Botta-Boom Case Study
ETI Group "Answers"

This case study is intended to provide students with some experience by practicing the skills and knowledge learned through the instructional material. The case study was designed to illustrate a key point about internal auditing (or auditing in general, for that matter), which is that no situation is ever black and white - there are almost always shades of gray involved. People sometimes become frustrated as auditors when they realize that they will rarely encounter instances where the situation they are auditing is clear-cut. Your responsibility is to interpret the requirements and compare them against the practices being observed and, using your best judgment, to come up with a decision regarding whether the practices comply with the requirement or do not.

Throughout all parts of the Botta-Boom case study, you have been required to use your judgment to decide whether what you were reading was compliant or not. Your judgment will only improve through practice, especially practice as soon as practical after this classroom training. During the first several months after this class, you need to take every opportunity to participate in internal or external audits in order to hone your skills as an auditor. Frequent practice will make you a better auditor and will make you more valuable to your company.

In these pages, we have provided what we consider "our answers" to be for the case study material. As noted above, since auditing is frequently an interpretive art, our answers are not necessarily the only correct answers — they are only our answers. Other auditors might provide different answers to the case study situations. Our answers are based on the collective experience and practice of our associates. We think these answers represent a relatively consistent set of answers that reflect what you would expect to see from external registrar's auditors.

The Botta-Boom Interviews

The interviews were designed to demonstrate that audit Findings of Nonconformity, as opposed to Observations, need to be based on **objective evidence** that a nonconformity exists. In several situations within the interviews, there are instances where it appears a nonconformity has occurred but there is not sufficient objective evidence to demonstrate this is so. In a real audit situation, this should lead you to "pull the thread" and follow your lead to see whether an actual nonconformity does, in fact, exist.

Before going through our list of the nonconformities in the case study, we want to discuss several instances where it appears there is a nonconformity but where there is, in actuality, insufficient evidence to warrant issuing a finding.

During the audit tour (Case 1), the auditor notices several handwritten changes to work instructions. Many people immediately call this a nonconformity. You must have a **specified requirement** if you are going to call something a nonconformity. The Standard does not prohibit handwritten changes. In fact, Botta-Boom procedure OP 7.5-1 (Control of Documents) specifically allows handwritten changes. This is an area where you would want to dig in and see if they are meeting their own requirements for changes.

Similarly in the first case, the lack of posted maintenance checklists and the checklist that looks as if it has not been updated are places where people may want to cite a nonconformity. Again, a specified requirement is needed and the auditor would have to ask more questions.

Also in the first case, the calipers in the inspection area lead to a great deal of debate. The sticker indicates that they are out of calibration, yet we learn later that those calipers do not have to be calibrated. Remember not to jump to conclusions; you must have objective evidence to state that a nonconformity exists. Findings should not be given based on a "glance." Once the situation is known however, an Observation would be appropriate since it is not good practice to have more than 1 sticker on a measuring device; it can only lead to confusion.

In Case 2, many students want to write a nonconformity regarding the customer complaints regarding order changes. Botta-Boom has already written up that problem and taken it through their corrective action system. It is true that we find out in later interviews that the corrective action was not effective, but during this case we only know that they have identified a problem and devised a solution for it. We do not want to write them up for something they have already written up themselves.

In case 3 it could be debatable whether there is "timely" action taken on audit closure, we have listed it as part of the nonconformity evidence but this could also be a situation where more research is needed on the organization's requirements for response times vs. the auditor's opinion.

In Case 5, there is often debate about whether the "vague" contract review procedure is a nonconformity. The Standard does not require a documented procedure here, but the auditor

should follow up on the "formal" training program so see if it is adequately documented. Similarly, it could be debated whether the review of customer amendments and associated risk assessment should be recorded. AS9100 8.2.3.2 states "The organization shall retain documented info, *as applicable*: a) on the results of the review; b) on any new requirements for the products and services." This applicability could be argued; the auditor should dig deeper into whether there are any guidelines in the procedure or training materials for the types of changes/risks that should be recorded. At the least, an Observation could be written.

Some students want to link the evidence in Case 6, in which it is noted that the Bifurcon 2000 job was being built using Revision B of a drawing, to the evidence in Case 9, where it is stated that Revision C to the drawing had "been completed the previous week." You must be very careful because there is no information to show what the effectivity date of the engineering change is. It might be that, while the drawing has been changed, the change has not been implemented within production yet.

