

HAYGOR INSTRUMENT & COMPANY, INC

Quality Manual

Revision B

January 8, 2024

Conforms to ISO 9001:2015

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0.0 Welcome to Haygor Instrument & Company, Inc.

Haygor Instrument was founded in 1973 in Pasadena, TX and in the late 1970's was incorporated and became a Texas Corporation. Haygor Instrument and Company, Inc. has been and is currently owned by the Bishop family. In 1981 George Bishop moved the company to its current location near Hobby Airport in Houston, TX. After nearly 40 years of dedication to the company and the industry, in 2017 George decided it was time to retire and sold his company to his son, Allen Bishop. Growing up in the business over the past 40 years, Allen learned everything he knows from his father and proudly continues the legacy that George started.

Haygor has become a leading manufacturer of Diaphragm Seal Systems offering all standard diaphragm seal assemblies as well as made to order specific customer designs.

1.0 Quality Policy

Senior management has developed the following Quality Policy which governs day-to-day operations to ensure quality. The Quality Policy is communicated and implemented throughout the organization.

The Quality Policy of Haygor Instrument is as follows:

We will achieve customer happiness by continually improving processes, products, and services to ensure they consistently meet or exceed customer requirements.

2.0 Context of the Haygor Organization

Haygor Instrument has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to Haygor Instrument and its interested parties; the interested parties are identified per the Procedure: **Context of the Organization**.

Such issues are monitored and updated as appropriate and discussed as part of management reviews.

The issues determined above are identified through an analysis of risks facing Haygor Instrument and its interested parties. "Interested parties" are those stakeholders who receive our Products and Services or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified per the document Procedure: **Context of the Organization**.

This information is then used by senior management to determine the company's strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

Context of the Organization



3.0 Scope of the Haygor Instrument Quality Management System

The scope of the quality management system is the design, manufacture, inspection, and shipping of diaphragm seal systems. The quality system applies to all processes, activities, and employees within the company.

The facility locations are:

6322 Nunn St.
Houston, TX 77087
Phone: 713-641-1791

540 Preston Rd.
Pasadena, TX 77503
Phone: 713-641-1791

4.0 QMS Processes

Haygor Instrument has adopted a process approach for its management system. By identifying processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming Products and Services discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the core processes.

Note: not all activities are considered “processes” – the term “process” in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.

The following core processes have been identified per the scope of Haygor Instrument:

- Sales
- Purchasing

-
- Design and Development
 - Production

Each core process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of core processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each Core Process has a **Process Definition** document which defines:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources
- criteria and methods employed to ensure the effectiveness of the process
- quality objectives related to that process

The sequence of interaction of these processes is illustrated in Appendix A.

Note: Appendix A represents the typical sequence of processes and may be altered depending on customer or regulatory requirements at the job or contract level, as needed.

Additional QMS documented procedures have been developed to support the QMS and its processes; these are listed in Appendix B. This list only provides some top-level procedures and may not reflect the entirety of all QMS documentation.

Each core process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one “metric” or key performance indicator (KPI) which is then measured to determine the process’ ability to meet the quality objective.

Throughout the year, metrics data is measured and gathered by process owners or other assigned managers to present to Senior management. The data is then analyzed by Senior management for review of currently set goals and adjust for the purposes of long-term continual improvement.

The specific quality objectives for each process are defined in the applicable **Process Definition Document**.

Metrics, along with current standings and goals for each objective, are recorded in records of management review.

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement may be sought and implemented, for the identified processes.

Any process performed by a third party is considered an “outsourced process” and must be controlled. The company’s outsourced processes, and the control methods implemented for each, are defined in the procedure: - **Outsourced Processes**.

