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# THE BOTTA-BOOM REQUIREMENTS

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The following documents are the “rules” we’ll audit by for Botta-Boom



# *Botta-Boom, Inc.*



## **Quality Assurance Manual**

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## 1.0 Purpose

This manual is the management statement of policy for the Quality Management System at Botta-Boom, Incorporated.

## 2.0 Scope

The requirements of this manual apply to operations within Botta-Boom.

## 3.0 Applicable Documents

The following documents (most current revisions apply), form a part of, and provide support to, the policy statements within this manual:

- ISO 9000 Quality Management Systems — Fundamentals and vocabulary
- ISO 9001 Quality Management Systems — Requirements
- ISO 9004 Quality Management Systems — Guidelines for performance improvements

## 4.0 Quality Management System

### 4.1 General Requirements

Botta-Boom maintains a documented Quality Management System that meets the requirements of applicable legal or regulatory requirements, and any policies we have applied to our own system. All policies and procedures within the Quality Management System must be adhered to. The effectiveness of the Quality Management System is monitored and continually improved.

Key processes of our business have been identified and are defined, as needed, in documented procedures. In implementing the system, we have identified the processes needed in the system and have defined:

- The sequence and interaction of these processes,
- The criteria and methods for ensuring effective operation and control of these processes,
- The information necessary to support the operation and monitoring of these processes, and
- The measurement, monitoring, and analysis activities needed to manage the processes and to implement related improvement actions when needed.

Each identified process is assigned to a responsible manager. The manager is responsible for managing the process to ensure it meets the requirements of our quality management system and customer requirements.

## 4.2 Quality Management System Documentation

### 4.2.1 Documentation Structure

The Botta-Boom quality manual defines the structure and operation of our Quality Management System. This manual is controlled under the document control system described in section 4.2.3.

The basic structure of the Quality Management System and the information needing control is comprised of four levels, which correspond to the levels of our information control system:

Level	Description
Level 1	Quality System Manual – Sets policies for the quality management system. References to Level 2 and 3 documents are included where applicable.
Level 2	Procedures - Define the sequence and interaction of processes that make up our system. The manager responsible for a process determines the need for documentation of the process.
Level 3	Work Instructions – Define detailed instructions for performing specific tasks within a process. The manager responsible for the process determines whether this level of information is needed and in what detail.
Level 4	Records such as data, contracts, completed quality system forms, etc. — they provide additional information and/or historical proof of operation. (See 4.2.4 herein.)

**Table 1 - Levels of Documentation**

### 4.2.2 Document Approvals

Quality System documents are reviewed and approved prior to use. The approvals for the various documents are:

Level 1 – Quality Manager and President

Level 2 – Process Owner and Quality Manager

Level 3 – Process Owner

Note: Where the Process Owner is the Quality Manager, the President will sign in place of the Quality Manager.

### 4.2.3 Control of Documents

Botta-Boom Incorporated ensures that all employees have the current version of all documents and data needed to perform their assigned tasks. Only current, controlled documents are permitted for company manufacturing operations. Exceptions must be approved by the President or designee. All documentation related to specifications, procedures, parts, and processes used in the manufacture of customer orders are maintained under the Document Control system.

All company personnel have the authority to request changes or additions to the document system. The Process Owner and Quality Manager are authorized to approve changes to documents.

Documents of external origin, such as standards, regulations, and customer specifications are identified and the distribution of such documents is controlled.

#### Reference Documents:

- OP 4.2.3 Control of Documents
- OP 7.3.1 Engineering Change Orders

**Responsibility:** Quality Manager, Engineering Manager

### 4.2.4 Control of Records

Quality records are the records that we create to demonstrate compliance to requirements. Quality records are held on file for the minimum term specified in OP 4.2.4, and/or as specified by the customer's contract.

If a correction must be made to any paper format Quality Record, it should be accomplished by a single line through the original entry and writing the additional information adjacent to the original. The individual making a correction will initial and date adjacent to the correction.

Records are indexed, stored, and protected to preserve the record and legibility of the record. Computer files used as quality records are maintained on a secure computer with suitable backup. Backup files of computerized quality records must be stored in a fireproof safe.

#### Reference Documents:

- OP 4.2.4 Control of Records

**Responsibility:** Quality Manager

## **5.0 Management Responsibility**

### **5.1 Management Commitment**

Botta-Boom is committed to support its quality management system. We demonstrate this support through:

- Providing resources to maintain and improve the quality management system
- Communicating to the employees the regarding their contribution to the company's quality objectives
- Performing regular management reviews of the quality system as described in paragraph 5.6

### **5.2 Customer Focus**

Botta-Boom management works with their customers to understand their needs and expectations. These needs and expectations are used to ensure that objectives and plans are developed with the aim of achieving customer confidence and satisfaction.

