Botta-Boom, Inc.

A Subsidiary of

Bigtime Incorporated

Internal Audit Case Study

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THE BOTTA BOOM INC. CASE STUDY

This introduction sets the stage for a multiple part case study involving the design and production of parts by a fictitious company, Botta Boom Incorporated.

This case is based on actual incidents that occurred at many different companies during the design, production, assembly, test, and use of parts for different contracts. The case has been reconstructed and subdivided into a series of thought-provoking situations. Our purpose in presenting these situations is to provide you with the opportunity to:

- Use actual information and skills you have acquired to assess an audit situation and determine the nonconformity issues involved.

- Discuss possible solutions or actions for handling each situation and determine the most appropriate approach to take.

This case study serves as a basis for group discussions and asks for your response to different situations. Each situation relates to elements that have been covered in the training materials. The case study is designed to allow each individual to use analytical skills and to interact with others to share and learn as part of a team. By so doing, each individual will be better prepared when difficult problems arise during actual audits.

The case study consists of two connected parts. In the first part, you will be asked to review a Botta Boom procedure to determine whether it meets the requirements and intent of AS9100. Recall this is Step 1 in analyzing an audit situation — to determine whether the company has met the intent of the model being used. You will be asked to develop a Guidelist that you could use to audit that part of the quality system based on the procedure you will review. In part two of the case study, you will be asked to review audit interview narratives that describe situations that occurred during an audit of the Botta Boom Company. In this part, you must decide whether a nonconformity has occurred. If so, you must decide its severity and what requirement has not been fulfilled. Also in part two, you will be asked to write Nonconformity Finding notes. After the case study is completed, our answers will be provided for your guidance and study.

You should assess each of the situations independently and then discuss your assessments as a group. Each case study segment helps you focus on different aspects of the quality system issues and concerns that confront an auditor at that point in the process. For most of the case study segments, you will be asked to read the scenario or situation and answer a question or make a decision regarding the issues presented. Then you will discuss your response(s) within your small group to reach a consensus on the best approach for handling the situation presented. When you have completed the assessment, a representative from your group will present your conclusions to the class. After all the groups have presented their conclusions, the class as a whole will discuss the various approaches and determine the best course of action.

Botta-Boom Procedure #1

OP 8.7: Control of Nonconforming Product Revision: C

1 Purpose: This procedure defines the process used to identify and properly disposition nonconforming product at Botta-Boom, Inc.

2 Responsibility:

- All Botta-Boom employees are responsible for identifying nonconforming product they may find and proceeding according to this procedure.
- The QC Inspector is responsible for logging items in the NCP log.
- The Quality Manager is responsible for the review of nonconforming product and for assigning the appropriate disposition.

3 Procedure

3.1 Nonconforming material or product is identified by a red NCP tag, available at all workstations and the inspection area. The employee who discovered the nonconforming product completes the following information on the tag:

- Material/product description
- Description of nonconformity
- Job #
- Date
- Employee name

3.2 The nonconforming material or product is placed on a shelf in the area designated for such items.

3.3 The QC Inspector assigns an NCP number to nonconforming product(s), and enters it on the NCP Log.

3.4 The Quality Manager reviews the items in the nonconforming product area and determines the disposition. The disposition is recorded on the NCP log. Possible dispositions include

- Rework;
- Repair;
- Scrap;
- Return to Supplier
- Use-as-is; and
- Regrade for alternative applications.

3.5 The Quality Manager assigns responsibility for implementing the disposition decision to an appropriate person and records his/her name in the NCP log.
The person responsible for the disposition of the material or product notifies the functions concerned.

Documentation Review Procedure # 1
OP 8.7: Control of Nonconforming Product Revision: C

	8.7 Control of nonconforming outputs	Gap?	Notes
1.	**8.7.1** The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.		
2.	***NOTE: The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.***		
3.	The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services.		
4.	This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.		
5.	***The organization's nonconformity control process shall be maintained as documented information including the provisions for:***		
6.	– ***defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;***		
7.	– ***taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;***		
8.	– ***timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;***		
9.	– ***defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).***		
10.	***NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.***		
11.	The organization shall deal with nonconforming outputs in one or more of the following ways: a) correction;		
12.	b) segregation, containment, return or suspension of provision of products and services;		
13.	c) informing the customer;		
14.	d) obtaining authorization for acceptance under concession ***by a relevant authority and, when applicable, by the customer.***		

	8.7 Control of nonconforming outputs	Gap?	Notes
15.	***Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:*** – ***after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;***		
16.	– ***after authorization by the customer, if the nonconformity results in a departure from the contract requirements.***		
17.	***Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.***		
18.	***Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.***		
19.	Conformity to the requirements shall be verified when nonconforming outputs are corrected.		
20.	**8.7.2** The organization shall retain documented information that: a) describes the nonconformity;		
21.	b) describes the actions taken;		
22.	c) describes any concessions obtained;		
23.	d) identifies the authority deciding the action in respect of the nonconformity.		