Appendix A: Overall Processes Sequence & Interaction



Interaction of Processes for Haygor Instrument						
Core Processes	Starts with	Sales Process	Purchasing Process	Design and Development	Production Process	Ends with
Responsibilities of each core process		Quoting / communication / verification of customer requirements	Purchasing of material and outsourced processes; monitoring the quality of suppliers	Determine the stages and controls for design and development	The implementation of production and service provision under controlled conditions	The review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.
Objectives		To provide information relating to products and services; handling enquiries, contracts, or orders, including changes; obtaining customer feedback relating to products and services, including customer complaints; establishing specific requirements for contingency actions, when relevant.	To ensure that externally provided processes, products, and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.	To organize, establish, implement and maintain the design and development process to meet customer requirements.	To ensure customer requirements have been met per acceptance criteria for products and services.	To ensure the health of the quality management system by addressing trends and opportunities for continual improvement
Inputs	CUSTOMER COMMUNICATION	Requirements specified by the customer, including the requirements for delivery and post-delivery activities; requirements not stated by the customer, but necessary for the specified or intended use, when known; requirements specified by the organization; statutory and regulatory requirements applicable to the products and services; contract or order requirements differing from those previously expressed.	The adequacy of requirements prior to their communication to the external provider; Time frame for receipt of materials; any special requirements and/or processing needs.	The specifications, types of products and services to be designed and developed; functional and performance requirements; information derived from previous similar design and development activities; statutory and regulatory requirements; standards or codes of practice that the organization has committed to implement.	Documented information that defines characteristics of products and services; product definition data, drawings, parts lists, materials, and process specifications. Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards), and verification documents.	Status of the action items determined at the last management review; Customer satisfaction and feedback from relevant interested parties; trends to identify if quality objectives have been met; process performance and conformity of products and services; trends in nonconformities and corrective actions; monitoring and measurement results; audit results; the performance of external providers; the adequacy of resources; the effectiveness of actions taken to address risks and opportunities; opportunities for improvement
Output		A QT/WO that specifies exactly what the customer requirements are	PO to the supplier with all of the required information	A design drawing that meets all customer requirements for release to production	Product that meets all customer requirements	Opportunities for improvement, any need for changes to the quality management system, resource needs, risks identified, action items for the next management review.
Measures		Customer complaints, customer satisfaction	Supplier performance	Design and development of products meet all customer requirements.	Nonconformances escaping to the customer	Outcome of metrics review, corrective actions, opportunities for improvement, customer satisfaction
ISO 9001:2015 Reference		4.2, 6.2, 8.2, 8.2.1, 8.2.2, 8.2.3, 8.2.4, 8.5.5, 9.1.3, 10.0	6.2, 7.1-7.5.3, 8.4, 8.4.1, 8.4.2, 8.4.3, 9.1.3, 10.0	4.2, 6.2, 7.1-7.5.3.8.3, 8.3.1-8.3.3, 9.1.3, 10.0	4.2, 6.2, 7-7.5.3, 8.1-8.4, 8.5-8.5.6, 9.1.3	4.0, 4.2, 5.0, 6.0, 7.0, 8.5.5, 9.2.2, 9.3, 10.0

Appendix B: Subordinate QMS Procedures

All subordinate QMS Procedures once finalized, written, and approved will be added to the list below:

- Context of the Organization
- Control of Documents Procedure
- Control of NC Product Procedure
- Control of Records Procedure
- Corrective Preventive Action Procedure
- Customer Property Procedure
- Design of Diaphragm Seal Systems Procedure
- Production of Diaphragm Seal Systems
- Equipment Validation Procedure
- Identification & Traceability Procedure
- Internal Auditing Procedure
- Management Review Procedure
- Outsourced Processes Procedure
- Preservation of Diaphragm Seal Systems Procedure
- Preventive Maintenance Procedure
- Purchasing Procedure
- Shipping of Diaphragm Seal Systems
- Training Procedure
- First Article Inspection Procedure

5.0 Revision History and Approval

Rev.	Nature of changes	Approval	Date
A	Original release.	MPS/MvdE	December 16 2020
B	Address updates.	Eva Falcon	January 8, 2024