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		Last Rev.: 6/10/2024

QUALITY SYSTEM MANUAL



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1.0 **BASLER ELECTRIC COMPANY**

Basler Electric Company (founded in 1942) is a privately held family company that designs, manufactures and sells power conversion and control equipment for commercial, industrial, utility, and military applications. This includes but is not limited to voltage regulators and accessories, engine generator set controllers, protective relays, static excitation systems, and transformers.

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.

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

- Defines the company's interpretations of the standard
- Demonstrates how the company complies with this standard

Basler Electric's 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

1.1 **TRANSLATION AVAILABLE**

Also change the following document: AB100001S

2.0 **RELATED DOCUMENTS**

- ISO 9001:2015 Quality Management Systems - Requirements
- ISO 9000:2015 Quality Management Systems - Fundamentals and Vocabulary
- AA100001 Restricted Substance Compliance
- AC100001 Corrective and Preventive Action
- AC100002 Control of Equipment Used for Acceptance of Product
- AC100003 Internal Auditing
- AC100006 Nonconforming Material
- AC100007 Product Identification and Traceability
- AC100009 Receiving Inspection
- AC100012 Document Control - Quality Documentation and Records
- AC100015 Control of Quality System Manuals
- AC100017 Procedures, Forms and Work Instructions
- AC100019 Certificate of Conformance
- AC100020 Continual Improvement
- AC100024 Control of Records
- AC100028 Management Review
- AC100029 Quality System Index
- AC100030 Context of the Organization
- ACXXX010 Facility Quality Plan (XXX= appropriate facility identification)
- AGXXX001 Manufacturing Control Plan (XXX= appropriate facility identification)
- AE100018 Engineering Change Order Procedure
- AF100010 Customer Relationship Management
- AH100004 Supplier Approval and Verification
- AJ100001 Training
- AJ100002 Environmental Health & Safety Plan

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- AL100001 Contract Review
- AS100002 Explosive Atmosphere Product
- FB100006 Quality Policy – English
- FB100007 Quality Policy – Spanish
- WL100418 Customer Comment Log Entry
- Corporate and Facility Specific Procedures & Work Instructions

3.0 **TERMS AND DEFINITIONS**

The following are the definitions in the Quality Management System (QMS). The ISO standard is adopted if no definition is provided.

Term or Item	Equivalent Reference or Definition	Note(s)
Basler Electric Company	Basler Electric	-
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 who's 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 ELECTRIC**

4.1 **UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT**

Basler Electric 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 the position and direction of the organization. This activity requires profound understanding of interested parties/stakeholders as explained in AC100030, Context of the Organization.

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

The issues determined per section 4.1 above are identified through an analysis of risks facing Basler Electric and its interested parties/stakeholders who receive our products and/or services as defined in section 1.0, or who may be impacted by them, or those parties who may otherwise have a significant

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interest in our company. This information is used by management to determine the company's strategic direction. This is explained in AC100030, Context of the Organization.

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 Electric has determined the scope of the Quality Management System is as follows: The design and manufacture of transformers (3 phase power, industrial, filament/plate, reactors and magnetic amplifiers), voltage regulators and accessories, engine generator set controllers, protective relays, power system electronics and static exciter regulator systems.

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

- BASLER ELECTRIC COMPANY (Highland facility) 12570 State Route 143, PO Box 269, Highland, Illinois 62249 USA
- BASLER ELECTRIC COMPANY (Taylor facility) 204 Highland Drive, Taylor, Texas 76574 USA

Per the ISO 9001:2015 standard there are no exclusions for the Highland facility. Other Basler Electric facilities may identify process applicability in their Facility Quality Plans, ACXXX010.

4.4 QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES

Basler Electric has developed a QMS and associated processes that addresses issue resolution, risk and opportunity assessment and continual process improvement involving employees, suppliers and associates. The management of Basler Electric has established, implemented and maintains this documented QMS 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: Sales & Marketing, Design Development – Power Systems & Magnetics, Supply Chain Management, Manufacturing, Manufacturing Support and Administrative. The management of Basler Electric 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 continual 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

5.1.1 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 objectives and success of the company.

5.1.2 CUSTOMER FOCUS

Management has established and maintains procedures contained in the 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.

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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 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 and Quality Policy will be reviewed and revised annually, as necessary, to support policy objectives. Refer to Forms FB100006 & FB100007.

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

AC100017, Procedures, Forms and Work Instructions, documents and communicates responsibility and authority appropriate for the QMS.

AC100029, Quality System Index, defines responsibility and authority for the ISO sections.

AS100002, Explosive Atmosphere Product, defines responsibility and authority for Ex product.

The Vice President of Corporate Quality is a member of the senior management staff, reports directly to the President, and is the appointed ISO Management Representative. The Vice President of Corporate Quality is responsible for ensuring the quality system processes are established, implemented, maintained and ensures continuing suitability.

