

	Bureau of Environmental Health Services Manufactured Food Program	Page 1 of 31
	<b>Inspection Audit Policy</b>	Effective Date: 10/31/13
	Approved By: <u>Russell Lilly</u> Manufactured Food Program Manager	Date: <u>10-29-13</u>
	Approved By: <u>[Signature]</u> Bureau Chief	Date: <u>10/29/13</u>

**I. Purpose**

The purpose of this procedure is to describe the basic quality assurance reviews performed to (1) evaluate the effectiveness of the inspection program, (2) recognize trends in inspectional coverage and (3) identify best practices used to achieve quality inspections and sample collections.

**II. Overview**

The Manufactured Food Program conducts quality assurance reviews to assess the effectiveness of its inspections and sample collections. The data used to determine such performance is obtained from observing an inspector conducting an inspection and the inspector's written reports. The purpose of this policy is not to evaluate individual performance, however, Performance Expectations do require that field staff complete satisfactory inspections.

**III. Program Elements**

The Manufactured Food Program's quality assurance program (QAP) is set up to identify elements of the inspection and sample collection processes that need improvement. The QAP has two components: (1) a field audit component, which is an on-site performance evaluation of inspections and (2) a desk audit component, which is a performance review of the written reports of inspections and sample collections. Contract and non contract inspections are represented in the audit process. The Manufactured Food Database will be used to: (1) calculate an overall audit rating for each review (field inspection performance and written reports of inspections and samples collections) and (2) evaluate ratings for a single performance factor. The Program Manager will use the ratings to identify specific aspects of its inspection program that need improvement. When performance ratings fall below 80 percent, a corrective action plan will be completed and recorded in the Manufactured Food Database.

The Manufactured Food Program compiles and summarizes the results of the field and desk audits annually and determines an overall performance rating, which is reported on the self-assessment worksheet. The results of the audits are evaluated every 12 months to:

- (1) determine the effectiveness of the food inspection program,
- (2) recognize trends in inspectional coverage, and
- (3) identify best practices used to achieve quality inspections and sample collections.

The results are recorded, summarized and tracked in the Manufactured Food Database.

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**A. Field Inspection Audit**

The Program Manager or qualified designated auditor conducts field inspection audits to verify that inspections are consistently performed according to the established policies and procedures. The quality of each inspection is audited using the performance factors identified on the appendix 4.5 and follows the process described in FDA's Field Management Directive No. 76. An overall rating for field inspection performance is calculated and tracked in the Manufactured Food Database.

**Frequency** The Manufactured Food QAP requires a minimum of two field inspection audits of each inspector be conducted every 36 months. Inspections selected for audit will include high-risk food firms.

**B. Inspection Report Audit**

The MFRPS Coordinator performs a periodic review of inspection reports to verify that inspectional findings are obtained and reported according to established procedures and policies. The quality of each inspection report is audited and the overall inspection report rating is documented and calculated in the Manufactured Food Database.

**Frequency** A minimum of 75 inspection reports, including reports from field inspection audits, are randomly selected across inspectors and supervisors, and geographical locations each year. Approximately seven percent of the inspection reports reviewed will be taken from inspections that were audited.

**C. Sample Report Audit**

The Missouri Manufactured Food Program does not routinely collect surveillance samples or food products as evidence. Samples may be collected as part of a foodborne illness investigation. If samples are collected at manufactured food facilities the MFRPS Coordinator will perform a periodic review of sample reports to verify that samples were properly collected, identified, and submitted according to established procedures and policies and that appropriate information was recorded. The quality of each sample report is audited using the performance factors listed and an overall sample report rating is calculated using the appendix 4.7 and worksheet 4.4.

**Frequency** All sample reports will be audited within three months of the sample being collected.

**D. Corrective Action Plan**

A corrective action plan is required when an overall audit rating falls below 80 percent or when an individual performance factor is rated as "needs improvement." Appendix 4.8 is used to document how the deficiency was corrected.

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**IV. Outcome**

The Manufactured Food Program systematically evaluates and improves its inspection and sample collection systems to ensure that activities and information are accurate, complete, and comply with the jurisdiction's procedures and policies.

