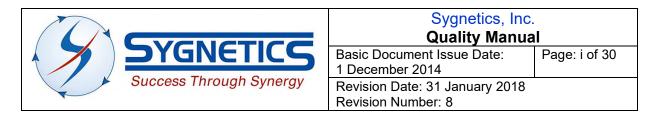


# QUALITY MANUAL REV #8

# Based on ISO 9001:2015 Quality Management System



Sygnetics, Inc. 37054 Cochise Clinton Township, MI 48036 http://www.sygnetics.com



## APPROVAL

The signatures below certify that this management system manual has been reviewed and accepted, and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their usage.

	Name	Signature	Position
Prepared By:	Kim Smith	Amontech	Quality Manager
Approved By:	Tony Tarkowski	Tom Serkouly	President / CEO

#### AMENDMENT RECORD

This quality manual is reviewed to ensure its continuing relevance to the systems and process that it describes. A record of changes is given below:

REV #	DETAILS OF CHANGE	DATE
0	Initial Release	1 Dec 2014
1	Changes were caused from Stage 1 Audit findings. Major rewrite. Refer to Stage 1 Audit Forms – 0411 dated December 22, 2014	5 Jan 2015
2	<ul> <li>Changes were made after Internal Audit.</li> <li>Additional verbage to quality objectives Sygnetics' overall goal is to provide quality products and services, meeting or exceeding client requirements, while growing profitably.</li> <li>Moved quality objectives to Section 5.4.1</li> <li>Delete Section 7.5, page 21</li> <li>Delete surveys Section 8.2.1, page 22</li> <li>Delete Project Leader, Section 8.2.4, page 25</li> </ul>	20 Feb 2015
3	<ul> <li>Updated org chart to include assignment of management rep</li> <li>Inserted the following sections         <ul> <li>Section 7.5.1, page 21</li> <li>Section 7.5.3, page 21</li> <li>Section 7.5.4, page 21</li> </ul> </li> </ul>	5 Mar 2015
4	<ul> <li>Updated org chart to include new position – VP Government Opportunities</li> </ul>	6 Jan 2016
5	<ul> <li>Section 5.4.1 Quality Objectives, pages 11-12         <ul> <li>Updated to include new quality objectives and measurable data</li> </ul> </li> </ul>	6 Mar 2016
6	<ul><li>Updated address</li><li>Updated org chart to include new positions/titles</li></ul>	30 Jan 2017
7	Rewritten to conform to 9001:2015 standard	1 Nov 2017
8	Updated to reflect audit suggested changes	31 Jan 2018



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## **1 INTRODUCTION**

The purpose of this quality manual is to describe the policies and company-wide control structure of the Quality Management System (QMS) used to achieve the corporate mission and vision at Sygnetics, Inc. The Quality Management System (QMS), which uses ISO 9001 as a framework, allows our organization to document and improve our practices in order to better satisfy the needs and expectations of our customers, stakeholders and interested parties.

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

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

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

## **2 NORMATIVE REFERENCES**

This quality manual references the below international standards:

Standard	Title
BS EN ISO 9001:2015	Quality Management Systems Requirements
BS EN ISO 9001:2015	Quality Management Systems Fundamentals and Vocabulary

#### **3 TERMS AND DEFINITIONS**

This document does not introduce any new terms or definitions but relies on the following:

- 1. Definitions typically used by our customers, stakeholders or marketplace;
- 2. Terms typically used in standards and regulations as they relate to our QMS or products;
- 3. Standard business terminology;
- 4. Terms and vocabulary commonly used in quality and staffing practices.



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## 4 CONTEXT OF THE ORGANIZATION

## 4.1 Organizational Context

Sygnetics is committed to defining our position in the marketplace and understanding how relevant factors that arise from legal, political, economic, social and technological issues can affect our strategic direction and our organizational context.

Sygnetics identifies, analyzes, monitors and reviews factors that may affect our ability to satisfy our customers and stakeholders, as well as; factors that may adversely affect the stability of our management system's integrity.

To ensure that our QMS is aligned with our strategy, taking into account relevant internal and external factors; we initially collect and analyze pertinent information in order to determine the potential impact on our business strategy.

Sygnetics then monitors and reviews this information to ensure that a continual understanding of each group's requirements is derived and maintained. To facilitate the understanding of our context, we regularly consider issues that influence our context during management review meetings and are conveyed via minutes and business planning documents.

The table below shows issues – both internal and external – that Sygnetics has determined to be an influence the context of our organization.

Internal Issues		External Issues		
Employees	Values / Culture	Customers	Economy	
Performance	Innovation	Competition	Technology	
Staffing	Knowledge	Regulations	Cultural / Social	

## 4.2 Relevant interested Parties

Sygnetics recognizes that we have a unique set of interested parties whose needs and expectations change and develop over time, and that only a limited set of their respective needs and expectations are applicable to our operations or to our Quality Management System. *See Interested Parties.xlsx.* 

## 4.3 Quality Management System

## 4.3.1 Management System Scope

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



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Our Quality Management System meets the requirements of ISO 9001:2015 and uses the Plan, Do, Check and Act approach to process planning. Our QMS addresses and supports our strategies for the supply of temporary, contract and permanent personnel. We provide our clients with complete solutions for, program, technological, and contract specific personnel requirements.

