STANDARD 6 – COMPLIANCE AND ENFORCEMENT INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

Using the Standard 6: Verification Audit Worksheet

The AUDITOR should have the *Standard 6: Verification Audit Worksheets* available as a reference when reading through this guidance. The following worksheet is provided at the end of these instructions:

- *Standard 6: Verification Audit Worksheet*

The Standard 6: Verification Audit Worksheet is designed to provide a listing of the establishments randomly selected from the jurisdiction's inventory that were reviewed as part of the SELF-ASSESSMENT process. This worksheet provides a summary as to whether or not the inspection file/records for each of the randomly selected establishments meet the Standard 6 criteria.

The Standard 6: Establishment File Worksheet provides a systematic way of collecting the COMPLIANCE AND ENFORCEMENT history for each of the randomly selected establishments. Jurisdictions do not have to use this form. However, a jurisdiction must provide documentation of the review process. The documentation must indicate if appropriate COMPLIANCE AND ENFORCEMENT actions were taken for out-of-control RISK FACTORS and *FOOD CODE* INTERVENTIONS at each establishment randomly selected for the SELF-ASSESSMENT.

STEP 1 – Verify the Elements in the Written Compliance & Enforcement Program

To meet the criteria of Standard 6, the jurisdiction must have written step-by-step procedures outlining its COMPLIANCE AND ENFORCEMENT process. The verification AUDITOR should review its COMPLIANCE AND ENFORCEMENT policies and procedures to ensure that there is clear guidance for staff. The policies and procedures should provide steps and actions to be taken when various categories of violations occur. The policies and procedures should also provide a progression of steps to be taken when violations are not corrected within regulatory or administratively established time frames.

Standard 6 does not dictate a required compliance process. The jurisdiction is free to determine any actions to be taken for violations of its regulations and the progression of consequences for repeated violations. The time frames and triggers for additional actions are also left to the discretion of the jurisdiction.

In addition, to meet the requirements of Standard 6, the jurisdiction's inspection form must use the IN compliance, OUT of compliance, Not Applicable, and Not Observed conventions to record the compliance status of the foodborne illness RISK FACTORS and the public health interventions identified in the *Food Code*.

Jurisdictions that have not adopted all the recommended foodborne illness RISK FACTORS and *FOOD CODE* INTERVENTIONS are not penalized under Standard 6 for these omissions.

STEP 2 – Verify the Effectiveness of the Compliance & Enforcement Program

Randomly selected establishment files must be reviewed to determine if documented violations were resolved satisfactorily. The results of the review will be used to assess the success of the COMPLIANCE AND ENFORCEMENT program. This section of the VERIFICATION AUDIT process has been broken down into the following four parts:

- **Part I** Verify that the jurisdiction reviewed the appropriate number of files
- **Part II** Randomly select establishment files from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*
- **Part III** Verify SELF-ASSESSMENT findings for each selected establishment file
- **Part IV** Verify that 80% of selected establishment files adhere to the jurisdiction's written COMPLIANCE AND ENFORCEMENT procedures

Part I - Verify that the jurisdiction reviewed the appropriate number of files

The number of establishment files a jurisdiction must review as part of the Standard 6 SELF-ASSESSMENT process is based on the size of their establishment inventory. Jurisdictions with less than 800 total establishments must select at least 40 files for review. If a jurisdiction has less than 40 establishments in the inventory, then all files will be reviewed. Jurisdictions with 800 or more establishments must select a sample size equal to 5% of the total establishments up to a maximum of 70 files.

