
	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>
TITLE: <b>QUALITY SYSTEM MANUAL</b>		<b>Page 1 of 14</b>
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton
		Last Rev.: 11/25/2020

# QUALITY SYSTEM MANUAL




CHECK THE MASTER LIST  
VERIFY THAT THIS IS THE LATEST VERSION BEFORE USE

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>
<b>TITLE: QUALITY SYSTEM MANUAL</b>		<b>Page 2 of 14</b>
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton
Last Rev.: 11/25/2020		

Index

PARAGRAPH TITLE .....	PAGE
1.0 BASLER PLASTICS LLC .....	3
2.0 RELATED DOCUMENTS .....	3
3.0 TERMS AND DEFINITIONS .....	4
4.0 CONTEXT OF BASLER PLASTICS LLC .....	4
4.1 UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT .....	4
4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES .....	4
4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM .....	5
4.4 QUALITY MANAGEMENT SYSTEM (QMS) AND ITS PROCESSES .....	5
5.0 LEADERSHIP .....	5
5.1 LEADERSHIP AND COMMITMENT .....	5
5.2 POLICY .....	5
5.3 ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES .....	6
6.0 PLANNING .....	6
6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES .....	6
6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM .....	6
6.3 PLANNING OF CHANGES .....	7
7.0 SUPPORT .....	7
7.1 RESOURCES .....	7
7.2 COMPETENCE .....	8
7.3 AWARENESS .....	8
7.4 COMMUNICATION .....	8
7.5 DOCUMENTED INFORMATION .....	8
8.0 OPERATION .....	9
8.1 OPERATIONAL PLANNING AND CONTROL .....	9
8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES .....	9
8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES .....	10
8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS, AND SERVICES .....	10
8.5 PRODUCTION AND SERVICE PROVISIONS .....	11
8.6 RELEASE OF PRODUCTS AND SERVICES .....	12
8.7 CONTROL ON NONCONFORMING OUTPUTS .....	12
9.0 PERFORMANCE EVALUATION .....	12
9.1 MONITORING, MEASUREMENT, ANALYSIS, AND EVALUATION .....	12
9.2 INTERNAL AUDIT .....	12
9.3 MANAGEMENT REVIEW .....	13
10.0 IMPROVEMENT .....	13
10.1 GENERAL .....	13
10.2 NONCONFORMITY AND CORRECTIVE ACTION .....	13
10.3 CONTINUAL IMPROVEMENT .....	13

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>
TITLE: <b>QUALITY SYSTEM MANUAL</b>		<b>Page 3 of 14</b>
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton Last Rev.: 11/25/2020

## 1.0 **BASLER PLASTICS LLC**

Basler Plastics LLC manufactures plastic components and assemblies, including secondary services for commercial and industrial applications.

Our mission is to sustain our position as a worldwide leader in providing quality products and services to our customers. Further, our mission is to operate our business at a profitable level that will sustain growth and provide security for our employees, customers, suppliers, and the communities where our facilities are located.

This Basler Quality System Manual (QSM) with respect to the ISO 9001:2015 standard:

- Defines the company's interpretations of the standard
- Is an aspect of demonstrating how the company complies with this standard
- Elaborates on how Basler Plastics LLC has customized its Quality Management System (QMS) to suite it purposes


Basler Plastics LLC products and services meet appropriate and applicable agency standards based on application, geographic location and market requirements; these may include product evaluation to domestic and international standards. Products that require evaluation to applicable standards and/or 3rd Party Agencies are documented and controlled accordingly.

Basler Plastics LLC quality objectives are shown below:

- Satisfy customer expectations while complying with corporate owner's requirements
- Meet product and service quality goals
- Meet product and service delivery goals

## 2.0 **RELATED DOCUMENTS**

ISO 9001:2015	Quality Management Systems – Requirements
ISO 9000:2015	Quality Management Systems – Fundamentals and Vocabulary
AA100001	Restricted Substance Compliance
AC100002	Control of Measuring Inspection & Test Equipment
AC605001	Corrective and Preventive Actions
AC605003	Internal Auditing
AC605006	Nonconforming Material
AC605007	Product Identification and Traceability
AC605010	Quality Plan
AC605012	Document Control – Quality Documentation
AC605015	Control of Quality System Manuals
AC605017	Procedures, Forms and Work Instructions
AC605020	Continual Improvement
AC605024	Control of Records
AC605028	Management Review
AC605029	Quality System Index
AC605030	Context of the Organization
AC605031	Planning
AC605032	Operational Planning and Control
AE605001	Engineering Change Order (ECO) Procedure
AG605001	Manufacturing Control Plan
AH100004	Supplier Approval and Verification
AJ605001	Training Procedure
AJ605002	Environmental, Health & Safety Plan
AL605001	Contract Review

