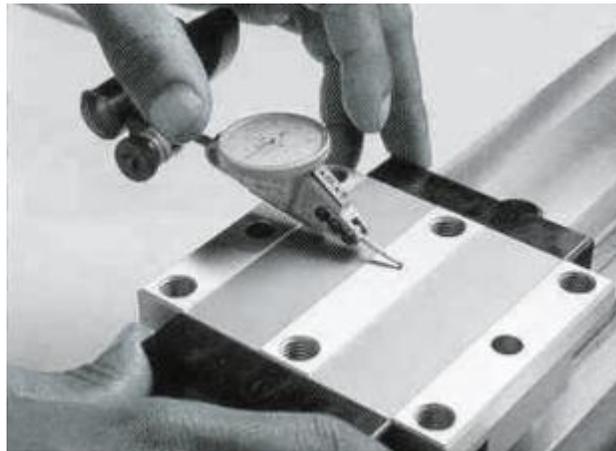# Baum Industrial Quality Manual

Quality Management System Manual

Baum Industrial
Quality Management System Manual

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Section 1

I. Introduction

This Quality Manual defines the Quality Management System implemented at Baum Industrial. The objective of this system is continuous, permanent quality improvement to prevent defects, reduce waste, improve product quality, exceed customer expectations, and sustain a successful business.

The Quality Management System described herein is designed to meet various customer requirements for ISO9001:2008 Based Quality Systems including the following specifications:

1.   ISO9001:2008

Baum Industrial's President is the designated authority, and has responsibility for implementing and maintaining the Quality Management System.

This Quality Manual is directed at assuring Baum Industrial compliance with customer contract requirements through the application and monitoring of a structured management system. Monitoring the effectiveness of the Baum Industrial's Quality Management System through planned management reviews and internal audits is emphasized.

The entire management team along with each Baum Industrial's employee recognizes the importance of effectively building "Quality" into every product and service we provide.

II. Quality Policy

Baum Industrial is committed to providing the highest quality and service to meet and exceed all applicable requirements. This is achieved through continuous improvement of our Quality Management System, and monitoring of our Measurable Quality Objectives.

III. Quality Manual Logistics

APPROVAL:

President: John Batchelder
Management Rep: Dianna Garcia

CONTROL:

Document and Data Control maintains the currency of the Quality Manual electronically.

IV. Quality Manual Revision Record

DATE	DESCRIPTION OF CHANGE(S)	Approval Date
07.5.2018	Original Quality Manual	07.5.2018

Section 2

1. Company Service

Baum Industrial's responsibly assesses risk and provides focused information, developing ingenious answers to perplexing challenges. The end result is a road map to a repeatable, simpler product.

Primary Markets Served Include:

- Medical and Dental
- Commercial
- Aerospace and Defense

2. Purpose

This Quality Manual describes the Quality Management Systems and serves as a guide for employees whose functions affect the quality and reliability of our processes. Through adherence to the documented system, there resides the highest degree of assurance that no compromise will take place in the meeting of our customers' expectations. The Quality Management Systems itself is complete and responsive to all requirements of the ISO 9001:2008 International Standard.

The Management Representative for the Quality System has full responsibility and authority for its establishment, implementation, and maintenance. This includes control of the Quality Manual and other documentation comprising the Quality System: Procedures, Work Instructions, Forms, and Reference Documents. In addition, the Management Representative ensures that Internal Quality Audits are properly scheduled and conducted to verify compliance of quality-related activities and overall effectiveness of the Quality Management System.

As a document itself, this Quality Manual is updated, as necessary, to reflect changes in the Quality Management System and improvements in the organization. Since its purpose is to help ensure both the quality and reliability of our products, any suggestions for modification to its content are always welcome.

3. Scope

The scope of this Quality Manual is a description of the capability of Baum Industrial's Quality Management System to meet the requirements of the ISO 9001:2008 Standard.

As the focus of these requirements is that of achieving customer satisfaction through the prevention of nonconformances, this top-level document addresses the manner in which Baum Industrial accomplishes this through all stages of its processes.

In terms of layout and coverage, the Quality Manual provides confirmation of adherence to each of the necessary provisions of the Standard. It does this through the use of the same clause numbering system of the ISO 9001:2008 Standard. This approach provides for a most comprehensive coverage of all of the requirements, serving also as a checklist for internal auditing purposes.

