

# ELBEX

## CORPORATION

### Quality Policy Manual

Issued To: **Operations Manager**

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## INTRODUCTION

This quality manual describes the quality system in operation at Elbex Corporation, its policies and the company-wide control system. This quality system addresses the requirements of the Quality Standards as stated in ISO 9001:2008, without design.

Elbex Corporation takes exception to the following section of the ISO 9001:2008 Standard:

- Section 7.3: Design and Development
  - Elbex does not design/develop its own products. Customers supply their prints or samples, which are replicated to their specifications.

## 1.0 COMPANY OVERVIEW, APPLICATION AND SCOPE

Elbex Corporation was founded in November of 1991 in Kent, Ohio. It is located at 300 Martinel Drive and all operations are performed at this location. Elbex Corporation's scope is the manufacture and sale of rubber and silicone extruded products, along with any secondary operations that may be required per customer needs.

All employees of Elbex Corporation are to perform their job duties according to the quality guidelines within the Elbex quality system.

## 2.0 MISSION & QUALITY POLICY STATEMENT

### 2.1 Mission Statement:

Elbex Corporation is dedicated to the support of customer success and growth in the marketplace as demonstrated through our employee dedication, our corporate investment in training and equipment, our responsive and proactive customer care and service, and our premium quality assurance performance.

Elbex is also committed to maintaining leading edge technology to augment value and performance for customers while operating as a responsible corporate citizen in civic and environmental practices.

### 2.2 Quality Policy:

To instill and maintain a total quality practice in our corporate culture that commands a proactive support of our customers' goals, as well as exceeding their needs and expectations in a timely manner.

To monitor and continuously improve business, products, our organization, employee performance and safety.

**3.0 QUALITY OBJECTIVES**

- **Customer Focus:** Elbex is committed to working proactively with their customers to understand product performance, dimensional and material requirements. This understanding translates into defined standards that are used to meet or exceed the customer expectations.
- **Team Involvement:** The Elbex team members are experienced in their relative fields, by relying on them to make quality and performance driven decisions. We not only empower our employees, but also enable the cooperation to benefit from their respective talents. Creating a work environment where associates are valued and contribute to the team is a vital factor to our success.
- **Supplier Relationships:** We at Elbex strongly believe that our suppliers are the experts in their respective fields and are the best qualified to identify areas for improvement. Our close working relationships with our suppliers are crucial for the long-term success of our organization. When evaluating suppliers, we not only look at the quality of the products and services provided in terms of first pass yield and on-time delivery, we also extend the evaluation to include price, technical competence, support, lead times and customer focus.
- **Continual Improvement:** Elbex will continue to strive to identify areas where improvements may be needed. Through internal, external, customer and supplier audits, as well as our documented corrective and preventive action system, all data is reviewed by team members as a tool used to drive our continuous improvement program throughout the Elbex system.

This quality manual has been approved by:



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**Quality Assurance Manager**



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**ISO Management Representative**



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**Operations Manager**



## 4.0 QUALITY MANAGEMENT SYSTEM

### 4.1 General Requirements

Elbex Corporation has established, documented, implemented and currently maintains a quality management system which continually improves its effectiveness in accordance with the International Standard ISO 9001:2008 without design.

The quality management system shall:

- Determine the processes needed for the quality management system and their application throughout the organization.
- Determine the sequence and interaction of these processes.
- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective.
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
- Monitor, measure where applicable, and analyze these processes.
- Implement actions necessary to achieve planned results and continual improvement of these processes.

### 4.2 Documentation Requirements

The quality management system documentation shall include, but is not limited to, the following:

#### 4.2.1 General

- Documented statements of a quality policy and quality objectives.
- A quality manual.
- Documented procedures and records required by the International Standard ISO 9001:2008 without design.
- Documents, including records, determined to be necessary to ensure the effective planning, operation and control of the processes.

#### 4.2.2 Quality Manual

Elbex Corporation has established and continuously maintains a quality manual that includes the following:

- The scope of the quality management system, including details and justification for any exclusions.
- References to documented procedures established for the quality management system.



- Definitions and descriptions of the interactions between the processes of the quality management system.

#### 4.2.2.1 Reference

Elbex Process Flow Chart: PFC-394

#### 4.2.3 Control of Documents

Elbex Corporation controls all quality related documents and records that relate to ISO 9001:2008 without design. Records are a special type of document and are controlled according to the requirements stated in 4.2.4.