Establishment Inventory	Number of Files to Review for the Self-Assessment
Less than 800	40 establishment files
800 or more	5% of the total number of establishments (Up to a maximum of 70 files)

Some of the randomly selected establishment files listed on the *Standard 6: Self-Assessment Summary Worksheet* may not qualify for the SELF-ASSESSMENT process. Deletion of an establishment from the sample of files to be reviewed as part of the SELF-ASSESSMENT process is limited to those establishments where:

1. The selected establishment has not been in business long enough to have at least three regularly scheduled ROUTINE INSPECTIONS; or
2. A review of inspection reports in the selected establishment file reveals that there were no RISK FACTOR or FOOD CODE INTERVENTION violations documented on the "start-point" inspection

The jurisdiction's SELF-ASSESSMENT process must include a listing of the substitute establishment files that were reviewed as replacements for those that did not qualify. When an establishment does not qualify for the SELF-ASSESSMENT process, the substitute establishment must not be recorded on the *Standard 6: Self-Assessment Summary Worksheet*, but instead on the *Standard 6: Self-Assessment Summary Worksheet Substitute Establishment Files Worksheet*. The AUDITOR should verify this.

Part II - Randomly select establishment files from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*

Using a table of random numbers or a random number generator is the preferred method of sample selection. The random selection will be made from the establishment files listed on the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*. The number of establishment files that must be selected for review as part of the VERIFICATION AUDIT process is indicated in the chart below.

Establishment Inventory	Number of Files to Review for the Self-Assessment	Number of Files to Select for the Verification Audit
Less than 800	40 establishment files	5
800 or more	5% of the total number of establishments (Up to a maximum of 70 files)	10

Using the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*, the verification AUDITOR will identify the establishment files that correspond to the randomly selected number recorded on the *Standard 6: Verification Audit Worksheet*. The verification AUDITOR must record the establishment name or identification number for each of the randomly selected numbers on the *Standard 6: Verification Audit Worksheet.*

The verification AUDITOR must only review establishment files that the jurisdiction has indicated as meeting all the elements of their COMPLIANCE AND ENFORCEMENT procedures. This will require the verification AUDITOR to eliminate establishment files that are marked "NO" on the jurisdiction's Self-Assessment Summary Worksheet. (An "X" placed in the "NO" box indicates that the SELF-ASSESSMENT review process determined that the inspection history documented in the establishment file did not meet, or only partially met, the Standard 6 criteria and all the elements in the jurisdiction's written COMPLIANCE AND ENFORCEMENT procedures.)

In instances where the verification AUDITOR has randomly selected an establishment file from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet* that did not qualify (D.N.Q.) for the self-assessment review process, the substitute establishment that the jurisdiction selected for that disqualified establishment should be used.

NOTE: *There are two types of substitutes for the audit process, which are treated differently:*

1. *If the AUDITOR selects an establishment that was previously failed by the self-assessor, then use the AUDITOR-generated substitute list of random numbers to select a substitute establishment.*
2. *If the AUDITOR selects an establishment that "did not qualify" for the original SELF-ASSESSMENT, then use the substituted establishment that was already assigned in the original self- assessment review.*

Part III - Verify SELF-ASSESSMENT findings for each selected establishment file

Using the jurisdiction's written COMPLIANCE AND ENFORCEMENT procedures, the verification AUDITOR will review the Establishment File Worksheet for each of the establishments randomly selected for the VERIFICATION AUDIT.

The *Standard 6: Establishment File Worksheet* provides a systematic way of documenting the COMPLIANCE AND ENFORCEMENT history for each of the randomly selected establishments. Jurisdictions do not have to use this form but must provide documentation of the review process conducted to determine whether the appropriate COMPLIANCE AND ENFORCEMENT actions for out-of-control RISK FACTORS and *FOOD CODE* INTERVENTIONS were taken for each selected establishment.

Review the inspection history in each selected file beginning with the identified "start-point" inspection and moving forward through two additional inspections. Verify that either on-site corrective action, follow-up corrective action or enforcement action occurred by the end of the third inspection for each out-of-compliance RISK FACTORS or FOOD CODE INTERVENTIONS marked on the start point inspections. In addition, verify that the actions taken on each violation documented on the "start-point" inspection followed the jurisdiction's written compliance policy and procedures.

