STANDARD 6 – COMPLIANCE AND ENFORCEMENT
INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

Using the Standard 6 Establishment File Worksheet

The self-assessor should have the Standard 6 SELF-ASSESSMENT worksheets available as a reference when reading through this guidance. The following worksheets are provided at the end of these instructions:

- *Standard 6: Self-Assessment Summary Worksheet*
- *Standard 6: Establishment File Worksheet*

The *Standard 6: Self-Assessment Summary Worksheet* is designed to provide a listing of the establishment files or ROUTINE INSPECTIONS 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 selected establishments or ROUTINE INSPECTIONS. 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 selected for the SELF-ASSESSMENT.

STEP 1 – Assess 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 jurisdiction 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.

In addition, 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* to meet the requirements of Standard 6.

STEP 2 – File Selection Process

In order to meet the criteria in Standard 6, jurisdictions must select files for review. There are three different methods that can be utilized for file selection, outlined as option 1, 2 and 3. Jurisdictions must select one of the three options.

- **Option 1:** Review each inspection when an FBI RISK FACTOR or Public Health intervention was marked out of compliance;

  Part I – All inspection files are selected by the jurisdiction for review

- **Option 2:** Using a selection method as described in this standard set forth in Parts I-II**;**

Part I - Determine the number of establishment files to review

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 equal to 5% of the total establishments (up to a maximum of 70 files). This initial selection of sample files must be the first files reviewed.

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

Part II - Randomly select establishment files from the jurisdiction's inventory

Sample selection using a table of random numbers, or a random number generator is preferred. This can be performed with a card file, ledger, list, or automated data system. The card file, ledger, list, or automated database must be numbered or ordered in some fixed fashion so that the establishment files can be associated with the numbers selected by the random number generator.

There are many ways a jurisdiction can produce a listing of all the establishments in its inventory. The listing can be produced alphabetically; by permit number; permit date, etc. The establishment listing can be computer generated or it can be produced manually. Any method can be used as long as all the establishments are included once and only once.

When randomly selecting establishments, the self-assessor must perform the following steps:

1. Record the random numbers in the order they were selected under the column "Randomly Selected Numbers" on the *Standard 6: Self-Assessment Summary Worksheet*;
2. Identify the establishment file that corresponds to the randomly selected number recorded on the *Standard 6: Self-Assessment Summary Worksheet*; and
3. Record the establishment name or identification number for each of the randomly selected numbers on the *Standard 6: Self-Assessment Summary Worksheet*.

- **Option 3:** Using a selection method, other than those described in Option 1 and 2 above, established by the jurisdiction with written procedures that includes supporting documentation and worksheets that:

Part I – Describe the COMPLIANCE AND ENFORCEMENT review process;

Part II – Describe and include the random selection of establishment files or ROUTINE INSPECTIONS that have at least one Foodborne Illness or Public Health Intervention Violation marked OUT of compliance; and

Part III – Is equivalent to the published Standard 6 statistical model for the number of inspections reviewed and the method of selection.

Determine the need to review additional randomly selected establishment files.

If using Option 2 or 3, determine the need to review additional files or inspections. Randomly selected establishment files or ROUTINE INSPECTIONS should be removed from the sample only if:

- The establishment has not been in business long enough to have at least three ROUTINE INSPECTIONS; or
- Files in which no RISK FACTOR or public health intervention violation was documented on the "start-point" inspection.

When an establishment file is eliminated from the initial random draw, a new establishment file must be selected using the random selection methodology used for the original sample. The *Establishment File Worksheet* contains a specific page for listing the results from the randomly selected substitute establishment files. If there is a need to identify other substitute establishment files, continue to use the randomly generated numbers in the order they appear to identify the corresponding establishments from the jurisdiction's inventory. The file number and the name of the originally selected establishment that did not qualify for the SELF-ASSESSMENT review process must be recorded under the first column of the "Substitute Establishment" summary worksheet. This provides a direct association between the newly selected establishment file and the one it is replacing.

STEP 3 - Assess the Effectiveness of the Compliance & Enforcement Program

Each jurisdiction shall measure the effectiveness of their COMPLIANCE AND ENFORCEMENT program to determine if the jurisdiction has satisfactorily resolved FBI RISK FACTOR and Public Health Intervention violations.

The results of the review will be used to assess the success of the COMPLIANCE AND ENFORCEMENT program. The following process are methods that jurisdictions can use for Option 1 (all files reviewed) or for Options 2-3 (randomly selected establishment files or ROUTINE INSPECTIONS).

Conduct a review of each selected inspection (Option 1) , or randomly selected establishment file / ROUTINE INSPECTION (Option 2 or 3). When reviewing the COMPLIANCE AND ENFORCEMENT history for each of the randomly selected files, the self-assessor should use a form similar to the Standard 6: Establishment File Worksheet to document their findings. This worksheet is included at the end of these instructions.

