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Improve Your Audit Score:

How to Prevent Major Audit Non-Conformances

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Introduction

Every audit takes on a life of its own. Despite the usual trepidation prior to and during an audit, the experience should be viewed as an opportunity for learning and improvement, especially if the audit team identifies major non-conformances. That's why it's considered a process.

Every food processor or manufacturer can and should take advantage of specific steps to help improve its audit results before, during, and after the audit. In this e-book, I will share the top 10 major non-conformances identified in audits to assist you and your company to address them and prevent similar occurrences.

In addition, I'll provide some insights and tips I've shared with clients over decades to help them achieve a 100-percent pass rate with scores in the top tiers of their chosen audit scheme. As a certified auditor and consultant, I have seen some outstanding and commendable audit preparation, as well as glaring examples of what not to do throughout the process.

I am presenting both in order for you to learn and profit from these examples.

Audits: Opportunities & Challenges

Every audit is a snapshot in time. Ideally, the audit is supposed to be an accurate representation of the company's food safety and quality systems' effectiveness. Some may believe that auditors' only purpose is to find non-conformances—their version of "gotcha" moments. Such beliefs actually put food manufacturers at a disadvantage and in a defensive posture, when a proactive approach would better serve their purpose.

Why? Because what auditors really want is verifiable evidence of conformances. They don't come into your facility with the sole purpose of uncovering violations just to make your company look bad. Their responsibility is to ensure the company is complying with food management safety standards, such as GFSI. Just as an audience wants a performer to do well in a live presentation, auditors want companies to score well during the audit process. For the company, the key to a great performance is preparation. For the auditor, it is an unyielding insistence upon total adherence to food safety standards in every facet of the operation.

Acceptable audit scores aren't just good to have. They're necessary for complying with customer requirements. While those scores are mandatory for selling products and maintaining customers, there's a more important and, frankly, overriding reason for air-tight food safety and quality systems: to ensure that the company's products do not create a danger to public health in the form of foodborne illnesses.

So why should audits be considered opportunities? Because each and every audit is a key to learning and improvement. Should non-conformances be identified during the audit process, the steps a company takes to correct them can improve its food safety and quality systems. And, companies that examine audit scores to spot trends over time learn valuable lessons.

An audit finding should not be considered representative. Whether the audit is internal or supplier initiated, audit score trends will provide the most accurate view of improvements over time. There are, however, other challenges to continuous improvement.

One of the greatest audit challenges is inconsistency, not by the facility, but by auditors. Despite the efforts of all the certification bodies to calibrate their auditors, each auditor is human and applies the approach an individual perspective. Food manufacturers and processors just never know what to expect. Yet companies can use the same auditor for up to three audit cycles, so a relationship with the certification body enables you to request the same auditor, which is certainly a benefit that eliminates initial learning curves every year.

Another challenge in this (and every) industry is employee turnover. Resources required to train new staff are a perpetual obstacle. That's why it is important to maintain low turnover in key positions such as SQF practitioners, critical control point (CCP) monitoring, verification personnel, and QA technicians. When new hires are needed in these critical fields, make sure they complete the training necessary to maintain required credentials and demonstrate competency in assigned tasks.

Top 10 Major Non-Conformances & How to Prevent Them

Below is a list of the top ten major non-conformances. Following this list is a deeper dive into particular trouble areas, action items to reverse identified non-conformances, and best practices for future audit preparation.

1. Food Fraud

GFSI defines food fraud as "deception of consumers using food products, ingredients, and packaging for economic gain and includes substitution, unapproved enhancements, misbranding, counterfeiting, stolen goods, or others." Auditors issue major non-conformances whenever they detect shortcomings in a site's fraud prevention program that leaves it vulnerable to any fraud element. Non-conformances are generally issued due to insufficient vulnerability assessments completed or lack of effective mitigation measures to reduce the risk of food fraud.