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Botta-Boom Procedure #2

OP 7.5-1: Control of Documents Revision: B

1. Purpose: This procedure defines the process used to control documents at Botta-Boom, Inc. Records are controlled per OP 7.5-2.

2. Responsibility:

   - The Quality Manager is responsible for controlling quality system documents.
   - The Engineering Manager is responsible for controlling engineering drawings and specifications.

3. Procedure

   3.1. All documents and data are reviewed and approved by designated personnel before they are issued. These same personnel will review any changes to their documents. The approval authority is identified on the master list for each type of document.

   3.2. When a document is created or revised, the master list is updated. (There is a master list for quality system documents and another list for engineering drawings and specs.) The master list includes the document number, name, approval authority, and the current Revision.

   3.3. When a document is changed, the responsible party (see section 2, above) distributes the revised document and retrieves all copies of the old Revision. One old Revision document is saved for history (see OP 7.5-2 Control of Records), and all others are discarded. The archived copy is stamped “Obsolete” in red.

   3.4. 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.

Documentation Review Procedure # 2
OP 7.5: Control of Documents Revision: B

	7.5 Documented information	Gap?	Notes
	7.5.2 Creating and updating		
1.	When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number);		
2.	b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);		
3.	c) review and approval for suitability and adequacy.		
4.	***NOTE: Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization.***		
	7.5.3 Control of documented information		
5.	**7.5.3.1** Documented information required by the quality management system and by this International Standard shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed;		
6.	b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).		
7.	**7.5.3.2** For the control of documented information, the organization shall address the following activities, as applicable: a) distribution, access, retrieval and use;		
8.	b) storage and preservation, including preservation of legibility;	Records Only	
9.	c) control of changes (e.g. version control);		
10.	d) retention and disposition.	Records Only	
11.	e) ***prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.***		
12.	Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.		
13.	Documented information retained as evidence of conformity shall be protected from unintended alterations.	Records Only	
14.	***When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).***		
15.	NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.		

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Botta-Boom, Inc.

Audit Interviews

BACKGROUND INFORMATION:

Botta-Boom, a manufacturer of assemblies and components for a variety of industrial applications, has been in business since 1988. The company has been under pressure from several large-volume customers to become AS9100 registered. A year ago, they began the process and assigned Jim Newton, the Quality Manager, as the Management Representative.

Jim produced a very professional looking Quality Manual (QM-1, Rev. A) and system level procedures covering the requirements of the AS9100 Standard. The three internal auditors completed two rounds of audits, and Jim believed the company was nearly ready for a registration audit. He hired XYZ Consulting to perform a pre-assessment audit.

Mark Chen, the auditor from XYZ, arrived first thing in the morning, October 1, 2017, and began the day with a formal opening meeting. Jim Newton, Ginny Hopkins, Ron Balewa, and Brian Murphy attended the meeting. Mark then asked if he could spend some time with the management team discussing organizational context and risk assessment while they were gathered, but Jim suggested they go on a plant tour first.

CASE 1:

Ginny Hopkins took the auditor on a tour of the plant. They began at the receiving dock, where the QC inspector was busy checking in a truckload of materials. Everything seemed to be operating smoothly, and the area was clean and well organized.

They proceeded to the assembly area, which had 10 production lines. As they walked through the area, the auditor noticed that many of the work instructions in use had handwritten notes and changes. He also noted that some of the production lines had a maintenance checklist posted while other lines did not. He looked closely at one of the checklists and saw that the most recent entry was 3/5/17.

As they walked toward the inspection area, they passed an area marked “Nonconforming Product.” There were several racks containing assemblies and various components labeled with bright yellow “HOLD” tags. Ginny smiled and proudly explained how well the nonconforming product procedure was working. Everyone in the plant had been trained and knew that whenever they found nonconforming product or material, they had to bring it to this area so the QC Inspector could decide what to do about it.