Sygnetics is registered at 691 N. Squirrel Road, Suite LL150, Auburn Hills, MI 48326.

The following table identifies any ISO 9001:2015 requirements that are not applicable to our organization:

Clause	Title	
7.1.5	.5 Monitoring and Measuring Resources	
8.3	Design and Development of Products and Services	
8.5.1 (f)	Control of Production and Service Provision	
8.5.2	Identification and Traceability (Traceability only)	
8.5.4	Preservation	
8.5.5	Post-delivery Activities	

#### 4.3.2 Management System Processes

Sygnetics has adopted the process approach advocated by ISO 9001:2015 and the President/CEO has determined the processes required for achieving the intended outputs. By defining four key process-groups and by managing their inputs, activities, controls, outputs and interfaces; we ensure that system effectiveness is established maintained. These key process groups include:

- 1. Leadership and planning processes
- 2. Customer and stakeholder processes
- 3. Product/service development processes
- 4. Evaluation and improvement processes



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These process groups are described using tools such as documented procedures, process maps, flow diagrams, matrices, schedules, and charts, etc. Refer to the Sequence & Interaction of Processes in Attachment A which shows the sequence and interaction of the process groups within our management system.

It is recognized that defining, implementing and documenting our Quality Management System is only the first step towards fully implementing its requirements. The effectiveness of each process and its subsequent output is measured and evaluated through regular internal audits, quality inspections and data analysis.

We use key performance indicators (KPIs) that are linked to our objectives to control and monitor our processes, as well as



assessments to determine the risks and opportunities inherent to each process. We use trends and indicators relating to nonconformities, objectives and corrective action, as well as, monitoring and measurement results, audit results and customer satisfaction data, process performance and the conformity of our products.

#### 4.3.3 Outsources Processes

Where Sygnetics identifies the requirement to outsource any process which affects conformity with the stated requirements; we identify control criteria such as; the competence of personnel, inspection regimes, the provision of product conformity certificates, adherence to specifications and specific job files, etc. Refer to Section 8.4.

The controls identified do not absolve us of the responsibility to conform to client statutory and regulatory requirements but instead they enhance our capacity to effectively manage our supply chain.



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## 4.3.4 Documented Information

## 4.3.4.1 Management System Documents

Sygnetics ensures that our QMS includes the documented information that is required to be maintained and retained by ISO 9001, and additionally, any documented information identified by our organization that demonstrates the effective operation of our QMS.

Sygnetics applies the following criteria to all types of documented information in order to assess whether the information is necessary for demonstrating the effectiveness of our QMS, and whether it should be formally controlled.

- 1. Does it communicate a message internally or externally?
- 2. Does it provide evidence of process and product conformity?
- 3. Does it provide evidence that planned outputs were achieved?
- 4. Does it provide knowledge sharing?

If any of the above criteria apply, Sygnetics ensures that this information is retained and/or maintained as a form of documented information'

## 4.3.4.2 Creating and Updating

Sygnetics ensures that when we create documented information it is appropriately identified and described (e.g. title, date, reference number) and is available in an appropriate format (e.g. language, software version, graphics, etc.) and on appropriate media (e.g. paper, electronic). All documented information is reviewed and approved for suitability and adequacy.

## 4.3.4.3 Controlling Documented Information

Documented information is retained to provide evidence of conformity to the requirements specified by ISO standards, customer requirements and of the effective operation of our management system. Sygnetics uses an electronic document management system - SharePoint. It is backed up and updated as required, and is used to retain documented information ensuring only the current versions are available to users. All management system documents are controlled according to the Document Control Procedure which defines the process for:

- 1. Approving documents for adequacy prior to issue;
- 2. Reviewing and revising as necessary and re-approving documents;
- 3. Ensuring that changes and current revision status of documents are identified;
- 4. Ensuring that relevant versions of applicable documents are available at points of use;
- 5. Ensuring that documents remain legible and readily identifiable;
- 6. Ensuring that documents of external origin are identified and their distribution controlled;
- 7. Preventing the unintended use of obsolete documents;



8. Ensuring that documents of external origin are identified and their distribution controlled.

## 5 LEADERSHIP

## 5.1 Leadership and Commitment

## 5.1.1 Quality Management

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

Sygnetics' leadership is also responsible for implementing the QMS, which includes the development and deployment of the quality policy, the quality objectives, and product/project-specific plans that are customer focused.

The President/CEO provides the leadership and governance to all activities including defining the



strategic direction, responsibility, authority, and communication to assure the safe and effective performance.

Our management structure provides necessary support for creating and establishing appropriate processes that are important for maintaining and achieving our quality objectives and policies. In addition, management activities include systematic verification of the effectiveness of our QMS by undertaking internal audits and analyzing performance data.

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Regular management reviews ensure that our Quality Management System is adequate and effective, and that any necessary adjustments are made as a result. Management Reviews will be held twice a year.