2. Environmental Monitoring Program

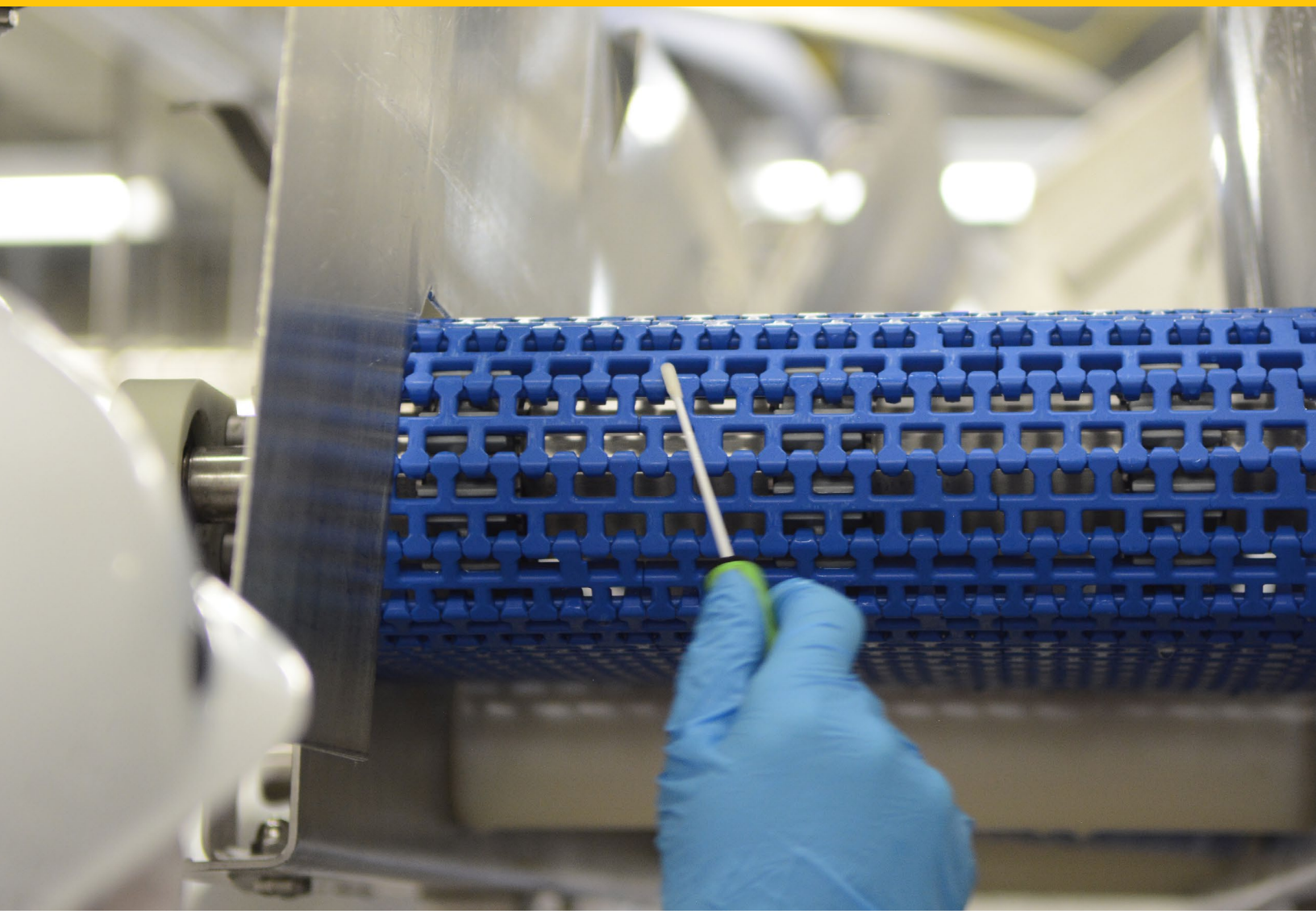
All facilities are required to have a risk-based environment monitoring program. As part of your risk assessment, you must identify specific environmental pathogens and how frequently your company tests for them. Companies that come up short in this area will likely face a major non-conformance and a reduced audit score.

