more details regarding this process refer to the QMS-070P-XX: Design and Development of Products and Services Procedure. For additional details regarding risk mitigation see the Sable Systems Primary Risk Assessment table in the QMS-050P-XX: Production Operations Planning and Control Procedure.

## Section 5.2: Policy

### Section 5.2.1: Establishing the Quality Policy

The Sable Systems Executive Team has established a Quality Policy that is appropriate to the purpose and context of the company, supports its strategic direction and provides a framework for setting the Quality Objectives (e.g., Annual Goals, Quarterly Rocks, and/or Quarterly Departmental Priorities). The Sable Systems International and Sable Systems Europe (GmbH) Corporate Quality Policy is stated as follows:



SABLE SYSTEMS INTERNATIONAL, INC.  
Instrumentation and Software Solutions  
 By Scientists, For Scientists

#### **Sable Systems Quality Policy:**


***Sable Systems designs and manufactures research tools for discovery and understanding. We are committed to consistently providing innovative, high-quality products and services that meet or exceed the needs and expectations of our customers. We do this by continuously improving our Quality Management System while also abiding by all applicable standards, laws, and regulations. We aim to enhance the skills of our Customers and all Sable Systems Team Members through ongoing training and growth opportunities.***

  
 Chief Operating Officer

1/30/2024  
  
 Chief Executive Officer

Document Number: QMS-001B-02

### Section 5.2.2: Communicating the Quality Policy

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The Quality Policy is communicated (e.g., in the Sable Systems Team Manual and during new hire orientation and refresher training), understood, and applied in all areas of Sable Systems.

The Quality Policy is available to all interested parties, as applicable. The policy is posted throughout both the Sable Systems International and Sable Systems Europe (GmbH) facilities (e.g., communication boards and breakrooms) and on the Sable Systems website. The Quality Policy is maintained and retained as documented information in the QMS-010P-XX: Context of the Organization, Leadership, Planning, and Management Review Procedure.

**Section 5.3: Organizational Roles, Responsibilities and Authorities**

The Executive Team has ensured that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization. These roles and responsibilities are communicated through a combination of the Organizational Chart and through Job Descriptions. The individual Job Descriptions contain information regarding which of the authorities and responsibilities listed below are relevant to that particular position.


The Executive Team, and in particular the Chief Operating Officer, has assigned the authority and accountability for:

- Ensuring that the Quality Management System conforms to the requirements of the applicable standards (e.g., ISO9001).
- Ensuring that the processes are delivering their intended outputs.
- Reporting on the performance of the Quality Management System and on opportunities for improvement, in particular to others in the Executive Team.
  - This can occur in either the daily, weekly and/or monthly Executive Team meetings and/or during the Management Review Meetings, as applicable.
- Ensuring the promotion of Customer focus throughout Sable Systems.
- Ensuring that the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

The Executive Team has appointed a specific member from the Sable Systems Management Team, identified as the Management Representative, who shall have the responsibility and authority for oversight of the above requirements. The Chief Operating Officer shall serve as the Management Representative. The Management Representative shall have organizational freedom and unrestricted access to the Executive Team to resolve any and all Quality Management System issues.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-010-XX: Context of the Organization, Leadership, Planning, and Management Review Procedure.

**Section 6: Planning**

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**Section 6.1: Actions to Address Risks and Opportunities**

When planning for the Quality Management System, Sable Systems considers the risks and opportunities associated with the organization, its context and the needs and expectations of interested parties. The risks and opportunities need to be addressed to give assurance that the Quality Management System can achieve its intended results, enhance desirable effects, prevent or reduce undesirable effects, and achieve improvement. The actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of the products and services. Details on how to address risks and opportunities are outlined in the QMS-010P-XX: Context of the Organization, Leadership, Planning, and Management Review Procedure. The Sable Systems primary risk assessment can be found in the QMS-050P-XX: Production Operations Planning and Control Procedure.

**Section 6.2: Quality Objectives and Planning to Achieve Them**

Sable Systems establishes Quality Objectives at relevant functions, levels and processes needed for the Quality Management System. These Quality Objectives may be in the form of Annual Goals, Quarterly “Rocks”, and/or Quarterly Departmental Priorities, as discussed in the QMS-120P-XX: Measurement, Analysis, Evaluation, and Improvement Procedure.


Quality Objectives are measurable goals that aim to improve the quality of products and services to enhance Customer satisfaction and can also be established for internal processes. The term “Quality Objectives” is used interchangeably with the terms “Annual Goals, Quarterly “Rocks”, and/or Quarterly Departmental Priorities” within this manual and within the documented information supporting the Quality Management System.

For further clarification, an Annual Goal is an objective or target that Sable Systems wishes to accomplish or achieve. A Quarterly “Rock” is a concrete, attainable objective usually expressed in terms of “from X to Y” within a time frame. It is a smaller, more specific portion of a strategic initiative that is identified as an objective across multiple departments helping Team Members to focus on execution. A Quarterly Departmental Priority is a concrete, attainable objective usually expressed in terms of “from X to Y” within a time frame. It is a smaller, more specific portion of a strategic initiative that is identified as an objective at the department level and is in support of the Quarterly “Rock” and/or Annual Goal.

The Quality Objectives are consistent with the Quality Policy, are measurable, take into account both Customer and applicable regulatory requirements, are relevant to the conformity of products and services to enhance Customer satisfaction, are monitored, are communicated, and are updated as appropriate.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-010-XX: Context of the Organization, Leadership, Planning, and Management Review Procedure.