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>
TITLE: <b>QUALITY SYSTEM MANUAL</b>		<b>Page 4 of 14</b>
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton
		Last Rev.: 11/25/2020

FB605001

Quality Policy

### 3.0 **TERMS AND DEFINITIONS**

The following are the definitions in the Quality Management System. If no definition is provided the ISO standard is adopted.

Term or Item	Equivalent Reference or Definition	Note(s)
Basler Plastics LLC	Basler Plastics	-
ISO 9001	Current release of the ISO 9001	Unless stated explicitly otherwise
Documented Information	Documents and Records	Control and effectiveness is important specific hierarchy is not
Documents	Information detailing how activity is done	Structured in the most efficient way
Records	Captured evidence of activity execution	Depending on criticality should include execution and result details
Design Intent	Meeting the explicit and implicit requirements.	-
Uncertainty	Deficiency of information concerning an event, its consequence or likelihood	Paraphrase: Likely outcome either unknown or not confidently known
Risk	Negative effect or result of uncertainty	Outcomes can have aspects of both risk and opportunity
Opportunity	Positive effect or result of uncertainty	
Suspect	<i>Typically</i> used in conjunction with a product and/or service whose characteristic or outcome may not be matching the (designed) intent	Variation exists being suspect does not yet mean it is defective
Nonconforming	Confirmed Suspect Product or Service not meeting the design intent	Typically non-conforming means there is some defect either with product or service
Rework	Efforts/Activity of reprocessing nonconforming product or service back to the design intent via original or alternative equivalent processing	Rework is defined as: "Actions taken on a nonconforming item so it will fulfill the originally specified requirements."
Repair	Efforts/Activity to make product or service conform to the design intent	Repair is defined as: "Action taken on a nonconforming item so it will fulfill the intended usage requirements, although it may not conform to the originally specified requirements."
Scrap	Discarding of nonconforming product, service and/or process	-
Quality Management System	QMS	-

## 4.0 **CONTEXT OF BASLER PLASTICS**

### 4.1 **UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT**


Basler Plastic has reviewed and analyzed key aspects of the organization, its position in the market, customers, suppliers, governmental agencies/regulators and other interested parties/stakeholders to determine position and direction of the organization. This activity requires profound understanding of interested parties/stakeholders as explained in AC605030, Context of the Organization.

This will be monitored, updated (as needed/appropriate) and discussed as part of management reviews.

### 4.2 **UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES**

The issues determined per 4.1 above are identified through an analysis of risks facing Basler Plastics and its interested parties/stakeholders who receive our Products and/or Services as defined in Section 1.0 Basler Plastics LLC, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. This is explained in AC605030, Context of the Organization.

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

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>	
<b>TITLE: QUALITY SYSTEM MANUAL</b>		<b>Page 5 of 14</b>	
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton	Last Rev.: 11/25/2020

### 4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, Basler Plastics has determined the scope of the Quality Management System is as follows: the manufacture of plastic components and assemblies, including secondary services for commercial and industrial applications.

QMS is applicable to all processes, activities and employees within the company;

- BASLER PLASTICS LLC 201 Center Point Rd, San Marcos, Texas 78666 USA

Per the ISO 9001:2015 standard all clause requirements are applicable to the above scope, except for 8.3 Design & Development of Product and Services. This is due to the organization does not design products and services, the Customers design their own products and tools. Clause 8.3 is therefore not applicable to our Quality Management System.

### 4.4 QUALITY MANAGEMENT SYSTEM (QMS) AND ITS PROCESSES

Basler Plastics has developed a Quality Management System and associated processes that stress issue resolution, risk and opportunity assessment and continuous process improvement involving employees, suppliers, and associates. The management of Basler Plastics established, implemented and maintains this documented Quality Management System as a means of ensuring that products conform to specified requirements and in accordance with ISO 9001:2015. The following processes and their sequence of interaction have been identified, responsibilities and authorities assigned for this QMS: Manufacturing, Manufacturing Support, and Administrative. The management of Basler Plastics is committed to provide the resources necessary to maintain this QMS at all levels and to determine criteria and methods needed to ensure that both the operation and control of these processes are effective while striving for continuous improvement.

