STANDARD 5 – FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE
INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

Program Self-Assessment & Verification Audit Form

The *Standard 5: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the SELF-ASSESSMENT and the VERIFICATION AUDIT process for Standard 5. The form is included at the end of these instructions. Whether one is performing a program SELF-ASSESSMENT or conducting a VERIFICATION AUDIT, it is recommended that the form be available as a reference to the Standard 5 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self-Assessment

Jurisdictions conducting a SELF-ASSESSMENT of Standard 5 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self-Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's SELF-ASSESSMENT for the specific Standard 5 criteria listed on this form are available for review.

The *Standard 5: Program Self-Assessment and Verification Audit Form* is the only form a jurisdiction needs to use to record the results of their SELF-ASSESSMENT. The *Standard 5: Program Self-Assessment and Verification Audit Form* divides the Standard 5 criteria into seven categories:

1. Investigative Procedures;
   - Written Operating Procedure; Contact Lists; Cooperative Agreements;
   - Documenting and Responding to Reported Complaints/Incidences;
   - Complaint/Incident Investigative Procedures;
2. Reporting Procedures;
3. Laboratory Support Documentation;
4. Trace-back Procedures;
5. Recalls;
6. Media Management; and
7. Data Review and Analysis.

The self-assessor must review each Standard 5 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 5: Program Self- Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 5 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the *Standard 5: Program Self-Assessment and Verification Audit Form*. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 5: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the AUDITOR with their completed *Standard 5: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 5 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 5: Program Self-Assessment and Verification Audit Form*. The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 5 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 5 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the VERIFICATION AUDIT must provide their completed *Standard 5: Program Self- Assessment and Verification Audit Form* to the AUDITOR for review. The AUDITOR must indicate on the *Standard 5: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the SELF-ASSESSMENT conclusion that the Standard criteria are met, the verification AUDITOR places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the SELF-ASSESSMENT conclusion that the Standard criteria are met, the verification AUDITOR places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification AUDITOR must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings. The jurisdiction must meet all seven program performance criteria outlined in Standard 5.

The verification AUDITOR must discuss their findings with the PROGRAM MANAGER or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any Standard 5 criteria for which the AUDITOR cannot confirm through a review of the SELF-ASSESSMENT should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The AUDITOR should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the AUDITOR must complete the Verification Audit Summary section located on the first page of the *Standard 5: Program Self-Assessment and Verification Audit Form*. The AUDITOR must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 5 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 5 criteria if the AUDITOR does not confirm the SELF-ASSESSMENT findings.

STANDARD 5 – FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE PROGRAM
SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person Who Conducted the Self-Assessment:	
Self-Assessor's Title:	
Jurisdiction Name:	
Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Standard 5 Self-Assessment Was Completed:	
Self-Assessment Indicates That the Jurisdiction MEETS the Standard 5 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standard 5 is true and correct. **Signature of the Self-Assessor:**	

VERIFICATION AUDIT SUMMARY

Printed Name of the Person Who Conducted the Verification Audit:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone:	
Fax:	
E-mail:	
Date the Verification Audit of Standard 5 Was Completed:	
Verification Audit Indicates That the Jurisdiction MEETS the Standard 5 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Standard 5 is true and correct. **Signature of the Verification Auditor:**	

STANDARD 5 – FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE PROGRAM
PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

Jurisdiction Name: _____

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Investigative Procedures	a) The program has written operating procedures for responding to and/or conducting investigations of foodborne illness and food-related injury that clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. (The procedures may be contained in a single source document or in multiple documents.)						
1. Investigative Procedures	b) The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illnesses, food-related injuries, or contamination of food.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Investigative Procedures	c) The program maintains a written operating procedure or a Memorandum of Understand (MOU) with the appropriate epidemiological investigation program / department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.						
1. Investigative Procedures	d) The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, food-related injury, or unintentional food contamination. The final disposition for each complaint is recorded in the database or log and is filed in, or linked to, the establishment record for retrieval purposes.						
1. Investigative Procedures	e) Program procedures describe the disposition, action, or follow-up and reporting required for each type of complaint or referral report.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Investigative Procedures	f) Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.						
1. Investigative Procedures	g) The program has established procedures and guidance for collecting information on the suspect foods' preparation, storage or handling during on-site illness, food-injury, or outbreak investigations.						
1. Investigative Procedures	h) Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.						
1. Investigative Procedures	i) Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.						
2. Reporting Procedures	a) Possible contributing factors to the illness, food-related injury, or intentional food contamination are identified in each on-site investigation report.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Reporting Procedures	b) The program shares final reports of investigations with the state epidemiologist and reports of confirmed disease outbreaks with CDC.						
3. Laboratory Support Documentation	a) The program has a letter of understanding, written procedures, contract, or MOU acknowledging that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological, contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental, food, and/or clinical sample analyses.						
3. Laboratory Support Documentation	b) The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) identified in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
4. Trace-Back Procedures	a) Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak, or intentional food contamination. The trace-back provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.						
5. Recalls	a) Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.						
5. Recalls	b) When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR Part 7 are followed.						
5. Recalls	c) Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
6. Media Management	a) The program has a written policy and procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The protocol should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.						
7. Data Review and Analysis	a) At least once per year, the program conducts a review of the data in the complaint log or database and the illness and food-related injury investigations to identify trends and possible contributing factors that are most likely to cause illness or injury. These periodic reviews of multiple complaints and contributing factors may suggest a need for further investigations may suggest steps for illness prevention.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
7. Data Review and Analysis	b) The review is conducted with prevention in mind and focuses on, but is not limited to, the following: (1) Foodborne disease outbreaks, suspect foodborne outbreaks and confirmed foodborne disease outbreaks in a single establishment;						
7. Data Review and Analysis	(2) Foodborne disease outbreaks, suspect foodborne outbreaks and confirmed foodborne disease outbreaks in the same establishment type;						
7. Data Review and Analysis	(3) Foodborne disease outbreaks, suspect foodborne outbreaks and confirmed foodborne disease outbreaks implicating the same food;						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
7. Data Review and Analysis	(4) Foodborne disease outbreaks, suspect foodborne outbreaks and confirmed foodborne disease outbreaks associated with similar food preparation processes;						
7. Data Review and Analysis	(5) Number of confirmed foodborne disease outbreaks;						
7. Data Review and Analysis	(6) Number of foodborne disease outbreaks and suspect foodborne outbreaks;						
7. Data Review and Analysis	(7) Contributing factors most often identified;						
7. Data Review and Analysis	(8) Number of complaints involving real and alleged threats of intentional food contamination; and						
7. Data Review and Analysis	(9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
7. Data Review and Analysis*	c) In the event that there have been no illness or food-related injury outbreak investigations conducted during the twelve months prior to the trend analysis, program management will plan and conduct a mock foodborne illness or food defense investigation to test program readiness. The mock investigation should simulate response to an actual illness outbreak and include on-site inspection, sample collection, and analysis. A mock investigation must be completed at least once per year when no illness outbreak investigations occur.						
GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT							

A "yes" affirmation to each statement is required to meet Standard 5. If an item contains multiple questions, then all questions must be answered in the affirmative in order to meet that element of the Standard. The source documents, such as the various policies and procedures, that support this summary record must be maintained in good order by the regulatory authority and must be made available upon request for purposes of a verification audit.

***NOTE**: Item 7c can be marked "not applicable" (NA) if the jurisdiction DID conduct a foodborne illness or food defense investigation within the twelve-month period since the last trend analysis. If the jurisdiction DID conduct a foodborne illness or food defense investigation within this twelve-month period, then they are not required to conduct a mock foodborne illness/food defense training exercise.*