The President/CEO is committed to implementing and developing the Quality Management System and this commitment is defined by our corporate policies and objectives. Sygnetics ensures that our policies are understood, implemented and maintained throughout at all levels of the organization through distribution of our policy statements and through management review of the policy statements and corporate level improvement objectives. Sygnetics communicates our mission, vision, strategy, policies and processes to all employees in order to:

- 1. Create and sustain shared values of fairness and ethical behavior;
- 2. Establish a culture of trust and integrity;
- 3. Encourage commitment to quality;
- 4. Provide people with the required resources, training and authority to act with accountability;
- 5. Inspire, encourage and recognize people's contribution.

## 5.1.2 Customer Focus

Sygnetics strives to identify current and future customer needs, to meet their requirements and to exceed their expectations. The President/CEO ensures that the focus on improving customer satisfaction is maintained by setting and reviewing objectives related to customer satisfaction at management review meetings.

The President/CEO also ensures that customer requirements are understood and met. Customer requirements are understood, converted into internal requirements and communicated to appropriate personnel within the organization. Customer complaints and other customer feedback are continually monitored and measured to identify opportunities for improvement. We continually look for ways to interact directly with our customers to ensure that we focus on their unique needs and expectations.

## 5.2 Quality Policy

## 5.2.1 Establishing and Communicating

Sygnetics' quality policy acts as a compass by providing the direction and framework for establishing key corporate level performance measures, as well as related objectives and targets. The President/CEO ensures that our corporate policies are established and documented, and that the policies are available to all interested parties via our website.

The Quality Manager has overall responsibility for defining, documenting, implementing and reviewing our quality policy in consultation with the management teams and other personnel, or their representatives. The policy is reviewed at least annually, as part of the management reviews or at a frequency determined by:



- 1. The changing needs and expectations of relevant interested parties, Section 4.2.
- 2. The risks and opportunities that are presented through the risk management process, Section 6.1.

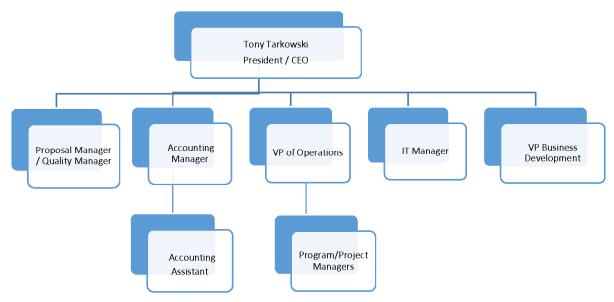
The quality policy is communicated to all employees at all levels throughout our organization via training, regular internal communications and reinforcement during annual employee performance reviews.

## 5.2.2 Quality Policy Statement

Sygnetics will maintain a company-wide Quality Management System (QMS) designed to ensure that our products and services meet or exceed client requirements. We will comply with requirements of the standard and plan for continuous improvement of the QMS while consistently striving to simplify our processes to prevent unnecessary work or waste. Sygnetics' overall goal is to provide quality products and services, exceeding client requirements, while growing profitably.

## 5.3 Roles, Responsibilities, and Authorities

Our organizational structure is defined in the chart below. The organization chart shows the interrelation of personnel within Sygnetics, and job descriptions define the responsibilities and authorities of each role. Job descriptions and the organizational structure are reviewed and approved by the President/CEO for adequacy as determined by the changing needs and expectations of the interested parties identified in Section 4.2, and any risk and opportunities presented through the risk management process, Section 6.1.



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## The President/CEO

The President/CEO is ultimately responsible for the quality of Sygnetics' products and services since he controls the resources, systems and processes by which conforming work is accomplished. The President/CEO is responsible for business planning, development and the communication of our policies, Quality Management System planning, the establishment and deployment of objectives, the provision of resources needed to implement and improve the Quality Management System, and for undertaking management reviews. The President/CEO has assigned the responsibility and authority to the management teams and departments to:

- 1. Ensure that QMS processes are delivering their intended outcomes;
- 2. Report on the operation of the QMS and identifying any opportunities;
- 3. Ensure that improvement is taking place;
- 4. Ensure that customer focus is promoted throughout the organization;
- 5. Ensure that changes to the QMS are planned and implemented;
- 6. Ensure the integrity of the system is maintained during changes;
- 7. Ensure that responsibilities and authorities relating to the QMS are communicated and understood.

#### <u>Managers</u>

All managers demonstrate their commitment to the development and improvement of the Quality Management System through the provision of necessary resources, through their involvement in the internal audit process and through their proactive involvement in continual improvement activities. Emphasis is placed on improving both the effectiveness and efficiency of key system processes.

All managers are responsible for the implementation of the policies, processes and systems described in this manual. All managers are responsible for planning and controlling the management system processes within their area of responsibility, including the establishment and deployment of operational level objectives and the provision of resources needed to implement and improve these processes.

#### **Employees**

All employees are responsible for the quality of their work and implementation of the policies and procedures applicable to processes they perform. Employees are motivated and empowered to identify and report any known or potential problems and to recommend related solutions to aid the corrective and preventive action process.

