Summary – Verifying the HACCP Regulatory Requirements

**Table 1** below summarizes the Steps that IPP perform during the HACCP verification task. **Table 2** and **Table 3** on the following pages provide a quick reference for the questions that IPP should seek answers to when verifying each of the HACCP Implementation regulatory requirements.

**Table 1**

**HACCP Verification Task Summary**

|  |  |  |
| --- | --- | --- |
| **Step 1:** Select Product Type and Specific Production | Select product type within the process category | Ensure all product types within process category are verified over time.  Select product type that the est. is currently producing. |
| Select specific production. |
| Verify all HACCP regulatory requirements at each CCP by following Steps 3-9 |
| **Step 2:** Review the HACCP Plan for the Selected Product Type | Understand the monitoring and verification procedures and frequencies |  |
| Note the most recent signature date (must be  entered into PHIS) | 417.2(d) |
| Note changes to the HACCP plan and update the establishment profile |  |
| **Step 3:** Verify Monitoring | Per Directive 5000.1 | 417.2(c)(4) |
| **Step 4:** Verify Verification | Per Directive 5000.1 | 417.2(c)(7), 417.4(a)(2)(i)(ii)(iii) |
| **Step 5:** Verify Recordkeeping | Per Directive 5000.1 | 417.2(c)(6), 417.5(a)(3), 417.5(b),  417.5(d), 417.5(e)(1), 417.5(e)(2),  417.5(f)-Note: contact supervisor if records are not made available |
| **Step 6**: Verify Implementation of Prerequisite program (PRP)/Other Control Measures Used to Support Hazards Not Reasonably Likely to Occur (NRLTO) | Per Directive 5000.1 | 417.5(a)(1) |
| Review PRP records for the specific production, Observe program implementation,  Verify implemented as written, and  Verify records continue to support decision that hazard is NRLTO | Contact supervisor if records are not made available per 417.5(f) |
| Consider whether implemented in a manner that supports the Hazard Analysis decisions |  |
| Contact supervisor if uncertain whether  implementation or records support the decision in the Hazard Analysis |  |
| **Step 7:** Verify Corrective Action (CA) | Per Directive 5000.1  Initiate a directed HACCP verification task to verify CA when no routine HACCP verification task is available | 417.5(c), 417.3(a), 417.3(b) |
| **Step 8:** Verify Pre-  shipment Review | Per Directive 5000.1 | 417.5(c) |
| **Step 9:** Consider the Implications of any noncompliance | Document findings of compliance and noncompliance.  Associate any previous noncompliances.  Use systems based thinking per Directive 5000.1 | 417.6 |

If IPP find that adulterated product may have entered commerce, they are to notify the DO personnel through supervisory channels immediately.

|  |  |  |
| --- | --- | --- |
| **Table 2 – Monitoring, Verification, and Recordkeeping Requirements** | | |
| **Step 3**  **CCP Monitoring** | **Step 4**  **Verification Procedures** | **Step 5**  **Recordkeeping** |
| **9 CFR 417.2(c)(4)**  **Review the HACCP Plan for each CCP**   1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits?   **Observe (Time Permitting)**   1. Are the monitoring procedures being performed as described in the HACCP plan?   **Review Est. Records**   1. Are the monitoring procedures being performed at the frequencies for the CCP listed in the HACCP plan? 2. Are the critical limit(s) met? | **9 CFR 417.2(c)(7)**  **Review the HACCP Plan for each CCP**   1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instrument(s)? 2. Does the HACCP plan contain procedures and frequencies for direct observations of CCP monitoring activities & corrective actions? 3. Does the HACCP plan list procedures and frequencies for the review of records (for the monitoring of CCPs and critical limits) generated and maintained in accordance with 9 CFR 417.5(a)(3)? 4. Does the HACCP plan list product sampling as a verification activity? If yes, refer to FSIS Dir. 5000.1. If no, no further actions needed.   **417.4(a)(2)(i, ii, iii)**  **Observe (Time Permitting) and/or Review Est. Records**   1. Are process-monitoring instrument calibration activities conducted as per the HACCP plan? 2. Are direct observation verification activities conducted as per the HACCP plan? 3. Are records documenting the monitoring of CCPs and their critical limits (generated in accordance with 9 CFR 417.5(a)(3)) being reviewed by the est.? | **9 CFR 417.2(c)(6)**  **Review the HACCP Plan for each CCP**   1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCPs?   **Review Est. CCP Record(s)**   1. Do the records contain actual values and/or observations obtained during CCP monitoring?   **9 CFR 417.5(a)(3)**  **Review Est. Records**   1. Do the records document the monitoring of each CCP and critical limits? 2. Do the CCP records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment’s HACCP plan? 3. Do the monitoring and corrective action records include product codes, product name/identity, or slaughter production lot, and the date? 4. Are verification procedures being documented as completed and the results of those procedures included? I.e., Acceptable or Unacceptable. 5. Do the verification procedure records include product codes, product name/identity, or slaughter production lot? 6. Is the date and time recorded when each verification activity was performed?   **Records Authenticity - 9 CFR 417.5(b)**  **Review Est. CCP Records**   1. Was each entry on the CCP record made at the time the event occurred? 2. Does each entry include the time? 3. Was each entry on the record signed or initialed by the establishment employee making the entry?   **Record Retention and Availability 9 CFR 417.5(e)(1,2)**   1. Are all HACCP records being maintained for the required amount of time, i.e., one year for slaughter and refrigerated products and two years for frozen, preserved, or shelf-stable products? 2. Are the records kept on-site for at least 6 months? 3. If the records are stored off-site, can they be retrieved in 24 hours?   **Official Review of Records - 9 CFR 417.5(f)**  Are all records, plans, and procedures required by 9 CFR 417 (HACCP) available for official review? |