**V. Documentation**

The self assessment and results from the audits will be summarized and tracked in the manufactured foods access database.

The Manufactured Food program maintains the records listed here.

- Appendix 4.1 Self assessment worksheet
- Appendix 4.2 Summary of field inspection audit findings (includes worksheet 4.2)
- Appendix 4.3 Summary of inspection report audit findings (includes worksheet 4.3)
- Appendix 4.4 Summary of sample report audit findings (includes worksheet 4.4)
- Appendix 4.5 Contract Audit - FDA Form 3610
- Appendix 4.5a Guidance for completing contract audit form
- Appendix 4.6 Inspection report audit form
- Appendix 4.7 Sample report audit form
- Appendix 4.8 Corrective action plan (includes table 4.8)

**Appendix 4.1  
Self-Assessment Worksheet**

The results of the field inspection and desk audits are summarized below. Performance ratings that fall below 80 percent indicate a need for improvement and require corrective action.

Worksheets 4.2 – 4.4 can be used to identify the specific aspects of the inspection program that need improvement.

<b>Overall Audit Rating</b> (based on five-year average)	
<i>Circle one:</i>	<i>Performance rating criteria:</i>
<b>Acceptable</b>	All performance rating averages $\geq$ 80 percent.
<b>Needs improvement</b>	One or more performance rating averages $<$ 80 percent.

**Audits**

Year	Field inspection	Inspection report	Sample report
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Year _____	_____	_____	_____
<b>Five-year average</b>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**Assessment completed by:**

\_\_\_\_\_  
(NAME) (DATE)

## Appendix 4.2 Summary of Field Inspection Audit Findings

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The summary of the performance factor ratings for all field inspection audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

The Manufactured Food Database is used to calculate an overall rating for the performance period and identify single performance factors rated as "needs improvement" in multiple audits. The performance factors are described in appendix 4.5. A rating below 80 percent indicates a need for improvement and requires corrective action.

**INSTRUCTIONS:** (1) For each field inspection audited, record the auditor's initials and date of audit in the box.

(2) For each field inspection audited, record the rating for each performance factor listed in appendix 4.5.

A = acceptable; NI = needs improvement.

(3) Record the  $A_t$  and  $NI_t$  for each performance factor.

$A_t$  = horizontal total of acceptable ratings.

$NI_t$  = horizontal total of needs improvement ratings.

(4) Calculate the overall rating for the field inspection audits.

Record the rating in the space provided in the box located at the top of worksheet 4.2.

### FORMULA:

Field inspection audit performance rating =  
$$\left[ \frac{\sum A_t}{(\sum A_t + \sum NI_t)} \right] \times 100$$

*NOTE:  $\Sigma$  is the statistical symbol for the sum of all numbers.*

$\sum A_t$  = vertical sum of acceptable ratings.

$\sum NI_t$  = vertical sum of needs improvement ratings.

(5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of worksheet 4.2 to identify and make notes about single performance factors rated as "needs improvement" in multiple audits

Worksheet 4.2 Calculation of Performance Ratings for field inspection audits

<b>State Agency:</b>	Missouri Department of Health & Senior Services	<b>Performance Period:</b>			
<b>Reviewed by:</b>	<b>Office:</b>	<b>Date:</b>			
Performance Factors (5)	Auditor's initials and date of audit (1)				
Performance Ratings (2)					
1.1					At (3)
1.2					Nit (3)
II.1					
II.2					
II.3					
II.4					
II.5					
II.6					
II.7					
II.8					
II.9					
II.10					
IIA.1					
IIA.2					
IIA.3					
IIA.4					
III.1					
III.2					
III.3					
III.4					
III.5					
III.6					
Subtotal	Enter the sum of the totals from all continuation sheets				
Total	Enter the final sums (subtotal + sums of (3) on this form).				
(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.					