**Section 6.3: Planning of Changes**

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When Sable Systems has determined that there is a need for change to the Quality Management System, the changes shall be carried out in a planned manner, the process of which is outlined in the QMS-010P-XX: Context of the Organization, Leadership, Planning, and Management Review. In order to carry out the changes in a planned manner, Sable Systems considers the purpose of the changes and their potential consequences, the integrity of the Quality Management System, the availability of resources such as labor and equipment, and the allocation or reallocation of responsibilities and authorities.

**Section 7: Support**

**Section 7.1: Resources**

**Section 7.1.1: General**

Sable Systems has determined and provides the resources necessary for the establishment, implementation, maintenance, and continual improvement of the Quality Management System. Resources include people, infrastructure, environment, and organizational knowledge, which allow for the effective operation and control of processes.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-020P-XX: Organizational Knowledge Procedure.


**Section 7.1.2: People**

Sable Systems ensures that it provides sufficient staffing and training of Team Members to support the effective operation of the Quality Management System and of all processes at Sable Systems. Further details on this process are outlined in the QMS-020P-XX: Organizational Knowledge Procedure.

**Section 7.1.3: Infrastructure**

Sable Systems has determined, provides, and maintains the infrastructure (e.g., buildings and associated utilities) necessary for the operations of its processes to achieve product/process conformity. The Sable Systems Written Safety Program outlines the measures put in place at the US facility to provide a safe environment for all Team Members and visitors, and to display compliance with all applicable laws and regulations. Both facilities conduct a monthly Safety Walk. During these walks the findings are documented, and the report is made available to all Team Members. Should any repairs be required to the infrastructure, or any safety concerns observed, Team Members can submit a request for its remediation.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-020P-XX: Organizational Knowledge Procedure.

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**NOTE:** An External Provider is utilized for all Information Technologies (IT) services.

#### **Section 7.1.4: Environment for the Operation of Processes**

Sable Systems has determined, provides and maintains the environment necessary for the operations of its processes to achieve product/process conformity. In order to ensure that a suitable environment has been established for all Team Members, the following programs are available:

Social – Sable Systems has two Team Manuals, a US version and an EU version. The US version provides details under the Equal Employment opportunity section regarding professional behavior and a means for Team Members in the US facility to report any concerns if they witness or suspect unethical or discriminatory behavior. The EU version provides details regarding professional behavior and a means for Team Members in the Europe facility to report any concerns if they witness or suspect unethical or discriminatory behavior.


Psychological – The Sable Systems Team Member Assistance Program offers a free, confidential, full range of services for Team Members in the US facility from stress reduction to financial planning. Details regarding this program can be found in the Sable Systems International Team Manual. Assistance programs available to Team Members in the Europe facility are outlined in the Sable Systems Europe (GmbH) Team Manual.

Physical – The Sable Systems Management Team ensures its Team Members have the appropriate environmental working conditions such as heat, air conditioning, air sanitation/flow, and overhead lighting to ensure Team Members are comfortable in their areas of work. More details regarding physical environmental factors at the US facility are outlined in the Sable Systems International Team Manual and for the Europe facility in the Sable Systems Europe (GmbH) Team Manual.

#### **Section 7.1.5: Monitoring and Measuring Resources**

Due to the types of products developed, manufactured, and calibrated at Sable Systems, monitoring and measurement processes are of the highest importance. Sable Systems has identified the requirements for control, calibration, adjustment, and maintenance of the monitoring and measuring equipment to demonstrate product conformity to the determined requirements in support of the Quality Management System. Resources are to be provided to ensure that results are reliable and valid. The equipment used in monitoring and measuring activities is suitable for the specific type, range, accuracy, and tolerance. The equipment is maintained and safeguarded to confirm its continuing fitness to ensure product conformance. Documented information pertaining to the calibration records is maintained and retained. Further details on these processes are outlined in the QMS-030P-XX: Monitoring and Measuring Resources Procedure.

#### **Section 7.1.6: Organizational Knowledge**

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Sable Systems has determined the knowledge necessary for the operation of processes to achieve product and service conformity. Processes have been established to acquire and access any necessary and/or additional knowledge through multi-department best practice Team meetings, held on-site or through Microsoft Teams®. These meetings, which include but are not limited to Daily Departmental Standup Meetings, Weekly Departmental Meetings, Priorities Meeting, Debrief Meetings, and Daily/Weekly/Monthly Executive Meetings. This provides a 360° view in decision making, best practice sharing, and information exchange. The discussions and the assignments, called *Who-What-When(s)* (e.g., WWW), that result from these meetings are maintained and are available to Team Members in appropriate designated Microsoft Teams® channels.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-020P-XX: Organizational Knowledge Procedure.

### **Section 7.2: Competence**

In support of the Sable Systems Quality Management System, all Team Members performing tasks that affect conformity to product requirements (either directly or indirectly) shall have suitable education, training, skills, and experience, as appropriate, to demonstrate competency in their area of responsibility. Each department Manager determines the necessary competency for those Team Members performing tasks that can affect the performance and effectiveness of the Quality Management System. Competency can be established through education, prior training and experience, and on-the-job training. Suitable training is provided for newly issued or revised documented information (e.g., procedures and process flow charts) and the evidence of competency training is maintained and retained.

### **Section 7.3: Awareness**


Training is provided for new hires and includes references to the Sable Systems Purpose (as discussed in Section 4.1. above), Scope (discussed in detail in Section 4.3 above), Quality Policy (discussed in detail in section 5.2.1. above), the Core Values (located in [Appendix 2](#)), and an overview of the Annual Goals, Quarterly “Rocks” and Quarterly Departmental Priorities. A review of these items ensures that new Team Members are aware of the Sable Systems Quality Management Systems program as well as the Sable Systems Core Values.

