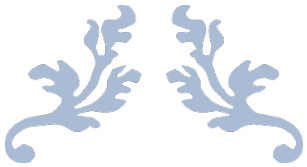


THE BOTTA-BOOM REQUIREMENTS

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

Botta-Boom, Inc.

Standard Operating Procedure: Control of Documents

Revision	Revision Date	Document Number
A	9/28/18	OP 4.2.3

Approval	Signature	Date
Quality Manager	Michael Butler	9/28/18
Process Owner	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

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.

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

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

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.

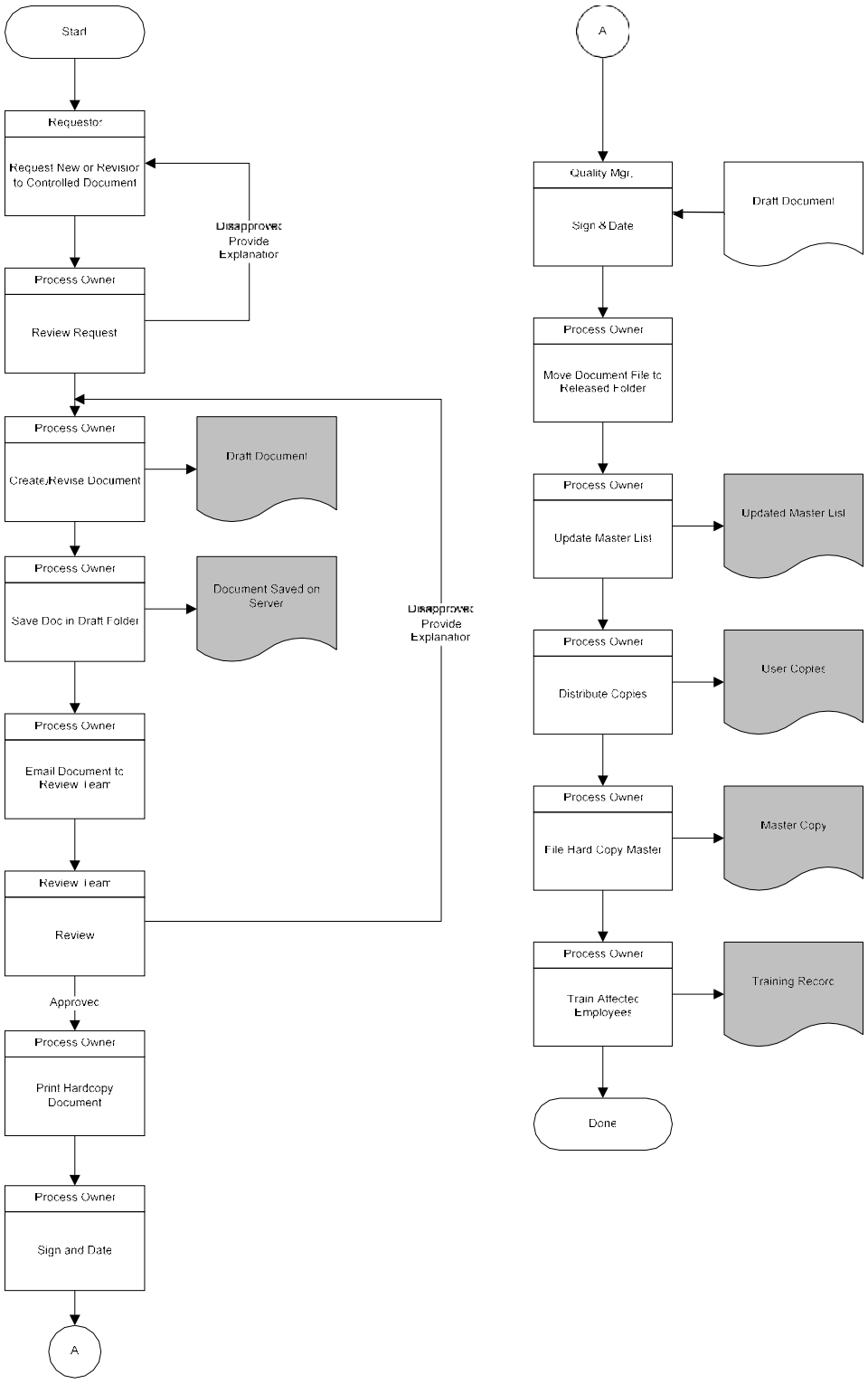
- Handwritten changes are allowed as a matter of convenience. Control of these changes is more difficult, and an effort will be made to avoid making changes in this manner.

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

Document Control Process
Quality Documents


Start
Requestor
Request New or Revision to Controlled Document
Disapproved Provide Explanation
Process Owner
Review Request
Process Owner
Create/Revise Document
Draft Document
Process Owner
Save Doc in Draft Folder
Document Saved on Server
Disapproved Provide Explanation
Process Owner
Email Document to Review Team
Review Team
Review
Approved
Process Owner
Print Hardcopy Document
Process Owner
Sign and Date
A
A
Quality Mgr.
Sign & Date
Draft Document
Process Owner
Move Document File to Released Folder
Process Owner
Update Master List
Updated Master List
Process Owner
Distribute Copies
User Copies
Process Owner
File Hard Copy Master
Master Copy
Process Owner
Train Affected Employees
Training Record
Done

Botta-Boom, Inc.