**(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS**

Worksheet 4.3 Performance rating for the inspection report audits

State agency: Missouri Department of Health and Senior Services Performance period: \_\_\_\_\_

Performance rating (4): \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Office: \_\_\_\_\_ Date: \_\_\_\_\_

Performance factors (5)	Firm identification number and date of inspection (1)												A <sub>1</sub> (3)	N <sub>1</sub> (3)	
	Performance ratings (2)														
I.1															
I.2															
II.1															
II.2															
II.3															
II.4															
II.5															
II.6															
II.7															
II.8															
II.9															
II.10															
II.11															
II.12															
III.1															
III.2															
III.3															
III.4															
IV.1															
IV.2															
IV.3															
IV.4															
IV.5															
IV.6															
V.1															
V.2															
V.3															
V.4															
V.5															
V.6															
V.7															
V.8															
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>														
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>														

Worksheet 4.3 Performance rating for the inspection report audits

Continuation sheet

State agency: \_\_\_\_\_

Performance period: \_\_\_\_\_

Performance factors (5)	Firm identification number and date of inspection (1)												A (3)	NI, (3)	
	Performance ratings (2)														
I.1															
I.2															
II.1															
II.2															
II.3															
II.4															
II.5															
II.6															
II.7															
II.8															
II.9															
II.10															
II.11															
II.12															
III.1															
III.2															
III.3															
III.4															
IV.1															
IV.2															
IV.3															
IV.4															
IV.5															
IV.6															
V.1															
V.2															
V.3															
V.4															
V.5															
V.6															
V.7															
V.8															
<b>Total</b>	<i>Enter the sums of (3)</i>														

Worksheet 4.3 Performance rating for the inspection report audits

5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

## Appendix 4.4

Summary of Sample Report Audit Findings The summary of the performance factor ratings for all sample report audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Worksheet 4.4 is used to calculate an overall rating for the performance period and identify single performance factors rated as "needs improvement" in multiple audits. The performance factors are described in appendix 4.7. A rating below 80 percent indicates a need for improvement and requires corrective action.

### INSTRUCTIONS:

- (1) For each sample report audited, record the sample report identification number and date of sample collection in the box.
- (2) For each sample report audited, record the rating for each performance factor listed in appendix 4.7.

A = acceptable; NI = needs improvement.

- (3) Record the A<sub>i</sub> and NI<sub>i</sub> for each performance factor.

A<sub>i</sub> = horizontal total of acceptable ratings.

NI<sub>i</sub> = horizontal total of needs improvement ratings.

- (4) Calculate the overall rating for the sample report audits.

Record the rating in the space provided in the box located at the top of worksheet 4.4.

### FORMULA:

$$\text{Sample report audit performance rating} = \left[ \frac{\sum A_i}{\sum A_i + \sum NI_i} \right] \times 100$$

*NOTE:  $\Sigma$  is the statistical symbol for the sum of all numbers.*

$\Sigma A_i$  = vertical sum of acceptable ratings.

$\Sigma NI_i$  = vertical sum of needs improvement ratings.

- (5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of worksheet 4.4 to identify and make notes about single performance factor. Use the space at the bottom of worksheet 4.4 to identify and make notes about single performance factors rated as "needs improvement" in multiple audits.

Worksheet 4.4 Calculation of Performance Ratings for sample report audits

State: Missouri Department of Health & Senior Services Agency: Performance Period: Performance rating (4): Office: Date:

Reviewed by: Auditor's initials and date of audit (1)

Performance Factors (5)	Performance Ratings (2)										At (3)	NIt (3)	
I.1													
I.2													
I.3													
I.4													
I.5													
II.1													
II.2													
II.3													
IIA.4													
III.1													
III.2													
III.3													
<b>Subtotal</b>	<b>Enter the sum of the totals from all continuation sheets</b>												
<b>Total</b>	<b>Enter the final sums (subtotal + sums of (3) on this form).</b>												

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

**Missouri Department of Health and Senior Services  
Bureau of Environmental Health Services  
Contract Audit**

MDHSS AUDITOR

STATE INSPECTOR

FIRM

CFN/FEI NUMBER

PRODUCT(S) COVERED

DATE

TIME IN

TIME OUT

OVERALL RATING

**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)

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)

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)

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**

1. 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)

2. 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)

3. 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)

4. DID THE INSPECTOR RECOGNIZE EFFICIENCIES 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)

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 IETM 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.