In case 8, the process for prevention of counterfeit parts seems pretty loose, but this is a case where the auditor needs to dig deeper and probably talk to the Quality and Purchasing Managers for more information.

There are a couple places where what seems to be evidence of nonconformity is based on hearsay by a person not responsible for the process (Case 1, Ginny Hopkins, Ops Mgr on the QC Inspector dispositioning product and Case 6, Carter Taylor saying that Kenny never heard back on any of his Continuous Improvement Requests). To have a nonconformity based on a statement, it must be made by a person with authority, and best practice is to validate statements with additional objective evidence.

The retrieval of the customer complaint records is a situation where people sometimes want to write a nonconformance right away. It is reasonable to give the organization until the end of the audit (unless there is a documented requirement for a shorter time period). In this case, an observation is warranted regarding the poor retrievability and/or retention of records.

The actual nonconformities (or at least our determination of what the nonconformities are) are provided on the following Finding of Nonconformity forms.

FINDING OF NONCONFORMITY

Controlling Specification: OP 8.7 Control of Nonconforming Product Rev. C	Nonconformity Severity	
	Major ☐	Minor ☒
Area Audited: Nonconforming Holding Area Area Representative: Karin Khanna	Date: 10/1/17	NC Number: BB-001 Case 1, 7

Positive Comments:

Requirement:

Botta-Boom Procedure, OP 8.7 states that nonconforming product will be identified with a red NCP tag.

Nonconformity & Objective Evidence:

Actual practice does not meet documented procedure.

All of the items in the nonconforming product area were identified with yellow "HOLD" tags.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

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Explanation:

This nonconformance is very clear. Most of the discussion of how to document it revolves around classifying it as major or minor. The argument for major is that this is happening all the time; it is not an isolated occurrence. We called this a minor because it appears that they are still identifying and segregating their nonconforming product and the term "Hold" is understood to mean the product is not to be used. Remember our discussion of the INTENT of each AS9100 clause. Even though they are using the wrong color tag, they are meeting the intent of clause 8.7 —preventing the unintended use of nonconforming product. But, it could be argued that there is still risk with using "Hold" as someone could interpret its meaning differently.

In addition, the auditor is told that the QC Inspector decided what to do with nonconforming product. The procedure states that the QA Manager is responsible for determining the disposition. This appears to be another nonconformity; at this time, however, we do not have enough evidence. Ginny Hopkins said the QC Inspector does it, but she may be incorrect. Remember to consider the source of your information.

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clauses 9.2 Internal Audit, 10.2.1 Nonconformity and Corrective Action	Nonconformity Severity	
	Major ☒	Minor ☐
Area Audited: Internal Auditing Area Representative: Joe Parisi	Date: 10/1/17	NC Number: BB-002 Case 3

Positive Comments:

Requirement:

AS9100, clause 9.2 states in part "The organization shall conduct internal audits at planned intervals... select auditors and conduct audits to ensure objectivity and the impartiality of the audit process ; … take appropriate correction and corrective actions without undue delay;… retain documented information as evidence of the implementation of the audit program and the audit results. Clause 10.2.1 states in part the organization shall "take specific actions when timely and effective corrective actions are not achieved."

Nonconformity & Objective Evidence:

The internal audit procedure is not implemented according to the requirements of AS9100.

1. Records were not available for two audits performed in June.
2. The internal audit manager stated that they haven't done all of the audits that were scheduled.
3. According to the internal audit database, the January and May audits of Assembly were conducted by the Assembly Supervisor, violating the objectivity requirement.
4. Corrective Action responses not completed "without undue delay" and specific actions were not taken.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

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Verification of Corrective Action (describe evidence):

Corrective Action Accepted:	Date:

Explanation:

This is clearly an area of nonconformance, but it may be written up several different ways. Each nonconformity may be written individually, or they may be combined into one **system** nonconformity. This is not an instance of small parts of the process malfunctioning; it is obvious that the system is broken. We chose to call this one major nonconformity and present all of the objective evidence together to back up our conclusion.

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 8.4.1 Control of Externally Provided Processes, Products, and Services, General	Nonconformity Severity	
	Major ☒	Minor ☐
Area Audited: Purchasing Area Representative: Maria Castillo	Date: 10/1/17	NC Number: BB-003 Case 4

Positive Comments:

Requirement:

AS9100, clause 8.4.1 states in part, "The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations."