Standard Operating Procedure: Purchasing

Revision	Revision Date	Document Number
D	9/28/18	OP 7.4

Approval	Signature	Date
Quality Manager	Jim Newton	9/28/18
Process Owner	Maria Castillo	9/28/18

Revision Record

Revision Number	Revision Date	Revision Details	# of pages
New	3/30/18	Initial Release	5
A	7/22/18	Revised to add Form 7.4-3, Supplier Evaluation Survey Form to the records listed in paragraph 4 Revised flow chart to add Supplier Evaluation Survey Form.	6
B	8/2/18	Revised table 1 to add minimum survey score requirements. Revised paragraph 6 supplier definitions to clarify categories.	6
C	8/15/18	Revised approval criteria in table 1.	6
D	9/28/18	Added paragraph 7.1.6 to specify required information for purchase orders	6

1 Purpose

The purpose of this procedure is to ensure that purchased materials, products, and services comply with stated requirements.

2 Scope

This procedure applies to all purchases that directly impact the quality of product manufactured by Production department.

3 Responsibility and Authority

Process Owner Responsibilities

It is the responsibility of the Purchasing Manager to:

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

4 Records Created

The following records are created or modified as a result of this process. Reference Botta-Boom OP 4.2.4 for storage and retention information.

- Approved Vendor List – System Records of Vendors with Approval Status showing "Approved"
- New Vendor Approval Form – Form # 7.4-1
- Supplier Evaluation Mail-in Survey Form – Form # 7.4-3
- Purchase Order – System Record

5 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
- Control of Records, OP 4.2.4
- New Vendor Approval Form – Form # 7.4-1
- Purchase Request Form – Form # 7.4-2
- Supplier Evaluation Mail-in Survey – Form # 7.4.3

6 Definitions

Critical Supplier –	A supplier providing Custom materials and parts, Design, Testing, Out-source Processing, Calibration, etc.
Major Supplier –	A supplier providing Off-the-shelf Component Parts, Adhesives, Wire, etc.
Minor Supplier –	A supplier providing Office Supplies, Manufacturing Consumables, Non-Product related items
PO To Start Report –	A printout from the MRP system showing items to be purchased to support orders and forecast production in the system.

7 Procedure

7.1 Purchasing

7.1.1 For in-house requirements, the Requestor identifies the item to be purchased, the desired supplier (if known), the quantity, need by date, special requirements, and other information. The Requestor completes a Purchase Request Form, Form # 7.4-2 and forwards the form to their manager for approval.

7.1.2 For normal manufacturing needs, the PO to Start report replaces the Purchase Request Form.

7.1.3 Purchasing reviews the request form to determine if all information is complete and legible. If further information is required, the form is returned to the Requestor's manager.

7.1.4 Purchasing determines if the requested supplier is already in the purchasing system. If a supplier is not specified, Purchasing determines the appropriate supplier for the item being ordered.

7.1.5 If the supplier is not in the purchasing system, go to paragraph 7.2.

7.1.6 Purchasing creates the purchase order ensuring that all required information is provided.

For Off-the-shelf items:

- Vendor's part number
- Description
- Quantity
- Price
- Due Date

For custom items:

- Botta-Boom Part Number and Revision
- Description
- Vendor's Part Number (if applicable and known)
- Quantity
- Price
- Due Date
- Any Applicable Quality Requirements Not Shown on the Drawing

7.1.7 The Purchasing Manager must review and sign all purchase orders before they are forwarded to the supplier.

7.2 Supplier Evaluation and Approval

7.2.1 Purchasing determines the appropriate classification for the supplier, and then completes the New Vendor Approval Form, form #7.4-1.