The Vice President of Corporate Quality reports on the performance and effectiveness of the QMS to top management, normally during the documented Management Review meeting. Continual Improvement and Quality System 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

Action to address risk and opportunities are described in the facility control plan, manufacturing control 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 areas identified in section 6.1 to ensure compliance with objectives and that the integrity of Basler Electric's QMS is maintained during process and product changes. Requirements for new product release are also addressed in these procedures.

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

- What will be done
- What resources will be required
- Who will be responsible
- When it will be completed
- How the 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

Periodically 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 appropriate Facility Manager determines requirements for buildings, workspace and associated utilities. When a facility 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 all locations. 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 Facility Manager and is performed by personnel assigned. Procedures ACXXX010, Facility Quality Plan, address the responsibility for acquiring equipment and supporting services.

7.1.4 ENVIRONMENT FOR THE OPERATION OF PROCESSES

Basler Electric maintains an appropriate work environment for the operation of processes needed to achieve conformity to product and regulatory requirements as documented in AJ100002, Environmental Health & Safety Plan.

7.1.5 MONITORING AND MEASURING RESOURCES

7.1.5.1 GENERAL

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Resource 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 facility quality plan and the manufacturing control plan. Control of monitoring and measuring devices are documented in AC100002, Control of Equipment Used for Acceptance of Product.

7.1.5.2 MEASUREMENT TRACEABILITY

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 AC100002, Control of Equipment Used for Acceptance of Product.

7.1.6 ORGANIZATIONAL KNOWLEDGE

Department managers and supervisors, 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 provide availability to the extent necessary
- Understand changing needs and trends compared to current knowledge
- Acquire necessary additional knowledge

7.2 COMPETENCE

Basler Electric has established and maintains AJ100001, Training, 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 Managers 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 QSM exists as a general outline of the formal QMS. The detailed procedures referenced herein are available through the quality department and as identified in AC100017, Procedures, Forms and Work Instructions. This QSM, associated procedures and work instructions are controlled as

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documented in appropriate procedures. The policies that define Basler Electric's 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

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 AC100017, Procedures, Forms and Work Instructions.

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, AC100012, Document Control - Quality Documentation and Records; AC100015, Control of Quality System Manuals; and AC100017, Procedures, Forms and Work Instructions.

Control of records consistent with the requirements of ISO 9001:2015 are implemented and documented in accordance with Basler Electric's QMS. Appropriate records are identified and controlled in AC100024, 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 ACXXX010, Facility Quality Plan and/or AGXXX001, 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 products and services, review of requirements and customer communications as described in AL100001, 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, Project Coordinator and Marketing representatives are the primary customer contact personnel. Communications regarding product information, correspondence, inquiries, contracts, order handling, amendments to contracts and customer feedback and satisfaction are routed through Customer Service, Project Coordinator, Marketing and the appropriate Design Engineering Department. Customer feedback is recorded in a database and addressed.

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8.2.2 DETERMINING THE REQUIREMENTS FOR PRODUCTS AND SERVICES

Contract review for acceptance and capability is performed by Customer Service, Marketing, Proposal Engineer, Project Coordinator and the appropriate Design Engineering Department.

8.2.3 REVIEW OF THE REQUIREMENTS FOR PRODUCTS AND SERVICES

Proposal Engineer, Sales and the Marketing Department or Customer Service initiate a product quotation after determining that requirements are adequately defined. Records of such contract reviews are maintained.

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.

8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

8.3.1 GENERAL

Each Design Engineering Department has established, implemented and maintains procedures for the product design and development process. Refer to AC100029, Quality System Index, for listing of procedures for Design and Development.

8.3.2 DESIGN AND DEVELOPMENT PLANNING

Design and Development Planning activities are documented in AE100002, AE100003 & AE203001. These activities include the planning of development stages, interfaces between different groups, responsibilities and authorities along with appropriate reviews, verification and validation. Planning is updated appropriately as the design and development progresses.

8.3.3 DESIGN AND DEVELOPMENT INPUTS

Design and Development Inputs are documented in AE100002, AE100003 & AE203001. Inputs will include functional and performance requirements, statutory and regulatory requirements; where applicable, information derived from previous similar designs and development activities and other requirements essential for design and development. Reviews are conducted to ensure the design input is adequate prior to beginning a project and to ensure incomplete, ambiguous and conflicting requirements are resolved.

8.3.4 DESIGN AND DEVELOPMENT CONTROLS

Controls to the Design and Development process are documented in AE100002, AE100003 and AE203001. Results to be achieved are defined.

Reviews are conducted to evaluate the ability of the results to meet requirements and to identify any problems and propose necessary actions.

Design and development verification is performed to ensure that the design and development outputs have met the design and development input requirements.