Nonconformity & Objective Evidence:

The requirement to evaluate and re-evaluate suppliers has not been fully met in accordance with the intent of AS9100.

The Purchasing Manager stated that there is no supplier evaluation once a supplier is placed on the approved list.

(Observation: A related requirement in 8.4.1 states that "The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer." The Purchasing Manager stated that customer-specified suppliers were automatically put on the "Approved Supplier List" without an audit. This could be a risky practice.)

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

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Explanation:

The requirement for evaluation and re-evaluation of suppliers is widely interpreted to mean an **ongoing** evaluation. To place a supplier on the approved supplier list and never evaluate them again goes against the intent of this AS9100 clause. We called this a major nonconformity because this is a systemic problem — they are not performing ongoing evaluations on ANY of their suppliers.

A related issue is putting customer-specified suppliers on the list with no evaluation. This is a risky practice and should be considered in determining criteria for supplier control. We showed it as an Observation since the requirement is worded around responsibility, not a particular method.

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 5.3 Organizational Roles, Responsibilities, and Authorities, and OP 8.4 Purchasing Rev. D	Nonconformity Severity	
	Major ☐	Minor ☒
Area Audited: Purchasing Area Representative: Maria Castillo	Date: 10/1/17	NC Number: BB-004 Case 4

Positive Comments:

Requirement:

AS9100, clause 5.3 states that "Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization."

Botta-Boom Purchasing Procedure requires the Purchasing Manager to sign all purchase orders as evidence of approval.

Nonconformity & Objective Evidence:

Actual practice does not meet documented procedure.

Ten PO's were sampled. Seven had the Purchasing Manager's signature and three did not.

Auditor: Mark Chen		Date: 10/1/17
Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

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Explanation:

This is another example of the actual practice differing from the documented procedure, as well as a lack of clarity on definition of roles, responsibilities and authorities.

We called this a minor finding because it appears that a review is taking place, although not by the designated person. It can be argued that this is a major finding because 30% of the PO's were not done according to this procedure, or the impact of those PO's could be great. (And, best practice would be to note the PO #'s sampled, and which were nonconforming.

Responsible Manager:	Date:

Verification of Corrective Action (describe evidence):

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 7.5.3 Control of Documented Information and OP 7.5-1 Control of Documents Rev. B	Nonconformity Severity	
	Major ☐	Minor ☒
Area Audited: Production - Assembly Area Representative: David Cooper	Date: 10/1/17	NC Number: BB-005 Case 5

Positive Comments:

Requirement:

AS9100, states: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;
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;
c) control of changes (e.g. version control);

The Master List identifies the current revision of OP 8.2 Contract Review as Rev. B.

Nonconformity & Objective Evidence:

Employee was working to an old revision of a document.

The version of OP 8.2 Contract Review in use in the Sales area was Rev. A. Practice did not meet the requirements of the procedure.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

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Explanation:

This is a situation where you must use the information available to you to verify that the information being used is current. Checking the Master List shows that the employee is using an incorrect version of OP 8.2.

Responsible Manager:	Date:

Verification of Corrective Action (describe evidence):

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 7.3	Nonconformity Severity	
	Major ☐	Minor ☒
Area Audited: Production - Assembly Area Representative: David Cooper	Date: 10/1/17	NC Number: BB-006 Case 6

Positive Comments: There was some awareness of the requirements of clause 7.3 among 2 out of 6 production employees interviewed.

Requirement:

AS9100, clause 7.3 states "The organization shall ensure that persons doing work under the organization's control are aware of:

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d) the implications of not conforming with the quality management system requirements.
e) relevant quality management system documented information and changes thereto;
f) their contribution to product or service conformity;
g) their contribution to product safety;
h) the importance of ethical behavior."

Nonconformity & Objective Evidence:

The quality policy and objectives are not understood throughout Botta-Boom.

Four out of six people in the production area questioned about the quality policy and the objectives knew nothing about the policy, the objectives, or how they contribute to achieving them.
The requirements for awareness have not been fully implemented.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

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Verification of Corrective Action (describe evidence):

Corrective Action Accepted:	Date:

Explanation:

This is clearly a nonconformance, but the auditor has not taken a large enough sample to declare this a systemic problem. All employees questioned were from one department. Additional questioning would be required before we could determine if this problem exists across the organization.

