Effective Food Plant Management:
Lessons Learned From Certification Auditors

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The Center for Industrial Research and Service (CIRAS) is the industrial extension arm of Iowa State University, one of the nation's premier land grant institutions.

The CIRAS mission - to enhance the performance of Iowa industry - is an integral part of the history of Iowa State University and the Extension and Outreach Services.
Extension and Outreach For Food Manufacturers

• Food Safety Modernization Act Bi-Annual Education Series

• Mission: Empower food manufacturers with food safety knowledge and resources to maximize profitability and sustainability of their company

• Partnership with CIRAS, Food Industry Experts, and fellow University Extension and Outreach
Webinar Logistics

• Three distinct sections of various certification auditor insight

• Q&A opportunities for each sections topics
  – Send questions in via chat during section
  – Monitor addresses presenters during the Q&A

• Fourth section review Food Safety Modernization Act, sections 103 and 307
Section 1: Discussion Topics

• How Food Safety regulations interact with Food Safety certifications
• The basis of issuing a Non-Conformance/ Non-Compliance during an audit
• Evaluation methods used for reviewing Management’s role in a Food Safety Program
Section 2: Discussion Topics

• Messages sent without saying a word
• What auditors mean when they want a “validated” process
Section 3: Discussion Topics

- Expectations regarding understanding of documents and records
- Methods auditors use to audit documentation
- Common Food Safety Certification Audit Non-Conformances
Section 4: Discussion Topics

• Food Safety Modernization Act
  - The Four Pillars
  - Sections 103 and 307
  - What it means
  - Third Party Audits

• Summary

• Future Programs
Section 1

Regulations & Non-conformances
Section 1: Objectives

1. List three differences between regulatory and certification audits.
2. Explain how regulatory requirements interface with certification audits.
3. Identify the difference between non-conformance and non-compliance.
4. List what and auditor needs to write a non-conformance/non-compliance.
5. Understand how management’s role could change given the type of audit.
6. List three ways management’s role can be evaluated by auditors.
Audit Types & Differences

• Regulatory or Certification
  – Who hires auditors
  – Who sets the requirements
  – Voluntary vs. mandated requirements
  – Process/Depth of regulatory review
  – Process of handling audit findings
  – Negative audit finding repercussions
Non-Conformance or Non-Compliance

• Regulatory
  – Mandated requirements
    • What someone told the organization it HAD to do
      – Non-Compliance

• Certification
  – Requirements organization agreed to accept (voluntary)
    • What the organization said it WOULD do
      – Non-Conformance
Management’s Role

• Both audit types
  – General awareness of requirements
  – Availability of resources to meet requirements
  – Technical implementation (per org. framework)
    • Interpretation
    • Process Development & Documentation
    • Training of Staff
    • Relevant recordkeeping
    • Reporting
    • Continuing education (back to interpretation)
Q & A

• Types of Audits
• Non-Conformances and Non-Compliances
• Managements Role in audits
Section 2

Non-Verbal Cues and Validation
Section 2: Objectives

1. List three non-verbal messages auditor look for during an audit.
2. Define Validation
3. Understand Validation’s Role in HACCP
4. List at least five types of documentation that can be used for validation
The Power of Observation

- Messy Office/Desk
  - Documents, Records, Organization, Communication, Calibration
- Management Absence
  - Lack of commitment
- Lack of or Lax in Visitor Training or Process
  - Lack of Employee Training
  - Lack of Process Importance/Understanding
The Power of Observation

• Hesitancy of Personnel to answer questions
  – Process Non-Continuity

• Hesitancy of Auditees to Use Guidance Docs
  – Inconsistency of Process

• Older facilities
  – Maintenance and cleaning requirements

• Newer Personnel
  – Person should be trained on what is being audited
Validation Defined

• **Validation** (Quality Audit Handbook)
  
  – Confirmation by experimentation and provision of objective evidence that the particular requirements for a specific intended use are fulfilled

• FSIS proposed HACCP Systems Verification
  May 2012
Validation Explained Further

• Can adequately control a hazard
  – Scientific or Technical justification of basis
    • Will It Work in Theory?
• Can initially demonstrate system can perform as expected
  – Demonstration while in operation
    • Does the Plan Work in Practice?
• Consider: Plan, Product and Preservation
Regulatory Requirement for Validation of HACCP

• Each establishment validate the adequacy of its HACCP plans in controlling those food safety hazards identified during the hazard analysis.

• The hazard analysis must have supporting documentation for each step of a HACCP plan in order to show that the establishment accounts for all hazards likely to occur.
HACCP Validation Reg. (Continued)

• Specifically, the processing steps that reduce, eliminate, or prevent food safety hazards - critical control points - and their accompanying critical limits must be validated.