Documented information to support the operation of QMS processes are maintained, changes implemented when needed, and retained to the extent necessary.

## 5.0 LEADERSHIP

### 5.1 LEADERSHIP AND COMMITMENT

#### 5.1.2 GENERAL

Top Leadership's commitment to development, implementation, and continual improvement of the Basler QMS is demonstrated by the activities documented in this manual. Leadership establishes unity of purpose and direction to achieve the quality objectives and success of the company.


#### 5.1.3 CUSTOMER FOCUS

Management has established and maintains procedures contained in this QMS for determining and meeting customer requirements in a manner that is consistent with meeting applicable statutory and regulatory requirements, addressing risk and opportunities, and enhancing customer satisfaction.

### 5.2 POLICY

#### 5.2.1 ESTABLISHING THE QUALITY POLICY

Top Management is responsible for establishing, implementing and maintaining the quality policy. The Quality Policy supports the purpose and context of the organization and the strategic direction of the company while providing the framework for setting quality objectives. The Quality Policy identifies our commitment to satisfy applicable requirements and to the continual improvement of our QMS. The Strategic/business plan will be reviewed and revised annually, as necessary, to support quality policy objectives. Refer to Form FB605001.

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>	
TITLE: <b>QUALITY SYSTEM MANUAL</b>		<b>Page 6 of 14</b>	
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton	Last Rev.: 11/25/2020

## QUALITY POLICY

*We satisfy our customers by delivering defect-free, competitive products on time.*

*We accomplish this by knowing the requirements of our jobs and performing to the best of our abilities while striving for continuous improvement.*

### 5.2.2 COMMUNICATING THE QUALITY POLICY

It is the responsibility of Management to ensure that this policy is understood, implemented and maintained at all levels of the organization and available to relevant interested parties, as appropriate.

### 5.3 ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES

#### 5.3.1 RESPONSIBILITY AND AUTHORITY

AC605017, Procedures, Forms and Work Instructions, documents and communicates responsibility and authority appropriate for the QMS.

AC605029, Quality System Index, defines responsibility and authority for the ISO sections.

#### 5.3.2 MANAGEMENT RESPONSIBILITY

The Basler Plastics Management Team is responsible for ensuring the quality system processes are established, implemented, maintained and ensures continuing suitability.

#### 5.3.3 INTERNAL COMMUNICATIONS

The Quality Manager reports on the performance and effectiveness of the QMS to management, normally during the documented Management Review meeting. Continual Improvement and Management Review meeting minutes are located on the Basler Network and communicated within the organization as appropriate. Cost of quality, scrap, and quality analysis reports are distributed to managers.

## 6.0 PLANNING

### 6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES


Actions to address risks and opportunities is described in the manufacturing plan, quality plan, and other procedures addressing departments and processes to ensure the QMS can achieve its intended results, preventing or reducing undesired effects and achieving continual improvement.

### 6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

Planning is described in AC605031, Planning, and AC605032, Operational Planning and Control, to ensure compliance with objectives and that the integrity of Basler Plastics QMS is maintained during process and product changes. Requirements for new product release are also addressed in these procedures.

Planning of how to achieve established objectives at relevant functions, levels and processes shall include the following:

- What will be done
- What resources will be required
- Who will be responsible

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>	
<b>TITLE: QUALITY SYSTEM MANUAL</b>		<b>Page 7 of 14</b>	
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton	Last Rev.: 11/25/2020

- When it will be completed
- How results will be evaluated

### 6.3 PLANNING OF CHANGES

Changes to the QMS shall be carried out in a planned manner with consideration placed on the purpose of the change and potential consequences, integrity of the QMS, availability of resources and allocation of responsibilities and authorities.

## 7.0 SUPPORT

### 7.1 RESOURCES

#### 7.1.1 GENERAL

Each year manpower and resource requirements needed to implement and maintain the quality management system and continually improve its effectiveness to meet customer's requirements are reported by Department Managers in the financial budget for approval by the President. Consideration of the capabilities of, and constraints on, existing internal resources and what needs to be obtained from external providers is considered during this time and throughout the year as needed.