When they reached the Inspection area, the auditor took a quick look around and was impressed with how neat and well organized the room was. Ginny commented that the QC Inspector was one of their best employees and had really turned that area around in the two years since she arrived at Botta-Boom. They turned to leave, and the auditor glanced at a pair of calipers lying on a table. A sticker indicated that calibration was 6 months overdue.

CASE 2:

After the tour, Mark asked again about discussing some higher-level strategic concepts, but Jim said it would be better to wait until they met with Michael Butler. Jim said he had Michael on the agenda later in the day to discuss their processes for Strategic Planning, Risk Assessment and Management Review. Instead, the auditor went to Jim Newton's office to discuss the Corrective Action and Continuous Improvement system (OP 10, Rev. C). Jim showed him the database used to track Continuous Improvement Requests (CIRs), and Mark noted that the type of request (improvement opportunity or corrective action) was designated. Jim said internal audit findings were tracked separately by Joe Parisi. Most of the CIRs were initiated because of customer complaints. A few were generated by employees who saw a problem or had a suggestion for improvement.

Approximately half of the customer complaints stemmed from changes the customer made after the original order was taken. The complaints indicated that information about customer changes had not made it to the assembly area and so the assemblies were made without the update. The auditor studied one CIR form regarding this problem (See Exhibit D). He asked to see the specific customer complaint forms mentioned on the form. Jim said he did not keep them, but called Brian Murphy, the Sales Manager, who could get them. Brian said he would find those complaint forms and have them ready when the auditor came to interview him later that morning.

The auditor asked about the relatively low number of CIRs generated by Botta-Boom employees. Jim said that all employees had received training on the CIR system and how to fill out a CIR. The quality system was obviously well implemented and there weren't many problems for the employees to find.

CASE 3:

The auditor's next interview was with Joe Parisi, the internal audit manager. He showed Mark the database of internal audit findings (see Exhibit E). The auditor asked about the lack of closure in the engineering department. Joe said he had tried to meet with Al Stevens, the engineering manager, to work on the corrective action, but Al wouldn't return his calls or messages. Mark asked "what's the next step?" Joe replied that there was nothing more he could do until Al decided to get back to him.

The auditor asked Joe to show him the internal audit schedule. Joe pulled out a copy from his desk and handed it to Mark. Mark checked the report files and found there were no reports for two of the three audits scheduled for June. When Mark mentioned this to Joe, he responded, "I keep telling Jim that we need some more auditors. We haven't done all of the audits that are scheduled, and we haven't followed up on any of the audits we <u>have</u> done!"

CASE 4:

The auditor continued by interviewing Maria Castillo, the Purchasing Manager. He first asked about the process of evaluating suppliers. Maria explained that they audit potential suppliers to determine their ability to meet Botta-Boom's needs for goods and/or services. If they do well in the audit, they are added to the approved supplier list. In some cases, their customer stipulates which supplier they must use, so these suppliers are just put on the approved list without an audit. She pulled a stack of files containing supplier evaluations. Mark glanced at the top three files, reports on Perfect Plastics, Inc., Benchmark Products, and Stellar Manufacturing. All three files contained audit reports indicating that the suppliers had well implemented quality systems. The most recent report was that of Stellar Manufacturing, from an audit 3 years earlier. Maria showed the auditor Botta-Boom's Approved Supplier List, which included these three vendors and their scope of approval. The auditor asked Maria how they evaluate the suppliers who are already on the list. She responded, "If they are already on the list, they're approved. We don't have to do any more evaluations!" Mark then asked how she would decide whether to tighten controls on a supplier or disapprove one, since he had not seen that requirement covered in Botta-Boom's Purchasing Procedure (OP 8.4, Rev. D). Maria replied "I've never seen a need for that type of action."

The auditor asked to see where they kept the completed purchase orders (POs). Maria took him to a file cabinet, opened one of the drawers and told him to help himself. He pulled a sample of 10 POs and checked for approval. OP 8.4 (Rev. D) required that the Purchasing Manager sign all POs to indicate approval. Seven POs had Maria's signature and the other 3 were signed only by the buyers who had placed the orders.

CASE 5:

The auditor went to the sales department next. Brian Murphy greeted him and said they had not yet found the customer complaints he requested, but his Admin was busy searching for them. Mark thanked Brian and asked him how Botta-Boom ensured that Botta-Boom could meet the claims for the products and services they offer. Brian responded that their Design Control process was very rigorous and they did a lot of verification and validation testing. He suggested that Mark discuss this further with Al Stevens.