### **5.3 Quality Policy**

Botta-Boom is committed to excellence through:

- Continuous product improvement
- Providing a challenging and innovative workplace
- Delivering superior customer service

Management communicates this policy to all employees to ensure that each individual understands their role in supporting the policy.

### **5.4 Planning**

#### **5.4.1 Quality Objectives**

Botta-Boom is committed to establishing, communicating, and monitoring objectives critical to the achievement of its Quality Policy. These objectives are developed by the management team and are reviewed at least annually.

Management is responsible for communicating these objectives and for monitoring the performance of the quality system to these objectives.

#### **5.4.2 Quality Planning**

Botta-Boom periodically evaluates its operations against the stated objectives. Substantial changes necessary to achieve our objectives are determined by the management team. Changes to policies, procedures, human resources,



equipment, infrastructure, and facilities are planned to ensure that we maintain and improve the capability to meet our customers' needs. This evaluation occurs as a part of the periodic Management Review process as defined in section 5.6.

## **5.5 Administration**

### **5.5.1 General**

The following describes the administration of the quality management system.

### **5.5.2 Responsibility and Authority**

#### **Responsibility and Authority**

General responsibilities of Management and the Quality Manager are defined in this manual. Specific responsibilities for requirements of this system are defined in the procedures documenting our processes.

#### **Quality Manager**

The Quality Manager is responsible for the establishment and continued support of the quality systems. This position reports directly to the President. The Quality Manager:

- Provides guidance and suggestions on the improvement of the quality system
- Reports on the status of the Quality Management System to the Management Team
- Reports any concerns or problems regarding the Quality Management System to the Management Team

#### **Internal Communication**

Management of Botta-Boom ensures that company employees are provided with information on the effectiveness of our Quality Management System.

## **5.6 Management Review**

Management reviews the the quality management system on a planned basis to ensure its continued suitability and effectiveness. Meeting minutes are taken and provide the record for the meeting. Meeting minutes include decisions made regarding improvements to the quality system, changes to resources, and changes to infrastructure and work environment. Where necessary, actions and follow-up responsibilities are assigned to staff.

Management Reviews are held quarterly as a minimum, but may be held more frequently at the discretion of the President.

The inputs to the Management Review Meeting are:

- Status of the quality management system and processes
- Status on open action items from previous meetings
- Customer feedback
- Internal audit status and results
- Corrective and preventive action status
- Process and product performance results
- Changes affecting the quality management system

## **6.0 Resource Management**

### **6.1 General Requirements**

Botta-Boom shall determine and provide the resources needed to maintain the quality management system.

### **6.2 Human Resources**

#### **6.2.1 Assignment of Personnel**

All personnel who have responsibilities controlled by the quality management system are competent based on applicable education, training, skills, or experience.

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

Job descriptions are created for each position that affects the quality of our products and services. Each job description specifies the minimum competency requirements for that function.

All employees are evaluated for training needs to meet the competency requirements of the job description.

Job descriptions, competency requirements, training plans, and training records are maintained by the Human Resources department. It is the responsibility of each employee and his or her supervisor to ensure that their specific records are correct and up to date.

All employees are instructed in their role within the quality management system including their contribution to meeting the quality objectives of Botta-Boom, Incorporated.

#### **Reference Documents**

- OP 6.2 – Training

**Responsibility:** Human Resource Manager

### **6.3 Infrastructure and Work Environment**

Management is responsible for determining the infrastructure and work environment needed to provide our products and services. Infrastructure and work environment needs are discussed as part of the Management Review meetings.

Preventive maintenance is performed where appropriate. Production maintains schedules and records of preventive maintenance activities.

#### **Reference Documents**

- WI 7.5.5 – Equipment Maintenance

**Responsibility: President**

## **7.0 Product and Service Realization**

### **7.1 Planning of Realization Processes**

During the development and implementation of new processes, Botta-Boom defines the applicable quality objectives and requirements. Performance monitoring, Inspection, and test points are established and documented that are sufficient to ensure that all requirements and objectives are achieved.

All process documentation specifies the quality records that are created and maintained (reference paragraph 4.2.4 herein).

Where appropriate, data is collected at monitoring points and used for continual improvement efforts.