**ADDITIONAL COMMENTS**

SIGNATURE OF MDHSS AUDITOR

DATE

## Appendix 4.5a

### Guidance for Completing the Contract Audit Form (FDA Form 3610)

This document provides guidance on assigning ratings during an audit for each of the performance factors listed on the Contract Audit Form. For each performance factor examples of actions and observations that would likely result in a “needs improvement” rating are provided.

#### I. Pre Inspection 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?

###### References:

- State program's establishment files
- FDA compliance programs referenced in the contract

###### Examples of a “needs improvement” rating:

- a. The inspector does not review the State’s previous inspection report and follow-up on previously cited deficiencies.
- b. The inspector does not review a firm’s response letter that promised corrective actions after the last inspection, which was conducted by the State.
- c. The inspector does not verify the firm’s normal days of operation or seasonal hours.
- d. The inspector does not follow-up on a consumer complaint contained in the State's establishment file.

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

###### References:

- FDA compliance programs referenced in the contract
- FDA inspection guides

###### Examples of a “needs improvement” rating:

- a. During an inspection of a cream-filled pie manufacturer, the inspector does not have a calibrated thermometer to check the temperature of the pie.
- b. During an inspection of a cooked, ready-to-eat food processor, the inspector does not have a method to test the concentration of iodine sanitizer in the hand dip station.
- c. During the inspection, the inspector does not have a flashlight to examine poorly lit raw material storage areas.

## II. Inspection Observations and Performance

### 1. Was FDA jurisdiction established?

#### References:

- FDA Investigations Operations Manual (IOM), subchapter 432 - Documenting Interstate Shipments
- IOM, subchapter 701 – Statutory Authority

#### Examples of a “needs improvement” rating:

- a. The inspector fails to confirm interstate movement of a product or ingredients.
- b. The inspector conducts an inspection of a candy manufacturer assigned under FDA contract. He/she fails to discover that the manufacturer has not shipped product in interstate commerce in the past 24 months. This manufacturer has no ingredients or packaging components shipped interstate.

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

#### References:

- FDA compliance programs referenced in the contract

#### Examples of a “needs improvement” rating:

- a. The inspector covers only a low-risk product while the firm is producing a high-risk product on the day of the inspection.
- b. The inspector does not cover a small ready-to-eat sandwich operation in a large frozen dinner processing plant.
- c. While inspecting a beverage bottling plant whose primary product is institutional-sized root beer syrup, the inspector ignores a bottled water processing operation at that site.

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

#### Examples of a “needs improvement” rating:

- a. The inspector fails to evaluate the hygienic practices of employees working in a food processing area.
- b. The inspector is unaware of the need for employees who are processing cooked, ready-to-eat foods to wash and sanitize their hands every time they touch an unclean surface.
- c. The inspector notices that the firm has a trash bin and a reclaim bin in the same area. He/she does not, however, recognize the potential hazard. Consequently, the inspector misses an employee placing trash in the reclaim bin that contains product reintroduced into the manufacturing process.

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

References:

- FDA compliance programs referenced in the contract
- NLEA inspection guide

Examples of a "needs improvement" rating:

- a. The inspector fails to recognize when a firm's finished product labeling does not contain a sulfite declaration, even though the raw material does contain a sulfite declaration.
- b. The inspector fails to note the significance of "back hauling" raw eggs in a tanker used to carry pasteurized ice cream mix.
- c. During an inspection of a baby food manufacturer, the inspector notices a rapid moving belt is causing glass jars to rattle and shards of glass are on the belt. The inspector fails to relate that observation to a recent increase in complaints about glass in baby food.
- d. The inspector fails to recognize the addition of an allergen during the production of a breaded product and fails to follow-up on the label review.