The Purpose of Sable Systems is to: *“Catalyze Discovery and Understanding”*.

The Scope of Sable Systems is: *The design, manufacture, installation, and support of integrated metabolic and behavioral measurement systems for calorimetry, respirometry, metabolic/behavioral phenotyping, and gas analysis in non-clinical studies.*

The Core Values of Sable Systems ([Appendix 2](#)) are:

- *Value the Team*

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- *Promote Passion in Self and Others*
- *Create Quality*
- *Be an Expert*
- *Transcend the Imperfect*

## **Section 7.4: Communication**

Internal and external communications relevant to the Sable Systems Quality Management System include audit results, internal/external Customer feedback, Annual Goals, Quarterly “Rocks”, Quarterly Departmental Priorities, and any changes affecting the Quality Management System. These are communicated, as applicable, during the Executive Meetings, Departmental Meetings, Management Review Meetings, Company Standup Meetings and/or other meetings, as deemed appropriate. The Core Values, Quality Policy, Purpose, Scope, are posted throughout the facilities for heightened awareness. The Annual Goals, Quarterly “Rocks” and Quarterly Departmental Priorities are posted throughout the facilities to allow for heightened awareness and accessibility for Team Members.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-020P-XX: Organizational Knowledge Procedure.

## **Section 7.5: Documented Information**


### **Section 7.5.1, 7.5.2 & 7.5.3: General, Creating and Updating, Control**

Sable Systems controls the approval and issuance of documents that are determined to be necessary for the effectiveness of the Quality Management System. The documented information is required to meet internal requirements and requirements of the ISO9001 standard. Further details on these processes are outlined in the QMS-040P-XX: Control of Documented Information Procedure and the QMS-041P-XX: Document Approval Routing Procedure.

The structure of documented information at Sable Systems includes procedures, guides, manuals, specifications, process flow charts, bulletins, forms, logs, videos, records, electrical drawings, engineering drawings, and bill of materials (BOMs). Each of these documents has a unique document number and is revision controlled. Steps are taken to ensure that documents are reviewed, changes and modifications are controlled/documentated, and the approval process is followed to ensure suitability and accuracy. Unless otherwise specified, controlled documents are stored in the Document Information Team, located in Microsoft Teams® or on the Documented Information Shared Drive. This process ensures adequate distribution, access, retrieval, use, storage, protection, retention, disposition, preservation, and legibility is maintained.

## **Section 8: Operation**

### **Section 8.1: Operational Planning and Control**

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Sable Systems has identified the planning, implementation, and process controls needed to meet the requirements for the provision of products (e.g., manufacturing/production of products) to support the Quality Management System. When Sable Systems is determining the requirements for the production of its products, the following are taken into consideration:


- Personal and product safety (e.g., FOD (Foreign Object Debris)) prevention, as defined in the QMS-100P-XX: Preservation and Post-Delivery Activities Procedure.
- Producibility and inspect ability, as defined herein and detailed in the QMS-110P-XX: Release of Products and Services Procedure.
- Reliability, availability, and maintainability, as defined in the QMS-030P-XX: Monitoring and Measuring Resources Procedure.
- Suitability of parts and materials used in the product, as defined in the QMS-080P-XX: Control of Externally Provided Processes, Products, and Services Procedure.
- Selection and development of embedded software, as defined in the QMS-070P-XX: Design and Development of Products and Services Procedure.
- Products that are no longer manufactured shall be considered inactive and not obsolete. Making products inactive and the reintroduction of such a product requires initiating a Management Of Change Request (MOCR) and this process is outlined in the QMS-070P-XX: Design and Development of Products and Services Procedure.
- Prevention, detection, and removal of foreign objects (e.g., FOD (Foreign Object Debris)), as defined in the QMS-100P-XX: Preservation and Post-Delivery Activities Procedure.
- Handling, packaging, and preservation, as defined in the QMS-100P-XX: Preservation and Post-Delivery Activities Procedure.
- The recycling and final disposal of the product at the end of its life. This process is completed by the Customer and is not the responsibility of Sable Systems.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-050P-XX: Production Operations Planning and Control.

## **Section 8.2: Requirements for Products and Services**

### **Section 8.2.1: Customer Communication**

The appropriate Sales Team Member works directly with the Customer to determine the Customer's intended use and requirements for purchases. This includes Classic Line orders, Promethion orders, the development of new products, and/or the improvement (e.g., a new configuration) of an existing product. The process of the development of new products or the improvement of existing products is outlined in the QMS-070P-XX: Design and Development of Products and Services Procedure. Once all the applicable information has been gathered and processed into NetSuite®, the Sales Team is the responsible party who handles any continuation of inquiries, contracts, order details, changes, and Customer feedback, including complaints, from the Customer.

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Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-060P-XX: Requirements for Products and Services Procedure (Customer Company Contract Review).

### **Section 8.2.2: Determining the Requirements for Products and Services**

When determining the requirements for the products and services offered to the Customer, Sable Systems ensures that the requirements for the products and services are defined. This includes applicable statutory and regulatory requirements, and any additional requirements that Sable Systems deems necessary. Additionally, Sable Systems determines whether it has the ability/capability to meet the defined claims and requirements from the Customer.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-060P-XX: Requirements for Products and Services Procedure (Customer Company Contract Review).