### **7.2 Customer-Related Process**

#### **7.2.1 Identification and Review of Customer Requirements**

Each individual contract or order is reviewed by Botta-Boom to ensure that the customer requirements are clearly defined, differences are resolved, and to confirm that Botta-Boom has the capability to meet the customer's requirements.

Records of the contract review are maintained.

Changes to customer orders are reviewed in the same manner as new orders. Any changes to customer orders are documented in the sales order system, and communicated to engineering and production to ensure that changes are incorporated per customer requirements.

## **7.2.2 Customer Communication**

All literature and brochures are reviewed and approved by the Management Review team prior to being available for use.

The sales department receives and responds to requests for product information, inquiries, contracts, and orders. Quotations are maintained in a database by the Sales Department.

The Sales Department receives and responds to all customer feedback.

## **7.3 Design and Development**

### **7.3.1 General**

Botta-Boom utilizes controlled design and development processes. The general requirements for these processes are defined below.

### **7.3.2 Planning**

Design and development plans and schedules are prepared and documented to ensure that each product design effort is carried out in a controlled fashion. Plans define the major activities, all design reviews, customer specified milestones, verification, and validation activities.

Plans are updated as the design effort progresses and evolves to ensure that the design activities are carried out completely.

### **7.3.3 Design and Development Inputs**

Design input requirements are identified and documented, using records of the contract review, communications with the customer, and any applicable regulatory requirements. If Botta-Boom encounters any difficulties with meeting the requirements, the customer is contacted promptly to resolve the conflict.

### **7.3.4 Design and Development Output**

Design output is documented and includes design input, calculations, drawings, design verification, and design validation records. Design output ensures that: design input requirements are met; any acceptance criterion is referenced or included; and any critical characteristics, required for safe or proper function of the product, are identified.

### **7.3.5 Design Review**

At appropriate points in each design, design reviews are conducted. Each review includes affected personnel. The results of the reviews and any assigned actions are documented.

### **7.3.6 Design and Development Verification**

Design output is verified to ensure it meets design input requirements. Design verification is performed by qualified personnel, and is documented. Acceptable methods of verification include:

- Design reviews
- Alternate calculation methods
- Comparisons with similar proven designs
- Testing

### **7.3.7 Design and development validation**

Design validation is performed to ensure products arising from design work, perform as intended. Design validation is performed by qualified personnel and is documented as part of the design package.

### **7.3.8 Control of Changes**

Design changes are controlled to ensure they are identified, have necessary approval, are checked for accuracy, and are carried out completely. Changes are evaluated for impact to raw materials, work-in-process, finished goods, and products delivered to customers.

Changes are evaluated to determine the need for additional verification and/or validation of the design.

#### **Reference Documents:**

- OP 7.3 Design and Development
- OP 7.3.1 Engineering Change Orders

**Responsibility:** Engineering Manager

## **7.4 Purchasing**

### **7.4.1 General**

All Purchases are clearly documented and defined in accordance with Botta-Boom procedures and/or customer requirements.

### **7.4.2 Purchasing Process**

All sources selected for procurement of materials and services undergo appraisal prior to any orders being issued. The President or Designee may authorize purchases from unapproved suppliers.

Periodic review of supplier performance is performed by Purchasing. Records of these reviews are maintained.

### **7.4.3 Purchasing Information**

All purchases for materials, products, and services used in providing services to our customers are documented by a purchase order. The purchase order provides all information, including quality and service requirements, necessary to define the expectations of the purchase.

All purchase orders are reviewed for accuracy and completeness prior to release.

### **7.4.4 Verification of Purchased Products**

All purchased products are verified upon receipt, except where source inspection is appropriate. In such cases, Botta-Boom will provide detailed instructions when source inspections are to be performed.

#### **Reference Documents:**

- OP 7.4 Purchasing

**Responsibility:** Purchasing Manager

## ***7.5 Production Operations***

### **7.5.1 Production Control**

Production is controlled by internal Work Orders. Work Orders provide:

- Task descriptions and sequence
- Inspection and test points
- Tooling identification
- Drawings and other information required for production

**Responsibility:** Planning

### **7.5.2 Identification and Traceability**

Product identification is maintained throughout all our processes using Part Numbers and Work Orders.

Specific customer requirements for identification are documented in drawings or work orders as appropriate.

When required by the customer, traceability of material is maintained through all processes. The Work Order and related documentation are marked to indicate that traceability is required.