## 5.4 Communication

## 5.4.1 Internal Communication

Sygnetics communicates information internally regarding our QMS and its effectiveness, through documented training, internal audit reports and continual improvement processes. All managers are responsible for establishing regular formal and informal



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communications as needed to convey to their employees the relevance and importance of their activities; typically this information is conveyed through team meetings and crossfunctional improvement projects.

Communications regarding how employees contribute to the achievement of objectives are also conveyed and reinforced during employee performance reviews. Issues pertaining to our QMS that may be communicated internally include:

- 1. Day-to-day operations and general awareness;
- 2. Quality policy;
- 3. Information on achieving objectives and targets;
- 4. Risk and opportunities.

The President/CEO and his direct team are responsible for communicating the corporate policies as well as the importance of meeting customer, statutory and regulatory requirements to employees within their respective departments. He ensures the quality policy is understood and applied to the daily work of the organization through the establishment of measureable goals and objectives. Internal communication occurs on an on-going basis and is achieved through various mechanisms as appropriate:

- 1. Regular meetings and briefings;
- 2. Training sessions and training material;
- 3. Website, internal e-mails;
- 4. Product and process performance data analysis and audit results;
- 5. Targets, objectives, KPIs, management system manual and procedures;
- 6. Corrective action and non-conformance reports;
- 7. Minutes of ad-hoc and scheduled meetings.

## 5.4.2 External Communication

Sygnetics determines the need to communicate information externally to our interested parties regarding the effectiveness of our QMS.

Sygnetics ensures that all external communications are authorized prior to release.

Where required, advice appropriate to the context of the communication may be sought concerning the content and dissemination of certain external communications. Responses to external communications are recorded if they are transmitted by email or letter.

See Interested Parties.xlsx.



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## 6 MANAGEMENT SYSTEM PLANNING 6.1 Addressing Risks & Opportunities

The overall aim of risk and opportunity management within Sygnetics is to ensure that organizational capabilities and resources are employed in an efficient and effective manner to take advantage of opportunities and to mitigate risks.

The President/CEO is responsible for incorporating risk based thinking into our organization's culture. This includes the establishment of risk management policies and targets to ensure effective implementation of risk and opportunity management principles and activities by:

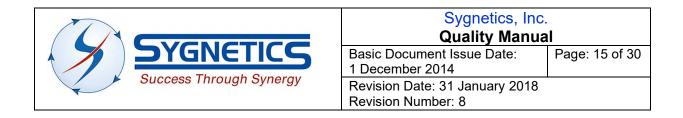
- Providing sufficient resources to carry out risk and opportunity management activities;
- 2. Assigning responsibilities and authorities for risk and opportunity management activities;
- 3. Reviewing information and results from audits and risk and opportunity management activities.

**PLAN** Create plans to address risks and opportunities DO Implement plans to mitigate risks or to adopt opportunities **RISKS AND OPPORTUNITIES** CHECK Monitor risk management plans using measurments and audits ACT Implement changes to the QMS and continually review

The scope of Sygnetics' risk and opportunity management process includes the assessment of the internal and external issues identified in Section 4.1, and the assessment of the needs and expectations of any interested parties identified in Section 4.2.

Risk and opportunity management is undertaken as part of Sygnetics' day-to-day operations and is captured at the following hierarchy:

- 1. Strategic level
- 2. Program level
- 3. Department level
- 4. Process level



Establishing such a hierarchy for capturing risk and opportunity ensures that each is managed at the most appropriate level within our organization. Typically, the following categories are assigned to each level in the hierarchy as shown in the table below.

Business Hierarchy	Risks / Opportunity
Strategic level	Budgets and profitability
Program Level	Performance and efficiency
Department Level	Resources and targets
Process Level	Evaluation and assurance

## 6.2 Quality Objectives

Sygnetics sets out its objectives and targets on a regular basis within the management review minutes where details of program dates and responsibilities are defined. Improvements in quality and performance are incremental and are in keeping with the size and complexity of our organization.

When setting objectives and targets, our organization ensures that they are consistent with the needs and expectations of our interested parties, as defined in Section 4.2, and to our corporate policies. In addition, technological options, financial, operational and business requirements are considered.

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

Objectives have been established for the following:

- Sales/Business Development Federal and Commercial
- Recruiting
- Project Management
- Invoicing
- Quality Management System

See Quality Objectives xxxx.xlsx

## 6.3 Planning for Change

The Quality Management System is planned and implemented in order to meet our corporate objectives and the requirements of ISO 9001:2015. The planning process involves establishing and communicating our policies, objectives and associated operational procedures.

This document constitutes our overall plan for establishing, maintaining and improving the Quality Management System. For each instance of management system planning, the output is documented and retained accordingly and changes are conducted in a



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controlled manner. The management review and the internal audit processes ensure that the integrity of the QMS is maintained when significant changes are planned which may affect key processes.

Whenever Quality Management System changes are planned, The President/CEO ensures that all personnel are made aware of any changes which affect their process, and that subsequent monitoring is undertaken to ensure that QMS changes are effectively implemented.

