General Instructions for Use of the Field Verification Audit Form

This field verification form, compiled from the FDA “FD312 Field Guide,” provides supporting documentation for detailed evaluation of an approved HACCP plan. This supporting documentation can serve as an addendum for inspection reports and may be used independently for full HACCP verification of all processes. Relevant Food Code citations are provided in each section of the form. The Food Code citations provided are related to specific processes and HACCP requirements. Jurisdictions must confirm before approving each HACCP plan that the establishment has the equipment, materials and controls on hand to perform the process requested, as well as the written prerequisite policies and procedures supporting the process. Once a plan has been approved, a HACCP verification audit should be performed to confirm that the plan has been implemented as approved. It is further suggested that jurisdictions conduct more detailed, demonstrative field verification audits at least once every three years to ensure the approved process is being followed and maintained in compliance with the details of approved plan. In the case of some processes, multiple visits may be required to see an entire process. When possible, verification visits should be scheduled in a manner that allows the inspector to see more than one step of those multi-day processes within a single day.

In preparation for the verification audit, the inspector should review and become familiar with each approved plan that will be audited.

* Bring copies of the approved plans to the inspection.
* If pH is a critical control point in a process that will be verified, calibrate a pH meter on the morning of the inspection and bring the pH meter along with the other necessary supplies and routine inspection equipment. You may use the establishment’s pH meter to determine it is functioning and can be accurately calibrated.
* Routine inspections are conducted on an unannounced basis. However, in the case of processes that are conducted over multiple days, it may be necessary on the day of the initial visit to schedule follow-up days with the PIC to be able to observe parts of a process that could not be observed on the day of the initial visit.

It may be helpful to complete some of Parts A through D of the Facility Overview and General HACCP Criteria/Observations section in advance. However, Parts A – G must be completed to cover all general criteria. When some of the data is completed in advance, all items must still be verified during the inspection. Each section of the form is a separate table, to which additional rows may be added.

* Process-specific sections that are not reviewed should either be marked “N/A” using the designated field, or they may be deleted to avoid “clutter” in the final report. To delete one of these tables, click on the top left corner of the table. When the box with a four-way arrow appears at that corner, right-click in that box and select “Delete Table.”
* In Process-Specific Section R, while some general criteria have been provided, it will be necessary to review the approved HACCP plan and add specific points that must be reviewed based on the process. Add more rows as necessary. Consult your jurisdiction’s Special Processes Team or Variance committee if you have questions or are uncertain about the specific details that must be reviewed.

As required during standardization, all data relating to three process batches should be examined for compliance with requirements of the approved HACCP plan and local regulations. Select three dates representing three process batches at random, giving preference to non-consecutive batches within six months preceding the date of the verification. (For a pre-approval verification, there will not be six months of records available.) Using the selected batch dates, request monitoring and training records relating to those process batches for review.

Use the checklists in the relevant process-specific sections of the verification audit form to provide criteria for evaluating compliance. Use the first line of each process category table to enter the dates of the three process batches selected. For each item listed for the process category, determine and mark whether the establishment was IN compliance (“Yes”) or OUT of compliance (“No”). For each item requiring a “Yes” or “No” response, a “Yes” indicates compliance with the HACCP plan and local regulation; a “No” response indicates non-compliance.

**If the HACCP verification is occurring during a routine (mandated) inspection:**

**Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan**

**IN/OUT** This item should be marked IN or OUT of compliance based on direct observations, discussion and record review with the PIC to determine if there are specialized food processes in use, applicable approvals for such processes, standard operating procedures, and HACCP plan if required. Each item should be marked IN compliance when observations, discussions, and record review indicate compliance is being met. This item should be marked OUT of compliance if the inspection reveals the process is being used in a manner not approved by the regulatory authority (not conducted according to a variance or HACCP plan approval). Any non-compliance identified in this verification would result in an OUT mark on the Routine Inspection item. How the inspector should address observed non-compliances must follow the standard operating procedure of their jurisdiction.

**Variance obtained for specialized processing methods**

When a food establishment wants to utilize Specialized Processing Methods as specified in 3-502.11, a variance must first be obtained from the regulatory authority. A HACCP plan may also be required as listed in 8- 201.13(A) as part of the variance request.This item refers only to receiving variance and HACCP plan approvals, where required. Therefore, the regulatory authority will need to determine which approval is needed for the process in question.

**IN/OUT** When noncompliance is observed, the specialized process must stop immediately, and no food involved in that process may be sold or served. The operator should be required to stop the process immediately and be instructed to seek approval of the process before further use.

**N.A.** This item on the verification audit form may be marked N.A. for each process category not being used in the establishment.

**If the HACCP verification is occurring not as a part of the routine inspection:**

Compliance and Enforcement will depend on the program policy. Follow your program’s SOP on regulatory compliance. The safety of the product is determined by the severity and possible consecutive nature of non-conformance. This may result in enforcement actions determined by regulatory policy.

Guidance from regulatory program management would be needed on potential actions, including:

* Remedial correction
  + Discard food being made at the time of the verification that is not following steps in the approved HACCP plan
  + Get correction at the time of the verification
  + Cite details as a violation under inspection item **Conformance with approved procedures**
  + Take permitting action giving days to bring training requirements, working copies, and record keeping into compliance with approved HACCP plan
* Immediate action
  + Cease processing activities
  + Potentially stop operations in the entire facility depending on the volume of specialized processed foods being offered
  + Discard food not properly labelled per the CCP’s of the approved HACCP plan
  + Embargo product

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| **Food Code Reference** | **Foodborne Illness Risk Factors and Public Health Interventions** | **Corrective Action- Corrected During Inspection, Verification,**  **Enforcement Action** | **Intervention for Long-term Compliance** |
| 3-404.11(A)(B)  3-502.11 (A)(B)(C)(D)(E)(F)(G)(H)  3-502.12(A)(B)(C)(D)(E)  4-204.110(A)(B)  8-103.12(A)(B)  8-201.14(A)(B)(C)(D)(E) | Conformance with Approved Procedures:  Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan.  Violation of **Conformance with approved procedures** results in violation on this item and the HACCP process that is being violated. | 3-404.11 (A) - PIC must  provide documentation or discard the food.  3-404.11(B) - Properly label or discard the food.  3-502.11 (A)(B)(C)(D)(E)(F)(G)(H)  Discard the food  3-502.12 (A)(B)(C)(D)(E) -  Provide documentation or discard the food.  4-204.110 (A) - Discontinue service of the food. Label tank properly.  (B) - Discard the food  8-103.12 (A) - Discard the food (B) - PIC must provide documentation or discard the food  8-201.14 (A)(B)(C)(D)(E) - PIC  must provide documentation or discard the food. | 3-404.11(A) - Contact local regulatory authority for guidance. Obtain approved HACCP plan.   1. - Train employees to label properly.   3-502.11(A)(B)(C)(D)(E)(F)(G)(H)  Contact local regulatory authority for guidance. Obtain variance.  3-502.12(A) - Obtain documentation.  (B) - Obtain approved HACCP plan. Obtain required documentation.  (C) - Train employees.  (D) - Obtain approved HACCP plan. Train employees.  (E) - Change source. Obtain approved HACCP plan. Train employees to properly label and discard.  4-204.110(A)(B) - Contact local regulatory authority for guidance. Obtain approved HACCP plan.  8-103.12(A) - Train employees.  (B) Make records available. Obtain additional copies of records.  8-201.14(A)(B)(C)(D)(E) -  Obtain a HACCP plan. Alter existing HACCP plan. |