7.2.2 New suppliers are evaluated using the criteria described in table 1 below.

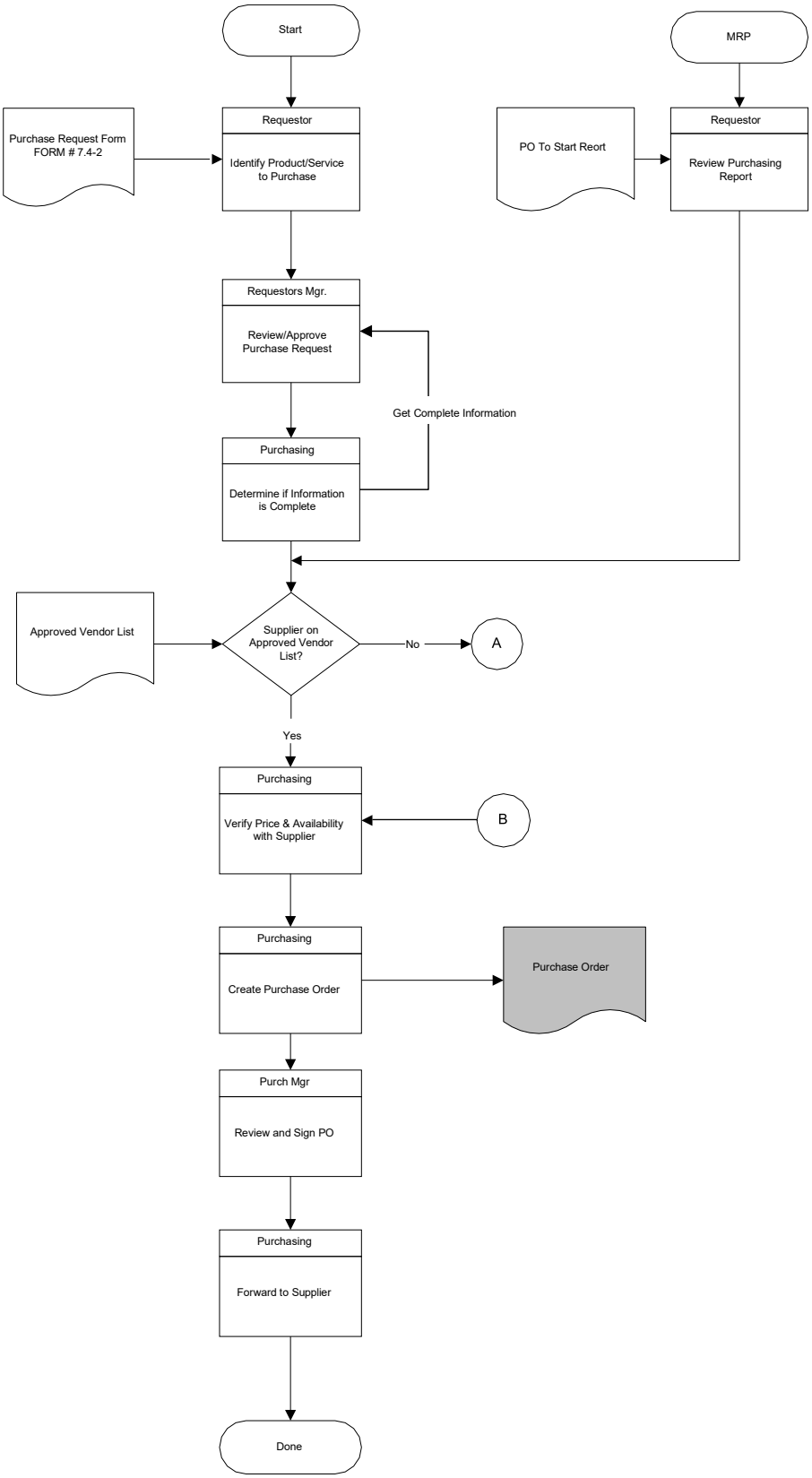
7.2.3 Suppliers meeting the criteria may be added to the purchasing system.

7.2.4 Suppliers that do not meet the criteria in table 1 may be used with approval from the Senior Vice President or designee.

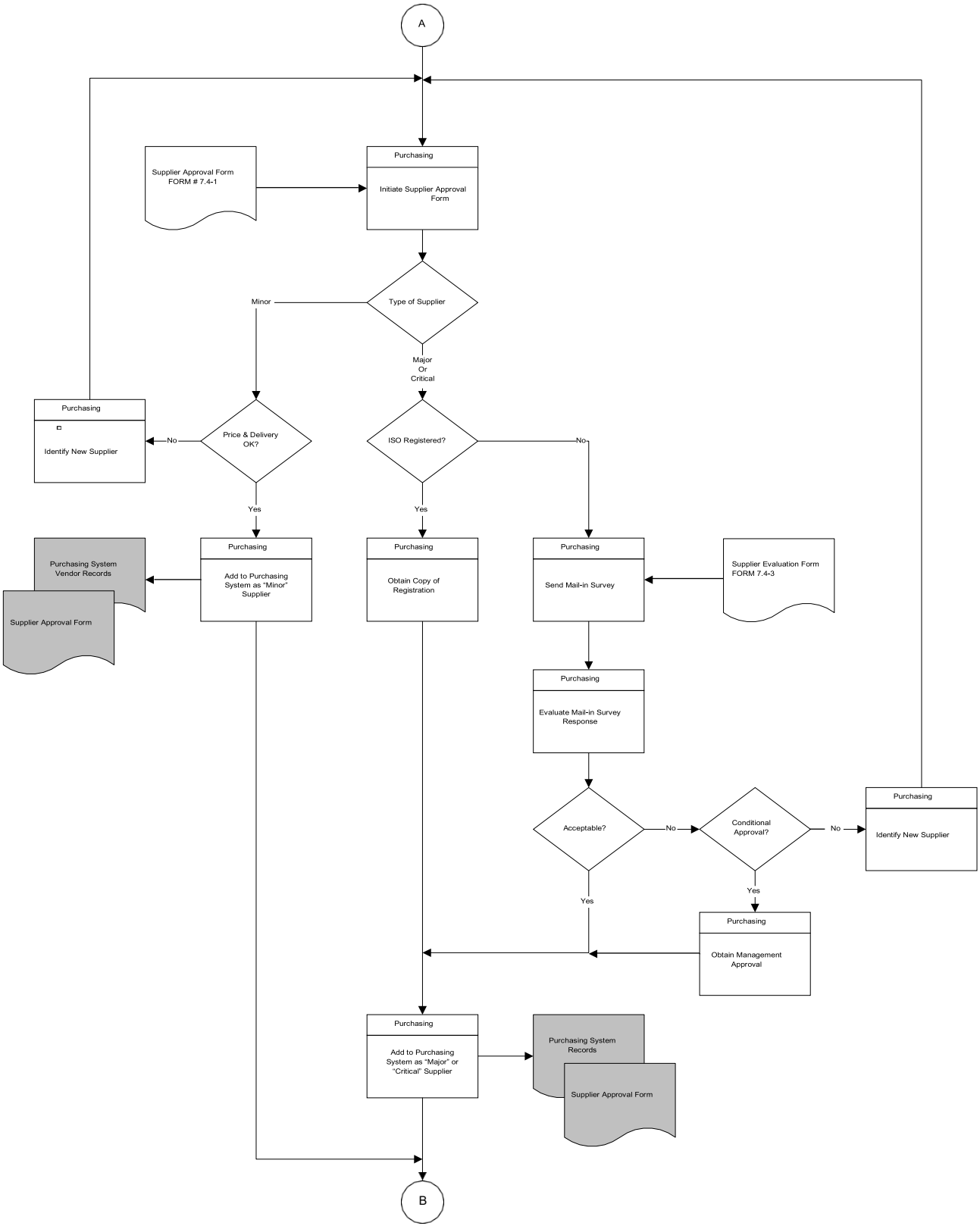
Supplier Type	Approval Requirements
Minor	Product, Price & Availability Meet Needs
Major	ISO Registration (or similar) OR Mail-in Survey with minimum 18 "Yes" Responses
Critical	ISO Registration (or similar) OR Mail-in Survey with minimum 18 "Yes" Responses OR On-site Survey based on recommendation of person performing on-site survey.