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

Examples of a "needs improvement" rating:

- a. The inspector fails to recognize that the food residues and mold growth on food contact surfaces are violations.
- b. The inspector does not recognize that employees handling cooked, ready-to-eat product with soiled hands is a deficiency.
- c. The inspector doesn't notice that machine parts over food contact surfaces are lubricated with automobile oil.
- d. The inspector fails to recognize that condensate dripping from a freezer onto finished product may cause cross contamination.

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

References:

- FDA compliance programs referenced in the contract

Examples of a "needs improvement" rating:

- a. The inspector notes minor deficiencies such as chewing gum and nail polish while failing to note places where cross contamination of cooked and raw product might occur.
- b. The inspector identifies record keeping deficiencies in records that are two months old. The inspector objects to these deficiencies without appropriately considering that the firm's weekly management review of the records has identified the deficiencies, which have not been repeated within the last seven weeks.

- c. During an inspection of a ready-to-eat salad processor, the inspector focuses primarily on filthy, non-food contact surfaces.
- d. During the inspection of a warehouse, the inspector focuses on products stored against the wall but doesn't notice several pallets of rice infested with moths.

**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?**

Examples of a "needs improvement" rating:

- a. During a review of the processing records, the inspector fails to detect that cooking times are outside the scheduled process.
- b. The inspector fails to detect possible evidence of record falsification such as inconsistencies among different types of records, unrealistic and repetitive data, and inconsistencies in signatures.
- c. Can teardown records are reviewed, but the inspector didn't realize teardown measurements were not done at appropriate intervals.

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

Examples of a "needs improvement" rating:

- a. The inspector fails to adequately document findings according to State requirements when violations are found in the firm.
- b. The inspector fails to follow State requirements when collecting samples of processed food necessary to document violative conditions.
- c. In an acidified food processing plant, the pH of the final product is questionable. The inspector does not, however, collect a sample of the product for pH determination.

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

Examples of a "needs improvement" rating:

- a. Although significant time-temperature abuse of coconut cream pies was identified during the previous inspection, the inspector does not determine if the deficiencies were corrected.
- b. In the previous inspection, the inspector reported that a private well was not equipped with a sanitary seal. During the current inspection, the manager tells the inspector that the well was repaired, and the lab results were acceptable. The inspector reviews the microbiological lab results, but does not go to the well to verify that the sanitary seal was installed.

- c. The inspector fails to follow up on deficiencies from the previous inspection for cooked, ready-to-eat product because that product was not being made at the time of the inspection. Nor does the inspector review process records for the product to determine if the firm took appropriate corrective actions.

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

Examples of a "needs improvement" rating:

- a. The inspector does not use the boot bath when entering in the firm's processing areas.
- b. The inspector fails to sanitize his/her thermometer prior to probing product.
- c. The inspector fails to wear protective clothing when entering an aseptic processing area.
- d. The inspector wears dangling earrings, bracelets, and necklaces in the food processing areas of a baby food manufacturer.

**II.A Inspection Observation and Performance for 'HACCP-Required' Facilities**

**Note: Questions 1-4 are rated ONLY when the firm is required by regulation to have a HACCP plan.**

References:

- FDA compliance programs referenced in the contract
- Title 21 Code of Federal Regulations (21 CFR) parts 110, 120, 123, and 1240
- Fish and Fishery Products Hazards & Controls Guide
- HACCP Regulation for Fish & Fishery Products: Questions and Answers
- Juice HACCP Hazards and Controls Guide

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

Examples of a "needs improvement" rating:

- a. In a tuna processing plant, the inspector fails to identify histamine as a hazard inherent to the incoming raw material and fails to question its absence in the firm's HACCP plan. (Failure to identify a hazard reasonably likely to occur.)
- b. A firm is producing fresh, raw, refrigerated fish in Cryovac packaging. The inspector is not aware that *C. botulinum* is a significant hazard.
- c. An inspector incorrectly identifies aquaculture drugs as a significant hazard for a secondary processor of a product that it receives from the primary processor. (Identification of a hazard not reasonably likely to occur.)
- d. The inspector fails to recognize that a batter tank in a breaded shrimp processing operation is a possible CCP. (Failure to recognize an appropriate CCP.)

