

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CONTRACT AUDIT

FDA AUDITOR		STATE INSPECTOR	
FIRM		CFN / 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. INSPECTION OBSERVATIONS AND PERFORMANCE FOR 'HACCP-REGULATED' FACILITIES

Note to Auditor: These four questions apply to only 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 FISHER 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. INSPECTION OBSERVATIONS AND PERFORMANCE FOR 'HACCP-REGULATED' FACILITIES (Continued)

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 FORM/DOCUMENT LEFT WITH THE FIRM?

Acceptable Needs Improvement

COMMENTS (required for Needs Improvement)

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

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 questions must be answered "acceptable" or "needs improvement," except for section II.A. *Inspection Observations and Performance for 'HACCP-Regulated' firms*. **If the establishment is not subject to Seafood or Juice HACCP regulations, leave the scoring for these four questions blank.**

If four or more evaluated items are marked as "needs improvement," the state program manager must be notified by the appropriate FDA liaison that additional training or other performance improvement measures for the inspector being audited should be initiated. 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 FDA Project and Co-Project Officers prior to resuming contract inspection duties.