Table 1

Purchasing Process



Supplier Evaluation Process



Botta-Boom, Inc.

Standard Operating Procedure:
Control of Monitoring and Measuring Devices

Revision	Revision Date	Document Number
New	8/22/18	OP 7.6

Approval	Signature	Date
Management Rep.	Michael Butler	8/22/18
Process Owner	Jim Newton	8/22/18

Revision Record

Revision Number	Revision Date	Revision Details	# of pages
New	8/22/18	Initial Release	6

1 Purpose

This procedure describes the processes used by Botta-Boom, Inc. for controlling measurement and monitoring equipment used to verify that product meets requirements and specifications.

2 Scope

This procedure applies to all monitoring and measurement devices used for inspection and test of products and validation of processes at Botta-Boom, Inc.

3 Definitions

None

4 Responsibility and Authority

Management Responsibilities

Management has the responsibility to:

- Understand the requirements of this procedure
- Ensure that the Process Owner, and each contributing Manager understands this procedure and is competent to perform expected tasks

Process Owner Responsibilities

It is the responsibility of the Design Process Owner to:

- Execute the requirements of this procedure

Employee Responsibilities

It is the responsibility of each employee to:

- Verify that the measurement or test devices that they use are within the calibration due date
- Notify the Sr. Test Technician of any devices that are found to be due or past due for calibration
- Notify the Sr. Test Technician of any new measurement or test devices that have been purchased, but are not yet calibrated
- Notify the Sr. Test Technician of any devices that have been damaged, or that are providing suspicious results

5 Records Created

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

- Calibration Log
- Calibration Certifications
- Calibration Reports
- Maintenance Log

6 References

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

- ISO 9001
- BB Quality Manual, QM001
- Control of Records, OP 4.2.4
- Out of Tolerance Report Form, Form # 7.6-1

7 Procedure

7.1 New Devices

7.1.1 Any new monitoring or measurement device that is purchased for use in the inspection and test of products, or the validation of processes, must be calibrated prior to use.

7.1.2 The Quality Inspector receives the new device and logs it into the calibration log.

7.1.3 The calibration service is notified of the new device and the device is sent to the calibration service for initial calibration. NOTE: If the supplier of the new device provides a calibration certificate that is traceable to the National Institute of Standards (NIST), then the initial calibration step can be waived. Apply a calibration sticker to the device with the appropriate due date for calibration.

7.1.4 Once the device is received from the calibration service, the Quality Inspector records the calibration in the calibration log, files the calibration records, and forwards the device to the using area.

7.2 Calibration Cycle

7.2.1 The Quality Inspector reviews the calibration log each month for devices that are coming due for calibration within the next month.

7.2.2 The Quality Inspector notifies the calibration service and schedules the calibration activity.

7.2.3 The Quality Inspector notifies the users of the devices of the scheduled calibration. The devices are collected and provided to the calibration service.

7.2.4 The Quality Inspector receives the calibrated devices and records the calibration in the calibration log.

7.2.5 The Quality Inspector reviews each calibration report and determines if any device was found to be out of tolerance when tested by the calibration service. If a device was found out of tolerance, the Quality Inspector copies the report, highlights the out of tolerance condition and provides the report to the Quality Manager.