### **Section 8.2.3: Review of the Requirements for Products and Services**


All new orders and amendments to existing orders are reviewed prior to acceptance. This review includes ensuring that:

- Requirements for products specified by the Customer, including the related specifications and special requirements, delivery, and post-delivery instructions are adequately defined and documented as verbal orders/changes are not accepted.
- Requirements not stated by the Customer but necessary for the intended/specified use, statutory/regulatory requirements, and additional requirements that Sable Systems determines are pertinent to the product are adequately defined and documented.
- Requirements differing from those previously expressed/defined are resolved.
- Sable Systems International and Sable Systems Europe (GmbH) have the ability/capability to meet the defined claims/requirements from the Customer.

The determination and review of the requirements for products and services offered by Sable Systems is outlined in detail in the QMS-060P-XX: Requirements for Products and Services Procedure (Customer Company Contract Review).

### **Section 8.2.4: Changes to Requirements for Products and Services**

The documented information relating the review of the Customer order, any new requirements needed as a result of this review, and the amendment to documented information, including evidence that relevant persons were made aware of the subsequent changes, shall be retained in Sable Systems Enterprise Resource Planning System (ERP) system, NetSuite®, and/or Microsoft Teams® per the requirements stated in the QMS-040P-XX: Control of Documented Information Procedure.

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## **Section 8.3: Design and Development of Products and Services**

### **Section 8.3.1: General**

Sable Systems has established, implemented, and maintains a design and development process that is appropriate to ensure the subsequent manufacturing (e.g., provision of products) and services.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-070P-XX: Design and Development of Products and Services Procedure.

### **Section 8.3.2: Design and Development Planning**


In determining the stages and controls for the design and development of products and services, Sable Systems has considered the following:

- The nature, duration and complexity of the design and development activities.
- The required process stages, including applicable design and development reviews.
- The required design and development verification and validation activities.
- The responsibilities and authorities involved in the design and development process.
- The internal and external resources needed for the design and development of products and services.
- The need to control interfaces between persons involved in the design and development process.
- The need for involvement of Customers and users in the design and development process.
- The requirements for subsequent provision of products and services.
- The level of control expected for the design and development process by Customers and other relevant interested parties.
- The documented information needed to demonstrate that design and development requirements have been met.

Additional details on how the process has been conducted at Sable Systems can be found in the QMS-070P-XX: Design and Development of Products and Services Procedure.

### **Section 8.3.3: Design and Development Inputs**

Sable Systems has determined the requirements essential for the specific types of products and services to be designed and developed. During each design and development process for a product or service, the following is considered:

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- Functional and performance requirements, as outlined in the Specifications of a particular product or service.
- Information derived from previous similar design and development activities, as documented on the Test Report.
- Statutory and regulatory requirements, as documented on the Specifications and Test Report of a particular product or service.
- Standards or codes of practice that Sable Systems is committed to implement, as outlined on the applicable Design and Development Guide.
- Potential consequences of failure due to the nature of the products and services, as documented on the Test Report or Test Report Summary of a particular product or service.

The inputs into the Sable Systems design and development process have been deemed adequate for the design and development purpose and are complete and unambiguous. Sable Systems resolves conflicting design and development inputs and maintains and retains the appropriate documented information thereof. This process is outlined in detail in the QMS-070P-XX: Design and Development of Products and Services Procedure.

#### **Section 8.3.4: Design and Development Controls**

Sable Systems applies controls to the design and development process to ensure that:


- The results to be achieved are defined.
- Reviews are conducted to evaluate the ability of the results of design and development activities to meet requirements.
- Verification activities are conducted to ensure that the design and development outputs meet the input requirements.
- Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use.
- Any necessary actions are taken on problems determined during the reviews or verification and validation activities.

The controls implemented during the design and development process at Sable Systems are outlined in detail in the QMS-070P-XX: Design and Development of Products and Services Procedure.

#### **Section 8.3.5: Design and Development Outputs**

Sable Systems ensures that the outputs of the design and development process:

- Meet the input requirements.
- Are adequate for the subsequent processes for the provision of products and services.

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- Include or reference monitoring and measuring requirements, as appropriate, and the acceptance criteria.
- Specify the characteristics of products and services that are essential for their intended purpose and their safe and proper provision.

More details on the outputs of the design and development process are outlined in the QMS-070P-XX: Design and Development of Products and Services Procedure.

### **Section 8.3.6: Design and Development Changes**

Sable Systems identifies, reviews, and controls changes made during or subsequent to the design and development of products and services to the extent necessary to ensure that there is no adverse impact on conformity to requirements, the process of which is outlined in the QMS-070P-XX: Design and Development of Products and Services Procedure.

## **Section 8.4: Control of Externally Provided Processes, Products and Services**

### **Section 8.4.1, 8.4.2, & 8.4.3: General, Type and Extent of Control & Information for External Providers**


Sable Systems has established requirements for ensuring that externally provided processes, products, and services, used in the manufacturing/production process, remain in the control of and conform to the established External Provider requirements in support of the Quality Management System. Subsequently, Sable Systems is responsible for the conformity of all externally provided processes, products, and services, including, as applicable, sources defined by the Customer. Sable Systems has defined criteria for the evaluation, selection/approval, monitoring of performance, and re-evaluation of External Providers based on their ability to provide products and services in accordance with the established requirements, which may include products that are either intended for incorporation into Sable Systems (e.g., components) products and/or products and services provided directly to the Customer on behalf of the organization (e.g., direct shipments from an External Provider to Customer).

Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-080P-XX: Control of Externally Provided Processes, Products and Services Procedure.