#### 7 SUPPORT

#### 7.1 Resources

#### 7.1.1 General

Resources at Sygnetics include human resources and specialized skills, infrastructure, technology, work environment and financial resources. The resource requirements for the implementation, management, control and continual improvement of the Quality Management System, and activities necessary to enhance customer satisfaction, are defined in our operational procedures, work instructions and the following sections of this QMS manual:

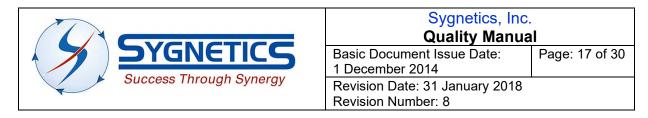
- 1. Planning; Section 6.0
- 2. Management review; Section 9.3
- 3. Human resources; Section 7.1.2
- 4. Infrastructure; Section 7.1.3
- 5. Work environment; Section 7.1.4
- 6. Planning of product realization; Section 8.1
- 7. Determination of customer requirements; Section 8.2

## 7.1.2 People

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications, experience and responsibilities that are required for each position that affects product and system conformity. Qualifications include desired requirements for education, skills and experience. Appropriate qualifications, along with the provision of any required training, provide the competence required for each position.

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

All employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of our policies and objectives. The company



operates a formal system to ensure that all employees within the organization are adequately trained to enable them to perform their assigned duties.

Staff training records are maintained to demonstrate competency and experience. Training records are maintained and include as a minimum; copies of certificates for any training undertaken to date, current job description and curriculum vitae (resume).

#### 7.1.2.1 Competence

The President/CEO identifies emerging competency needs during management reviews. Emergent competency needs are converted into job descriptions for the type and number of positions that need to be filled through internal or external recruitment.

Where required; competency training and monitoring is conducted in-house, although for more specialist skills, external courses are utilized. The effectiveness of training is evaluated and recorded. The company induction includes an introduction to our policies and objectives. Future competency training needs are identified as part of the Management Review process.

#### 7.1.2.2 Awareness

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of our policies and objectives. The company operates a formal system to ensure that all employees within the organization are adequately trained to enable them to perform their assigned duties.

Where required; awareness training and monitoring is conducted in-house, although for more specialist skills, external courses are utilized. The effectiveness of awareness training is evaluated and recorded. The company induction includes an introduction to our organization's policy statements and objectives. Future training needs are identified as part of the management review process.

#### 7.1.3 Infrastructure

Sygnetics is responsible for planning, providing and maintaining the resources needed to achieve product and process conformance, including buildings, workspace and associated utilities; process equipment (hardware and software); and supporting services. The Director of Operations has overall responsibility for managing our services.

## 7.1.4 Operational Environment

Sygnetics ensures that our office complies with relevant health and safety regulations. Executive Management ensures that the appropriate human and physical factors of the work environment are considered and provided, including such factors as noise, temperature, lighting and etc. Sygnetics, Inc. is committed to maintaining its facilities in a safe and healthy manner and establishing and providing an infrastructure that is needed to comply with product requirements.



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## 7.1.6 Organizational Knowledge

Sygnetics recognizes that organizational knowledge is a valuable resource that supports our quality management activities and ensures continual product and service conformity. There is a strong link between organizational knowledge and the competence of our people, the latter being peoples' ability to apply knowledge to their work.

To ensure that organizational knowledge is retained and transferred, organizational knowledge is recorded in documented information, and is embedded in our processes, products and services. Examples of organizational knowledge include:

- 1. Documented information regarding a process, product or service;
- 2. Previous specifications and work instructions;
- 3. The experience of skilled people and their processes and operations;
- 4. Knowledge of technologies and infrastructure relevant to our organization.

Sources of internal knowledge also include our intellectual property; knowledge gained from experience; lessons learned from failures and successes; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services.

Sources of external knowledge often include other ISO standards; research papers; webinars from conferences; or knowledge gathered from customers, stakeholders or other external parties. Sygnetics determines and reviews internal and external sources of knowledge, such as:

- 1. Lessons learned from non-conformities, corrective actions, and the results of improvement;
- 2. Gathering knowledge from customers, suppliers and partners, benchmarking against competitors;
- 3. Capturing knowledge existing within the organization, e.g. through mentoring/succession planning;
- 4. Sharing knowledge with relevant interested parties to ensure sustainability of the organization;
- 5. Knowledge from conferences, attending trade fairs, networking seminars, or other external events.

## 8 PRODUCT & SERVICE DEVELOPMENT

## 8.1 Operational Planning & Control

Sygnetics establishes and implements documented plans and procedures that describe the processes (Refer to Section 4.3.2) and the controls required for the provision of services in awareness to the objectives, the potential for planned or unintended change, and the risks and opportunities identified in Section 6.1. During this planning phase, management or other responsible personnel identify the following parameters:



- 1. Objectives and requirements for the service
- 2. Verification, validation, monitoring, and inspection
- 3. Documented information to demonstrate conformity
- 4. Documented information to demonstrate process effectiveness
- 5. Necessary resources; or outsourced processes and their controls
- 6. Criteria for process performance and product/service acceptance
- 7. Potential consequences and mitigation to change affecting input requirements
- 8. Resources necessary to support the ongoing operation of the service

The output of planning activity includes documented plans, resource schedules, process requirements and procedures

## 8.2 Requirements for Products or Services

## 8.2.1 Customer Communication

In accordance with our commitment to exceed our customer's expectations, Sygnetics highlights effective customer communication as an essential element of delivering customer satisfaction. Appropriate handling of customer communication helps to reduce customer dissatisfaction and in many cases turn a frustrating situation into a satisfying experience. Customer communication occurs through the following formats, events and processes:

- 1. Capability Statements relating to our services
- 2. Enquiries, quotations, proposals and invoices
- 3. Confirmation of contracts and amendments (modifications)
- 4. E-mails, letters and general correspondence
- 5. CPARs
- 6. Customer feedback and complaints process

The Quality Manager is responsible for establishing methods of communication with our customers to ensure inquiries, contracts - including amendments, customer feedback, and complaints are handled expeditiously and professionally.