7.3 Out of Tolerance Devices

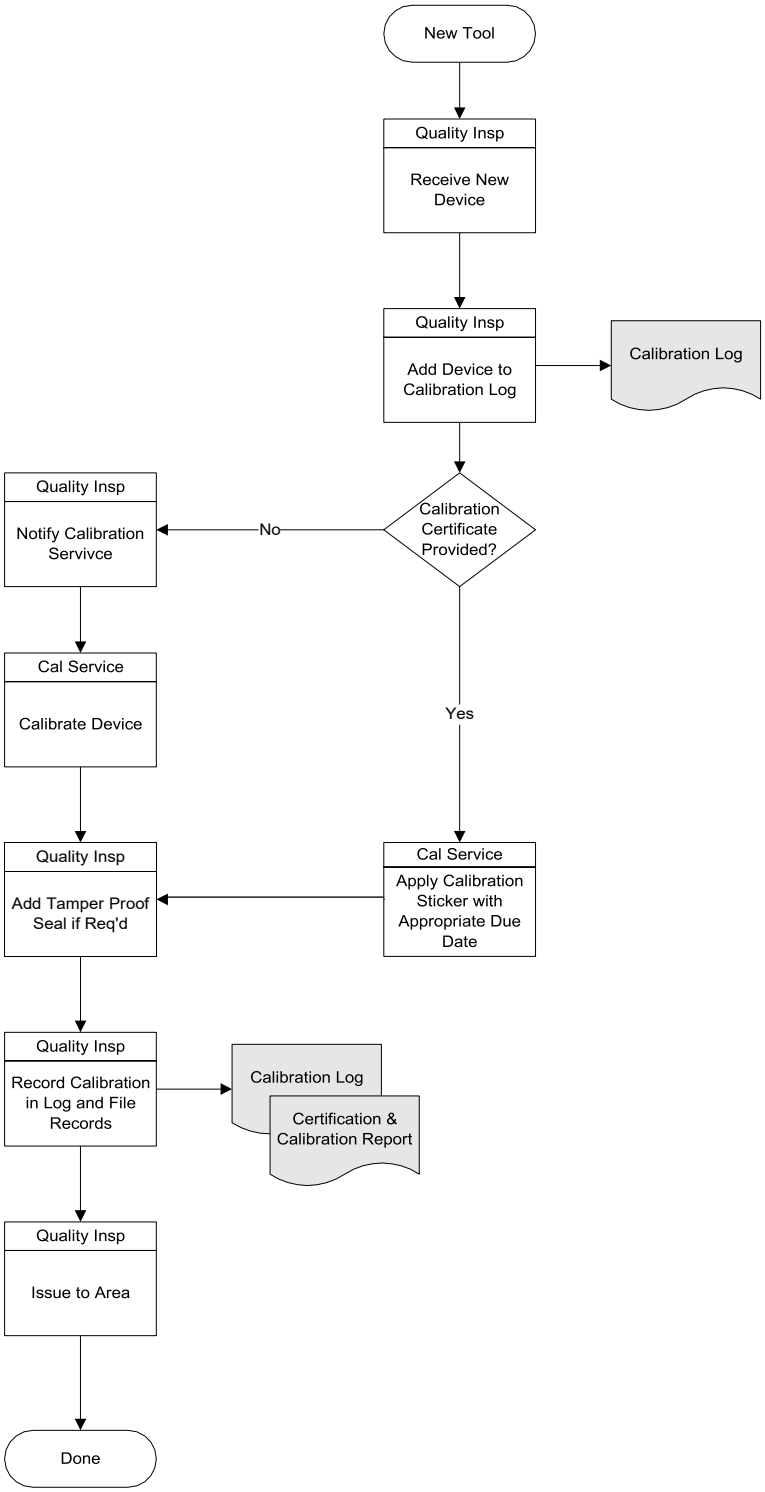
7.3.1 Any device that is out of tolerance by more than two times the specified tolerance range must be documented in an out of tolerance report and an investigation must be performed.

7.3.2 The Quality Manager completes an Out of Tolerance Report, form # 7.6-1 and investigates the out of tolerance condition to determine the impact of the condition and the actions to be taken regarding product inspected or tested by that device.