3. Cleaning & Sanitation

Cleaning and sanitation programs must be fully defined, especially regarding cleaning procedures and methods to verify effectiveness. Many auditors actually perform pre-operational inspections during the audit, so it is essential to have clean food contact surfaces and microbial monitoring programs to verify the sanitation program.

4. Food Safety Plans

More items related to the food safety plan are under scrutiny than in the past, such as critical control points and preventive control monitoring procedures, methods, or frequencies. Major non-conformances here tend to result from companies either failing to perform monitoring at the frequency specified in the plan, performing the procedure incorrectly or failing to verify the flow charts of the process to include all steps.



5. Food Safety Plan (Monitoring)

This refers not to the plan, but the implementation and monitoring of it. Essentially, it requires companies to ensure plan controls and overall product food safety. If a food manufacturer hasn't identified the right hazards, critical control points, or preventive controls, then it would fall under this major non-conformance.

6. Pest Prevention (Identified Activity)

Observation of actual pest activity such as rodents, ants or roaches in the facility can lead to major non-conformances, particularly if there are multiple observations in various areas of the facility.

7. Pest Prevention (Effective Program Implementation)

Whether an organization retains an outside pest control officer or chooses to take this responsibility internally, it is essential that pests are kept out of your plant.

8. Detection of Foreign Objects

Avoidance of a major non-conformance takes more than a metal detector. A company must be able to demonstrate verification of other types of foreign material control monitoring, validation procedures to ensure monitoring at the specified frequency, and its effectiveness in rejecting products that may be suspect for foreign material. If foreign material is detected, it is critical to perform and document a root cause investigation and corrective actions.

9. Internal Audits and Inspections

Internal audits and inspections are specific to the SQF system audit, so keep in mind that for other internal audits, you have two different components: one for the SQF system and the other for plant inspections. It does say specifically in the SQF code that you should use the SQF code checklist (or a similar tool) to make sure that you're looking at all the requirements of the code. You must also conduct an annual review.

10. Validation & Effectiveness

This major non-conformance deals with the limits associated with critical control points or preventive controls in the company's food safety plan, as well as validating changes such as new products, equipment, or raw materials being used.

The Takeaway from this Top 10 List

A major non-conformance is just that. It's a major systematic failure and must be avoided. Often, the identification and subsequent deductions in the audit score can mean the difference between an "Excellent" or "Good" rating versus "Comply." In addition to customer ramifications, a rating of simply complying means your company will be required to undergo another surveillance audit within six months, which is yet another reason to always avoid major non-conformance findings.

A Closer Look at Mission-Critical Non-Conformances

1. Food Safety Plan

It's imperative to have a food safety team leader or HACCP coordinator with Basic HACCP training. Ideally, all members of the team should undergo it so they're capable of contributing to the defined food safety plan. Make sure your food safety team meets on a regular basis, at least quarterly, but preferably more often as needed to help keep the processes on track.

Look at all the major components of the HACCP plan and/or the food safety plan in terms of product description, flow chart, hazard analysis and CCP or Preventive Control determination. Examine the HACCP plan and preventive control summaries to confirm the flow charts are complete and display all steps in the process. Ensure the team has identified the right hazards and critical control points of preventive controls.

Many companies often lack validation data for supporting CCPs and hazards documentation, an oversight that must be addressed. Team members need to be able to justify hazards that have been identified and those that were not. Also, it's important to be able to explain the choice of critical control points and limits to demonstrate that they will be effective in controlling those hazards.

Make sure all CCP monitoring and verification personnel are capable of performing well in interviews. They should be confident in explaining their responsibilities and how they fulfill recordkeeping requirements. And, of course, be certain the organization's CCP records are complete, accurate, and timely.