**Responsibility:** Production Manager

### **7.5.3 Customer Property**

All products supplied by our customer are verified upon receipt for damage or deterioration. When required, inspections are conducted according to the relevant documentation. Any discrepancies are communicated with the customer.

Customer supplied material shall be controlled and handled in such a manner as to preclude deterioration or damage. When deterioration, damage or loss occurs, it is documented using the Nonconforming Material Control procedure, OP 8.3.

Customer-supplied products are identified by a unique part number.

**Reference Documents:**

- OP 8.3 Control of Nonconforming Material

**Responsibility:** Quality Manager

### **7.5.4 Preservation of Product**

Materials and products are protected from damage and degradation. Where special packaging or storage considerations are necessary, these instructions are documented and made available to the appropriate personnel.

Delivery of product will meet the customer's instructions and/or expectations.

**Reference Documents:**

- OP 7.5.4 Preservation of Product

**Responsibility:** Production Manager

### **7.5.5 Validation of Processes**

Special processes at Botta-Boom are subject to special controls to ensure quality of the finished product. These controls are:

- Validation of the process before use
- Revalidation of the process after major changes to equipment or process

- Training of process operators

For a description of Botta-Boom's special processes, see the Botta-Boom Process Control procedure.

**Reference Documents:**

- OP 7.5 Process Control

**Responsibility:** Production Manager

## ***7.6 Control of Measuring and Monitoring Devices***

All measuring and test equipment, including test software, used at Botta-Boom are controlled, verified and/or calibrated with traceability to recognized standards. A calibration log is maintained showing the status and calibration due date for each affected piece of equipment. Calibration stickers are placed on the equipment indicating the calibration due date.

Measuring and monitoring devices that are not used for process validation or product acceptance will be labeled as "Reference Only".

Product acceptance is performed using test and measurement equipment that is calibrated or verified prior to use.

Software used for automated testing of product is validated prior to production use. Validation is performed using alternate methods of testing to ensure that accurate results are achieved.

Test and Inspection equipment is selected to ensure that measurement results are accurate and consistent. During initial contract review, any measurement requirements that exceed our existing capability are identified and steps taken to increase our capability.

The Control of Measurement and Monitoring Devices is described in OP 7.6, "Control of Monitoring and Measurement Devices".

**Reference Documents:**

- OP 7.6 Control of Monitoring and Measuring Devices

**Responsibility:** Engineering Manager

## **8.0 Measurement, Analysis and Improvement**

### ***8.1 Planning***

Botta-Boom has implemented measurement and monitoring activities to assure conformance of product and services to requirements and to drive continuous improvement in all key processes.



For new processes, the measurement and monitoring requirements are determined as part of the process design activity when necessary to support the overall quality objectives.

## **8.2 Measurement and Monitoring**

### **8.2.1 Customer Satisfaction**

The Sales department at Botta-Boom performs an annual customer satisfaction survey in order to determine the customer's perception of the quality of products and services provided by Botta-Boom. A standard survey form is used to ensure consistent results. The results of the survey are reviewed during the Management Review meeting. The meeting minutes provide the record for this review.

### **8.2.2 Internal Audits**

Internal audits are performed on a planned basis to ensure continuing compliance to the requirements of this manual and to evaluate the effectiveness of the processes in the quality management system.

#### **Performance of Audits**

Audits are performed by trained and experienced employees of Botta-Boom. Auditors must not audit functions and activities within their department. Auditors must not audit their own work. Audits are performed in accordance with a plan, or schedule, developed by the Quality Manager.

#### **Frequency of Audits**

Internal audits of each requirement within this Quality Manual are completed on at least an annual basis. Where certain areas or functions are determined to be critical, have a history of problems, or past audit discrepancies, audits may be performed more frequently.

The Quality Manager is responsible for developing the audit schedule. The Management Review team approves the audit schedule.

#### **Audit Reporting**

The Quality Manager provides a report of each audit to the Department Manager of each area audited. The Quality Manager reviews any findings with the responsible manager(s).

Corrective Action Requests are generated as a result of any audit findings. These are documented and processed in accordance with the Corrective and

Preventive Action system described in section 8.5 of this manual. All audit findings require follow-up activity to ensure that the proposed action was taken, and that it was effective.

A summary of the audit results is reported at the Management Review Meeting. The summary includes a description of the audits performed, the findings of each audit, and an updated audit schedule showing the current status of each audit.

**Reference Documents:**

- OP 8.2.2 Internal Quality Audits

**Responsibility:** Quality Manager

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

Management determines the key processes that require measurement and monitoring in order to meet our quality objectives. Processes are monitored using performance measurements defined in the Quality Objectives spreadsheet.