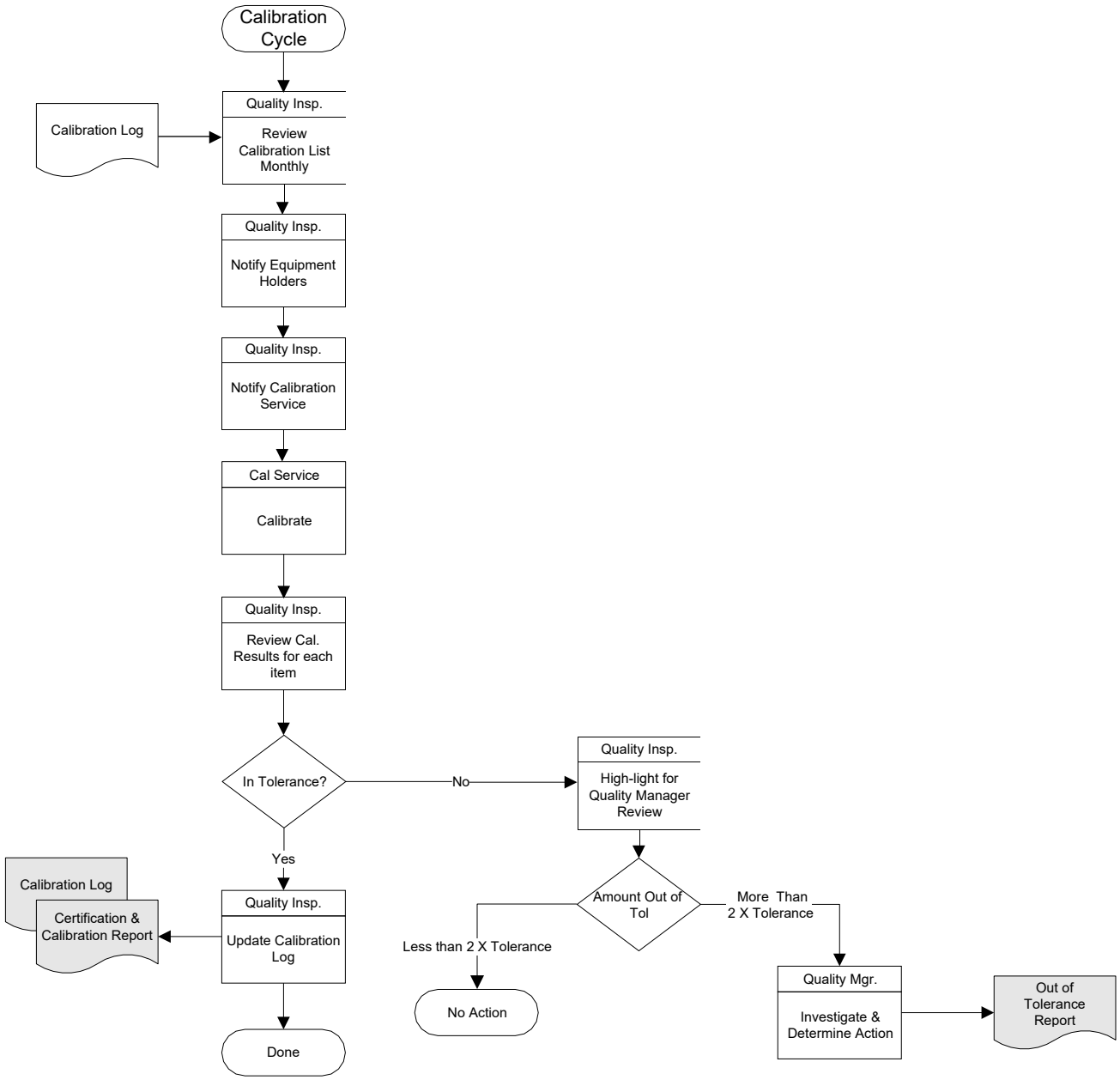
7.3.3 The Quality Manager should consider increasing the calibration frequency on any device that is found to be out of tolerance. This will be communicated to the Quality Inspector and the calibration log will be updated accordingly.

7.3.4 The completed Out of Tolerance Report is filed with the calibration records of the device after the investigation is complete and any required actions have been taken.

Calibration Process – New Devices



Calibration Process – Calibration Cycle



Botta-Boom, Inc.

Standard Operating Procedure: Control of Nonconforming Product

Revision	Revision Date	Document Number
A	8/30/18	OP 8.3

Approval	Signature	Date
Management Rep.	Michael Butler	8/30/18
Process Owner	Jim Newton	8/30/18

Revision Record

Revision Number	Revision Date	Revision Details	# of pages
New	4/6/18	Initial Release	5
A	8/30/18	Revised to change identification of Nonconforming material from using Yellow Hold Tags to Red NCP Tags.	5

1 Purpose

This procedure describes the processes used by Botta-Boom, Inc. to identify, segregate and disposition nonconforming material.

2 Scope

This procedure applies to all nonconforming material at Botta-Boom including purchased materials, work-in-process, and finished products.

3 Definitions

Nonconforming Material – Material and assemblies that do not meet the requirements defined in customer and/or Botta-Boom documentation such as drawings, winding sheets, etc.

4 Responsibility and Authority

Process Owner Responsibilities

It is the responsibility of the 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
- Identify nonconforming material at any location within receiving, inventory, production, inspection, test, and shipping.
- Notify their supervisor/manager of any nonconforming material identified

5 Records Created

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

- Nonconforming Product Tag – Form 8.3-1
- Nonconforming Product Log – Form 8.3-2

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
- Control of Records, OP 4.2.4
- Nonconforming Product Tag – Form 8.3-1
- Nonconforming Product Log – Form 8.3-2

7 Procedure

7.1 Identification and Segregation of Nonconforming Material

If any employee suspects that they have identified nonconforming material, QA is notified of the nonconformance.

If QA determines the nonconformance is valid, a red nonconforming product tag (NCP TAG), Form # 8.3-1 is filled out for the nonconformance and attached to the material. The material and tag are moved to the nonconforming product area.

7.2 Nonconforming Product Disposition

The Quality Manager reviews the NCP TAG for completeness and logs the NCP TAG into the Nonconforming product log. The NCP TAG number from the log is written onto the NCP TAG.

