## 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)*
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 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 HAACP 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

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)*

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### 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, 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 or if they are a qualified facility that attested under 21 CFR 117.201(a)(2)(i)). If this question does not apply, select Not Applicable.

   ☐ Acceptable  ☐ Needs Improvement  ☐ Not Applicable

   COMMENTS *(required for Needs Improvement)*

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

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

   ☐ Acceptable  ☐ Needs Improvement  ☐ Not Applicable

   COMMENTS *(required for Needs Improvement)*
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. INSPECTION 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. INSPECTION 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.