Process performance is reviewed by the responsible manager on a routine basis. Where necessary, the manager takes corrective action to correct for process deficiencies.

Process performance is reviewed by the management team during the Management Review meeting. Where necessary, actions are assigned to improve performance. The meeting minutes are the records of this activity.

**Reference Documents:**

- OP 8.2.3 Monitoring and Measurement of Processes

### **8.2.4 Measurement and Monitoring Of Product**

Products produced are evaluated to ensure that all requirements are met.

The Work Order specifies the minimum inspections to be performed and records to be completed. Personnel have the authority to perform additional examinations if necessary.

Acceptance criteria are typically specified by the drawing(s) and other information included with the Work Order.

**Reference Documents:**

- OP 8.2.4 Monitoring and Measurement of Product

**Responsibility:** Quality Manager

## **8.3 Control of Nonconformity**

### **8.3.1 Product and Material Nonconformity**

Material or product that does not conform to requirements is identified, segregated (when practical), documented, and controlled to prevent its inadvertent use or delivery.

The Quality Manager has the authority and responsibility for determining disposition of nonconforming product. Use-As-Is dispositions require customer notification and approval. Such notification is coordinated through the Sales Department.

All material that has been reworked or repaired is re-inspected using the original acceptance criteria to determine acceptability. Product is released when all manufacturing and inspection operations have been completed and no unresolved nonconformities remain.

#### **Reference Documents:**

- OP 8.3 Control of Nonconforming Product

**Responsibility:** Quality Manager

## **8.4 Analysis of Data for Improvement**

The collection and reporting of data is defined in the Quality Objectives spreadsheet.

Analysis of collected data occurs on at least two levels:

- The manager responsible for the process analyzes the performance of the process on a routine basis. When performance is not meeting expectations, the manager is responsible for determining the appropriate preventive action to improve performance. Significant actions are documented according to 8.5, Improvement, below.
- The Management Team reviews the performance of all monitored processes during the Management Review meeting. When performance is not meeting expectations, action appropriate to the problem is taken. Actions may include preventive action to improve process performance, or revision of the quality objective(s) where appropriate.

#### **Reference Documents:**

- Quality Objectives Spreadsheet

## **8.5 Improvement**

### **8.5.1 General Requirements**

Botta-Boom has established Corrective Action and Preventive Action systems in order to drive our continuous improvement efforts. This policy describes these systems.

### **8.5.2 Corrective Action**

Botta-Boom has established a Corrective Action system. Actions must be taken to prevent the recurrence of problems. Corrective Actions are expected to be taken for:

- Nonconforming material
- Process performance problems
- Supplier performance problems
- Customer complaints
- Customer returns of product that does not meet specifications
- Customer audit findings
- Third party audit findings
- Internal Audit Findings

A procedure has been established to provide a structured process for:

- Determining the root cause of problems
- Implementing a suitable corrective action
- Verifying that the action taken was effective

### **Corrective Action Review and Approval Authority**

The Quality Manager has the responsibility and authority for the review and approval of Corrective Action Requests. Once approved, Corrective Action Requests must be responded to by the assigned manager. The Corrective Action Response is reviewed for acceptability by the Quality Manager.

### **Initiating a Corrective Action Request**

Any Botta-Boom employee, customer, or related regulatory agency may initiate a Corrective Action Request.

### **Corrective Action Request Turn-time**

When a Corrective Action Request is assigned to a Botta-Boom manager for investigation and response, that manager is allowed two weeks to perform the investigation and provide a written report back to the Quality Manager.

**Data Collection**

The Quality Manager collects relevant corrective action data for trend analysis to support preventive action activity.

**Reporting**

The corrective action system status is reported at each meeting of the Management Review team.

**Reference Documents:**

- OP 8.5.2 Corrective Action

**Responsibility:** Quality Manager

**8.5.3 Preventive Action**

Botta-Boom utilizes data collected from processes, suppliers, customers, internal audits, corrective actions and other sources to identify trends that may exist. Appropriate preventive actions are taken to improve process, product, or system performance.

The Management Review team has the responsibility to direct the collection and analysis of pertinent data from the operations at Botta-Boom. The information is reviewed at each Management Review meeting. When the team determines that action is needed to improve performance, the Corrective and Preventive Action System is used to document, track, and follow-up on the actions taken.

**Reference Documents:**

- OP 8.5.3 Preventive Action

**Responsibility:** Quality Manager