Lists of Applicable Procedures, Work Instructions, Forms, and Reference Documents are maintained electronically. Consistent with the layout of the Quality Manual, these documents are numbered and grouped for easy identification with the individual clause of the ISO 9001:2008 Standard to which they pertain.

Company Scope

The Scope of Registration covers the Quality Management System for precision CNC machining and fabrication of tight tolerance component's for the aerospace, automotive, medical, dental, and commercial industries.

Exclusions

Manufacturing is the sole function of Baum Industrial. For this reason, Baum Industrial has excluded the following sections of the standard:

- 7.3 Design and Development-Baum Industrial builds all parts to customer specifications, and all products are validated by the customer.

4. Quality Management System

4.1 General Requirements

Baum Industrial has established, documented, implemented and maintained a quality management system and continually improve its effectiveness in accordance with the requirements of ISO 9001:2008, Baum Industrial has:

- Identified the processes needed for the quality management system and their Application throughout the organization,

- Determine the sequence and interaction of these processes,
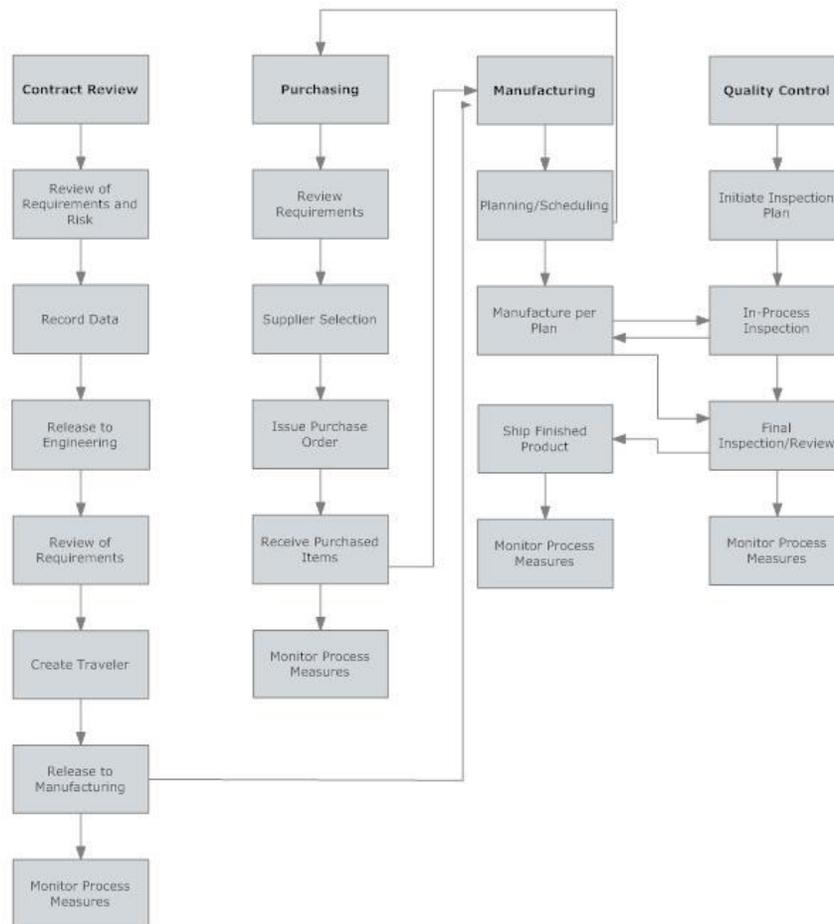
- Determined criteria and methods needed to ensure that both the operation and control of these processes are effective,

- Ensured the availability of resources and information necessary to support the operation and monitoring of these processes,

- Monitored, measured and analyzed these processes, and

- Implemented actions necessary to achieve planned results and continual improvement of these processes.

These processes will be managed by Baum Industrial in accordance with the requirements of ISO 9001:2008.

Where Baum Industrial chooses to outsource any process that affects product conformity with requirements, it will ensure control over such processes. Control of such outsourced processes will be identified within the quality management system. Outsourced processes are: Calibration, Metal finishing, Heat Treating, Machining

4.2 Documentation Requirements
4.2.1 General

The Quality Management System documentation includes:

Documented statements of a Quality Policy and Quality Objectives defined at specific levels of the organization.

- A Quality Manual consistent with the requirements of the ISO 9001:2008.

- Documented Procedures describing the specific manner in which the organization performs necessary activities or processes.