• Initial validation contains the recorded documentation that shows that the HACCP plan functions as intended.
Validation Doc Expectations*

• Two types:
  – Design Documentation
  – Execution Documentation

**MUST SHOW:** Establishment can implement it and make it work on a day by day basis.

*Based on FSIS sources
Documentation Examples

- Scientific articles or other published scientific literature;
- FSIS regulations, or regulatory performance standards;
- FSIS compliance guidelines or directives;
- Trade association guidelines/Industry standards or surveys;
- Pathogen modeling programs;
- Processing authority documents, instructions, or research;
- Written information from industry experts or consultants;
- University extension publications;
- In-plant studies, research or historical data;
Documentation Examples (Continued)

• Written materials from equipment manufacturers.
• Once the scientific design or technical justification or documented validation can be achieved through:
  • Shelf life testing results – both microbiological and organoleptic
  • Production process control records
  • Customer feedback
  • Consumer complaints
Q & A

- Non-Verbal Cues
- Validation
Section 3

Expectations and Methods
Section 3: Objectives

1. Explain what an auditor expects from auditees regarding documents and records
2. List three methods auditors use to audit documents and records
3. List three common Food Safety Non-Conformances
Documentation Expectations

- It exists
- It can be found
- It is current/reviewed on periodic basis
- It moves from point to point
- Mgmt general awareness & Staff’s use
- It is complete
- It is readable
Audit Methods

- Product
- Lab Result
- Supplier
- Customer
  - Customer Complaint/Return
- Process (e.g. Training, Lab)
Federal Regulatory Violations

• Based on 9CFR that indicate a definite loss of the Food Safety System’s Process Control.
  – May or may not result in adulterated product entering commerce
  1. Process Scheduling
  2. Deviations in Processing
  3. Items held for further examination
  4. General Rules
  5. Inadequate HACCP Systems
Federal Regulatory Violations

6. Bears or Contains Poisonous or deleterious sub
7. FSIS Verification Sampling
8. Consists of any filthy, putrid or decomposed sub
9. Prepared, packed or held under unsanitary conditions
10. Foreign Materials
Federal Regulatory Violations

• Small Plant Resources (July 2011)
  • Storage of Pesticides, Insecticides, Cleaners
  • Improper Cooling of Food Products
  • Cross Contamination Probability (Raws vs. FG)
Certification Non-Conformances

- Facilities
- Planning
- Training
Q & A

• Document & Record Expectations
• Audit Methods/Techniques
• Common Findings
Section 4

Food Safety Modernization Act
The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4th, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing...
Four Pillars of Legislation

1. Prevention

– Mandatory preventive controls for food facilities
– Mandatory produce safety (science based)
– Authority to prevent intentional contamination
– Transportation
2. Inspection, Compliance, and Response

- Mandated inspection frequency
- Mandatory recall
- Expand records access
- Suspension of registration
- Enhanced product tracing abilities
- Testing by accredited laboratories
- Expanded administrative detention
3. Imports

– Importer accountability
– Third Party Certification
– Certification for high risk foods
– Voluntary qualified importer program
– Authority to deny entry
4. Enhanced Partnerships
   – State and local capacity building
   – Foreign capacity building
   – Reliance on inspections by other agencies
   – Improved foodborne illness surveillance
   – National agriculture and food defense strategy
   – Consortium of laboratory networks
Section 103  Hazard Analysis
Risk-based Preventive Controls

The owner, operator, or agent *shall* evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated, monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.
Section 307
Accreditation Of Third Party Auditors

• Key Words: Accredited third party auditor, foreign government/ cooperatives, may be individual,
• Who: Foreign importers
• In 2 years establish a system for the recognition of accreditation bodies
What does it mean?

• Must agree to issue a written and, as appropriate, electronic food certification
• Third party may not perform a regulatory audit of an eligible entity if such agent has performed a consultative audit or a regulatory audit of such eligible entity during the previous 13-month period
• New conflict of interest rules
Third-Party Audits
Third-Party Audits

• Third-Party Audits provide a credible verification system to the entire food processing industry
• Audits are voluntary tools of the food manufacturer and are not meant to replace regulatory inspection
• Not a federal inspection but a guidance measure of success
Summary

• Food Regulations and Certification
• Non-Compliance/Conformance
• Management Role in Food Safety System
• Messages without Words
• What is a Validated Process?
• Documentation and Record Keeping
• Top Challenges of Audits
Future Outreach
Contact
• FSMA: Suppliers Requirements
• Industry Microbiology Short Course
• HACCP Course: Non-Meats

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