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

Examples of a "needs improvement" rating:

- a. The inspector insisted the firm perform medical check-ups for crabmeat pickers.
  - b. The inspector cannot determine which of the eight areas of sanitation are relevant to the firm's operations.
  - c. The inspector fails to inquire about the firm's SSOPs and monitoring practices.
3. **Did the inspector review 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?**

Examples of a "needs improvement" rating:

- a. The inspection reveals that the firm is processing a product that requires a HACCP plan. The inspector cites the firm's failure to have a HACCP plan, but the inspector does not determine if the necessary controls were put into place without a HACCP plan.
  - b. Although the inspector is told that the firm uses well water, not potable water, as its source for ice, the inspector does not verify that the firm has the water tested for coliforms to ensure its safety.
  - c. The inspector does not ask the plant manager for records of pest control after learning that the service is contracted to a private company.
  - d. The inspector does not accompany the firm's sanitarian on a routine pre-operation inspection that would have given him an indicated that the sanitation and/or sanitation monitoring may be inadequate.
4. **Did the inspector recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations?**

Examples of a "needs improvement" rating:

- a. The inspector fails to recognize that cumulative times and temperatures for cooling, holding, and picking of cooked crabs were substantially above such times and temperatures specified in the firm's HACCP plan.
- b. The inspector fails to recognize that a firm's finished product labeling does not contain a sulfite declaration even though an ingredient contains a sulfite declaration.
- c. The inspector fails to recognize that the presence of food residues and mold growth on processing equipment immediately prior to processing is evidence of unsanitary conditions.
- d. The inspector does not recognize that food-contact surfaces are being sanitized with a product that is not approved for use on food contact surfaces.

### **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?**

Examples of a "needs improvement" rating:

- a. The inspector fails to explain why he/she is at the firm.
- b. The inspector enters through the back door and begins examining a storage area without notifying anyone at the firm.

2. **Did the inspector use suitable interviewing techniques?**

Examples of a "needs improvement" rating:

- a. The inspector requests for information are vague; consequently, the firm provides documents that are unrelated to the inspection.
- b. The firm manager is unable to respond to a request for information, because the inspector spoke in unfamiliar and confusing jargon.
- d. When the plant manager's responses are evasive, the inspector does not ask follow-up questions to obtain the necessary information. Consequently, the answers to the questions are incomplete.

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

Examples of a "needs improvement" rating:

- a. The inspector does not discuss a significant observation at the close-out meeting.
- b. The inspector does not discuss with the general manager a significant deficiency observed in the processing area before going to the packing area of the cannery.
- c. The inspector is vague during his discussion with the managers at the end of the inspection. Therefore, the managers are unaware of the significance of the observations and that corrective actions are needed.

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

Examples of a "needs improvement" rating:

- a. The inspector fails to alert the appropriate manager that food containing undeclared FD&C Yellow #5 is being packaged, and, if shipped, could result in a health hazard.
- b. The inspector didn't notify the plant manager when he saw blood dripping from boxes of boneless beef onto raw carrots.
- c. The inspector documented condensate dripping from bins of ready-to-eat salad not packaged.

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

Examples of a "needs improvement" rating:

- a. The inspector discusses specific information about a pending compliance action against a competitor with an employee on the processing line.
- b. The inspector gives a competitor's product formula to a friendly plant manager.
- c. The inspector fabricates an answer to a policy question that could lead the firm to take an inappropriate corrective action.
- d. The inspector dictates an inappropriate corrective action for a deficiency.