Design and development validation is performed to ensure that the resulting product and/or services is capable of meeting the requirements for the specified application or intended use, where known. Validation is completed prior to the delivery or implementation of the product.

Necessary actions are taken on problems determined during the reviews, or verification and validation activities.

Record of the control activities are retained.

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8.3.5 DESIGN AND DEVELOPMENT OUTPUTS

Design and Development Outputs are documented in AE100002, AE100003 & AE203001. Engineers and other designated personnel create design output. It consists of drawings of component parts and assemblies, wiring diagrams, bills of material required to manufacture and raw test data. Design output includes acceptance criteria, such as tolerances. Design output documents are adequate defined to allow for subsequent processes. Design output documents enable manufacturing to construct equipment that meets the design input requirements and specifies the characteristics of the product that are essential for its safe and proper use. The design team reviews all design output drawings prior to releasing for manufacture.

8.3.6 DESIGN AND DEVELOPMENT CHANGES

Control of Design and Development Changes is documented in AE100018, Engineering Change Order Procedure. Changes are reviewed, verified and validated, as appropriate and approved to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The review of design and development changes includes evaluation of product already delivered. Records are maintained of design and development changes.

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.

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.

Inspection and other activities necessary for ensuring that purchased product or service meet specified requirements are established and implemented. Materials and processes are inspected when received in accordance with AC100009, 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

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- 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

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 AC100029, 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

Special processes which include but not limited to welding and soldering is validated and/or controlled via the following:

- Monitoring by Line Supervisors and Quality to defined criteria
- Approval 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 AC100007, 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, routing tickets, 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 applicable serial numbers, revision levels, date codes, lot numbers, etc.

Where items sold by Basler Electric are required to have traceability documents evidencing the chain of title through Certificates of Conformance (C of Cs – see AC100019, Certificate of Conformance) or Certificates of Traceability (C of Ts), items sold or used in the production of the product that is sold, must identify the C of C and C of T requirements to our suppliers. This certification requirement must be identified on the individual purchase orders issued to suppliers for those materials. The appropriate traceability documentation is kept as part of receipt records in each facility's receiving area.

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8.5.3 PROPERTY BELONGING TO CUSTOMERS OR EXTERNAL PROVIDERS

Customer-supplied product used in the manufacture of products by Basler Electric shall receive the same verification and control as purchased items. Customer-supplied items such as tooling used during the manufacture of products, or test equipment used during verification testing, will be clearly identified and shall be treated the same as equipment owned by Basler Electric. 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, electrostatic discharge (ESD) protection (where appropriate), first-in first-out storage, and attention to shelf-life sensitive materials. All materials and products shall be appropriately identified throughout the manufacturing process. The constituent parts of the product are included in this preservation process.

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 for production is documented in AE100018, Engineering Change Order 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 the Facility Quality Plan, ACXXX010, and the Manufacturing Control Plan, AGXXX001.

8.7 CONTROL OF NONCONFORMING OUTPUTS

Nonconforming outputs are identified and addressed for control through procedure AC100006, Nonconforming Material.

9.0 PERFORMANCE EVALUATION

9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

9.1.1 GENERAL

Products are inspected according to documented procedures. The procedures are identified in AC100029, Quality System Index.

QMS metrics being monitored are identified in AC100020, 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.

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9.1.2 CUSTOMER SATISFACTION

Customer perception as to whether Basler Electric has met requirements is monitored as documented following WL100418, Customer Comment Log Entry. Customer relations are managed following AF100010, Customer Relationship Management.

9.1.3 ANALYSIS AND EVALUATION

The metrics collected and analyzed as part of the continual improvement process as documented in AC100020, Continual Improvement, are used to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of QMS can be made.

9.2 INTERNAL AUDIT

Internal quality audits, as documented in AC100003, 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 products are subject to audit. Responsibility for scheduling of audits of the quality system will reside with the designated lead auditor, who shall be designated by the Vice President of Corporate Quality. 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 internal audits will be reviewed by the executive staff during the management review process.

9.3 MANAGEMENT REVIEW

9.3.1 GENERAL

Reviews of the QMS are conducted at a minimum 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 Corporate Quality in accordance with the requirements of AC100028, 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 AC100028, 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

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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 AC100006, 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 AC100001, Corrective and Preventive Action. 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 QMS is achieved through the use of the processes described within this document. The effectiveness of this QMS is continually improved through the use of the quality policy, quality objectives and preventive actions and management review. Refer to AC100020, Continual Improvement.

Documented procedures for addressing and implementing preventive actions are established. Emphasis is placed on preventive action to foster a proactive approach using appropriate sources of information as identified in AC100020, Continual Improvement, to detect, analysis and eliminate potential causes of nonconformities; also reference AC100001, Corrective and Preventive Actions. Relevant preventive action information on actions is submitted to management review in accordance with AC100028, Management Review.