Don't forget to conduct an annual reassessment. Use of a third party for reassessments is considered an industry best-practice because it's always a good idea to have a new and independent set of eyes to examine current processes for identifying shortcomings or recommending changes.

2. Environmental Monitoring Program

Look for potential hazards and then conduct a risk assessment to determine which hazards to monitor. Your environmental monitoring program requires a documented risk assessment that shows all potential hazards; e.g. listeria monocytogenes, salmonella, E. coli, or others.

Companies must have a written program to specify a sampling and testing schedule, number of samples and frequency of sampling. This must include a plant survey of all the different areas of the plant, including

high-risk areas. Determine samplings sites and frequency based on risk. Sample more frequently in higher risk areas.

There should be supporting documentation that justifies the level and frequency of testing and the number of sites that you test. It's never a good idea to make an arbitrary decision about sampling frequency without documentation. USDA and FDA are excellent resources as are trade associations like the American Frozen Food Institute. They provide food manufacturers and processors with solid compliance guidelines. Sampling frequency should be consistent with regulatory and industry recommendations to back up a company's program.

Keep proper records that demonstrate plant sampling is consistent and in accordance with the plan. Maintain corrective action records to show the company has taken the necessary steps in response to a hotspot or a positive sample. Then conduct re-sampling, as needed, to be able to prove that the issue has been remediated.

3. Food Fraud & Food Defense

For food defense, you must have a written program that specifically identifies the following procedures:

- Methods of accessing the site
- How employees (and guests) gain access to the site
- For storage and transportation
- Identification and description of sensitive processing points
- Identification of actionable process steps

For food fraud, be sure to conduct a documented assessment of both site and raw materials that identifies vulnerabilities and explains the identification process.

Every food manufacturer needs a documented mitigation plan to reduce risk. Mitigation plans for food fraud can include supplier controls, domestic or international suppliers, product testing, or COA results. Make sure the program is updated as needed and document an annual review.

It is imperative for companies to look at all the code requirements in their chosen GFSI scheme as part of this process. Often, companies can't demonstrate they've audited all elements of the system; e.g. SQF or BRC. This initiative needs to correlate with the company's FDA food safety plan and/or the food fraud program, especially if economically motivated adulterants are identified. The issue must be addressed and rectified. Consider these readily available industry tools:

- **PWC Vulnerability Assessment** (may be downloaded for free)
- **Food Fraud Database** (from Decernis)
- **Horizon Scan Database** (for supporting documentation)

New requirements state the food defense plan must be tested annually, but the testing procedure is not mandated. That's up to you. Some companies send an unauthorized employee into a plant to see how long it takes for someone to question them. In other situations, a company will send in a load of raw materials without a seal to determine if it will still be designated by receiving personnel.

Steps to Reverse Non-Conformances

During the Audit

It is important for management and personnel to be knowledgeable about the specific code and requirements in the event an auditor detects a non-compliance. Review the standard or code clause carefully and communicate closely with the auditor to clearly understand the nature of the non-conformance. If you disagree with the finding, you will have to determine if you should appeal it, which you have the right to do.

Take photos of non-compliant areas to include with corrective actions. Before and after pictures provide proof of change and are important to the documentation process to demonstrate the corrective actions that have been completed.

Correct non-conformances as soon as possible and show the auditor corrected areas to demonstrate your commitment and sponsorship. Auditors appreciate immediate

action, even though it may still be cited as a non-conformance. Remember, the finding is based on the observations made during the audit, even if some auditors give corrective action consideration (and they might). Regardless, a prompt correction of a non-conformance indicates a leadership committed to change with proper sponsorship to your food safety and quality system.