- Documents needed by the organization to ensure the effective planning, operation, and control of its processes according to the nature and complexity of sound business practices and their interactions, and the competence of personnel. Such documents include, but are not limited to, work instructions, workmanship standards, technical specifications, operating documents, training references, and defined competencies. Documentation exists in hard copy and/or electronic format.

- Quality Records required for compliancy with the International Standard. (see 4.2.4).

4.2.2 Quality Manual

This Quality Manual is established to meet the requirements of the ISO 9001:2008 Standard and includes:

- The scope of the Quality Management System, with any exclusions fully identified.

- Reference to Procedures and/or Work Instructions, as a separate set of documents.

- Interactions between the processes of the Quality Management System as described in flowcharted and/or written text Procedures.

4.2.3 Control of Documents

Documents required by the Quality Management System are controlled by Electronic Uploaded date.

Any document printed from the system is considered an "uncontrolled" copy.

A documented procedure is established 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 of documents are identified.

- To ensure that relevant versions of applicable documents are available at points of use,

- To ensure that documents remain legible and readily identifiable,

- To ensure that documents of external origin are identified and their distribution controlled, and

- To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of Records

Baum Industrial establishes and maintains records that contain data and information resulting from the implementation of processes. These records provide evidence of conformity to requirements and of the effective operation of the Quality Management System and are either electronic or hard copy format, both of which are legible, readily identifiable, and fully retrievable.

Responsibility, authority, and associated activities regarding records are documented in a Procedure, which further defines the controls for their identification, storage, protection, retrieval, retention time, and method of disposition.

5 Management Responsibility

5.1 Management Commitment

Top management has provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- Establishing the quality policy
- Ensuring that quality objectives are established
- Conducting Management Reviews, and
- Ensuring the availability of resources.

5.2 Customer Focus

Baum Industrial establishes systems to understand its customers' needs in order to consistently meet requirements and to strive to meet customer expectations. Key process characteristics are determined, measured, and monitored for customers. Customer needs and expectations take into consideration product conformity, dependability, availability, delivery, and environmental impact.

In addition to customers, Baum Industrial identifies and provides planned arrangements to meet needs and expectations of people in the organization, owners, suppliers, and the third party registrar that certifies the Quality Management System, as well as any facet of the public affected by the company and its products.

Baum Industrial demonstrates responsibility for the health and safety of its employees and the public through compliance with safety and environmental regulations.

5.3 Quality Policy

Top management has ensured that the quality policy:

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

5.4 Planning

5.4.1 Quality Objectives

Baum Industrial's business process planning and Quality Policy provide a framework for establishing Quality Objectives. Measurable Quality Objectives are determined by

process owners and top management in support of organizational performance improvements and maintenance of the Quality Management System. Metrics are compiled and documented in the form of statistical data to facilitate effective and efficient review by management. Objectives take into consideration, as necessary, results of the following activities:

- Current and future needs of the organization and the markets served.
- Relevant findings from management reviews.
- Current product and process performance.
- Levels of satisfaction of interested parties.
- Self-assessment results.
- Benchmarking, competitor analysis, and opportunities for improvement.
- Resources needed to meet objectives.

Quality Objectives are communicated internally in such a way that people in the organization can contribute to their achievement. They are systematically and mutually reviewed by management, as well as process owners, and revised as necessary.

5.4.2   Quality Management System Planning

Top management ensures that:

- The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

- The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.3   Responsibility, Authority, and Communication

5.5.1   Responsibility and Authority

Management has defined delegated responsibility and authority in Job Descriptions, Procedures, and an Organizational Chart in order to implement and maintain an effective and efficient Quality Management System. Process owners are enabled to contribute to the achievement of Quality Objectives and to establish their involvement, motivation, and commitment.

5.5.2   Management Representative

Top management has appointed the President (a member of management) who, irrespective of other responsibilities, has responsibility and authority that includes

- Ensuring that processes needed for the quality management system are established, implemented and maintained,

- Reporting to top management on the performance of the quality management system and any need for improvement,

- Ensuring the promotion of awareness of customer requirements throughout the organization, and

- The organizational freedom to resolve matters pertaining g to quality.

5.5.3 Internal Communication

Management provides for effective and efficient communication of the Quality Policy, requirements, Quality Objectives, and accomplishments through formal and informal meetings involving individual process owners and/or all employees and through documented memoranda and training, as appropriate.