#### 7.1.2 PEOPLE

Determination and provision of persons necessary for the effective implementation of the QMS and for the operation and control of its processes is executed.

#### 7.1.3 INFRASTRUCTURE

The Plant Manager determines requirements for buildings, workspace and associated utilities. When the Plant Manager determines that there is a need for additional buildings, workspace or utilities they make their request for funding during the yearly budgeting process to acquire appropriate resources. This includes IT hardware, software and process needs for the facility. IT infrastructure requirements are identified by the Information Systems and Operations Manager and fall underneath the responsibility of the Vice President Finance. Maintenance of buildings and associated utilities are determined by the appropriate Plant Manager and is performed by personnel assigned. AG605001, Manufacturing Control Plan, addresses the responsibility for acquiring equipment and supporting services.

#### 7.1.4 ENVIRONMENT FOR THE OPERATION OF PROCESSES

Basler Plastics maintains an appropriate work environment for the operation of processes needed to achieve conformity to product and regulatory requirements as documented in AJ605002, Environmental Health & Safety Plan.

#### 7.1.5 MONITORING AND MEASURING RESOURCES


##### 7.1.5.1 GENERAL

Resources needs are determined and provided to ensure valid and reliable results when monitoring and measuring is used to verify conformity of products and services to requirements. Resources provided are suitable for the specific type of activity being undertaken and are maintained.

Control of measurement and monitoring of product is documented in the quality and manufacturing plan. See AC605010 and AG605001. Control of monitoring and measuring devices are documented in the control of measuring, inspection & test equipment. See AC100002, Control of Measuring, Inspection & Test Equipment.

##### 7.1.5.2 MEASUREMENT TRACEABILITY



	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>	
<b>TITLE: QUALITY SYSTEM MANUAL</b>		<b>Page 8 of 14</b>	
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton	Last Rev.: 11/25/2020

All inspection, measuring and test equipment used for the verification of process and product shall be controlled by documented calibration and maintenance procedures identified in procedure AC100002, Control of Measuring, Inspection & Test Equipment.

### 7.1.6 ORGANIZATIONAL KNOWLEDGE

Department Managers, under their area of responsibility, perform the following:

- Determine the knowledge necessary for the operation of processes and for achieving conformity of products and services
- Maintain knowledge and making available to the extent necessary
- Understand changing needs and trends compared to current knowledge
- Acquire necessary additional knowledge

### 7.2 COMPETENCE

Basler Plastics has established and maintains procedure AJ605001, Training Procedure, for identifying training needs and provides for the training of personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training, and/or experience, as required. Appropriate records of training are maintained. Department Manager and Supervisors determine the necessary competence for personnel reporting to them. A minimum competency level is required of employees, whose work affects quality, for them to remain in their assigned job function. Competency is verified by one of the following methods:

- Test results, when appropriate
- Acceptable completion of duties identified in job descriptions
- Demonstrated ability to apply knowledge and skill

### 7.3 AWARENESS

Department Managers and Supervisors are responsible for ensuring all person's doing work under their control are aware of the quality policy, relevant quality objectives, their contribution to the effectiveness of the QMS, including the benefits of improved performance and implications of not conforming with the QMS requirements.

### 7.4 COMMUNICATION

Internal and external communications relevant to the QMS are identified throughout the organizations procedures.

### 7.5 DOCUMENTED INFORMATION


#### 7.5.1 GENERAL

This manual exists as a general outline of the formal QMS. The detailed procedures referenced herein are available through the quality department and as identified in AC605017, Procedures, Forms and Work Instructions. This QSM, associated procedures and work instructions are controlled as documented in appropriate procedures. The policies that define Basler Plastics quality system are contained in this QSM.

The quality system documentation has the following levels

- Quality System Manual
- Procedures (Corporate and Facility Specific)
- Work Instructions, Forms and Tags (Corporate and Facility Specific)
- Records



	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>	
<b>TITLE: QUALITY SYSTEM MANUAL</b>		<b>Page 9 of 14</b>	
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton	Last Rev.: 11/25/2020

## 7.5.2 CREATING AND UPDATING

The QMS including this QSM will be reviewed at least annually. This review is the responsibility of the Vice President of Corporate Quality. The results of this review will be presented during the Management Review process.