The Quality Manager determines and assigns the disposition for nonconforming product. The available dispositions are:

- Return to Vendor
- Rework
- Scrap
- Use-As-Is

7.3 Disposition

The Quality Manager updates the NCP TAG Log, writes the disposition instructions on the NCP Tag, and routes the material as appropriate.

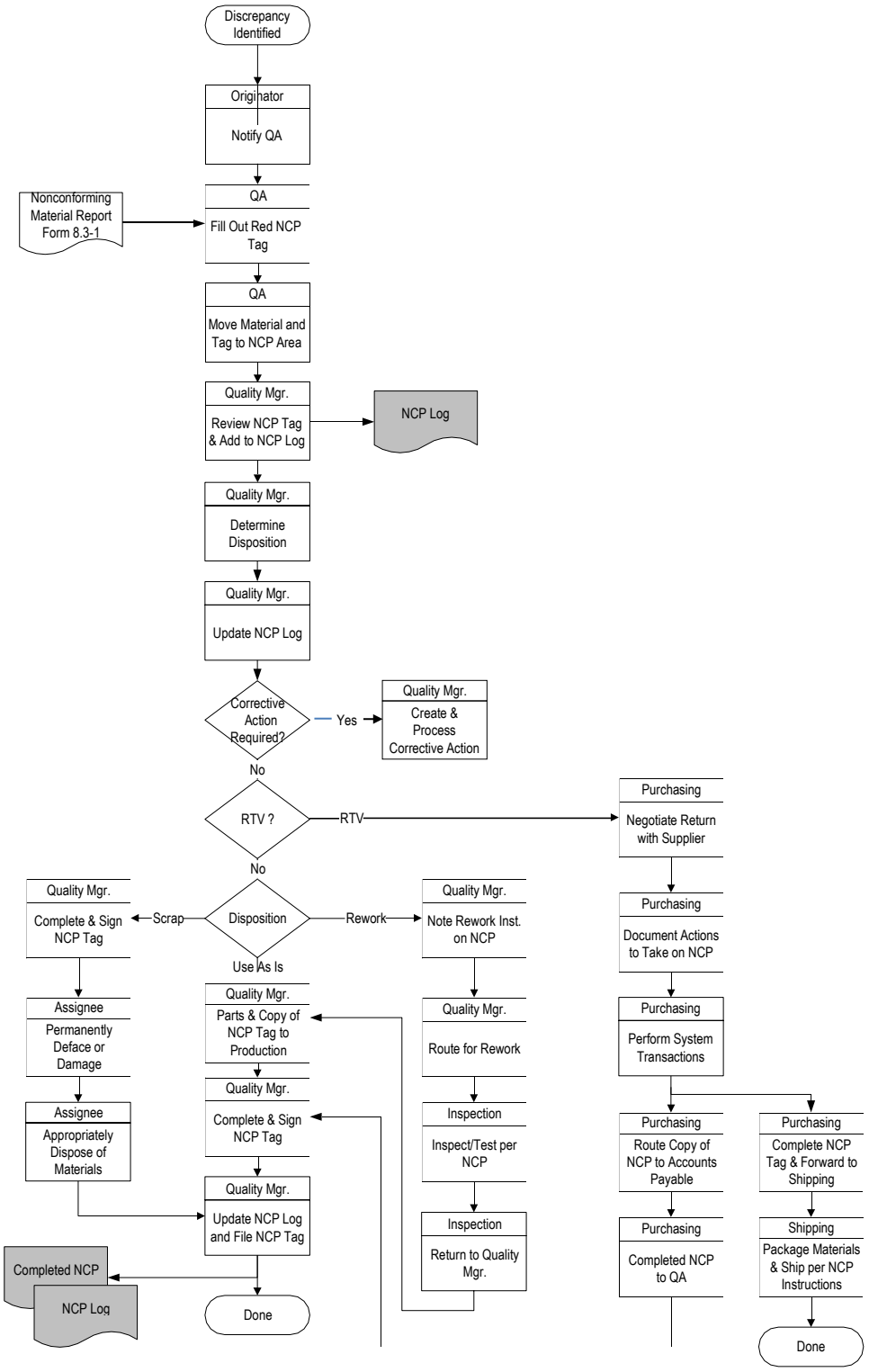
Return to Vendor – Route to Purchasing. Purchasing completes transactions with the supplier, updates the NCP TAG providing a copy to Accounts Payable and the original to QA.

Rework – Route the materials and a copy of the NCP TAG to the appropriate production process step.

Scrap – The person assigned by the quality manager defaces or otherwise renders unusable the nonconforming material, and disposes of the materials in the appropriate recycle bin. The assignee updates the NCP TAG, and returns the NCP TAG to the Quality Manager.

Use-As-Is – Return the materials to the point in production where the nonconformity was identified.

Control of Nonconforming Material



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Botta-Boom, Inc.