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 7.5.3 Control of Documented Information and OP 7.5-1 Control of Documents Rev. B	Nonconformity Severity	
	Major ☐	Minor ☒
Area Audited: Production - Assembly Area Representative: David Cooper	Date: 10/1/17	NC Number: BB-007 Case 6

Positive Comments:

Requirement:

AS9100, clause 7.5.3 states that "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;
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;
c) control of changes (e.g. version control);"

The Master List identifies the current revision of the Equipment Maintenance work instruction (WI 7.1.3) as Rev. B.

Nonconformity & Objective Evidence:

Employee was working to an old revision of a document.

The Equipment Maintenance work instruction in use on the Assembly floor was Rev. A. Practice did not meet the requirements of the procedure.

Auditor: Mark Chen	Date: 10/1/17
Finding Assigned to:	Date: Response Due:

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Explanation:

This is a situation where you must use the information available to you to verify that the information being used is current. Checking the Master List shows that the employee is using an incorrect version of WI 7.1.3. There are some concerns here with whether maintenance of equipment, as required by clause 7.1.3 and 8.5.1.1 of AS9100, is being properly performed and recorded but the only issue that has objective evidence is that an incorrect version of a document is being used. The auditor would have to look at the procedures to address the issues raised in Case 6 and earlier in Case 1.

Another concern is the lack of awareness of the procedure by C. Taylor, but we'll save this issue for a Training finding.

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 8.2.4 Changes to Requirements for Products and Services	Nonconformity Severity	
	Major ☒	Minor ☐
Area Audited: Quality Control Area Representative: Karin Khanna	Date: 10/1/17	NC Number: BB-008 Case 7

Positive Comments:

Requirement:

AS9100, clause 8.2.4, states "The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed."

Job #23761 for ACE Computers had been changed to include the customer logo on the product.

Nonconformity & Objective Evidence:

The amendment to the customer order was not correctly transferred to assembly per the established procedure.

This work order for Job #23761 had been completed and inspected to the original job requirements. This work order had already been in process when the customer change request was made, and the work order did not get updated.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

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Explanation:

This nonconformity can be written up a number of ways:

- 7.5.3 Control of Documents: The obsolete work order was not removed from point of use.
- 10.2 Nonconformity and Corrective Action: This situation was already identified by Botta-Boom's Improvement and Corrective Action system. It was supposedly corrected by the e-mail transfer described on the CIR form and explained by Kevin Watson in Case 5. Obviously, the solution was not effective.
- 8.2.4, Changes to req.'s for products and services: We chose to write this up as a "contract review" issue because the amendment process is what needs to be fixed in order to assure customer changes are forwarded to assembly in time. (This does not mean that the other processes do not need to be fixed.) We called this a major because of the direct impact on customer product.

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 5.3 Organizational Roles, Responsibilities, and Authorities, 8.7 Control of Nonconforming Outputs and OP 8.7 Control of Nonconforming Product Rev. C	Nonconformity Severity	
	Major ☒	Minor ☐
Area Audited: Quality Control Area Representative: Karin Khanna	Date: 10/1/17	NC Number: BB-009 Case 7

Positive Comments:

Requirement:

AS9100, clause 5.3 states that "Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization."
AS9100, clause 8.7 states in part that "The organization's nonconformity control process shall….include provisions for: defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;"

Botta-Boom Procedure, OP 8.7 states that the QA Manager determines the disposition of nonconforming product.

Nonconformity & Objective Evidence:

Actual practice does not match documented procedure.

The QC Inspector stated that she decides NC product disposition in most cases, but she asks the QA Manager for help if she isn't sure how to handle something. In addition, OP 8.7 does not describe how the decision is made on who is approved to review and disposition nonconforming outputs.

Auditor: Mark Chen	Date: 10/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

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Explanation:

We noted this as a possible nonconformity in Case 1, when Ginny Hopkins told us the QC Inspector made these decisions. At the time, we didn't have objective evidence that she was right. Now we have it straight from the QC Inspector herself. We called this a major because defining responsibility and authority for dispositioning NC product is an area with high risk, and we had already identified a gap in OP 8.7 regarding definition of authority for personnel making disposition decisions. However, the case could also be made for calling it a minor, since the product is being reviewed. At this point, we don't know if she is actually qualified to make these decisions, though. This is a place where you would want to dig a little more.