The auditor then spoke with Brian and Kevin Watson, one of the salespeople, about the contract review process. The documented procedure (OP 8.2, Rev. A) was very vague, so Mark asked about the training for that department. Brian explained that there is a formal 3-day class that each new salesperson attends, and then they typically work with an experienced employee for a week until they are ready to handle incoming calls on their own. Kevin had been with the company only 3 months, and confirmed that he had received the formal training and worked with another employee to prepare for his job.

Kevin described the contract review process and the records kept. Kevin said that the sales file was the key to the whole project, as it contained all of the customer and regulatory requirements, contract changes and

how Botta-Boom was to notify the customer of any changes or issues. The information relevant to production was forwarded to David Cooper, the assembly supervisor, who updated the work orders when changes were made to the order. “What about risk assessment for new or changed orders?” the auditor asked. Kevin replied that they recently documented a procedure for Risk Management (OP 6.1, Rev. A) and had added a class to the formal Sales training.

Mark asked to see an example of risk assessment for an order change, so Kevin showed him the file for Job #23761, which had been updated two days earlier. It was a big order of their newest product, the Bifurcon 2000. Their customer, ACE Supply, had called and requested that their company logo be added to each unit. Botta-Boom already had the logo since they had complied with this request on some previous orders. Mark asked if there was any record of the review of the change; Kevin replied that he didn’t need a record, since the procedure just required him to consider and address any possible risks. Kevin continued by saying “I sent an email message to David notifying him of the change, and included a copy in the sales file.”

The auditor asked to meet David Cooper to follow up on this particular job. As Kevin led him out of the office, they heard Brian ask his Admin about the customer complaint records. “I’m trying, I’m trying,” he sighed. “They just don’t seem to be here!”

When they got to the assembly area, Kevin introduced the auditor to David Cooper who confirmed the change that had been made to the job they had discussed in the Sales office. He pulled up Job #23761 on the computer and proudly displayed the addition in the production instructions. He then showed Mark the box of work orders pending for the plant, where a printed copy of an updated work order for Job #23761 was located, waiting to be pulled for assembly.

Mark then asked David about how process changes were handled, for example if an assembly process needed to be modified. David replied that he would discuss something like that with Quality and Engineering. Mark asked if any records were kept and David said he didn’t know, but that the auditor could ask Al or Jim.

CASE 6:

The auditor then moved out on the assembly floor. He wandered around for a few minutes, asking several employees about Botta-Boom’s quality policy and how they contributed to the achievement of the company’s quality objectives. Of the 6 people he questioned, only 2 could tell him anything about the quality policy and objectives. The two people that were aware of the policy and objectives did not know how they contributed to achieving the objectives, although they did mention that in the training they received covered ethical behavior, product safety and the importance of quality.

He introduced himself to Carter Taylor, one of the assemblers, and asked about the job he was doing. Carter showed Mark the Bifurcon 2000 job that he was assembling and the drawing (Rev. B) he was using, and showed where he initialed each step on the work order (Job # 23778) as he completed it. Marked noted that for this order of the Bifurcon, the customer was Magnus Manufacturing.The auditor spotted a stack of CIR forms at the workstation, and asked about them. “We’re supposed to fill those out if we find a problem,” Carter replied, “but it’s a whole lot quicker just to fix the problem and not hassle with the paperwork. I don’t think they really read them anyway. See Kenny over there in the red shirt? He’s filled out about 5 or 6 of those forms, and never heard back on any of them.”

The auditor asked about equipment maintenance: “did Carter have any written instructions and were there any records kept on the equipment?” Carter said he’d been working with that machine so long, he knew exactly what to do when it went down, and as far as records go, it was all in his head. Another assembler who was observing the interview said he had a procedure and went to get it for the auditor. He returned with a copy of the work instruction for Equipment Maintenance (WI 7.1.3, Rev. A), which had some handwritten changes signed and dated by David Cooper. The auditor asked Carter if he had seen it before. Carter shrugged and shook his head no.

CASE 7:

When Carter completed the current job, he called Karin Khanna, the QC Inspector. She checked the assemblies he had finished, and initialed the appropriate spaces on the work order, explaining each step to the auditor as she went along. When she finished, the auditor asked about receiving inspection. “Let’s go to my office and I’ll show you the log book.” As they walked across the production floor, they passed a rack of new Bifurcon 2000 modules. She told Mark they were assembled the previous afternoon and had been inspected first thing this morning. Mark looked at the completed work order, which was in a folder on the rack with the modules. It was the order for ACE, Job #23761, but the modules did not have the ACE logo as the customer had requested. He examined the work order closely. It had been printed three days earlier, and did not reflect the change to add the customer logo.