Internal communications are also accomplished through planning documents, internal audits, and corrective actions, as well as through the review of initiatives pertaining to human resource motivation, support, and effective and efficient personnel performance.

5.6 Management Review

5.6.1 General

Top management reviews the organization's quality management system, annually to ensure its continuing suitability, adequacy and effectiveness. This review will include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews are maintained (see 4.2.4).

5.6.2 Review Input

Management reviews are conducted according to an established agenda, with records of meetings being maintained, including supporting data and information. At a minimum, management reviews consider inputs to evaluate the efficiency and effectiveness of the Quality Management System. In addition, reviews address the following, as applicable:

- Status and results of Quality Objectives and improvement activities
- Status of management review action items
- Results of audits and self-assessments of the organization
- Feedback on the satisfaction of interested parties
- Status of Corrective and Preventive Actions
- Opportunities for improvement
- Control of process and product nonconformities
- Other factors which may impact the organization, such as financial, social or environmental conditions, as well as relevant statutory and regulatory changes

5.6.3 Review Outputs

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

- improvement of the effectiveness of the Quality Management System and its processes;
- improvement of product and processes related to customer requirements; and
- Resource needs.

Results of management reviews are to be recorded and maintained.

Figure 5.6 - Management Review Process
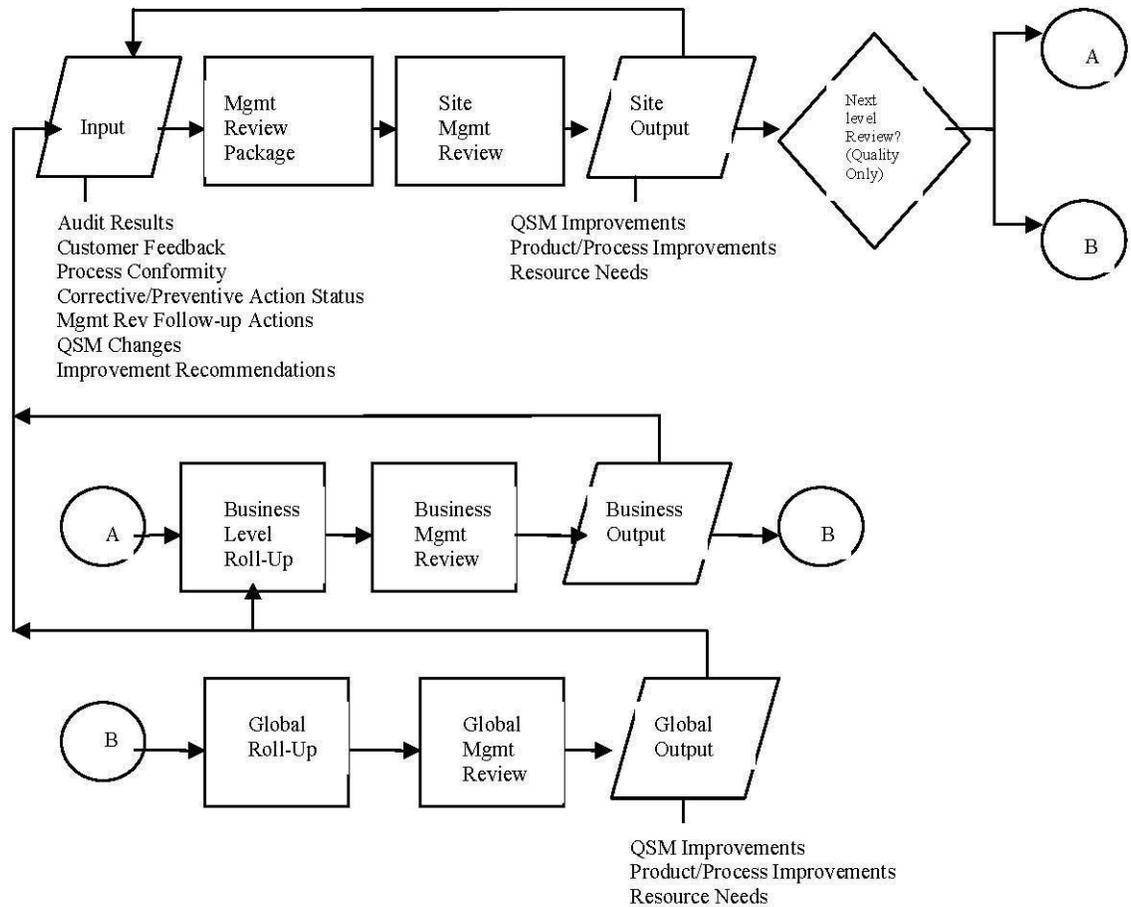
6. RESOURCE MANAGEMENT