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 7.5.3 Control of Documented Information and OP 7.5-1 Control of Documents Rev. B	Nonconformity Severity	
	Major ☐	Minor ☒
Area Audited: Quality Control Area Representative: Karin Khanna	Date: 10/1/17	NC Number: BB-010 Case 8

Positive Comments:

Requirement:

AS9100, clause 7.5.3 states that "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;
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;
c) control of changes (e.g. version control);"

The Master List identifies the current revision of OP 7.1.5 Control of Monitoring and Measuring Devices as Rev. D and WI 7.1.5 Calibration and Verification as Rev. D.

Nonconformity & Objective Evidence:

Employee was working to old revisions of documents.

The versions in use were: OP 7.1.5 Rev. C and WI 7.1.5 Rev. C. Practice did not meet the requirements of the procedure.

Auditor: Mark Chen		Date: 10/1/17
Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

Action

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Explanation:

This one is obvious. An incorrect version of a document is being used to make quality decisions. The document control findings are mounting!

Verification of Corrective Action (describe evidence):

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 7.5.3 Control of Documented Information and OP 7.5-1 Control of Documents Rev. B	Nonconformity Severity	
	Major ☐	Minor ☒
Area Audited: Engineering Area Representative: Al Stevens	Date: 10/1/17	NC Number: BB-011 Case 9

Positive Comments:

Requirement:

AS9100, clause 7.5.3 states that "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;
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;
c) control of changes (e.g. version control);"

The Master List identifies the current revision of WI 8.3.4-1 Customer Notification of Design Changes as Rev. C. Practice did not meet the requirements of the procedure.

Nonconformity & Objective Evidence:

Employee was working to an old revision of a document.
The work instruction in the controlled binder in the Engineering office was Rev. B.
Practice did not meet the requirements of the procedure.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

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Explanation:

This one is obvious. An incorrect version of a document is being used to make quality decisions.

The biggest question that arises here is do we now have enough evidence to say that the document control system is broken? Should we combine BB-005, BB-007, BB-010 and this nonconformity together and call it a major, citing these issues as evidence that the system is not functioning effectively? This is a judgment call, although it would seem from the audit results that it is a systemic problem.

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 8.3.6 Design and Development Changes and OP 8.3 Design and Development Rev. C	Nonconformity Severity	
	Major ☒	Minor ☐
Area Audited: Engineering Area Representative: Al Stevens	Date: 10/1/17	NC Number: BB-012 Case 9

Positive Comments:

Requirement:

AS9100, clause 8.3.6, states in part " The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements." And "The organization shall retain documented information on:
a) design and development changes;
b) the results of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impacts"

Nonconformity & Objective Evidence:

The intent of the AS9100 requirement for retaining documented information on design and development changes has not been met.

A project engineer stated that the review and risk assessment of changes to designs during the development process are not documented and retained. The auditor was not shown any records of design change reviews/risk assessments.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

Action

Explanation:

We chose to call this finding a major nonconformity because we believe it is very important to retain records of decisions made during design development, both from a risk standpoint and for organizational knowledge related to design of products/services.

Responsible Manager:	Date:

Verification of Corrective Action (describe evidence):

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 8.5.6 Control of Changes	Nonconformity Severity	
	Major ☒	Minor ☐
Area Audited: Engineering Area Representative: Al Stevens	Date: 10/1/17	NC Number: BB-013 Case 9

Positive Comments:

Requirement:

AS9100, clause 8.5.6, states in part "Persons authorized to approve production or service provision changes shall be identified." And "The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review."

Nonconformity & Objective Evidence:

The intent of the AS9100 requirement for retention of documented information in regards to review and control of changes for production provision has not been met.

The Engineering manager stated that records of production process changes were not kept. The auditor was not shown any records related to review and authorization of process changes.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

Explanation:

Similar to the previous NC, we chose to call this finding a major nonconformity because of the risk involved in production process changes and the importance of making these types of changes in a controlled manner and retaining organizational knowledge related to these decisions.