As they continued toward Karin’s office, they passed the nonconforming product area Mark had seen during the tour that morning. He asked Karin how that system worked at Botta-Boom. She replied, “Employees who find defective material or product bring it to this area and tag it with Yellow Hold tags like you see here. Each day I review what is in the area and decide what to do with it. Sometimes it can be fixed, sometimes it has to be scrapped and other times we may be able to get the customer to accept it as is. If a part is scrapped, I keep it here until someone has time to physically destroy it.” The auditor asked who made the decisions regarding what to do with the nonconforming product. She said that she decided in most cases, but she would ask Jim Newton for help if she wasn’t sure how to handle something.

CASE 8:

They arrived at Karin's office and Mark took a look at the receiving logbook. He noticed that a shipment of components from Stellar Manufacturing was rejected the previous day. When asked about the problem, Karin responded, "They didn't meet our dimensional spec's. We've been having this same problem for months!" Mark asked to see the receiving inspection records on all shipments from Stellar in the last six months. Five of the last ten shipments were rejected for the same reason. Karin showed Mark the report she compiled monthly for her boss on receiving inspections.

Mark asked Karin if she had any controls for the prevention of counterfeit parts. She replied that their parts were at a low risk for that type of thing, but that she made sure every lot received was accompanied by a Certificate of Conformance.

Next they discussed the calibration system. Karin showed the auditor a copy of the calibration schedule and the procedure (OP 7.1.5, Rev. C) and work instructions (WI 7.1.5, Rev. C) she used. Mark asked what she did if any equipment was found to be out of calibration. "We pull it immediately!" Karin responded. "I label the equipment with an orange "DO NOT USE" sticker and record the information in the calibration record. Then I have it recalibrated and put back into use or scrapped and replaced if it cannot be brought back into tolerance. You can see our whole method described here in OP 7.1.5 (Rev. C)." Mark looked over her shoulder and noted that the OP also covered action to take to assess validity of previous measurement results and determination of affected products. The auditor then looked to the side and saw the pair of calipers he had noticed during the tour that morning. "The sticker indicates those are past due for calibration," he said. "Oh, that pair is not used for inspection, just for reference," Karin responded. "They aren't accurate enough, so we bought a better pair to use when checking components." The auditor walked over and picked up the calipers. He turned them over and saw a yellow sticker that said "FOR REFERENCE ONLY."

CASE 9:

The auditor walked to Engineering and asked to speak with Al Stevens, the manager of that department. Al was on the phone, so Mark asked for their controlled document binder and looked around the area for a few minutes while he waited. On the wall was a chart showing the status of current engineering projects, all in various stages of completion. Project #BB-72 was due for final review the next week. Project #BB-69, a Revision to the Bifurcon 2000, had been completed the previous week, and led to the Revision C drawing for that product. As the auditor looked at a copy of the work instructions for Customer Notification of Design Changes (WI 8.3.4-1, Rev. B) in the controlled binder, Al Stevens hung up the phone and asked Mark to come into his office. Al described the design control process at Botta-Boom, noting that some products were designed by customers and others by Botta-Boom to a customer specification.

The auditor asked to see the file on Project #BB-72 (a Botta-Boom design), which was almost complete. Al called to Phillip Kato, the engineer in charge of that project, and asked him to bring the file. Mark flipped through the pages contained in the file as Phillip described the design stages represented there. “You’ve done a great job documenting all of your verification and validation results in the Design File, and it’s clear that product safety and the consequences of obsolescence are considered” the auditor said. “What about records of the review and approval of design changes and the related assessments of risk that took place while the product was in development?” “Well, the designs are always changing,” Phillip replied. “We’re allowed to work to red-lined drawings before production release, but we don’t keep all of those versions. Al jumped into the conversation and said “we have project meetings regularly and I make sure everyone involved knows exactly what’s happening. Besides, what’s important is having a record of the final design. Nobody cares about how we got there.”

Mark then asked Al and Phillip how production process changes were reviewed. Al said that generally those kinds of changes would be discussed by Engineering, Quality and Assembly. The auditor then asked what sorts of records were kept of the reviews and authorization of changes. Al responded that they didn’t keep records of every conversation in the company, but if a procedure got changed it would get signed by the approval authority.