## **Section 8.5: Production and Service Provision**

### **Section 8.5.1: Control of Production and Service Provision**

Sable Systems has an established program that ensures the provision of products and services will be performed under controlled conditions (as applicable). These controlled conditions include:


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- The availability of documented information that defines the characteristics (e.g., drawings, schematics, specifications) of the products produced and activities to be performed, as well as the results to be achieved (e.g., bill of material, procedures).
- The availability and use of suitable equipment (e.g., tooling, lighting, work surfaces).
- The availability and use of suitable monitoring and measuring resources (e.g., meters and gauges within a specified calibration date).
- The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for the control of processes and acceptance criteria for products have been met (e.g., voltage tests and leak checks).
- The use of suitable infrastructure and environment for the operation of the process. Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-020P-XX: Organizational Knowledge Procedure.
- The appointment of competent persons, including any required qualification. Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-020P-XX: Organizational Knowledge Procedure.
- The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production, where the resulting output cannot be verified by subsequent monitoring or measurement.
- The quality of manufactured products shall be fully verified through inspection and testing by both Production and Quality Personnel. Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-110P-XX: Release of Products and Services Procedure.
- The implementation of release, delivery, and post-delivery activities. For additional details regarding these subjects refer to the QMS-100P-XX: Preservation and Post-Delivery Activities Procedure and the QMS-110P-XX: Release of Products and Services Procedure.
- The implementation of actions to prevent human error (e.g., error-proofing the process) through the use of computerized systems, validation and verification checks, as applicable.

Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-050P-XX: Production Operations Planning and Control Procedure.

### **Section 8.5.2: Identification and Traceability**

Sable Systems has ensured that suitable means are implemented for product identification and traceability throughout the production process and service provision. This process encompasses the manufacturing of the product(s) through delivery/installation, including product returned from the Customer for evaluation, to ensure identification and traceability conformity is

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maintained in support of the Sable Systems Quality Management System. The traceability and identification process includes that:

- Identification (e.g., serial numbers) are maintained throughout the production life cycle.
- The numerical record (e.g., Order Confirmation or Quote Number) of production (e.g., manufacturing, calibration, quality control/verification) for a given product provides the ability to trace the input materials by serial number(s) and is retrievable.
- There is an identified status (e.g., pass/fail) of the manufactured goods with respect to the monitoring and measurement requirements throughout the production and service provision.
- There is a process for identification and traceability of Customer property that has been returned to Sable Systems for rework.
- There is a process to identify, verify, protect, and safeguard Customer and/or External Provider property that is provided for use or incorporation into Sable Systems products.

Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-090P-XX: Identification, Traceability, Including Property Belonging to Customers or External Providers.


**Section 8.5.3: Property belonging to Customers or External Providers**

Sable Systems has established a process to identify, verify, protect, and safeguard Customer and/or External Provider property that is provided for use or incorporation into Sable Systems products. Sable Systems exercises care with property belonging to Customers and/or External Providers while such property is under Sable Systems’ control/possession. In the unlikely event that the property of a Customer and/or External Provider is lost, damaged, or otherwise found to be unsuitable for use, this is reported to the Customer/External Provider and Sable Systems retains documented information on what has occurred.

Additional details on the process of how implementation has been conducted can be found in the QMS-090P-XX: Identification, Traceability, Including Property Belonging to Customers or External Providers.

**Section 8.5.4: Preservation**

Sable Systems preserves the outputs during the production and service provision to the extent necessary to ensure conformity to requirements. This includes identification (e.g., using serial numbers), handling (e.g., Foreign Object Debris/Foreign Object Damage (FOD) Control), storage, packaging, and transportation of products. Additional details on the process of how

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implementation has been conducted at Sable Systems can be found in the QMS-100P-XX: Preservation and Post-Delivery Activities Procedure.

**Section 8.5.5: Post-delivery Activities**

Upon delivery, Sable Systems products can either be installed by the Customer or by Sable Systems.

When installation services are requested by the Customer, Sable Systems International and/or Sable Systems Europe (GmbH) (depending on the location of the installation) contact the Customer to discuss the Customers requirements, statutory/regulatory requirements, intended use, site preparation (e.g., receiving requirements, specialized equipment needed), installation criteria (including proposed installation dates) and provide the Customer with the applicable Sable Systems forms. The appropriate Sable Systems Customer Support Team Member prepares for the installation (e.g., booking travel, confirming visit/installation dates with the Customer) and then completes the installation. After completion of the installation, and when the Customer is satisfied with the installation, Sable Systems provides the Customer with the Installation and Acceptance Form. Upon return the Sable Systems, the Customer Support Team Member who completes the installation then completes the SSI & SSE GmbH Debrief Form and addresses any necessary Customer follow-ups, which are subsequently discussed during the bi-weekly debrief meetings.

When installation services are not requested by the Customer, Sable Systems provides the Customer with installation instructions as well as contact information for Customer Support for any questions during the Customers' self-installation.


Sable Systems, while considering the nature, use and intended lifetime of the products sold, offers the Customer a standard warranty based on the product purchased. A Customer can submit a request for repair and/or replacement under warranty. Extended warranties are available for purchase by the Customer.

Sable Systems offers a maintenance and analytical support program for products purchased through Sable Systems International and/or Sable Systems Europe (GmbH). The program, which can be purchased by the Customer, provides an annual onsite preventative maintenance and performance evaluation by the appropriate Sable Systems Customer Support Team Member.

Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-100P-XX: Preservation and Post Delivery Activities Procedure.

**Section 8.5.6: Control of Changes**

Sable Systems reviews and controls changes for products to ensure the continued conformity to requirements. If a change is deemed necessary, the change shall go through the Management of Change process as outlined in the QMS-070P-XX: Design and Development of Products and Services. Documented information describing the results of the review of changes, the Team

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Members authorizing the change, and any necessary actions arising from the review is maintained and retained on Microsoft Teams®.