## 8.2.2 Determining Requirements

Sygnetics develops appropriate requirements to ensure that we satisfy the needs and expectations of our customers or relevant interested parties. We ensure that customer requirements are clearly articulated and that their requirements are captured and understood before the acceptance of an order. Customer requirements include the following:

- 1. Statement of Work of Performance Work Statement of contract
- 2. Statutory and regulatory requirements related to the contract
- 3. Quality Metrics of contract



4. Any additional requirements determined by Sygnetics

## 8.2.3 Review of Requirements

Prior to committing to the customer, Sygnetics ensures and confirms our capacity to supply the required service. Pre-acceptance reviews are conducted to ensure that:

- 1. Requirements are defined and are appropriate
- 2. Any additional requirements determined by Sygnetics are appropriate
- 3. Contract or order requirements differing from those previously expressed are resolved
- 4. Sygnetics has the ability to meet the defined requirements
- 5. Documented information is retained and maintained showing the results of the review

## 8.2.4 Changes in Requirements

Sygnetics ensures that all relevant documented information; relating to changes in product or service requirements, is authorized and amended where necessary, and that all relevant personnel are made aware of the documented requirement changes.

## 8.4 Control of Suppliers & External Processes

## 8.4.1 General

The purchasing process is essential to our organization's ability to provide our customers with services that meet their requirements. Sygnetics accomplishes this by closely working with a network of external clients (subcontractors, teammates). Performance and capability are continually assessed through periodic, performance data analysis and inspection or verification of the supplied services.

## 8.4.2 Type and Extent of Control

The type and extent of control applied to our suppliers and the purchased service is dependent upon the effect that the outsourced service may have on our final service. The following considerations are taken in to account by:

- 1. Ensuring that we understand the capabilities and competencies
- 2. Ensuring that we clearly communicate the roles and responsibilities
- 3. Defining the quality requirements for the outsourced activity
- 4. Selecting and qualifying appropriate suppliers

It is the responsibility of management to evaluate based on their ability to supply services in accordance with specified requirements. This can be accomplished through audits and annual evaluations of the subcontractor/teammate. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.



## 8.4.3 Information for External Providers

It is Sygnetics' responsibility to give our subcontractors/teammates the best opportunity to be successful. This is accomplished by providing:

- Identification of the service to be delivered
- Qualifications of personnel providing the service
- Agreed upon cost
- Quality Management requirements

## 8.5 Production & Service Provision

## 8.5.1 Control of Production & Service Provision

In order to control the planning, administrative support and implementation of work, our organization's policy is to describe the work methods, the controls applied and the records required.

The following controlled conditions are applied where applicable:

- Quality control checks are performed
- Evidence of completed inspections
- Detailed process work instructions and specifications for all products
- Criteria for workmanship and competence

## 8.5.2 Identification

When not specifically stated by the contract, the contract name and contract number are the identification mechanism that Sygnetics utilizes.

## 8.5.3 Property Belonging to Customer

We identify, verify, protect and maintain customer property provided for use. Sygnetics exercises care with customer property while it is under the company's control or being used. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records are maintained.

Customer property can include a desk space, telephones, computers, and other items necessary to maintain an office environment.

## 8.6 Release of Products & Services

Service delivery does not proceed until all compliance has been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

Measurement and acceptance criteria that are necessary for service acceptance are retained as documented information.



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## 8.7 Control of Non-conforming Outputs

It is Sygnetics' policy to detect, control and rectify any aspect of an output that does not conform as quickly and efficiently as possible. Where necessary, any service output that does not conform to requirements is properly identified and controlled to prevent unintended use. The nonconformity is analyzed and the cause(s) are investigated.

Improvement actions are implemented to ensure the non-conformance does not reoccur. Once the non-conforming outputs are corrected, the outputs are then verified for conformity against requirements. Documented information concerning the nature of any non-conformances, the resolving authority, and the resulting corrective action is retained. Where necessary, details concerning any authorized concessions are documented as evidence of acceptance.