Procedure, work instruction, and form creation, revision, review and approval controls are documented in procedure AC605017.

## 7.5.3 CONTROL OF DOCUMENTED INFORMATION

This QMS documents the control of this QSM, documented procedures, work instructions, forms and data related to the requirements of ISO 9001:2015. Detailed procedures and processes are considered proprietary and may not be available for copying, if not pre-arranged contractually. Responsible managers are authorized to determine what documents and data may be viewed and/or copied. See related procedures, AC605012: Document Control – Quality Documentation and Records; AC605015: Control of Quality System Manuals; AC605017: Procedures, Forms and Work Instructions.

Control of records consistent with the requirements of ISO 9001:2015 are implemented and documented in accordance with Basler Plastics QMS. Appropriate records are identified and controlled in procedure AC605024: Control of Records.

## 8.0 OPERATION

### 8.1 OPERATIONAL PLANNING AND CONTROL

The processes, planning, objectives, requirements for the product, verification, validation, monitoring and records needed for product realization is addressed in AC605010, Quality Plan, and AG605001, Manufacturing Control Plan, and other procedures and work instructions documented in the QMS.

### 8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES

The company has established and maintains procedures to determine requirements for product and services, review of requirements and customer communications as described in AL605001, Contract Review. Restricted Substance Compliance (RSC), AA100001, defines the process and control to ensure our products meet applicable regulatory requirements for restricted substance compliance where required.

#### 8.2.1 CUSTOMER COMMUNICATION


Customer Service (Corporate), Sales (Corporate), and Marketing (Corporate) representatives are the primary customer contact personnel. Communications regarding product information, correspondence, inquires, contracts, order handling, amendments to contracts and customer feedback and satisfaction are routed through Customer Service, Sales, Marketing and Quality Department. Customer feedback is recorded in a database and addressed in accordance with section 10.0 of this manual as required.

#### 8.2.2 DETERMINING THE REQUIREMENTS FOR PRODUCTS AND SERVICES

Contract review for acceptance and capability is performed by Customer Service (Corporate), Marketing (Corporate), Sales (Corporate).

#### 8.2.3 REVIEW OF THE REQUIREMENTS FOR PRODUCTS AND SERVICES

Customer Service initiates a product quotation after determining that requirements are adequately defined. Records of such contract reviews are maintained in accordance with AC605024, Control of Records, by Customer Service (Corporate).

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>
TITLE: <b>QUALITY SYSTEM MANUAL</b>		<b>Page 10 of 14</b>
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton
Last Rev.: 11/25/2020		

#### 8.2.4 CHANGES TO REQUIREMENTS FOR PRODUCTS AND SERVICES

Exceptions to the Customer's specifications and requirements are documented in the quotation and relevant parties are made aware of the changed requirements. Records are maintained in accordance with AC605024, Control of Records.

#### 8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

Basler Plastics is exempt from this clause due to the organization does not design products and services, the Customers design their own products and tools. Clause 8.3 is therefore not applicable to our Quality Management System.

#### 8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

##### 8.4.1 GENERAL

Suppliers of externally provided processes, products and services are selected to ensure conformity to requirements. Controls are applied when products or services are intended for incorporation into Basler product or services, are provided directly to the customer of Basler on behalf of the organization, or a process or part of a process is provided by an external provider as a result of a decision of Basler.

Suppliers of externally provided processes, products and services are selected and maintained to support the organization's needs for material and service requirements. Selection of Suppliers is documented in AH100004, Supplier Approval and Verification, and performed by Purchasing (Corporate).

##### 8.4.2 TYPE AND EXTENT OF CONTROL

Type and extent of control is documented in AH100004, Supplier Approval and Verification, to ensure no adverse effect to Basler's ability to consistently deliver conforming products and services.


Suppliers are approved in accordance with AH100004, Supplier Approval and Verification, which establishes criteria for selection, evaluation and re-evaluation. Records of results of evaluation and any necessary actions arising from evaluations are maintained by Purchasing (Corporate).

Inspection and other activities necessary for ensuring that purchased product or service meet specified requirements are established and implemented. Materials are inspected when received in accordance with AC605009, Receiving Inspection, and work instructions to ensure that purchased product conforms to specified purchase requirements.