**Section 8.6: Release of Products and Services**

Sable Systems has established a program for the release of products (internally between departments and externally to the Customer) through planned arrangements, at appropriate stages, to verify that established requirements have been met. This is accomplished through verification, monitoring, measuring, inspection, and testing that occurs in the manufacturing, quality calibration and validation, and quality control systems test processes. In-process inspection and testing during the manufacturing process includes visual, leak, voltage and power checks as outlined in the manufacturing build procedures and the results of which are documented on the applicable manufacturing traveler log. During the quality calibration/validation and systems testing process the manufactured product is calibrated, tested and validated, per the criteria outlined in the appropriate quality procedure, and the results are documented in the associated manufacturing traveler log in the “Quality” area. If all criteria have been met, the products are moved to the Order Fulfillment department to be released to the Customer. This process is outlined in detail in the QMS-110P-XX: Release of Products and Services (Quality Control) Procedure.


Return Material Authorization (RMA) products are assessed, repaired (as applicable), calibrated, validated, and released as outlined in the QMS-110P-XX: Release of Products and Services (Quality Control) Procedure and the QMS-140P-XX: Nonconformity and Corrective Action Procedure.

**Section 8.7: Control of Nonconforming Outputs**

All Sable Systems products and processes that do not conform to internal requirements, external requirements (e.g., Customer, regulatory,) product requirements, products from External Providers, internal manufacturing, and returned from a Customer or a Support Team Member (i.e., nonconforming outputs), are identified and controlled to prevent their unintended use or delivery. Sable Systems reacts to the nonconformity, material, or process, by taking action to control/correct it and deal with the consequences (e.g., communicate with the affected internal/external Customers as applicable). Sable Systems implements immediate containment actions and assessment of any similar nonconformities that exists within the Quality Management System. Corrective/Preventive actions shall be appropriate to the effects (magnitude) of the nonconformities or potential problems encountered and commensurate with the risks encountered. This process is outlined in detail in the QMS-140P-XX: Nonconformity and Corrective Action Procedure.

**Section 9: Performance Evaluation**

**Section 9.1: Monitoring, Measurement, Analysis and Evaluation**

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### Section 9.1.1: General

Sable Systems has established a program to ensure that suitable planning and implementation occurs for the monitoring, measurement, analysis, and evaluation needed to ensure that valid results are obtained to demonstrate product conformity, conformity to Customer requirements, conformity to the Quality Management System, and to ensure the continual improvement of the Quality Management System.

The Executive Team, with help and input from Department Managers, establishes Annual Goals, Quarterly “Rocks”, and/or Quarterly Departmental Priorities that are monitored and measured regularly for effectiveness. During each weekly Executive meeting the results of the monitoring and measurement are reviewed, analyzed, and evaluated. Subsequently, the results from each Quarterly “Rock” and Quarterly Departmental Priority are summarized and presented to all Sable Systems Team Members at the scheduled monthly, quarterly and/or annual standup meetings, as applicable, and the meetings are recorded and readily accessible to all Team Members.

Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-030P-XX: Monitoring and Measuring Resources Procedure.


### Section 9.1.2: Customer Satisfaction

Sable Systems monitors Customers satisfaction and their perception of the extent to which their needs and expectations have been fulfilled. Customer satisfaction is gathered and evaluated through the use of the following, as applicable:

- Customer survey
- Customer Feedback on Delivered Products and Services, which may include the following:
  - Meetings with potential and existing Customers (e.g., physically in person or virtually).
  - Verbal Customer feedback during installations and site visits, which is documented on the SSI & SSE GmbH Debrief Template Form.
  - During the Returned Material Authorization process, Customer feedback is gathered for warranty claims, as applicable, and entered into the Support Case in NetSuite.
  - Customer feedback received via telephone or emails sent from the Customer-to-Customer Support Personnel and/or Order Fulfillment Personnel.
  - Customer feedback received via the “Support” page on SableSys.com/support.


Additional details on the process of how implementation has been conducted at Sable Systems in regard to Customer Satisfaction can be found in the QMS-120P-XX: Measurement, Analysis, Evaluation and Improvement Procedure.

### Section 9.1.3: Analysis and Evaluation

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Sable Systems analyzes and evaluates the appropriate and applicable data and information arising from monitoring and measurement processes. The results are used to evaluate:

- The conformity of products and services,
  - Production/Manufacturing and Quality Team Members review the applicable procedures, Bill of Materials, manufacturing traveler logs and other applicable documents to ensure the product conforms to the established criteria. The evidence of conformity with the acceptance criteria shall be maintained and retained and these records shall indicate the person(s) authorizing the release of the product. Final product release (e.g., shipment) to external Customers shall not proceed until all planned arrangements have been satisfactorily completed, as detailed in the QMS-110P-XX: Release of Products and Services (Quality Control) Procedure.
  - Applicable Customer Support Team Members perform services (e.g., site visits) and record the details of the visit on the SSI & SSE GmbH Debrief Form, which is subsequently discussed during the Field Service Debrief Meeting with the cross-departmental stakeholders and includes the presentation of Customer feedback.
- The degree of Customer satisfaction, as outlined above in Section 9.1.2: Customer Satisfaction,
- The performance and effectiveness of the Quality Management System,
  - The appropriate and applicable data shall be gathered prior to and presented at the Management Review Meetings for analysis to demonstrate the effectiveness of the Quality Management System and to evaluate where improvements can be made.
- If planning has been implemented effectively,
  - The Manufacturing Schedule Log is reviewed during the Daily Standup for Production-Quality-Order Fulfillment Meeting, as applicable, to determine compliance with manufacturing, quality calibration, quality systems test and order fulfillment dates to both internal and external Customers.
- The effectiveness of actions taken to address risks and opportunities, as outlined in the QMS-050P-XX: Production Operations Planning and Control Procedure.
- The performance of External Providers,
  - Any products deemed nonconforming that were supplied by an External Provider shall be entered into the QMS-001L-XX: Nonconformance Database Log. The External Provider nonconforming data, including the severity of the issue, whether the nonconformance is a recurring issue, and what the External Providers resolution was, are discussed and analyzed during the weekly Nonconformance Meeting as well as during the Management Review Meetings.
- Any improvements needed to the Quality Management System.
  - Sable Systems shall continuously improve the performance, suitability, adequacy, and effectiveness of the Quality Management System. This shall be accomplished by analyzing and evaluating the results of the monitoring and measuring activities from its various sources to determine if there are needs or opportunities that shall be addressed as part of Sable Systems continual improvement process.