## 9 PERFORMANCE EVALUATION

#### 9.1 Monitoring, Measurement, Analysis and Evaluation

#### 9.1.1. General

Sygnetics applies suitable methods for determining which aspects of the Quality Management System and its processes are to be monitored, measured and evaluated. The frequency and methods by which our processes are monitored, measured and evaluated is determined and informed by:

- 1. Statutory and regulatory requirements
- 2. Customer feedback and specification requirements
- 3. Process and QMS requirements
- 4. Process performance and audit results
- 5. Level of risk and types of control measure
- 6. Trends in non-conformities or corrective actions
- 7. Criticality for service conformity

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

Services are not delivered until all compliance has been completed and documented information exists to provide evidence of conformity to acceptance criteria and identifying the person(s) authorizing release. The Quality Manager monitors information and trends relating to customer perception as to whether the organization has fulfilled the customers' requirements. Customer complaints, whether received in writing, verbally or electronically through our website are immediately forwarded to the Quality Manager for action. If the problem cannot be resolved, the complaint is escalated to the Operations Director or to the President/CEO for resolution.



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Customer survey data along with other customer feedback, including written or verbal complaints, is reviewed by the Quality Manager who initiates appropriate corrective actions. The level of customer satisfaction is monitored using various sources of customer data:

- 1. Repeat customers and trends in market share
- 2. Monthly Reports
- 3. CPARs
- 4. Analysis of customer complaints and customer satisfaction surveys
- 5. Yearly Reviews

#### 9.1.2 Customer Satisfaction

As one of the measurements of the performance of the quality management system, information relating to customer perception as to whether the company has met customer requirements is monitored. The method's for obtaining and using this information include:

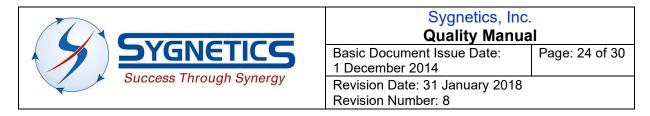
- Customer Requirements
- Customer Complaints
- Repeat Customers
- Yearly Reviews

## 9.1.3 Analysis and Evaluation

The President/CEO and other managers and supervisors collect and analyze data using appropriate statistical techniques to determine the suitability and effectiveness of key Quality Management System processes applicable to their area(s) of responsibility and to identify opportunities for improvement. At a minimum, data is analyzed to assess achievement of the corporate level objectives and customer requirements.

A process is effective if the desired results are measurably achieved. Effectiveness is measured in terms of product quality, process accuracy, delivery schedule performance, cost and budgetary performance, employee function performance against established objectives and levels of customer satisfaction. In order to identify strengths, weaknesses, threats and opportunities in our Quality Management System, Sygnetics monitors and analyses trends using the following quality data points:

- 1. Characteristics of processes, services and their trends
- 2. Conformity to product, customer and legal requirements
- 3. Customer satisfaction and perception data
- 4. Supplier and external provider performance data
- 5. Results of actions taken to address risks and opportunities
- 6. Effective implementation of QMS planning
- 7. Improvement opportunities identified during internal audits and management reviews



Control limits for process and product performance are expressed as objectives and disseminated via documented information as appropriate. Sygnetics undertakes corrective action when the data shows a trend toward the defined control limit.

#### 9.2 Internal Audit

Sygnetics, Inc. plans and conducts internal audits according to the Internal Audits Procedure for the following purposes:

- To verify whether quality activities and related results comply with planned arrangements, ISO 9001 and Quality Management System requirements established by Sygnetics.
- To determine the overall effectiveness of the Quality Management System as implemented and maintained.

The Quality Manager produces an Internal Audit Schedule, which identifies when each element or process of the Quality Management System will be audited. An internal audit is conducted at least quarterly to ensure that every element or process of the Quality Management System is audited at a minimum of once per year. The frequency at which an individual element or process is audited is based upon the importance and status of the element or process and the results of previous audits.

The Quality Manager is responsible for organizing and coordinating the internal audit to ensure that the audit criteria, scope, frequency and methods are defined, and that the following requirements are met:

- Definition of audit responsibilities
- Definition of requirements for planning and conducting the audit, including follow-up activities
- Recording of audit results
- Communication of audit results to management

The Quality Manager is responsible for ensuring the selection of auditors and the conduct of audits ensure objectivity and impartiality of the audit process.

Only qualified personnel may perform internal auditing activities. These qualified personnel are classified as internal auditors and are required to have received training on internal auditing techniques. This training may be performed by a certified auditor or by previously trained internal auditors. Records of internal audit training are maintained according to the Record Control procedure.

In the case of non-compliances or weaknesses (in either the Quality Management System or procedures, or the performance and adherence to those systems and procedures), the Quality Manager initiates a Corrective Action.



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The Quality Manager is responsible to ensure that the corrective actions are resolved in a timely manner to eliminate detected problems and their causes. Follow-up audits are used to verify the implementation and effectiveness of the corrective and preventive actions. The verification results are recorded and reported to the appropriate personnel.

Records documenting the audit process and results are maintained according to Record Control and utilized in the Management Review process.

#### 9.3 Management Review

#### 9.3.1 General

To ensure the continuing suitability, adequacy and effectiveness of our Quality Management System in meeting Sygnetics' strategies, the President/CEO conducts formal management review meetings. This review also identifies opportunities for improvement and needed changes. Records are maintained for each management review meeting.

Management reviews will be twice a year. This will enable the President/CEO and other executive leadership to review the entire scope of the QMS annually, in increments – focusing on particular processes, matrices, and effectiveness.