##### 8.4.3 INFORMATION FOR EXTERNAL PROVIDERS

Purchasing ensures the adequacy of requirement and communicates the requirement to external providers. Information provided during communication includes the following where appropriate:

- the processes, products and services to be provided
- the approval of
  1. products and services
  2. methods, processes and equipment
  3. the release of products and services
- competence, including any required qualification persons
- external providers' interactions with Basler
- control and monitoring of the external providers' performance to be applied by the organization
- verification or validation activities Basler, or a customer of Basler, intends to perform at the external providers' premises

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>	
TITLE: <b>QUALITY SYSTEM MANUAL</b>		<b>Page 11 of 14</b>	
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton	Last Rev.: 11/25/2020

## 8.5 PRODUCTION AND SERVICE PROVISION

### 8.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

Production and service provisions are planned and carried out under controlled conditions. Refer to AC605029, Quality System Index, for a list of procedures addressing the control of production and service provision.

Where applicable the following controlled information is available:

- Documented information that defines characteristics of the product to be produced, services to be provided or the activities to be performed and results to be achieved
- Availability of suitable monitoring and measuring resources
- Implementation of monitoring and measuring activities at appropriate stages to verify that acceptance criteria has been met
- use of suitable infrastructure and environment for operation of processes
- appointment of competent persons, including any required qualification
- Implementation of release, delivery and post-delivery activities
- Monitoring by Supervisors and Quality to defined criteria
- Maintenance of equipment and qualification of personnel
- Use of specific methods and procedures
- Records of qualification are maintained
- Appropriate re-validation as required

### 8.5.2 IDENTIFICATION AND TRACEABILITY


Identification and Traceability is addressed in AC605007, Product Identification and Traceability. All parts and materials used in the manufacture of products shall be assigned part numbers to allow for identification. All items will be clearly identified throughout the manufacturing process, as to part number, current stage of manufacture and acceptability of quality. This may be by labels, tags, location or other suitable means. This marking may be either individually or by lot. All products will be traceable after shipment by the use of date codes and Sales Order, etc.

### 8.5.3 PROPERTY BELONGING TO CUSTOMERS OR EXTERNAL PROVIDERS

Customer-supplied product used in the manufacture of products by Basler Plastics shall receive the same verification and control as purchased items. Customer-supplied items such as tooling used during the manufacture of products will be clearly identified and maintained. Special customer requirements will be documented with appropriate procedures and work instructions.

### 8.5.4 PRESERVATION

The conformity of product is preserved during internal processing and delivery to the intended destination. Necessary protection of all products is provided to prevent damage, loss, deterioration or substitution. Appropriate procedures, work instructions and/or bills of material shall specify packaging materials and methods for all finished products. Internal storage and handling procedures shall emphasize prevention of damage, first-in first-out storage. All materials and products shall be appropriately identified throughout the manufacturing process. The constituent parts of the product are included in this preservation process.

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>	
<b>TITLE: QUALITY SYSTEM MANUAL</b>		<b>Page 12 of 14</b>	
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton	Last Rev.: 11/25/2020

### 8.5.5 POST-DELIVERY ACTIVITIES

Requirements for post-delivery activities are determined during contract review and acceptance, including warranty provisions and potential associated undesired consequences.

### 8.5.6 CONTROL OF CHANGES

Control of changes is documented in AE605001, Engineering Change Order (ECO) Procedure. Changes are reviewed, verified and validated, as appropriate and approved to the extent necessary to ensure continued conformity with requirements.

### 8.6 RELEASE OF PRODUCTS AND SERVICES

Release of products and services to the customer is completed when planned arrangements have been satisfactorily completed, unless approved by a relevant authority and, as applicable, by the customer. Documented information on the release includes evidence of conformity with acceptance criteria and traceability to the person(s) authorizing the release.

Monitoring and measurement of product along with the product acceptance process for shipment is documented in AC605010, Quality Plan and the AG605001, Manufacturing Control Plan.

### 8.7 CONTROL OF NONCONFORMING OUTPUTS

Nonconforming outputs are identified and addressed for control through the Corrective and Preventive Actions procedure, AC605001.

## 9.0 PERFORMANCE EVALUATION

### 9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

#### 9.1.1 GENERAL

Products are inspected according to documented Mold Book instructions. These Mold Books are part specific, controlled by revision, and maintained by Plant Manager and Quality Manager.