A documented procedure is established and maintained to define the controls needed:

- To approve documents for adequacy prior to issue.
- To review and update as necessary and re-approve documents.
- To ensure that changes and the current revision status is appropriately identified.
- To ensure that relevant versions of applicable documents are readily available.
- To ensure that documents remain legible and readily identifiable.
- To ensure that documents of external origin are identified and their distribution is controlled.
- To prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

Documents under this control shall include, but are not limited to, the following:

- The quality manual and externally generated standards.
- Standard procedures and work instructions.
- Drawings, purchase orders and customer orders.

#### 4.2.3.1 Reference

Document Control Procedure: QP-0012

#### 4.2.4 Control of Records

Elbex Corporation maintains quality records using a documented procedure to demonstrate conformance to requirements and the effective operation of the quality management system.



A documented procedure is established and maintained to define the controls needed:

- To ensure the identification, storage and protection of all records.
- To ensure proper retention and disposition of all records.
- To ensure all records remain legible, readily identifiable and retrievable.

#### 4.2.4.1 Reference

Control of Records Procedure: QP-0011

## 5.0 MANAGEMENT RESPONSIBILITY

### 5.1 Management Commitment

At Elbex Corporation, all levels of management provide evidence of their commitment to the development and implementation of the quality management system and continuous improvement. This is achieved through the following means:

- Periodic communication between management and personnel throughout the organization indicating the importance of meeting customer needs and continuous improvement efforts in all areas of business.
- Involvement in establishing and developing the quality policy.
- Involvement in establishing and developing quality objectives.
- Ensuring that necessary resources are available.
- Involvement in the internal audit procedures, including management reviews.

### 5.2 Customer Focus

The management at Elbex Corporation ensures that customer requirements are determined and met with the goal of enhancing customer satisfaction.

### 5.3 Quality Policy

The management at Elbex Corporation ensures that the quality policy meets the following objectives:

- Is appropriate to the purpose of the organization.
- Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system.
- Provides the framework for establishing and reviewing quality objectives.
- Is communicated and understood within the organization.
- Is reviewed for continuing suitability.





## 5.4 Planning

### 5.4.1 Quality Objectives

The management at Elbex Corporation ensures that quality objectives, including those needed to meet requirements for products, are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

### 5.4.2 Quality Management System Planning

The management at Elbex Corporation ensures the following:

- The planning of the quality management system is carried out in order to meet the requirements given in section 4.1, as well as the quality objectives.
- The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

## 5.5 Responsibility, Authority and Communication

### 5.5.1 Responsibility and Authority

The management at Elbex Corporation ensures that responsibilities and authorities are defined and communicated within the organization.

### 5.5.2 Management Representative

The Operations Manager has been given the authority to appoint the Quality / Engineering Manager as the ISO management representative.

### 5.5.3 Internal Communication

The management at Elbex Corporation ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

## 5.6 Management Review

### 5.6.1 General

The management at Elbex Corporation reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability,



adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The management representative maintains records from the management review.

### 5.6.2 Review Input

The input to management review includes information on the following:

- Results of audits.
- Customer feedback.
- Process performance and product conformity.
- Status of preventative and corrective actions.
- Follow-up actions from previous management reviews.
- Changes that could affect the quality management system.
- Recommendations for improvement.

### 5.6.3 Review Output

The output from the management review includes any decisions and actions related to the following:

- Improvement of the effectiveness of the quality management system and its process.
- Improvement of product related to customer requirements.
- Resource needs.

## 5.7 Reference

Management Review Procedure: QP-0013

## 6.0 RESOURCE MANAGEMENT

### 6.1 Provision of Resources

Elbex Corporation determines and provides the resources needed for the following:

- To implement and maintain the quality management system and continually improve its effectiveness.
- To enhance customer satisfaction by meeting customer requirements.



## **6.2 Human Resources**

### **6.2.1 General**

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

### **6.2.2 Competence, Training and Awareness**

Elbex Corporation ensures the following:

- Determine the necessary competence for personnel performing work affecting conformity to product requirements.
- Where applicable, provide training or take other actions to achieve the necessary competence.
- Evaluate the effectiveness of the actions takes.
- Ensure that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- Maintain appropriate records of education, training, skills and experience.