6.1 Provision of Resources

Baum Industrial has determined and provided the resources needed

- To implement and maintain the quality management system and continually improve its effectiveness, and

- To enhance customer satisfaction by meeting customer requirements

6.2   Human Resources

6.2.1   General

Personnel performing work affection product quality are competent on the basis of appropriate education, training, skills and experience.

6.2.2   **Competence, Awareness and Training**

Baum Industrial has:

- Determined the necessary competence for personnel performing work affecting product quality,

- Provided training or take other actions to satisfy these needs,

- Evaluated the effectiveness of the actions taken,

- Ensured that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,

- Maintained appropriate records of education, training, skills and experience (see 4.2.4)

6.3   Infrastructure

Baum Industrial has determined, provided and maintained the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

- Buildings, workspace and associated utilities,
- Process equipment (both hardware and software), and
- Supporting services (such as transport or communication).

6.4   Work Environment

Baum Industrial has determined and managed the work environment needed to   achieve conformity to product requirements.

7   PRODUCT REALIZATION

7.1   Planning of Product Realization

Baum Industrial 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 (see 4.1).

In planning product realization, Baum Industrial determines the following, as appropriate:

- Quality objectives and requirements for the product;

- The need to establish processes, documents, and provide resources specific to the product;

- Required verification, validation, monitoring, 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 (see 4.2.4);

The output of this planning will be in a form suitable for the Elastomer Technologies' method of operations.

7.2   Customer-Related Processes

7.2.1   Determination of Requirements related to the Product

Baum Industrial will determine:

- Requirements specified by the customer, including the requirements for delivery and post delivery activities,

- Requirements not stated by the customer buy necessary for specified or intended use, where known,

- Statutory and regulatory requirements related to the product, and

- Any additional requirements determined by the organization.

7.2.2   Review of Requirements Related to the Product

Baum Industrial will review the requirements related to the product. This review will be conducted prior to the Baum Industrial's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and will ensure that

- Product requirements are defined,
- Contract or order requirements differing from those previously expressed are resolved,
- The organization has the ability to meet the defined requirements, and

Records of the results of the review and actions arising form the review will be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements will be confirmed by Baum Industrial before acceptance.

Where product requirements are changed, Baum Industrial will ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3   Customer Communication

Baum Industrial will determine and implement effective arrangements for communicating with customers in relation to
- Product information,
- Enquiries, contracts or order handing, including amendments, and
- Customer feedback, including customer complaints.

7.4 Purchasing

7.4.1   Purchasing Process

Baum Industrial ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product will be dependent upon the effect of the purchased product on subsequent product realization or the final product.

Baum Industrial evaluates and selects suppliers based on their ability to supply product in accordance with the Baum Industrial requirements, criteria for selection, evaluation, and re-evaluation is established. Records of the results of evaluations and any necessary actions arising from the evaluation will be maintained (see 4.2.4).

7.4.2   Purchasing Information

Purchasing information will describe the product to be purchased, including where appropriate

- Requirements for approval of product, procedures, processes and equipment,

- Requirements for qualification of personnel,

- Quality management system requirements,

Baum Industrial will ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3   Verification of Purchased Product

Baum Industrial will establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Verification activities may include:

Purchased product will not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

When Baum Industrial utilizes test reports to verify purchased product, the data in those reports will be acceptable per applicable specifications. Baum Industrial will periodically validate test reports for raw material.

Where Baum Industrial delegates verification activities to the supplier, the requirements for delegation will be defined and a register of delegations maintained.

Where Baum Industrial or its customer intends to perform verification at the supplier's premises, Baum Industrial will state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and Service Provision

7.5.1   Control of Production and Service Provision

Baum Industrial will plan and carry out production and service provision under controlled conditions. Controlled conditions include, as applicable

- 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 devices,

- The implementation of monitoring and measurement,

- The implementation of release, delivery and post-delivery activities,

7.5.2   Validation of processes for production

Baum Industrial will validate any processes for production where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or has been shipped. Validation will demonstrate the ability of these processes to achieve planned results

Baum Industrial will establish arrangements for these processes including as applicable:

- defined criteria for review and approval of these processes

- approval of equipment and qualification of personnel

- requirements for records (see 4.2.4)

- Re-validation.