CASE 10:

Next, the auditor sat down with Jim Newton and Michael Butler to discuss strategic planning and the management review process. Mark mentioned that he’d read the Quality Manual’s description of Botta-Boom’s organization context and the needs and expectations of relevant interested parties. He then asked “how do you monitor and review information about these issues in an ongoing way and address any risks and opportunities?” Michael responded that they already figured all that out when Jim was writing the Quality Manual and he didn’t anticipate changes or see any need to keep reviewing that information.

Mark moved on and asked about the management review meetings. Michael explained that the meetings took place once a quarter, and they discussed things like internal audit results, the improvement and corrective action system and training needs. The auditor asked to see the records, so Jim went to his office and returned with the minutes from the previous two meetings. Mark took a few moments to skim the pages, and asked Michael, “I don’t see any discussion about the purchasing program, or the contract review process. How do you know your system is adequate?” “Well, we only discuss the areas that had audit findings or any internal corrective action requests,” Michael responded. “If an area hasn’t generated any need for corrective action, we can assume it’s OK. Besides, we don’t have time to discuss the entire system. We’ve got a business to run!”

The auditor then asked to speak with someone about training and was introduced to Fritz Adler in Human Resources. Fritz explained that he coordinates all of the training that takes place at Botta-Boom and pulled out a copy of the operating procedure for training (OP 7.2, Rev. A). Mark asked to see the training records as referenced in the Training Matrix of OP 7.2 for Linh Nguyen, Maria Castillo, Kevin Watson, Phillip Kato, Carter Taylor and Karin Khanna. Fritz pulled three files, but there were no files for Phillip Kato, Carter Taylor or Linh Nguyen.

Mark asked how the organizational knowledge described in the Quality Manual would get updated and how needs for new information would be identified. Fritz paused for a moment and replied “I don’t know, that hasn’t happened yet, but I guess Jim would let me know.” The auditor next asked if training competency needs were periodically reviewed. Fritz replied that since the documented system was fairly recent, they hadn’t seen a need yet to update any of the job descriptions or skills requirements lists.

As the auditor was leaving Fritz’s office, Brian Murphy rushed down the hall carrying several files. “Here are the customer complaint records you were looking for earlier. Sorry it took so long.” “Thank you,” replied the auditor. “I’ll review these in a few minutes, and come to your office if I have any questions.” With that, Mark headed for the conference room to review his notes from the day, and finalize his plan for the next day’s audit.

Exhibit A: Organization Chart

Botta-Boom, Inc.