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Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-120P-XX: Measurement, Analysis, Evaluation and Improvement Procedure.

**Section 9.2: Internal Audit**

Sable Systems has established an audit program in which internal audits are conducted, at planned intervals, to ensure that the Quality Management System is effectively implemented and maintained. The internal audits are performed against internal requirements (e.g., procedures), the ISO9001 standard, Customer requirements and statutory/regulatory (as applicable) requirements. The requirements for scheduling, performing, documenting, and tracking internal audit activities are described in the QMS-130P-XX: Internal Audit Procedure. Prior to conducting internal audits, the auditors are adequately trained on appropriate auditing techniques such as how to handle nonconformities, how to follow up on nonconformities, and how to document audit results. The internal auditors shall be adequately qualified and the extent to which the established qualifications have been met shall be documented on the QMS-009F-XX: Auditor Qualifications Template Form. The audit program also serves as means to verify the effectiveness of the corrective and preventative action program as it applies to nonconformances and continuous improvement.

Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-130P-XX: Internal Audit Procedure.

**Section 9.3: Management Review**

**Section 9.3.1: General**


The Executive Team reviews the Quality Management System at planned intervals to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of Sable Systems.

Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-010P-XX: Context of the Organization, Leadership, Planning and Management Review Procedure.

**Section 9.3.2: Management Review Inputs**

The Management Review is carried out twice in a twelve-month period. The following inputs are taken into consideration during the meetings:

- The status of actions from the previous Management Review Meetings,
- Changes in external and internal issues that are relevant to the Quality Management System, including regulatory requirements,

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- Information on the performance and effectiveness of the Quality Management System, including trends in:
  - Customer satisfaction and feedback from relevant interested parties, as detailed in the QMS-100P-XX: Preservation and Post-Delivery Activities Procedure.
  - The extent to which the Quality Objectives (e.g., Annual Goals, Quarterly “Rocks”, and/or Quarterly Departmental Priorities) have been met, as detailed in the QMS-120P-XX: Measurement, Analysis, Evaluation, and Improvement Procedure.
  - Process performance and conformity of products and services, as detailed in the QMS-110P-XX: Release of Products and Services (Quality Control) Procedure.
  - Nonconformities and corrective actions, as detailed in the QMS-140P-XX: Nonconformity and Corrective Action Procedure.
  - Monitoring and measurement results, as detailed in the QMS-120P-XX: Measurement, Analysis, Evaluation, and Improvement Procedure.
  - Audit results, the process of which is detailed in the QMS-130P-XX: Internal Audit Procedure.
  - The performance of External Providers, as detailed in the QMS-080P-00 Control of Externally Provided Processes, Products, and Services Procedure.
  - The adequacy of resources, as detailed in the QMS-020P-XX: Organization Knowledge Procedure.
  - The effectiveness of actions taken to address risks and opportunities, as detailed in the QMS-050P-XX: Production Operations Planning and Control Procedure.
  - Opportunities for improvement, as detailed in the QMS-120P-XX: Measurement, Analysis, Evaluation, and Improvement Procedure.

Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-010P-XX: Context of the Organization, Leadership, Planning and Management Review Procedure.

### **Section 9.3.3: Management Review Outputs**

The Management Review includes decisions and actions related to the following outputs:


- Opportunities for improvement,
- Any need for changes to the Quality Management System, and
- Resource (tangible and intangible) needs.

Inputs and outputs of the Management Review Meetings are documented on the QMS-010F-XX: Management Review Meeting Minutes Template Form, which is maintained and retained on Microsoft Teams®.

## **Section 10: Improvement**

### **Section 10.1: General**

Sable Systems is committed to the improvement of the Quality Management System by determining and selecting opportunities for improvement and implementing any necessary actions to meet Customer requirements, enhance Customer satisfaction and to consider the

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future needs or expectations of Customers. The purpose of this is to open new opportunities for discovery and understanding for the Customer, to engage in collaborative research, to beta test new configurations of integrative systems in partnership with a Customer and subsequently to evaluate the scientific relevance of the data collected.

The implementation of improvement activities, which also includes correcting, preventing, or reducing undesired effects, is monitored and the effectiveness of the results are evaluated.


Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-120P-XX: Measurement, Analysis, Evaluation, and Improvement Procedure.

