

**DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG
ADMINISTRATION FIELD INSPECTION AUDIT**

AUDITOR		STATE INSPECTOR	
FIRM NAME		FEI NUMBER	
FIRM ADDRESS			
PRODUCT(S) COVERED		DATE	
TIME IN	TIME OUT	OVERALL RATING	
		<input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement	

I. PREINSPECTION ASSESSMENT

1. Did the Inspector review the state's establishment file for the previous inspection report and possible complaints or access other available resources in preparation for the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector have the appropriate equipment and forms to properly conduct the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE

1. Was FDA jurisdiction established?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

2. Did the inspector select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the firm was producing?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. Did the inspector assess the employee practices critical to the safe production and storage of food?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

4. Did the inspector properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

5. Did the inspector recognize significant violative conditions or practices if present and record findings consistent with state procedures?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE (Continued)

6. Did the inspector demonstrate the ability to distinguish between significant versus insignificant observations and isolated incidents versus trends?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

7. Did the inspector review and evaluate the appropriate records and procedures for this establishment's operation and effectively apply the information obtained from this review?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

8. Did the inspector collect adequate evidence and documentation in accordance with state procedures given the nature of the inspectional findings?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

9. Did the inspector verify correction of deficiencies identified during the previous state inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

10. Did the inspector act in a professional manner and demonstrate proper sanitary practices during the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II.A. INSPECTIONAL OBSERVATIONS AND PERFORMANCE FOR "HACCP REGULATED" FACILITIES

Note to Auditor: These four questions only apply to firms subject to HACCP regulations. These four questions should be left blank for firms not subject to HACCP regulations.

1. Did the inspector use the "Fish and Fishery Products Hazards and Controls Guide" or the "Juice HACCP Hazards and Controls Guide," as appropriate, to identify and evaluate the hazards associated with the product and process?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. Did the inspector review the firm's HACCP plan (or necessary process controls in the absence of a HACCP Plan) and applicable monitoring, verification, and corrective action records, including those related to sanitation?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II.A. INSPECTIONAL OBSERVATIONS AND PERFORMANCE FOR “HACCP REGULATED” FACILITIES

4. Did the inspector recognize deficiencies in the firm’s monitoring and sanitation procedures through in-plant observations?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION

1. Did the inspector identify himself/herself and make appropriate introductions, which include explaining the purpose and scope of the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector use suitable interviewing techniques?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. Did the inspector explain findings clearly and adequately throughout the inspection?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION (Continued)

4. Did the inspector alert the firm's appropriate management when an immediate corrective action was necessary?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

5. Did the inspector answer questions and provide information in an appropriate manner?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

6. Did the inspector write their findings accurately, clearly and concisely on the state document/form left with the firm?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

**IV. INSPECTIONAL OBSERVATIONS AND PERFORMANCE
FOR PC LIMITED SCOPE AND MODIFIED SCOPE AUDITS**

1. Did the inspector properly evaluate the good manufacturing requirements (117 Subparts A, B, and F, or equivalent state regulation)? This question applies to all audits performed including food, seafood and juice. It cannot be left blank.

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. Did the inspector conduct a broad-based assessment of the preventative controls program where necessary? This question applies to limited scope PC inspections or if it is a qualified facility that attested under 21 CFR 117.201(a)(2)(i). If the question does not apply, select Not Applicable.

Acceptable Needs Improvement Not Applicable

COMMENTS *(required for Needs Improvement)*

3. Did the inspector evaluate if the facility was in compliance with its attestation? Only applies when a firm self-attests under 21 CFR 117.201(a)(2)(i) or (ii). If the question does not apply, select Not Applicable.

Acceptable Needs Improvement Not Applicable

COMMENTS *(required for Needs Improvement)*

4. Did the inspector properly evaluate the implementation of time/temperature controls? Only answer if the facility is a warehouse solely engaged in the storage of unexposed packaged food that requires refrigeration for safety. If the question does not apply, select Not Applicable.

Acceptable Needs Improvement Not Applicable

COMMENTS *(required for Needs Improvement)*

ADDITIONAL COMMENTS

SIGNATURE OF AUDITOR

DATE

NOTE: EVERY ITEM MARKED "NEEDS IMPROVEMENT" MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS MARKED AS NEEDING IMPROVEMENT.

Special Instructions:

Section II.A. INSPECTIONAL OBSERVATIONS AND PERFORMANCE FOR "HACCP-REGULATED" FACILITIES

- Answer this section if the establishment is subject to Seafood or Juice HACCP regulations. These four questions should be left blank for firms not subject to HACCP regulations.

Section IV. INSPECTIONAL OBSERVATIONS AND PERFORMANCE FOR PC LIMITED SCOPE AND MODIFIED

SCOPE AUDITS

- Question one applies to ALL audits performed including food, seafood and juice and should be answered for every audit.
- Questions 2, 3, and 4 should be marked Not Applicable when a firm is not subject to the regulation.

Overall Rating:

If three or less items are marked "needs improvement," the overall rating is "acceptable." If four or more items are marked "needs improvement," the overall rating is "needs improvement." The overall rating must be marked in the space provided in the header on the first page.

All contract inspectors who receive an overall audit score of "needs improvement" shall receive remedial training in deficient areas or as agreed upon by the state and FDA Division prior to resuming contract inspection duties.

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