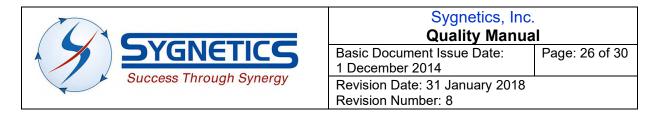
#### 9.3.2 Inputs

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

- Status of actions from previous Management Reviews
- Changes in External and Internal Issues
- Results of audits
- Customer satisfaction
- Process performance and product conformity
- Status of corrective and preventive actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the QMS
- Effectiveness of actions to address risks and opportunity
- Adequacy of Resources
- Recommendations for improvement

## 9.3.3 Outputs

The primary outputs of management review meetings are management actions that are taken to make changes or improvements to our Quality Management System. The Quality Manager creates written minutes of meetings summarizing the Management Review



activities, the conclusions reached and action items identified. These minutes are used to guide and improve the Quality Management System at Sygnetics, Inc. by documenting:

- 1. Actions taken to continually improve the effectiveness of the Quality Management System and related processes.
- 2. Actions taken to continually improve the company's products and services in order to maintain a high level of customer satisfaction and consistently meet customer requirements.
- 3. Additional resources necessary for the effective operation of the Quality Management System, including human resource, infrastructure and work environment needs.
- 4. Changes to Sygnetics' quality objectives (including those defined for product).

The minutes of the Management Review serve as records for Sygnetics' Quality Management System and are filed and maintained according to the Record Control Procedure.

## **10 IMPROVEMENT**

## 10.1 General

It is the overall responsibility of management at Sygnetics to continually improve the effectiveness of the Quality Management System. In order to determine and select opportunities for improvement or to implement any necessary actions to meet the requirements of customers and relevant interested parties, or to enhance customer satisfaction, Sygnetics drives improvement via the analysis of relevant data. The data inputs for the improvement process include:

- 1. Risk and opportunity evaluations
- 2. Assessment of the changing needs and expectations of interested parties
- 3. The conformity of existing products and services
- 4. The effectiveness of our QMS
- 5. Subcontractor/Teammate performance
- 6. Levels of customer satisfaction, including complaints and feedback
- 7. Internal and external audit results
- 8. Corrective action and non-conformance rates

The overall effectiveness of continual improvement program (including corrective actions taken as well as the overall progress towards achieving corporate level improvement objectives) is assessed through our management review process.

## **10.2** Non-conformity and Corrective Action

Evidence of non-conformance, customer dissatisfaction or service weakness is used to drive our continual improvement system.



The Quality Manager is responsible for ensuring the corrective action process is managed effectively. Sygnetics' Corrective Action Procedure is used in the following situations:

- 1. To resolve nonconformities found during internal, external (customer), or third party audits;
- 2. To revise the quality systems, work processes, quality procedures, or work instructions to eliminate the cause of a poor quality product or service, customer complaint, or internal quality failure; and
- 3. To resolve quality system problems found during the Management Review Process.

The Corrective Action Procedure defines requirements for:

- 1. Identifying and reviewing nonconformities (including customer complaints);
- 2. Determining the causes of the nonconformity;
- 3. Evaluating the need for actions to ensure that the nonconformity does not recur;
- 4. Determining and implementing the corrective action needed;
- 5. Recording the results of corrective action taken; and
- 6. Reviewing the implementation and effectiveness of corrective actions taken.

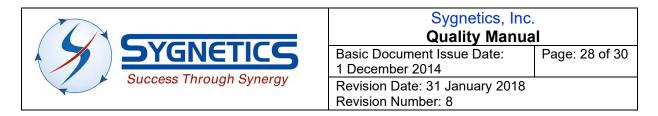
Follow-up audits are conducted in accordance with the internal audit process to ensure that effective corrective action is taken and that the action is appropriate to the impact and nature of the problem encountered. In addition, the Compliance Manage summarizes and analyses corrective action data to identify trends in order to assess the overall effectiveness of the corrective action system and to develop related recommendations for improvement.

The resulting corrective actions are reviewed for effectiveness and are reported to The President/CEO in order to determine if changes to the QMS are required, or whether any new risks or opportunities need to be considered during planning. Documented information concerning the nature of any nonconformances and their resulting corrective actions is retained.

The corrective actions are considered effective if the specific problem was corrected and data indicates that the same or similar problems have not recurred. Results of data analysis and subsequent recommendations are presented to the President/CEO for review.

## 10.3 Improvement

Sygnetics continually improves the effectiveness of its Quality Management System through the effective application of the corporate policies, objectives, auditing and data analysis, corrective and preventive actions and management reviews.



The continual improvement process begins with the establishment of our corporate policies and objectives for improvement, based on objectives contained in our business plan, customer targets and goals. Customer satisfaction, internal audit data, process and product performance data, and the cost of poor quality or risk control are then compared against objectives to identify additional opportunities for improvement.

The overall effectiveness of continual improvement program, including corrective actions taken, as well as the overall progress towards achieving corporate level improvement objectives, are assessed through our management review process.



# ATTACHMENT 1 SEQUENCE AND INTERACTION OF PROCESSES