7.5.3   Identification and Traceability

Where appropriate, Baum Industrial will identify the product by suitable means throughout product realization.

Baum Industrial will identify the product status with respect to monitoring and measurement requirements.

Where traceability is requirement, Baum Industrial controls and records the unique identification of the product (see 4.2.4).

7.5.4 Customer Property

Baum Industrial will exercise care with customer property while it is under the organization's control or being used by the organization. Baum Industrial will identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any reported to the customer and records maintained (see 4.2.4)

7.5.5 Preservation of Product

Baum Industrial will preserve the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 Control of Monitoring and Measuring Devices

Baum Industrial 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.

Baum Industrial will ensure that environmental conditions are suitable for the calibrations, inspections measurements and tests being carried out.

Where necessary to ensure valid results, measuring equipment will

- Be calibrated or verified 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 shall be recorded;

- Be adjusted or re-adjusted as necessary;

- Be identified to enable the calibration status to be determined;

- Be safeguarded from adjustments that would invalidate the measurement result;

- Be protected from damage and deterioration during handling, maintenance and storage;

In addition, Baum Industrial will assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Baum Industrial will take appropriate action on the equipment and any product affected. Records of the results of calibration and verification will be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application will be confirmed. This will be undertaken prior to initial use and reconfirmed as necessary.

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Baum Industrial will plan and implement the monitoring, measurement, analysis and improvement processes needed

- To demonstrate conformity of the product,

- To ensure conformity of the quality management system, and

- To continually improve the effectiveness of the quality management system.

This will include 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, Baum Industrial will monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information will be determined.

8.2.2   Internal Audit

Baum Industrial will conduct internal audits at planned intervals to determine whether the quality management system

- Conforms to the planned arrangements (see 4.7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

- Is effectively implemented and maintained.

An audit program will be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods will be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.

Auditors will not audit their own work.

The responsibilities and requirements for planning and conduction of audits, and for reporting results and maintaining records (see 4.2.4) are defined in a documented procedure.

The management responsible for the area being audited will ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities will include the verification of the actions taken and the reporting of verification results (see 8.5.2).

8.2.3   Monitoring and Measurement of Processes

Baum Industrial will apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods will 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, to ensure conformity of the product.

8.2.4   Monitoring and Measurement of Product

Baum Industrial will monitor and measure 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 (see 7.1).

Evidence of conformity with the acceptance criteria will be maintained. Records will indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery will not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of Nonconforming Product

Baum Industrial will ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in a documented procedure.

Baum Industrial will deal with nonconforming product by one or more of the following ways:

- By taking action to eliminate the detected nonconformity;

- 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.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started Baum Industrial will take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of Data

Baum Industrial will determine, collect and analyze 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 shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- Customer satisfaction (see 8.2.1),

- Conformity to product requirements (see 7.2.1),

- Characteristics and trends of processes and products including opportunities for preventive action, and

- Suppliers.

8.5 Improvement

8.5.1 Continual Improvement

Baum Industrial will continually improve the effectiveness of the quality management system through 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

Baum Industrial will take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure is established to define requirements for

- Reviewing nonconformities (including customer complaints),

- Determining the causes of nonconformities,

- Evaluating the need for action to ensure that nonconformities do not recur,

- Determining and implementing action needed,

- Records of the results of action taken (see 4.2.4),

- Reviewing corrective action taken,

8.5.3 Preventive Action

Baum Industrial will determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

- A documented procedure is established to define requirements for

- Determining potential nonconformities and their causes,

- Evaluating the need for action to prevent occurrence of nonconformities,

- Determining and implementing action needed,

- Records of results of action taken (see 4.2.4), and

- Reviewing preventive action taken.

Appendix A - Definitions

Within the ISO 9000 Standard, there appear certain words that require universal understanding. The definitions that are to be associated with these words are contained in ISO 9001:2008 Standard: Quality Management Systems-Fundamentals and vocabulary.

The following represent definitions that are absolutely essential to the correct interpretation of the standard and are either stated directly or paraphrased from the Standard:

These definitions are not all-inclusive but, rather, are ones that form the framework for the implementation and Management of the Quality Management System.