Ask the auditor for an exit meeting each day to review results, identified non-conformances and ratings assessments. You don't want to be blindsided at the final exit meeting and you won't be if you have good communication during the audit. By asking the auditor for a daily summary of findings, you have a better opportunity to negotiate issues before they're set in stone. Discuss the types of non-conformances identified, the ratings that could be assigned to each non-conformance, and whether they are major or minor.

After the Audit

Work with your food safety team to determine appropriate corrective actions for each non-conformance identified. Investigate and determine the root cause of each non-conformance. Fill out a CAPA (Corrective Action and Preventive Action) record for each non-conformance and submit the required corrective action forms to the certification body. CAPA will help you identify the why behind the what. After submission, check back with the auditor to assure non-conformances are closed and that there are no open issues to address.

Remember, you can always appeal non-conformance findings, but pick and choose your battles carefully. If you believe you have a strong case or dispute with a specific non-conformance, you have the right and, frankly, a responsibility to try to reverse the decision.

Note: if the appeal is going to affect your company's overall audit score, and particularly if it keeps the company in a "Good" rather than a "Comply" rating, this may be a good time to consider going forward with the appeal process.

Audit Preparation & Readiness

Audit Preparation

Typically, within 30 days of the audit, companies should complete awareness training in HACCP and GMPs with all employees, as well as their GFSI scheme if it is a GFSI audit. That way these topics are fresh in everyone's minds. If an auditor asks a question, employees should be able to answer quickly and correctly.

Confirm that all members of your food safety team can confidently answer questions during interviews. That means QA technicians, CCP or preventive control personnel, line operators, supervisors, maintenance, sanitation, receiving, and shipping department members should be prepared for the auditor's questions. They should know what types of hazards they are controlling, the location of CCPs, and how they are monitored and validated. Hold a meeting one week prior to the audit to ensure everyone is on board.

Employee Prep Checklist:

- Prepare employees for interviews by educating them on how to answer questions.
- Ensure employees can explain their responsibilities to auditors.
- Review any records they complete as part of their job.
- Ensure all employees can explain the following:
  - What is the standard being audited?
  - GMP requirements for handwashing, glove use, product handling, etc.
  - Job-specific responsibilities

Address any employee sanitation or maintenance issues prior to the audit. Examine all equipment. Look closely at conveyor belts, which are notorious for frayed edges, and all utensils to make sure no plastic is chipped or frayed. Eliminate any mobile unused equipment from the production area. The less there is to inspect, the fewer opportunities for non-conformance.

Schedule the pest control operator for the day prior to the audit so that all bait is fresh, that there are no issues with pest activity inside the plants.

Complete a detailed plant inspection. Address any employee, equipment, sanitation, and maintenance issues that are identified. Prior to the inspection, have a group of supervisors from maintenance, sanitation, or operations check for condensation, dripping, or other major issues.

Examine all storage areas for proper housekeeping and allergen segregation. To ease processing, schedule products with minimal waste.

Consider having an independent consultant participate during the audit. The consultant can support and serve as a liaison between company and auditor. This approach generally helps reduce non-conformances and sometimes even mitigates the potential severity or rating of the non-conformances identified.

During the Audit

One of the best ways to demonstrate commitment during an audit is to include senior management and representatives of each department in the entrance and exit meetings. Run production lines at appropriate speeds for proper product handling and housekeeping, the latter through the use of extra sanitation personnel.

Insist on having key QA, operations, maintenance, and sanitation representatives accompany the auditor during inspections. QA rules the day. Always ensure proper product handling, including allergen handling, and proper labeling.

I strongly advise you to never allow a contractor in your plant on audit days. A contractor's presence increases your risk; e.g. a contractor without a helmet, no GMP compliance, an open coffee cup or a seemingly careless demeanor. Any or all of these are likely to quickly send an audit downhill.

Best Practices for Ensuring Compliance

In my experiences as an auditor and consultant, I've found that certain best practices will to help you avoid non-conformance findings during either scheduled or unscheduled audits. Even if some of them seem obvious, none should be taken for granted. One example—know the standard GFSI requirements in detail and pay close attention to updated or new program requirements. The auditor will, and so should you and other company representatives.