In order for an establishment file to meet the Standard 6 criteria, each column marked with a violation at the "start-point" inspection must have a subsequent indication that at least one type of follow-up action was taken, and the jurisdiction's written procedures must have been followed. A single violation on the "start-point" inspection without a final resolution, either correction or compliance/enforcement activity, will result in a determination that the establishment file does not meet the Standard 6 criteria. In any instances where the AUDITOR disagrees with the jurisdiction's SELF-ASSESSMENT of a file, the AUDITOR must meet with the jurisdiction's PROGRAM MANAGER or representative to gain a full understanding of the rationale used for the SELF-ASSESSMENT determination.

The verification AUDITOR will record his or her findings for each of the establishment files reviewed on the *Standard 6: Verification Audit Worksheet*. If the VERIFICATION AUDIT of the establishment file review indicates that the full intent of the Standard 6 criteria is met, place an "X" in the "YES" box. If full intent of the Standard 6 criteria is not met, place an "X" in the "NO" box. If the verification AUDITOR disagrees with the jurisdiction's SELF-ASSESSMENT decision, an explanation must be provided in the last column of the *Standard 6: Verification Audit Worksheet*. Additional sheets can be used to document the need for expanded explanations.

Part IV - Verify that 80% of selected establishment files adhere to the jurisdiction's written compliance and enforcement procedures

The criteria for Standard 6 requires that 80 percent of the files with an identified violation of a foodborne illness RISK FACTORS or a *FOOD CODE* INTERVENTIONS on the "start-point" inspection adhere to the jurisdiction's written COMPLIANCE AND ENFORCEMENT procedures. Files that "did not qualify" (D.N.Q.) for the SELF-ASSESSMENT review are not used in the calculation of the percentage.

Legitimate differences of opinion regarding stringency of language may occur during the VERIFICATION AUDIT process. An approximate ten percent (10%) discrepancy allowance is made to accommodate potential differences in interpretations.

Jurisdictions with less than 800 Establishments - If two or more of the five audited establishment files rated as passing by the jurisdiction are not verified by the AUDITOR as having met the Standard 6 criteria, the Part III element fails to meet the criteria, and no further sampling is necessary. Even if no additional disagreements are found by sampling an additional set of randomly drawn establishment files, the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Determine the need for supplemental sampling. If only one establishment file from the initial sample is determined by AUDITOR to have not met the Standard 6 criteria, then randomly select an additional 5 establishment files. Follow the same audit process used to review the first set of establishment files.

The *Standard 6: Verification Audit Worksheet* for substitute establishment files, provided on a following page, can be used to record all the information related to the supplemental sampling of establishment files.

If no additional disagreements in the review of establishment files are noted, then the jurisdiction meets the Standard 6 criteria. If one or more additional establishment files fails the audit review, then the Standard 6 criteria are not met, since the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Jurisdictions with more than 800 Establishments - If three or more of the ten audited establishment files rated as passing by the jurisdiction are not verified by the AUDITOR as having met the Standard 6 criteria, then the jurisdiction fails to meet Standard 6. Even if no additional disagreements are found by sampling an additional set of randomly drawn establishment files, the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Determine the need for supplemental sampling. If one or two establishment files from the initial sample are determined by AUDITOR to have not met the Standard 6 criteria, then randomly select an additional 10 establishment files. Follow the same audit process used to review the first set of establishment files. The *Standard 6: Verification Audit Worksheet* for substitute establishment files, provided on a following page, can be used to record all the information related to the supplemental sampling of establishment files.

No more than a total of two of 20 establishment files drawn can be determined by the AUDITOR as not meeting the Standard 6 criteria. If more than two establishment files fail the audit review, then the Standard 6 criteria are not met, since the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Standard 6 – Compliance and Enforcement
Verification Audit Worksheet
Establishment Files

Jurisdiction Name: _____

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
1						
2						
3						
4						
5						
6						
7						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
18						
19						
20						