## **6.3 Infrastructure**

Elbex Corporation determines, provides and maintains the infrastructure needed to achieve conformity to product requirements, which includes the following:

- Buildings, workspace and associated utilities.
- Process equipment, both hardware and software.
- Supporting services, communication and information systems.

## **6.4 Work Environment**

Elbex Corporation determines and manages the work environment, which is needed to achieve conformity to product requirements.



## 7.0 PRODUCT REALIZATION

### 7.1 Planning of Product Realization

Elbex Corporation plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system.

In planning product realization, Elbex Corporation determines the following:

- Quality objectives and requirements for the product.
- The need to establish processes and documents, and to provide resources specific to the product.
- Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance.
- Records needed to provide evidence that the realization processes and resulting product meet requirements.

### 7.2 Customer-related Processes

#### 7.2.1 Determination of Requirements Related to the Product

Elbex Corporation determines the following:

- Requirements specified by the customer, including the requirements for delivery activities.
- Requirements not stated by the customer, but necessary for specified or intended use, where known.
- Statutory and regulatory requirements applicable by the product.
- Additional requirements considered necessary by Elbex.

#### 7.2.2 Review of Requirements Related to the Product

Elbex Corporation reviews the requirements related to the product. This review is conducted prior to Elbex's commitment to supply a given product to a customer, while ensuring the following:

- Product requirements are defined.
- Contract or order requirements differing from those previously expressed are resolved.
- Elbex has the ability to meet the defined requirements.

Records of the result of the review and the actions arising from the review are maintained.

Where the customer provides no documented statement of requirement, the customer requirements are to be confirmed by Elbex prior to acceptance.

Where product requirements are changed, Elbex ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

### **7.2.3 Customer Communication**

Elbex Corporation determines and implements effective arrangements for communicating with customers in relation to the following:

- Product information.
- Inquiries, contracts or order handling, including amendments.
- Customer feedback, including customer complaints.

### **7.2.4 Reference**

Contract Review Procedure: CP-0002

## **7.3 Design and Development**

Elbex Corporation takes exception to this section of the ISO 9001:2008 Standard. Elbex does not design/develop its own products. Customers supply their prints, which are replicated to their specifications.

## **7.4 Purchasing**

### **7.4.1 Purchasing Process**

Elbex Corporation ensures that purchased products conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

Elbex Corporation evaluates and selects suppliers based on their ability to supply product in accordance with Elbex's requirements. A criterion for selection, evaluation and re-evaluation is established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

## 7.4.2 Purchasing Information

Purchasing information shall describe the product to be purchased, including the following:

- Requirements for approval of product, procedures, processes and equipment.
- Requirements for qualification of personnel.
- Quality management system requirements.

Elbex ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

## 7.4.3 Verification of Purchased Product

Elbex Corporation establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where Elbex Corporation or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

## 7.4.4 References

Purchasing Procedure: AP-0001  
Receiving of Raw Compound Procedure: SP-0001  
General Receiving Procedure: SP-0005  
Receiving Inspection of Raw Materials: QP-0008

## 7.5 Production and Service Provision

### 7.5.1 Control of Production and Service Provision

Elbex Corporation ensures that the production and service provisions are planned and carried out under controlled conditions, which include the following:

- The availability of information that describes the characteristics of the product.
- The availability of work instructions, as necessary.
- The use of suitable equipment.
- The availability and use of monitoring and measuring equipment.
- The implementation of monitoring and measurement.

- The implementation of product release and delivery.

## 7.5.2 Validation of Processes for Production and Service Provision

Elbex Corporation validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.

Validation demonstrates the ability of these processes to achieve planned results.

Elbex Corporation establishes arrangements for these processes including:

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

## 7.5.3 Identification and Traceability

Where appropriate, Elbex Corporation identifies the products by suitable means throughout product realization.

Elbex Corporation identifies the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records.

## 7.5.4 Customer Property

Elbex Corporation exercises care with customer property while it is under Elbex's control or being used by Elbex. Elbex Corporation shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, Elbex reports this to the customer and maintains records.

### 7.5.4.1 Reference

Customer Supplied Product Procedure: EP-0004

## 7.5.5 Preservation of Product



Elbex Corporation preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to the requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of the product.