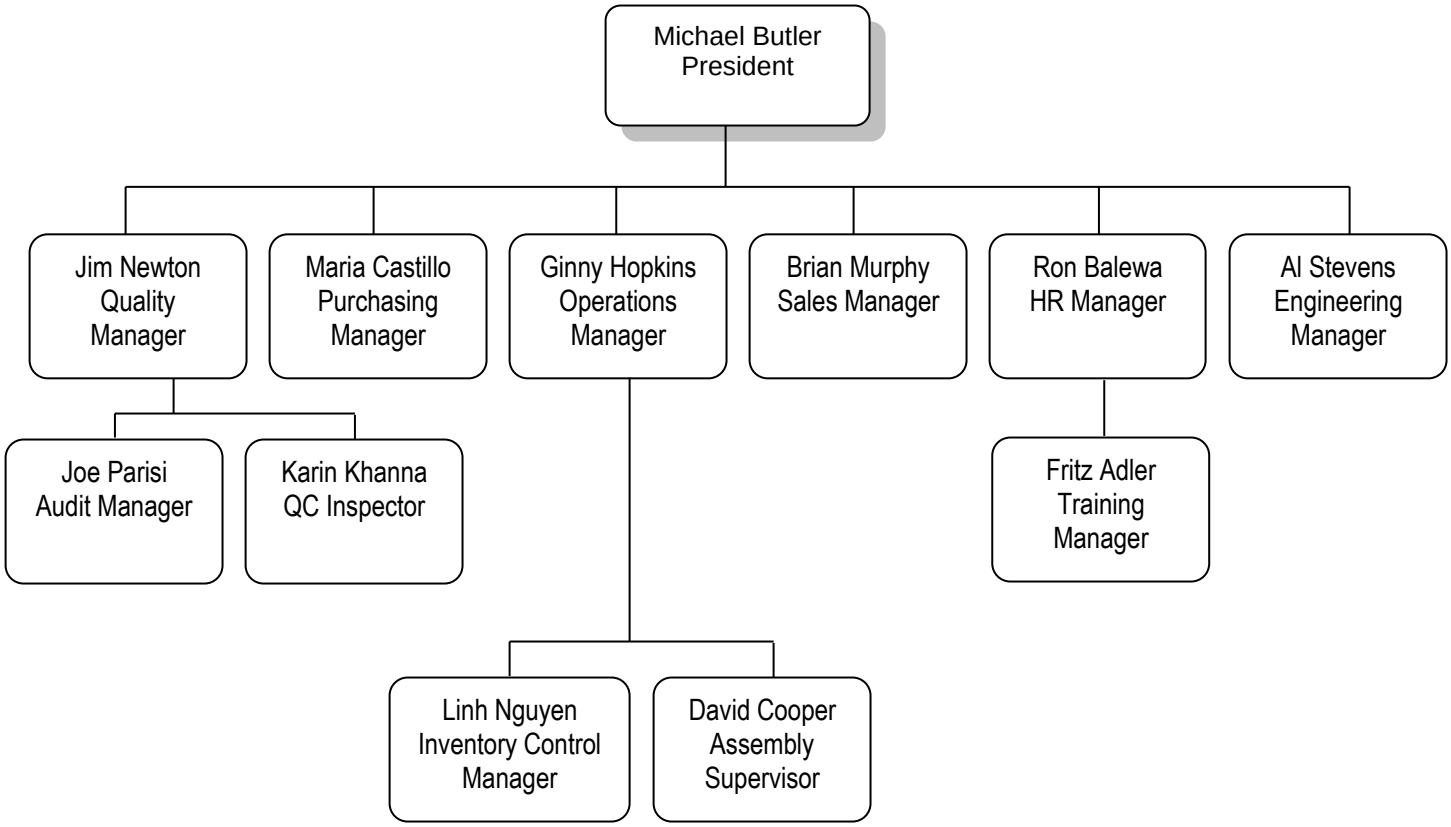

Exhibit B: Excerpt from Document Master List

Document Number	Document Name	Approved By:	Current Revision:
QM-1	Quality Manual	M. Butler	A
OP-6.1	Risk Management	B. Murphy	A
OP 7.1.5	Control of Monitoring and Measuring Devices	J. Newton	D
OP 7.2	Training	R. Balewa	A
OP 7.5-1	Control of Documents	J. Newton	B
OP 7.5-2	Control of Records	J. Newton	E
OP 8.2	Contract Review	B. Murphy	B
OP 8.3	Design and Development	A. Stevens	C
OP 8.4	Purchasing	M. Castillo	D
OP 8.5.4	Preservation of Product	G. Hopkins	B
OP 8.5.6	Control of Process Changes	G. Hopkins	A
OP 8.7	Control of Nonconforming Product	J. Newton	C
OP 9.1	Monitoring, Measurement, Analysis and Evaluation	J. Newton	C
OP 9.2	Internal Quality Audits	J. Newton	D
OP 9.3	Management Review	M. Butler	A
OP 10	Corrective Action & Continuous Improvement	J. Newton	C
WI 7.1.3	Equipment Maintenance	D. Cooper	B
WI 7.1.5	Calibration and Verification	K. Khanna	D
WI 8.3.4-1	Customer Notification of Design Changes	A. Stevens	C
WI 8.4.2	Receiving Inspection	K. Khanna	C
WI 8.5-1	Inventory Control	L. Nguyen	B
WI 8.6	Final Inspection	J. Newton	G

Exhibit C: Excerpt from Quality Records List

Record Name:	**Responsible Party:**	**Retention time: (minimum)**
Audit reports on potential suppliers	Purchasing Manager	5 years
Calibration data	QC Inspector	5 years
Continuous Improvement Request (CIR)	Quality Manager	3 years
Customer complaint forms	Sales Manager	2 years
Design file	Engineering Manager	5 years
Final Inspection reports	QC Inspector	3 years
Internal Audit reports	Audit Manager	3 years
Job files	Assembly Supervisor	2 years
Management Review minutes	Quality Manager	2 years
NCP log	QC Inspector	2 years
Preventive Maintenance records	Operations Manager	2 years
Purchase Orders	Purchasing Manager	2 years
Receiving Inspection reports	QC Inspector	1 year
Traceability certificates for calibration standards	Quality Manager	5 years
Training records	Training Manager	Term of employment + 2 years
Sales file (contract review records – including changes to orders)	Sales Manager	3 years

Exhibit D: Continuous Improvement Request

Continuous Improvement Request

CIR Number: CIR - 12 Date: 7/15/17 ☑ Corrective Action ☐ Improvement

Initiated by: Kevin Watson Department: Sales

Description of problem:

Changes requested by customers after they have already made an order are not always incorporated into the product. Sales transfers the information to Assembly, but sometimes they don't find out about the change at all, and other times they find out too late.