**Section 10.2: Nonconformity and Corrective Action**

Sable Systems has established a program that defines the methods used to ensure products and processes that do not conform to internal/external requirements, product requirements, products from external providers, internal manufacturing and items returned from a Customer/support (e.g. nonconforming outputs) are identified and controlled to prevent their unintended use or delivery. Nonconforming products detected after delivery and returned from a Customer site shall be segregated upon receipt and placed into the nonconforming cage with a red 'Hold' tag. If a product has been found to be nonconforming internally, a red 'Hold' tag shall be affixed to the product, and it shall be placed into the nonconforming cage or segregated (e.g., large/heavy items). The nonconforming product information shall be entered into the QMS-001L-XX: Nonconformance Database Log and an investigation of the root cause and subsequent immediate corrective actions, corrective and preventative actions shall commence.

Sable Systems reacts to the nonconformity, material, or process by taking action to control/correct it (corrective action) and deal with the consequences (e.g., communicate with the affected internal/external Customers as applicable), as well as implement immediate containment actions and assessment if any similar nonconformities exist within the Quality Management System. If internally produced product is not within specification but is believed to be useable the QMS-004F-XX: Internal Deviation Template Form can be utilized, and applicable information is entered into the QMS-009L-XX: Sable Systems Internal- External Provider- Customer Deviation Log. If the product is considered nonconforming per specifications, Sable Systems may ask/obtain authorization for acceptance on concession from the Customer by utilizing the QMS-008F-XX: Customer Deviation Template Form and entering the applicable information into the QMS-009L-XX: Sable Systems Internal- External Provider- Customer Deviation Log. If nonconforming product is deemed to be unusable the material shall be rejected and scrapped. Corrective/preventive actions are appropriate to the effects (magnitude) of the nonconformities or potential problems encountered and commensurate with the risks encountered. Once each nonconformance has been adequately completed, they shall be reviewed, validated, and closed by the Chief Operating Officer.

Additional details on the process of how implementation has been conducted at Sable Systems can be found in the QMS-140P-XX: Nonconformity and Corrective Action Procedure.

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### Section 10.3: Continual Improvement

Sable Systems is committed to continuously improving the performance, suitability, adequacy, and effectiveness of the Quality Management System. This is accomplished by analyzing the results of the monitoring and measuring evaluation from its various sources to determine if there are needs or opportunities to be addressed as part of the Sable Systems continual improvement process. Evaluation tools include, but are not limited to, analysis of internally generated and externally supplied data, corrective and preventive actions, the status and results of company Annual Goals, Quarterly “Rocks” and/or Departmental Priorities and information gathered from the debrief meetings, Management Review Meetings, Executive Team meetings, and audit results.

Additional details on how the process of implementation has been conducted at Sable Systems can be found in the QMS-120P-XX: Measurement, Analysis, Evaluation, and Improvement Procedure.

### Appendix 1: Example of a Sable Systems Key Process SIPOC Operational Planning and Control (QMS-050P-XX) - Production, Surface Mount Technology

Suppliers	<ul style="list-style-type: none"> <li>-External Providers</li> <li>-Material Control Team</li> <li>-Order Fulfillment Team</li> <li>-Product Development Team</li> <li>-Customer Support Team</li> <li>-Sales Team</li> </ul>
Inputs	<ul style="list-style-type: none"> <li>-Notification of quote/sale</li> <li>-Sales order entered and/or Sable Trac Ticket entered</li> <li>-Materials used in the manufacturing processes</li> <li>-Applicable monitoring and measurement equipment/tools</li> <li>-Selection and development of embedded software</li> </ul>



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	<ul style="list-style-type: none"> <li>-Documented information (e.g., drawings, schematics, specifications, BOMs, procedures, etc.)</li> <li>-MF-100L-XX: Manufacturing Schedule Log</li> <li>-Monitoring and measurement activities (e.g., voltage tests, leak tests)</li> <li>-Qualified Production Team Members</li> </ul>
Processes	<ul style="list-style-type: none"> <li>-Material Control procures materials from External Providers</li> <li>-Supervision assigns tasks in NetSuite for SMT Team to manufacture boards</li> <li>-SMT Team updates NetSuite tasks/assignments on the status of builds</li> <li>-Supervision assigns tasks in NetSuite for Material Control to pull parts for Production.</li> <li>-Supervision assigns tasks in NetSuite for Production Team to build product</li> <li>- Material Control provides materials to Production</li> <li>-Product is manufactured per applicable documented information</li> <li>-Production Team fills out appropriate Traceability Logs</li> <li>-Production Team update NetSuite tasks/assignments on the status of builds</li> <li>-Completed product is physically moved to the next (internal) Customer</li> </ul>
Outputs	<ul style="list-style-type: none"> <li>-Documented information (records retained)</li> <li>-Completed boards/products</li> <li>-Release of products</li> </ul>
Customers	<ul style="list-style-type: none"> <li>-Internal Customers (e.g., Quality, Order Fulfilment, Customer Support, Product Development)</li> <li>-External Customers</li> </ul>



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**Appendix 2:  
Sable Systems Core Values**

# OUR CORE VALUES

## VALUE THE TEAM

Sable is one Team of many Teams. We win by building trust, embracing healthy conflict, and being accountable.

### PROMOTE PASSION IN SELF & OTHERS

Inspire contagious enthusiasm as we progress toward our goals and the goals of our customers. When we do what we love and love what we do passion comes to life!

### CREATE QUALITY

Our tools build trust. We deliver reliable results with stunning clarity to enable confidence in new discoveries.

### BE AN EXPERT

Experts lead. Lead in knowledge. Lead in innovation. Never stop learning. Share your knowledge.

## TRANSCEND THE IMPERFECT

Learn from success and failure to shape the future in wonderful ways.  
Persevere and stay agile.