## Manufactured Food Regulatory Program Standards Inspection Report Audit Form

Auditor	Date of audit
Firm identification number	Date of inspection

### I. Introduction

1. FORMAT OF THE INSPECTION REPORT FOLLOWED THE STATE PROGRAM'S CURRENT PROCEDURES AND POLICIES.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

2. REQUIRED FIELDS ON INSPECTION REPORT OR RELATED REPORT FORMS ARE COMPLETED.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

### II. Evidence Development

1. DOCUMENTED NAME AND KEY RESPONSIBILITIES OF THE PERSON TO WHOM CREDENTIALS WERE SHOWN AND WHO ACCOMPANIED THE INSPECTOR DURING THE INSPECTION.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

2. VERIFIED LEGAL STATUS OF FIRM AND CORPORATE OFFICERS.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

3. DOCUMENTED TYPE OF OPERATION AND PROCESSES REVIEWED.

Acceptable     Needs improvement

COMMENTS (required for needs improvement)

4. IDENTIFIED WHETHER FIRM WAS REGISTERED WITH FDA UNDER THE BIOTERRORISM ACT OF 2002 AND IF NOT PROVIDED INFORMATION ON HOW TO DO SO.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

5. DOCUMENTED VIOLATIONS.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

6. DOCUMENTED SIGNIFICANT FINDINGS.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

7. DOCUMENTED POSSIBLE CAUSES OF CONTAMINATION.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

8. CLASSIFICATION AND FOLLOW-UP CONSISTENT WITH INSPECTIONAL FINDINGS.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

9. DOCUMENTED PERFORMANCE OF RECONCILIATION EXAM (WHERE APPLICABLE).

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

10. DESCRIBED FIRM'S SYSTEM FOR PRODUCT AND LOT CODING.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

11. FOOD PRODUCTS PROCESSED AT THE FACILITY ARE LISTED.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

12. REVIEWED RECORDS OF COMPLAINTS RECEIVED BY FIRM.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

III. Discussions With Management

1. DISCUSSED FINDINGS AND VIOLATIONS.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

Page 3

2. REPORTED RESPONSES OR REPLIES FROM THE FIRM WHERE APPLICABLE

Acceptable

Needs improvement

COMMENTS (required for needs improvement)

3. RECORDED ANY WARNINGS OF POSSIBLE FURTHER ACTIONS (REINSPECTION, EMBARGO, REVOCATION OF LICENSE, OR LEGAL CONSEQUENCES OF VIOLATIVE CONDITIONS) GIVEN TO THE FIRM.

Acceptable

Needs improvement

COMMENTS (required for needs improvement)

4. RECORDED ANY REFUSALS ENCOUNTERED DURING THE INSPECTION.

Acceptable

Needs improvement

COMMENTS (required for needs improvement)

1. REGULATORY REFERENCES ARE CITED FOR OBSERVATIONS.

Acceptable

Needs improvement

COMMENTS (required for needs improvement)

2. WRITTEN OBSERVATIONS WERE CLEAR AND CONCISE.

Acceptable

Needs improvement

COMMENTS (required for needs improvement)

3. OBSERVATIONS WERE FACT BASED AND SUPPORTED BY LAWS AND REGULATIONS.

Acceptable

Needs improvement

COMMENTS (required for needs improvement)

4. EMPHASIZED SIGNIFICANT OBSERVATIONS.

Acceptable

Needs improvement

COMMENTS (required for needs improvement)

5. OBSERVATIONS WERE NOT REPETITIOUS.

Acceptable

Needs improvement

COMMENTS (required for needs improvement)

## 6. SUBMITTED REPORT WITHIN TIMEFRAMES.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

## V. Supervisory Review

## 1. STATED THE REASON FOR THE INSPECTION, A BRIEF HISTORY OF THE FIRM, AND FOLLOW-UP TO THE PREVIOUS INSPECTION, IF NECESSARY.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

## 2. A SUMMARY OF FINDINGS AND DISPOSITION OF INSPECTION WERE RECORDED IN THE REPORT.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

## 3. DOCUMENTED WHETHER FOLLOW-UP OR FURTHER ACTION WAS REQUIRED.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

## 4. CLASSIFICATION AND FOLLOW-UP WERE CONSISTENT WITH THE LAW, CURRENT POLICIES, AND INSPECTIONAL FINDINGS.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

## 5. PROGRAM MANAGEMENT REVIEW AND ACTION WERE DONE WITHIN ADMINISTRATIVE TIMEFRAMES.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