|  |  |  |
| --- | --- | --- |
| **Table 3 – Prerequisite Program Implementation, Corrective Action, Pre-Shipment Review Requirements, and Systems Thinking** | | |
| **Step 6**  **Prerequisite Program Implementation** | **Step 7**  **Corrective Actions** | **Step 8**  **Pre-Shipment Review** |
| **9 CFR 417.5(a)(1)**  **Review the Hazard Analysis, determine what hazards are considered NRLTO and answer each of the questions below for each prerequisite program.**   1. Is the establishment implementing the procedures in the program as written? 2. Does the establishment maintain records to support the implementation of the prerequisite program? 3. Do the records show that the prerequisite program continues to support the decision that the relevant hazard is not reasonably likely to occur on an ongoing basis? | **Corrective Actions in HACCP Plan - 9 CFR 417.2(c)(5)**  **Review the HACCP Plan for each CCP**   1. Has the establishment identified the corrective actions to be followed if a critical limit deviation occurs?   **Corrective actions in response to a critical limit deviation – 9 CFR 417.3(a)**  If a critical limit deviation occurred, verify that the establishment met the below corrective action requirements:   1. Did the establishment identify and eliminate the cause of the deviation? 2. Did the corrective actions ensure that the CCP is brought under control? 3. Were measures implemented to prevent recurrence of the deviation? 4. Did the actions ensure that no product injurious to health or other adulterated because of the deviation enters commerce?   **Corrective actions in response to an unforeseen hazard– 9 CFR 417.3(a)**  If an unforeseen hazard occurred, verify that the establishment met the below corrective action requirements:   1. Did the establishment segregate and hold all affected product? 2. Did the establishment perform a review to determine the acceptability of the affected product for distribution? 3. Did the establishment take necessary action with respect to the affected product to ensure that no product that is injurious to health, or otherwise adulterated because of the deviation, enters commerce? 4. Was a reassessment conducted to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan? | **Pre-Shipment Review Requirement – 9 CFR 417.5(c)**  **Observe (Time Permitting) and/or Review Est. Records**   1. Has the establishment performed and documented a final review (i.e., pre-shipment review) of the records associated with the production of the product, prior to shipment? 2. Has the pre-shipment review been signed and dated by an establishment employee? |
| **Step 9**  **Consider the implications of any noncompliance**   1. Is there a pattern of repeated failure to implement the HACCP procedures as written? 2. Is there reason to believe that the establishment’s food safety system is not effectively controlling the applicable food safety hazards? 3. Has the product been prepared, packed, or held under insanitary conditions where it may have become contaminated with filth or rendered injurious to health? 4. Has the establishment produced or shipped adulterated products into commerce? |

**NOTE:** See FSIS Directive 10,240.4 for additional information to verify during a HACCP Verification task at an RTE establishment producing post-lethality exposed products. See FSIS Directive 10,010.2 for additional information to verify STEC controls in an establishment producing Raw Intact and/or Raw Non-Intact Beef products.