## 7.6 Control of Monitoring and Measuring Equipment

Elbex Corporation determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to the determined requirements.

Elbex Corporation has established processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary, to ensure valid results, the measurement equipment shall conform to the following:

- Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded.
- Be adjusted or re-adjusted as necessary.
- Have identification in order to determine its calibration status.
- Be safeguarded from adjustments that would invalidate the measurement result.
- Be protected from damage and deterioration during handling, maintenance and storage.

In addition, Elbex Corporation assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

Records of the results of calibrations and verification are maintained.

If any type of computer software is to be utilized for monitoring requirements, the software system will be confirmed prior to use.

### 7.6.1 Reference

Calibration Procedure: QP-0005



## 8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

### 8.1 General

Elbex Corporation plans and implements the monitoring, measurement, analysis and improvement processes needed as follows:

- To demonstrate conformity to product requirements.
- To ensure conformity of the quality management system.
- To continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

### 8.2 Monitoring and Measurement

#### 8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Elbex Corporation monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information are determined.

#### 8.2.2 Internal Audit

Elbex Corporation conducts internal audits at planned intervals to determine whether the quality management system meets the following:

- Conforms to the planned arrangements, to the requirements of the International Standard ISO 9001:2008 without design, and to the quality management system requirements established by the organization.
- Is effectively implemented and maintained.

The audit program has been planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of the previous audits. The audit criteria, scope, frequency and methods are defined. The selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. The auditors do not audit their own work.

A documented procedure has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.



The management responsible for the area being audited is responsible for ensuring that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities include the verification of the actions taken and the reporting of verification results.

#### **8.2.2.1 Reference**

Internal Auditing Procedure: QP-0014

### **8.2.3 Monitoring and Measurement of Processes**

Elbex Corporation applies suitable methods for monitoring and measurement of the quality management system processes, where applicable. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

### **8.2.4 Monitoring and Measurement of Product**

Elbex Corporation monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained.

Records indicate the person authorizing release of product for delivery to the customer.

The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

#### **8.2.4.1 References**

Inspection of Spliced Materials Procedure: QP-0001

Lineal Footage Inspection Procedure: QP-0002

Sampling of Secondary Product Procedure: QP-0003

## **8.3 Control of Non-Conforming Product**



Elbex Corporation ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure has been established to define the controls and related responsibilities and authorities for dealing with non-conforming product.

Where applicable, Elbex Corporation deals with non-conforming product by one or more of the following ways:

- By taking action to eliminate the detected non-conformity.
- By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.
- By taking action to preclude its original intended use or application.
- By taking action appropriate to the effects, or potential effects, of the non-conformity when non-conforming product is detected after delivery or use has started.

When non-conforming product is corrected it shall be subjected to re-verification to demonstrate conformity to the requirements.

Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained, are maintained.

### **8.3.1 Reference**

Product Non-Conformance Procedure: QP-0006

## **8.4 Analysis of Data**

Elbex Corporation determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to the following:

- Customer satisfaction.
- Conformity to product requirements.
- Characteristics and trends of processes and products, including opportunities for preventive action.
- Suppliers.

## **8.5 Improvement**

### 8.5.1 Continual Improvement

Elbex Corporation continually improves the effectiveness of the quality management system throughout the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

### 8.5.2 Corrective Action

Elbex Corporation takes action to eliminate the causes of non-conformities to prevent recurrence. Corrective actions are appropriate to the effects of the non-conformities encountered.

A documented procedure has been established to define the requirements as follows:

- Reviewing non-conformities, including customer complaints.
- Determining the causes of non-conformities.
- Evaluating the need for action to ensure that non-conformities do not recur.
- Determining and implementing action needed.
- Records of the results of action taken.
- Reviewing the effectiveness of the corrective action taken.

#### 8.5.2.1 Reference

Corrective Action Procedure: QP-0009

### 8.5.3 Preventive Action

Elbex Corporation determines actions to eliminate the cause of potential non-conformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure has been established to define the requirements as follows:

- Determining potential non-conformities and their causes.
- Evaluating the need for action to prevent occurrence of non-conformities.
- Determining and implementing action needed.
- Records of results of action taken.
- Reviewing the effectiveness of the preventive action taken.

### 8.5.3.1 Reference

Preventive Action Procedure: QP-0010