Customer complaint forms numbered 12, 17, 26, 35, and 42 are all related to this type of problem.

Assigned to: Brian Murphy, Sales Manager

Improvement/Corrective Action:

Most of these errors happened because we didn't have time to get the information to Assembly. I worked with David Cooper to determine a method to correct this problem. When a customer requests a change, we immediately send David a message over company email. Before he prints any new work orders, he will check his email for updates.

We keep a copy of the email message in the sales file for that order.

Date Completed: 7/18/17 Signature of manager: *Brian Murphy*

Corrective/Preventive Action Verification: ☑ **Accepted** ☐**Not Accepted**

Audited change process and found new process being followed.

Date Closed: 7/20/17 Signature of Quality Manager: *Jim Newton*

Exhibit E: Excerpt from Internal Audit Database

Audit Schedule: Jan - Jun, 2017

Department	January	February	March	April	May	June
Purchasing	x				x	
Assembly	x				x	
Sales			x			x
Engineering		x			x	
Inspection				x		
Human Resources		x				x
Shipping		x				
Management			x			x
Inventory Control				x		

Audit Findings for completed audits: Jan - Jun, 2017

audit finding	**element**	**department**	**auditor**	**audit date**	**date closed**
7	8.5	Assembly	D. Cooper	1/7/17	3/17/17
8	8.5	Assembly	L. Nguyen	1/7/17	3/16/17
9	8.4	Purchasing	L. Nguyen	1/17/17	5/10/17
10	8.3	Engineering	J. Parisi	2/17/17	
11	8.3	Engineering	J. Parisi	2/17/17	
12	8.5	Shipping	J. Parisi	2/27/17	6/12/17
13	8.2	Sales	D. Cooper	3/15/17	7/10/17
14	9.3	Management Review	J. Parisi	3/30/17	8/16/17
15	8.4.2	Receiving Insp.	L. Nguyen	4/6/17	6/21/17
16	8.6	Inspection	D. Cooper	4/6/17	8/8/17
17	8.6	Inspection	J. Parisi	4/6/17	8/8/17
18	8.5	Assembly	L. Nguyen	5/12/17	9/20/17
19	8.5	Assembly	D. Cooper	5/12/17	9/2/17
20	7.2	Human Resources	D. Cooper	6/18/17	9/24/17

AS9100 Audit Guidelist

Requirement	Look **AT** (Talk To)	Sampling Plan	Look **FOR**

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FINDING of NONCONFORMITY

Documents Audited:		Nonconformity Severity	
		Major ☐	Minor ☐
Area Audited: Area Representative:		Date:	NC Number:
Positive Comments:			
Requirement:			
Nonconformity & Objective Evidence:			
Auditor:			Date:
Finding Assigned to:	Date:	Response Due:	
Corrective Action Taken:			
Action Taken to Prevent Recurrence:			
Responsible Manager:			Date:
Verification of Corrective Action (describe evidence):			
Corrective Action Accepted:			Date:

Form 9.2.2 Attachments: ☐

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FINDING of NONCONFORMITY

Documents Audited:		Nonconformity Severity	
		Major ☐	Minor ☐
Area Audited: Area Representative:		Date:	NC Number:
Positive Comments:			
Requirement:			
Nonconformity & Objective Evidence:			
Auditor:			Date:
Finding Assigned to:	Date:	Response Due:	
Corrective Action Taken:			
Action Taken to Prevent Recurrence:			
Responsible Manager:			Date:
Verification of Corrective Action (describe evidence):			
Corrective Action Accepted:			Date:

Form 9.2.2 Attachments: ☐

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FINDING of NONCONFORMITY

Documents Audited:	Nonconformity Severity	
	Major ☐	Minor ☐
Area Audited: Area Representative:	Date:	NC Number:
Positive Comments:		
Requirement:		
Nonconformity & Objective Evidence:		
Auditor:		Date:
Finding Assigned to:	Date:	Response Due:
Corrective Action Taken:		
Action Taken to Prevent Recurrence:		
Responsible Manager:		Date:
Verification of Corrective Action (describe evidence):		
Corrective Action Accepted:		Date:

Form 9.2.2 Attachments: ☐

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