

Botta-Boom, Inc.

	<i>Standard Operating Procedure: Control of Documents</i>
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Revision	Revision Date	Document Number
A	9/28/18	OP 4.2.3

Approval	Signature	Date
<i>Quality Manager</i>	Michael Butler	9/28/18
<i>Process Owner</i>	Jim Newton	9/28/18

Revision Record

Revision Number	Revision Date	Revision Details	# of pages
New	04/13/18	Initial Release	6
A	09/28/18	Revised to require President's signature as Quality Manager where the Quality Manager is also the Process Owner	6

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1 Purpose

This procedure describes the processes used by Botta-Boom, Inc. to create and revise Policies, Procedures, Drawings, Work Instructions, and Forms that support the Quality Management System.

2 Scope

This procedure applies to all documentation that is included within the BOTTA-BOOM quality management system.

3 Definitions

Controlled Document – A document that has been reviewed and approved by appropriate personnel within Botta-Boom.

Form – A type of document used to create a quality record.

Master List – A listing showing all quality management system documents, the owners of the documents and the current revision levels of the documents. This list is maintained to provide a single source where employees can determine the current, approved version of a document.

Minor Changes – Changes to correct typographical errors, provide more detail, or that change department name, titles, etc.

Quality Record – A record of an activity that provides objective evidence that the activity was completed, by whom, and on what date.

4 Responsibility and Authority

Process Owner Responsibilities

It is the responsibility of the Document Control Process Owner to:

- Implement, maintain and continually improve this process
- Monitor, measure, and report on the performance of this process and any process improvement activities undertaken

Employee Responsibilities

It is the responsibility of every employee at Botta-Boom to understand this process and to ensure that they are working with the current version of any document.

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5 Records Created

The following records are created or modified as a result of this process.

- Quality Document and Data Control Master List – Form 4.2-1

6 References

The following documents are either referenced within this procedure, or were utilized in the development of this procedure.

- ISO 9001
- Botta-Boom Quality Manual, QM001

7 Procedure

The purpose of a document control system is to ensure that anyone performing work that affects the quality of our products and services has the information that they need in order to perform their job properly.

In order to accomplish this, the document control system provides for the review and approval of procedures, drawings, and other documents prior to use. Changes to these documents are controlled and must also be reviewed and approved before being used. Obsolete documentation is removed from use to prevent any accidental use of out-of-date information.

7.1 Types of Quality Documents and Approval Requirements

Type of Document	Review & Approval
Policy	President
Procedure	Quality Manager (where the process owner is the Quality Manager, the President signs in place of the Quality Manager) Process Owner
Work Instruction	Process Owner
Drawings	Engineer Engineering Manager
Forms	Process Owner
Reports	Management Review Team

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7.2 Creating and Revising Documents

Anyone can request a change to an existing document or request a new document be prepared. A decision is made to determine if new documents are to be controlled. This decision may come from any sources including: Sales, Purchasing, Engineering, Production, QA or Management.

Management will make a determination whether it is to be a new document or a change to an existing document.

The assigned Process Owner creates the new document or revises an existing document. An electronic copy of the document is saved into the "Draft" folder on the server.

The Process Owner then provides a copy of the draft document to the review team. The review team must include those people indicated in table 1 above, but should also include other Botta-Boom personnel that may be affected by the document.

The review team reviews the document and provides comments back to the Process Owner.

The Process Owner revises the document according to the comments received. A final version of the document is created and printed.

The review team reviews and approves the document, then returns the document to the Process Owner. For forms, approval is indicated by signing and dating the back side of the form. For reports, the management review meeting minutes notes the approval of the report.

The Process Owner:

- Moves the final version of the document to the "Released" folder on the server
- Updates the Master List
- Makes copies of the document for distribution
- Distributes the document and retrieves obsolete copies of the document
- If a copy of the obsolete version is to be maintained for any reason the Process Owner marks the document as "Obsolete"
- Files the approved hard copy of the document

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The Process Owner determines what training is appropriate for the new/revised document and ensures that affected employees are trained. Records of the training are maintained according to the training procedure, OP 6.2.

Minor changes may be handwritten on the documents themselves if the approval authority signs and dates the change. If handwritten changes are to be used, ALL controlled copies must be noted with the change, signed and dated.

- Handwritten changes are allowed as a matter of convenience. Control of these changes is more difficult, and an effort will be made to avoid making changes in this manner.

Distribution

Distribution varies depending on the type of document

- Engineering drawings are placed in the Production File and old revisions are retrieved
- Quality system documents are duplicated and distributed to managers and old revisions are collected
- External documents are filed where appropriate
- Other document types are stored or disbursed as appropriate

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**Document Control Process
Quality Documents**