Quality system metrics (objectives) being monitored are identified in AC605020, Continual Improvement. When planned results are not achieved, corrections and corrective actions are taken, as appropriate, to ensure conformity of product. The Quality System Index includes additional procedures addressing monitoring and measurement of processes. Work Instructions may also address monitoring and measurement.

#### 9.1.2 CUSTOMER SATISFACTION


Customer perception as to whether Basler Plastics has met requirements is monitored by Customer Service and Sales (Corporate). Communication is provided to the Basler Plastics Management team via Customer Concerns, Customer rejects, and customer communication in general.

#### 9.1.3 ANALYSIS AND EVALUATION

The metrics collected and analyzed as part of the continual improvement process as documented in AC605020, Continual Improvement, are used to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of quality management system can be made.

### 9.2 INTERNAL AUDIT

Internal quality audits, as documented in AC605003, Internal Auditing, are performed by trained and qualified auditors to verify that quality system policies and procedures are being followed and that the system is effective in correcting practices that cause nonconformity's. All procedures, processes and

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>	
<b>TITLE: QUALITY SYSTEM MANUAL</b>		<b>Page 13 of 14</b>	
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton	Last Rev.: 11/25/2020

products are subject to audit. Responsibility for scheduling of audits of the quality system will reside with the Quality Manager. Auditors are selected and audits conducted to ensure objectivity and impartiality. Audit results are reported to relevant management. Nonconformance's resulting from internal audits must be formally responded to with appropriate corrective action and closed out within 2 months of initial issuance; this closure can be postponed for a suitable time as determined by management based on severity. Results of quality audits will be reviewed by the management during the management review process.

### 9.3 MANAGEMENT REVIEW

#### 9.3.1 GENERAL

Management reviews are conducted annually to ensure the organization's continuing stability, adequacy, effectiveness and alignment with the strategic direction of the company.

#### 9.3.2 MANAGEMENT REVIEW INPUTS

Reviews are conducted by Quality Manager in accordance with the requirements of AC605028, Management Review.

#### 9.3.3 MANAGEMENT REVIEW OUTPUTS

Minutes of the review meeting are recorded and distributed to management in accordance with the requirements of AC605028, Management Review.

## 10.0 IMPROVEMENT

### 10.1 GENERAL

Opportunities for improvement necessary to meet customer requirements and enhance customer satisfaction are determined and selected and include the following:

- Improving products and services to meet requirements as well as to address future needs and expectations
- Correcting, preventing and reducing undesired effects
- Improving the performance and effectiveness of the quality management system


### 10.2 NONCONFORMITY AND CORRECTIVE ACTION

Procedures shall be developed to assure that nonconforming product cannot be forwarded to the next production process. These procedures shall provide for the appropriate identification, segregation, and disposition of nonconforming product. Nonconforming product may be identified at point of the manufacturing process, as well as customer returns. Refer to AC605006, Nonconforming Material.

Documented procedures for addressing and implementing corrective actions are established. Emphasis is placed on the determination of corrective action needed to eliminate the cause of nonconformities. Effective handling of customer complaints, reports of product nonconformities and internally detected nonconformities are address as described in AC605001, Corrective and Preventive Actions. Investigation into the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation is addressed in the above procedure.

### 10.3 CONTINUAL IMPROVEMENT

Continual improvement of the Quality Management System is achieved through the use of the processes described within this document. The effectiveness of this Quality Management System is continually improved through the use of the quality policy, quality objectives and preventive actions and management review. Refer to AC605020, Continual Improvement.

	<b>QUALITY SYSTEM</b>	DOCUMENT NO. <b>AB605001</b>	
<b>TITLE: QUALITY SYSTEM MANUAL</b>		<b>Page 14 of 14</b>	
Author: Liz Morris	Created: 8/23/13	Saved: Bobbi Etherton	Last Rev.: 11/25/2020

Documented procedures for addressing and implementing preventive actions are established. Emphasis is placed on preventive action to foster a proactive approach utilizing the identification of risks and opportunities as identified in AC605020, Continual Improvement. The procedure is used to detect, analyze and eliminate potential causes of nonconformities; also reference procedure AC605001, Corrective and Preventive Actions. Relevant preventive action information on actions is submitted to management review in accordance with procedure AC605028, Management Review.

UNCONTROLLED COPY