## 6. DOCUMENTED VERIFICATION OF, AND DESCRIBED CORRECTIVE ACTIONS FROM PREVIOUS INSPECTION FINDINGS.

Acceptable                       Needs improvement

COMMENTS (required for needs improvement)

7. DATES IN REPORT AND ADMINISTRATIVE DATABASE ENTRIES WERE ENTERED ACCURATELY.

Acceptable

Needs improvement

COMMENTS *(required for needs improvement)*

8. FOR CONTRACT INSPECTIONS, INSPECTION RESULTS WERE ACCURATELY ENTERED IN eSAF

Acceptable

Needs improvement

COMMENTS *(required for needs improvement)*

Appendix 4.7

**Manufactured Food Regulatory Program Standards  
Sample Report Audit Form**

Auditor	Date of audit
Sample identification number	Date of collection

**I. Introduction**

1. REASON FOR SAMPLE COLLECTION WAS RECORDED.

Acceptable                       Needs improvement

COMMENTS *(required for needs improvement)*
2. SAMPLE SIZE WAS DESCRIBED.

Acceptable                       Needs improvement

COMMENTS *(required for needs improvement)*
3. LOT AND PRODUCT CODING WERE RECORDED ON SAMPLE REPORT.

Acceptable                       Needs improvement

COMMENTS *(required for needs improvement)*
4. MANUFACTURER, SHIPPER, DEALER, AND THE RESPONSIBLE FIRM WERE RECORDED.

Acceptable                       Needs improvement

COMMENTS *(required for needs improvement)*
5. REQUIRED FIELDS ON THE SAMPLE REPORT (SR) OR RELATED REPORT FORMS ARE COMPLETED.

Acceptable                       Needs improvement

COMMENTS *(required for needs improvement)*

**II. Evidence Development**

1. METHOD OF COLLECTION WAS APPROPRIATE FOR TYPE OF PRODUCT.

Acceptable                       Needs improvement

COMMENTS *(required for needs improvement)*
2. METHOD OF COLLECTION, INCLUDING SAMPLE SIZE, WAS APPROPRIATE FOR THE LABORATORY ANALYSES.

Acceptable                       Needs improvement

COMMENTS *(required for needs improvement)*
3. SAMPLE, LABELS, AND LABELING, BEAR IDENTIFICATION MARKS AND WERE ACCURATELY REPORTED ON THE SR.

Acceptable                       Needs improvement

COMMENTS *(required for needs improvement)*

Page 2	
4.	<p>PRODUCT LABEL AND LABELING WERE SUBMITTED WITH SR.</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (required for needs improvement)</p>
5.	<p>RECEIPT FOR SAMPLE WAS OBTAINED.</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (required for needs improvement)</p>
6.	<p>AFFIDAVITS WERE CLEAR, LEGIBLE, AND COMPLETE.</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (required for needs improvement)</p>
7.	<p>SR WAS SUBMITTED WITHIN TIMEFRAMES.</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (required for needs improvement)</p>
<b>III. Sample Integrity</b>	
1.	<p>SAMPLE WAS HANDLED, PACKAGED, AND SHIPPED TO PREVENT COMPROMISING THE CONDITION OR INTEGRITY OF THE SAMPLE.</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (required for needs improvement)</p>
2.	<p>SAMPLE WAS DELIVERED OR SHIPPED TO THE APPROPRIATE LABORATORY WITHIN ACCEPTABLE TIMEFRAMES.</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (required for needs improvement)</p>
3.	<p>SAMPLE DELIVERY (DATE AND CUSTODIAN) WAS RECORDED ON SR.</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (required for needs improvement)</p>

**Appendix 4.8  
Corrective Action Plan**

The corrective action for each deficiency reported during an audit should be described in the table below. Supporting documents should be referenced and maintained by the State program.

Completed by: \_\_\_\_\_  
(NAME) (DATE)

Type of audit:                      **FIELD INSPECTION**                      **INSPECTION REPORT**                      **SAMPLE REPORT**

Performance Factor (record number from audit form)	Description of Deficiency	Corrective Action(s)	Date of next audit