Assessment: For the purposes of this document the word assessment is used to describe the audits (Internal Audits - 8.2.2.a) conducted by Internal Assessors.

Audit: Systematic, independent process for obtaining evidence and evaluating it objectively to determine the extent to which certain criteria are fulfilled.

Continual improvement: Includes improvement of the QMS framework and business and product, service, or solution performance. NOTE: The process of continual improvement need not take place in all areas of activities, products and services simultaneously; business units and sites may prioritize continual improvement efforts based on their specific quality and business objectives.

Corrective Action: Action taken to eliminate the cause of an existing detected nonconformity or other undesirable situation; action taken to prevent recurrence. These actions may include but are not limited to: (1) root cause analysis; (2) changes to processes; 3) changes to procedures; (4) changes to requirements; and (5) changes to monitoring and measurement programs.

Conformity: Fulfillment of specified requirements.

Contract: Agreed requirements between a supplier and customer transmitted by any means.

Customer: The term customer is used in this document to describe both external customers and regulatory agencies.

Document: Information and its support medium; may include but is not limited to electronic, photographic, drawn, written or printed material

Functional organizations: Organization performing specific tasks or functions, for example: legal or procurement.

Nonconformity: Lack of fulfillment of a specified requirement.

DEFINITIONS (CONT'D)

Organization: Provider of a product to the customer.

Procedure: Specified way to carry out an activity or a process; a series of activities that define a particular task, which may include, but is not limited to, instructions, checklists, and flowcharts.

Process: Set of interrelated or interacting activities, which transform inputs into outputs.

Procurement: Purchasing function.

Product: Result of a process, services and items developed, manufactured, assembled, provided or sold by the organization. Products: components, assemblies, parts, software, support, education, management; includes products, services, intellectual property and solutions.

Quality: Degree to which a set of inherent characteristics fulfill requirements.

Quality Management: All activities of the overall management functions that determine the Quality Policy, Objectives, and Responsibilities and that implements them by such means as quality planning, quality control, quality assurance, and quality improvement within the quality system.

Quality Management System: Organization structure, procedures, processes, and resources needed to implement quality management.

Quality Manual: Document stating the Quality Policy and describing the quality system of an organization.

Quality Objectives: Something sought or aimed for, related to quality; generally based on the organization's Quality Policy and specified for relevant functions and levels in the organization.

Quality Policy: Overall intention and direction of an organization with regard to quality as formally expressed by top management.

Top Management: Person or group of people who directs and organizes at the highest level.

Quality & Environmental Policies: Statement by the organization, which provides a framework for setting quality & environmental objectives and targets at the SBE level.

Record: Document stating results achieved or providing evidence of activities performed; evidence that an event or activity occurred including, but not limited to, written evidence in the form of hard copy or soft copy memoranda, checklists, meeting minutes or notes, presentations, budgets, and capital and/or expense plans.

Services: see product

Shall: "must" or "is required."

Should: "suggested" or "recommended"
Supplier: Provider of a product to the organization.

Appendix B- Procedures

ISO 9000 ELEMENT		PROCEDURE NO.	PROCEDURE TITLE
4	Quality Management System		
4.1	General Requirements		
4.2	Documentation Requirements	PR-4.2.3-01 PR-4.2.4-01	Control of Documents Control of Records
5.1	Management Commitment		
5.2	Customer Focus		
5.3	Quality Policy		
5.4	Planning		
5.5	Responsibility, Authority and Communication		
5.6	Management review		
6.1	Provision of Resources		
6.2	Human Resources		
6.3	Infrastructure		
6.4	Work Environment		
7.1	Planning of Product Realization		
7.2	Customer-related Process	PR-7.2.0-01	Customer- Related Processes
7.3	Design and Development		
7.4	Purchasing	PR-7.4.0-01	Purchasing
7.5	Production and Service Provision	PR-7.5.1-01	Control of Production
7.6	Control of Monitoring and measuring Devices		

8.1	General		
8.2	Monitoring and Measurement	PR-8.2.2-01 PR-8.2.4-02	Internal Audit Final Inspection
8.3	Control of Nonconforming Product	PR-8.3.0-01	Control of Nonconforming Product
8.4	Analysis of Data		
8.5	Improvement	PR-8.5.2-01 PR-8.5.3-01	Corrective Action Preventive Action

End of Document