Standard Operating Procedure: Corrective Action

Revision	Revision Date	Document Number
C	10/5/18	OP 8.5.2

Approval	Signature	Date
Management Rep.	Michael Butler	10/5/18
Process Owner	Jim Newton	10/5/18

Revision Record

Revision Number	Revision Date	Revision Details	# of pages
New	8/28/18	Initial Release	6
A	9/15/18	Revised to add review and approval of new corrective action requests by the Quality Manager.	6
B	9/28/18	Revised to add Triage criteria	6
C	10/5/18	Revised to separate Preventive Action to a separate procedure. Changed title to Corrective Action	6

1 Purpose

This procedure describes the processes used by Botta-Boom, Inc. to use corrective and preventive action requests in order to implement continual improvement.

2 Scope

This procedure applies to all corrective and preventive action activities affecting the Botta-Boom quality management system.

3 Definitions

Corrective Action – An action taken to correct the root cause of an identified problem. Corrective actions are intended to prevent the recurrence of problems.

Risk Assessment – The evaluation of a problem to determine if it warrants corrective or preventive action.

4 Responsibility and Authority

Process Owner Responsibilities

It is the responsibility of the Quality Manager to ensure that the process described by this procedure is effectively implemented and maintained.

Employee Responsibilities

It is the responsibility of every Botta-Boom employee to understand the corrective and preventive action system.

It is the responsibility of every Botta-Boom employee to initiate a corrective action request to aid in correcting problems associated with processes, products, and customer satisfaction.

5 Records Created

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

- CAPA Database

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
- Control of Records, OP 4.2.4

7 Procedure

Corrective action requests are used to document issues where action is needed to correct the root cause of an identified problem. Appropriate subjects for corrective action requests are:

- Internal Audit Findings
- Customer Complaints
- Observed Process Failures
- Improvement Actions Directed by the Management Review Team

7.1 Initiating a Corrective Action Request:

Any employee may initiate a corrective action request. This is done using the CAPA form. See your supervisor, manager, or the Quality Manager for assistance in using this form.

The originator creates a Corrective Action Request and forwards it to their Supervisor/Manager.

7.2 Initial Review and Risk Assessment

The responsible Supervisor/Manager reviews the Corrective Action Request to ensure that the request is completely and correctly filled out. The request is also evaluated for appropriateness.

The criteria used for determining the appropriate level of risk for a corrective or preventive action are listed below. If any of these criteria are met, a corrective or preventive action will be taken unless otherwise directed by the President.

- Lot failure of greater than 50% of total lot quantity
- Failure cost (in terms of labor and materials) is greater than $500 per incident
- Customer complaint regarding product quality or 3rd party audit findings
- Problems affecting safety of employees, customers, or product operation.

The Supervisor/Manager may determine that the corrective action request is incompletely filled out, contains errors, or is not appropriate for action. The originator will be notified of the reason for not processing the request. A copy is forwarded to the Quality Manager for entry into the CAPA log. The CAPA log will be updated to show the reason why action was not pursued, and the request will be closed.

The originator has the option to resubmit the request with corrected or additional information.

7.3 Management Review & Assignment

If the corrective action request is valid, Supervisor/Manager will forward the form to the Quality Manager for review. If acceptable, the appropriate department manager is selected as the person responsible for response. The CAPA log is updated with the data from the form, the status is set to “Assigned”, and a serial number is assigned to the form. The form is forwarded to the person assigned responsibility for the action.

7.4 Response

The assigned employee must investigate the problem stated in the corrective action request to determine the following:

1) What immediate action is needed to contain any similar problems that may currently exist
2) What is the root cause of the problem stated in the request
3) What action can be taken to correct the root cause and prevent the problem for recurring
4) What is the timeframe for implementation of the actions
5) What activity or performance measurement can be put into place to ensure that the corrective action is effective

This information is entered into the CAPA form for the assigned corrective action request.

7.5 Response Review

When the investigation is complete, the Quality Manager reviews the response to ensure that the issue was properly addressed and resolved, and that the time-line for implementation is appropriate. If satisfied, the CAPA form is signed to show that the corrective action is accepted. The CAPA Log is updated with the date and the status is upgraded to “Approved”.

A follow-up verification is scheduled to ensure that corrective action has been taken and that the action taken effectively solved the original problem.

7.6 Follow-up Review

The Quality Manager, or designee, will perform a follow-up review of the corrective action response. When a follow-up evaluation is performed, the CAPA form is updated to show the completion of the evaluation. The CAPA form and CAPA Log are signed by the Quality Manager to indicate that the corrective action has been closed. The completed CAPA form is filed.

If the evaluation is unsatisfactory (actions not completed, problem still exists, etc.), the corrective action request will be re-issued to the original person it was assigned to with appropriate notes as to the results of the evaluation.

7.7 Extensions

The person assigned responsibility for investigation may request an extension via email to the Quality Manager. The Quality Manager will make the determination of the validity of the request.

7.8 Escalation Process

Each week, the Quality Manager runs a report of open corrective action requests and provides the report to all department heads. A report of overdue corrective action requests is supplied to the President.

Overdue corrective action requests are discussed in the weekly staff meeting and appropriate actions taken to resolve or close the request. Resources may be assigned to expedite action, or Management may decide that the action does not have high enough priority and will be closed. At that time, the Quality Manager, will update the CAPA Log accordingly.

Botta-Boom, Inc.	Document Title: Corrective Action		
	Rev. #: C	Rev. Date: 10/5/18	Doc. OP 8.5.2

Corrective Action Process