Action

Responsible Manager:	Date:

Verification of Corrective Action (describe evidence):

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 4.1 Understanding the Organization and Its Context and 4.2 Understanding the Needs and Expectations of Interested Parties	Nonconformity Severity	
	Major ☒	Minor ☐
Area Audited: Management Responsibility Area Representative: Michael Butler	Date: 10/1/17	NC Number: BB-014 Case 10

Positive Comments:

Requirement:

AS9100, clause 4.1, states in part "The organization shall monitor and review information about these external and internal issues." Clause 4.2 states in part "The organization shall monitor and review information about these interested parties and their relevant requirements."

Nonconformity & Objective Evidence:

External and internal issues relative to organizational context and requirements of relevant interested parties are not being monitored and reviewed on an ongoing basis, per the intent of the AS9100 requirements.

The President of Botta-Boom stated he did not anticipate any changes to organization context and interested parties, and did not see a need for ongoing monitoring and review. This approach does not meet the intent of the Standard.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

Explanation:

Understanding the organizational context and requirements of relevant interested parties is critical to the success of the QMS in that it is the starting point for strategies related to the Quality Policy and Objectives, risk assessment and the design of processes for production and service provision. We consider this a major finding since a lack of monitoring and review of changes in these areas could be detrimental to customer satisfaction as well as missing opportunities for new markets, products, services, etc.

Action

Responsible Manager:	Date:

Verification of Corrective Action (describe evidence):

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100, clause 9.3 Management Review	Nonconformity Severity	
	Major ☒	Minor ☐
Area Audited: Management Responsibility Area Representative: Michael Butler	Date: 10/1/17	NC Number: BB-015 Case 10

Positive Comments:

Requirement:

AS9100, clause 9.3, states in part "Top management shall review the organization's quality management system at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization"

Nonconformity & Objective Evidence:

Botta-Boom's management review does not satisfy the intent of the requirements of 9.3 for reviewing the quality system as a whole.

The President of Botta-Boom stated that they do not review the entire quality system. This approach does not meet the intent of the Standard.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

Corrective Action Taken:

Action

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Explanation:

The intent of management review is to evaluate the **entire** system. Reviewing only those areas that show weakness is not an adequate review of the whole system. Since an effective management review is one of the keys to a successful quality system, we consider this to be a major nonconformity, especially in light of the Finding regarding the ineffective internal audit system. (Note: reviews can occur at intervals, it often is not feasible to look at everything in one session).

By the way, think it's pleasant to sit in front of the President of your company and tell her or him that a process is not adequate? Auditing isn't easy but you have to be courageous enough to point out the deficiencies. If your leaders are using the audit process correctly, they should welcome this information and act on it!

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐

FINDING OF NONCONFORMITY

Controlling Specification: AS9100 7.2 Competence and OP 7.2 Training, Rev. A	Nonconformity Severity	
	Major ☒	Minor ☐
Area Audited: Training Area Representative: Fritz Adler	Date: 10/1/17	NC Number: BB-016 Case 10

Positive Comments:

Requirement:

AS9100, clause 7.2 states in part ""The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;…d) retain appropriate documented information as evidence of competence."
OP 8.2 Training contains a matrix by functional position for required QMS training.

Nonconformity & Objective Evidence:

Competence records were not available as required.

Out of a sample of six employees, competence records were not available for 3 persons: Philip Kato, Carter Taylor and Linh Nguyen. The record-keeping practice observed did not match the procedure.

Auditor: Mark Chen	Date: 10/1/17

Finding Assigned to:	Date:	Response Due:

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Explanation:

AS9100 requires training records to be kept for any person who can affect the quality of your product or service (and this is just about everyone in any organization!).

In this situation, Linh Nguyen, the Inventory Control Manager, Philip Cason, a project engineer, and Carter Taylor, an assembler, did not have training records or the records were not produced as requested. All of these individuals most definitely affect the quality of Botta-Boom's products and services and, therefore, you would expect to see a training record for each of them. Often, long-time employees like Carter Taylor are not included in updated training and/or do not get "grandfathered" into the training records.

Again, the primary issue here is the level of severity. The auditor asked for 6 records and only 3 were provided. What is your dividing line between a major and minor nonconformity? This tends to be a judgment call but you should try to "calibrate" each other within your company auditing program so there is consistency.

Corrective Action Accepted:	Date:

Form 9.2.2 Attachments: ☐