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

Recordkeeping & Verification Product:		
Process Step/CCP	**Records**	**Verification Procedures**
Grinding / CCP (1) B	Grinder Log	Daily check (verification and pre-shipment review) of grinder log by HACCP coordinator or designee, on days product is ground. Production personnel will be retrained and observed every 6 months by HAACP coordinator or designee.

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 a 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?