Another best practice is to establish effective internal audit processes. The goal is to avoid being shocked by anything discovered during an official GFSI audit.

Consider this a mantra: You must always know what's going on in your plant. You should never be surprised by an audit finding at your company.

Take all training necessary to meet requirements or raise awareness. Include Basic HACCP training among the requirements along with courses like Implementing SQF, Preventive Control for Human Food, CAPA and, Statistical Process Control Training. Take time to learn from the experience of standard owners and others. All of which can be found at **IntertekAlchemy.com**.

Ideally, the internal audit team will be composed of quality assurance, operations, maintenance, and sanitation experts who are also trained internal auditors experienced in plant inspections. Creating a regular internal auditing schedule is crucial. Start with inspections of all plant areas monthly.

Complete a clause-by-clause gap analysis or internal audit checklist when completing your system audit. This facilitates a visual line-by-line comparison to easily determine if your plant or facility is in compliance. For areas found to be non-compliant, complete a corrective action register to show actions taken, who was responsible for each action taken and when it was completed.

Food Safety Plan—Best Practice

Never underestimate the importance of the food safety plan, which must be fully implemented and validated. To ensure you have a sound food safety plan, I recommend the following steps:

- Complete and verify a **flow diagram** with the entire food safety team
- Correct **hazard analysis** with all hazards identified and assessed
- Correct **CCP or preventive control steps** identified for process, allergens, sanitation, and supply chain
- Complete **food safety plan reassessments** at least annually and when necessary for CCP failures, significant changes, unanticipated hazards or when new information becomes available
- Complete **HACCP/food safety plan validation** with sufficient supporting documentation available for review

Final Thoughts

Based on my experiences in this industry, I've found that companies demonstrating sincere efforts at employee engagement from top to bottom tend to perform better at audits. For frontline workers, this often begins with training. Companies that take advantage of the technology and tools designed for food manufacturing are in the best position for facilitating better training, enhancing their recordkeeping and above all, improving audits.

Start by creating compelling content in each employee's primary language, and base that content on the employee's role in the facility. Hold structured shift huddles and conduct educational games to help improve employee comprehension.

Visual tools, such as videos in break rooms or other strategic locations, posters, and digital displays back up training. They reinforce important messages around the clock. By using these outlets, companies:

- Fortify key training topics
- Improve control and message quality to the entire company
- Reinforce discussion topics
- Make an emotional impact

I'm not being simplistic in stating that the key to positive training outcomes is "rinse and repeat." After training is completed, reinforce those critical concepts on a regular basis to ensure they're understood.

I encourage you to check out **Alchemy's Training Solutions** for frontline workers to ensure employee engagement with your food safety culture.

In conclusion, avoiding non-conformances during audits will always be a challenge, but I hope you can apply the information I've gleaned from auditing so that you and your company can avoid non-conformances and achieve top tier ratings.

Committing to and investing in proper training are worth your effort for the benefit of your plant, your workforce and the public.

About the Author

Jeff Chilton, Vice President of Consulting at Alchemy Systems, has more than 30-years' experience in the food industry helping clients achieve and sustain certification under the SQF, BRC, and FSSC 22000 standards. He also provides USDA and FDA regulatory compliance services for HACCP and Food Safety Plans.

Prior to his two decades of consulting, Jeff worked for 15 years in food manufacturing facilities as director of quality assurance and as plant manager. He is a certified SQF Auditor, SQF Consultant, Preventive Control for Human Food Lead Instructor, and International HACCP Alliance Lead Instructor.

Jeff brings his comprehensive knowledge and understanding to provide practical solutions for avoiding non-conformance findings through actions that can be applied at every food processing and manufacturing facility.

Learn more about **Alchemy's Food Safety Consulting** services today!