Principle 6

Verification & Validation
Principle #6 - Verification

• Establish procedures to VERIFY that the HACCP system is working as intended
Verification - Defined

—Those activities, **other than monitoring**

- That determine the validity of the HACCP plan
- Confirm the system is operating according to the Plan
Verification

• Performed by
  – HACCP Team
  – Supervisors
  – Quality Assurance
  – Regulatory Agencies
  – External Experts

• Verification of single process
  • ie: mixing

• Review of the entire plan
Recognized Verification Activities

1. Routine
   – document review
   – observation of monitoring activities at a CCP & documentation review
   – calibration or accuracy checks of process-monitoring instruments
     • Have SOPs for calibration

2. Periodic testing
   – end-product
   – in-process
Routine Verification Documents

3. Flow diagram
   – Audit diagram against process on floor

4. Monitoring records
   – Is precision of measurements consistent with precision of instrument?
   – Do records indicate consistency across lines, shifts, & monitors?

5. Deviation summaries
   – any analysis done on deviation data
Routine Verification Documents

6. Corrective Action records
   – Disposition documentation
   – Corrective Action record corresponding to each deviation record?

7. Pre-shipment Record Review

8. Results from tests done on product samples
Routine Verification Documents

9. Review Hazard Analysis
   – Valid consumer complaints
   – New equipment
   – New hazards

10. Identification of CCPs

11. Critical Limits at each CCP
   – Adequate to maintain process control?
Periodic Verification Documents

1. HACCP Team documentation
2. Training documentation
   – SOPs
3. Accuracy of product description
Routine Verification Observation

• Is CCP monitoring done?
  1. By trained person?
  2. At specified point in process?
  3. In specified manner?
     • (described in SOP or HACCP Plan)
  4. At specified frequency?
  5. How variable is the process based on these results?
Routine Verification Observation

6. Are Corrective Actions taken following a deviation done according to HACCP Plan?
7. Is calibration done according to SOP or HACCP plan?
Verification – Calibration

• Accuracy checks
  • non-adjustable instrument

• Calibration
  • adjustable instruments

• Accuracy-check/Calibration
  – Done on all instruments?
  – Done at specified intervals?
  – Done using a recognized standard?
Verification - Calibration

• If a monitoring instrument is inaccurate, Corrective Actions must be taken
  – For non-adjustable instruments,
    • Corrective Action is removal from service & replacement
  – For adjustable instruments,
    • Corrective action is Calibration & subsequent re-check on accuracy

• Document Corrective Actions!
All Verification Activities MUST Be Documented

• What was done?
• When was it done?
  • Date & Time
• Who did it?
  • Signature or Initials
Document Review Verification

• Must be done by an individual who **did not** generate the records being reviewed
  -- Removes possible conflict of interest.
## RECORDKEEPING AND VERIFICATION

<table>
<thead>
<tr>
<th>Process Step/CCP</th>
<th>Records</th>
<th>Verification Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grinding / CCP (1) B</td>
<td>Grinder Log</td>
<td>Daily check (verification and pre-shipment review) of grinder log by HACCP coordinator or designee, on days product is ground.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Production personnel will be retrained and observed every 6 months by HAACP coordinator or designee.</td>
</tr>
</tbody>
</table>
Verification vs. Validation

- **Verification**: do we say what we do & do we do what we say?
- **Validation**: is what we’re doing the **right** thing to do to prevent illness or injury to the consumers of this product?
Validation

• Confirm the HACCP Plan’s adequacy to control the hazards identified in the Hazard Analysis
  – CCPs
  – Critical Limits
  – Monitoring frequency
  – Corrective Actions

• Verify that the HACCP Plan is effectively implemented
  • (the HACCP System is working)
Validation

Required

• Initially, after new HACCP Plan is written
  – Typically, collect 60-90 days worth of data
• Following Reassessment & Revision
  – good idea to validate annually

Always document!
Validation

May be accomplished by

• Expert advice
• Scientific studies
• Actual regulations
• In-plant records
  – Use of in-plant observations, measurements, test results, or other data to demonstrate that the control measures can achieve the intended objective
What Type Of Documentation Does FSIS Expect For Validation?

• Two types documentation:

  1. HACCP design type of documentation:
     • Theoretical principles
     • expert advice
     • scientific data
     • information demonstrating that particular process control measures can adequately address specified hazards
What Type Of Documentation Does FSIS Expect For Validation?

2. *HACCP execution type of documentation:*
   
   • In-plant
   
   • Observations
   
   • Data
     
     – measurements
     
     – test results
   
   • other information
     
     – demonstrating that the control measures, as written into a HACCP plan, can be operated within a particular establishment to achieve the intended food safety objective.
Reassessment of the HACCP Plan

• “Reassessment” is a USDA-FSIS term for an audit of the HACCP Plan
• Required at least annually
• Food Safety Assessment (FSA)
  – Conducted by EIAO
  – Every 4 years
HACCP Plan Reassessed When

- New information on the safety of the product becomes available
- Recent food borne outbreak is linked to a similar product
- Information on a newly-identified hazard indicates a risk to your product
HACCP Plan Reassessed When

✓ An unforeseen hazard occurs
✓ A deviation occurs that isn’t covered by existing Corrective Actions
✓ Government demands reassessment of plans for a particular product type
Reassessment of HACCP Plan

• Reassessment may or may not indicate a need to revise the HACCP Plan
  – Document the outcome

• If the Reassessment indicates that the HACCP Plan must be revised
  – Document why you came to this conclusion
  – Make modifications ASAP & document
  – Validate the modified HACCP Plan
REMINDER

• **Verification**: do we say what we do & do we do what we say?

• **Validation**: is what we’re doing the right thing to do to prevent illness or injury to the consumers of this product?