For each selected establishment or randomly selected establishment listed on the *Standard 6: Self-Assessment Summary Worksheet*, the self-assessor must complete a separate *Standard 6: Establishment File Worksheet*.

When using Options 1 or 2, the worksheet must document the following information:

- The name of the establishment and the permit number in the upper left-hand corner of the "Establishment File Worksheet;"

- The "Start Point Inspection Date" under the heading provided. The "start-point" inspection will be the third most recent ROUTINE INSPECTION in the establishment's file at the time of the review if it shows a violation of one of the RISK FACTORS or public health interventions. If no RISK FACTOR or public health intervention violation is shown on that inspection, then the fourth most recent ROUTINE INSPECTION may be used if it shows a RISK FACTOR or public health intervention violation. If no violation of a risk factor or public health intervention is documented on the third or fourth most recent ROUTINE INSPECTION, then no "start-point" inspection exists for that establishment. Therefore,

that establishment's file "does not qualify" for the SELF-ASSESSMENT review process. If the establishment "does not qualify," the self-assessor must check the D.N.Q (did not qualify) box under the "Status of Reviewed File" and remove it from the review process. A substitute establishment file must be chosen using the second set of randomly selected numbers to replace this file.

- The Establishment File Worksheet lists ten foodborne illness RISK FACTORS and public health interventions along the top line. The self-assessor will record item numbers or other identifiers from its inspection form that correspond with each of the ten listed RISK FACTORS and public health intervention in the spaces provided adjacent the heading *Reference to local inspection items*. **Note:** The self-assessor should use the *Standard 1: Self-Assessment Worksheet for Part I - Inte*rventions *and Risk Factor Controls* to identify the jurisdiction's code requirements that correspond to the *Food Code* provisions included under each of the ten foodborne illness RISK FACTORS and intervention categories. If there is no corresponding local requirement for a particular foodborne illness RISK FACTORS or *FOOD CODE* INTERVENTION, that item can be marked as "Not Applicable" in the *Reference Key*. Jurisdictions are not penalized under Standard 6 for items in the *Food Code* that have not been adopted.

- Using the *Start Point Inspection Violations* row of the worksheet, the self-assessor places an "X" under the appropriate foodborne illness RISK FACTOR or public health intervention headings if a violation was noted on the "start-point" inspection. The "X" must be entered under the appropriate heading even if the violations were corrected on site.

When using Option 3, the worksheet must document the following information:

- The number of inspections selected which must be statistically equal to the Option 2 number of establishment files
- The name of the establishment and the permit number in the upper left-hand corner of the "Establishment File Worksheet;"

- The "Start Point Inspection Date" under the heading provided. The "start-point" inspection will be randomly selected and must have at least one out of compliance RISK FACTOR or public health intervention at the time of the review and sufficient time must have passed to evaluate follow up depending on individual jurisdictional policy, to qualify for the review. For files that do qualify (at least one out of compliance RISK FACTOR or public health intervention and sufficient time to assess follow up based on the jurisdiction's policy) the inspection should be reviewed to ensure the jurisdiction's COMPLIANCE AND ENFORCEMENT policy was followed for the inspection. Additional inspections in the establishment file may need to be reviewed to determine if the policy was followed. The self-assessor may need to go back several inspections to obtain the violation history or may need to look forward, at more recent inspections to see if a correction was made.

- Documentation showing that the self-assessor has gone back as far as needed to ensure the policy was followed.

- If no violation of a RISK FACTOR or public health intervention is documented, then no "start-point" inspection exists for that inspection. Also, if the "start-point" inspection has an out of compliance RISK FACTOR or public health intervention but there has been insufficient time based on the jurisdictional policy time frames to evaluate if COMPLIANCE AND ENFORCEMENT protocols have been followed it "does not qualify" for the SELF-ASSESSMENT review process. If the establishment "does not qualify," the self-assessor must check the D.N.Q (did not qualify) box under the "Status of Reviewed File" and remove it from the review process. A substitute inspection file must be chosen using the second set of randomly selected numbers to replace this file.

Self-Assessment Review Process (Using Option 1, 2, or 3):

- For the purposes of the SELF-ASSESSMENT, follow-up actions have been divided into three types:
  - *Was on-site corrective action taken?* – On-site corrective action that occurs at the time of a routinely scheduled inspection;
  - *Was follow-up corrective action taken?* – Follow-up action that occurs after the ROUTINE INSPECTION such as re-inspection, training, RISK CONTROL PLANS, and informal conferences;
  - *Was enforcement action taken?* – Enforcement activities such as fines permit suspension, hearings, mandated training, restriction of operations, embargo, etc.

  Completion of these three items requires a complete review of the selected establishment file. To facilitate the documentation of the file review, the self-assessor may complete the table provided at the bottom of the Establishment File Worksheet. The summary table provides a method for defining the acronyms and notations used on the worksheet to describe the type of COMPLIANCE AND ENFORCEMENT action taken. The self-assessor must review all the documentation in the establishment file from the "start-point" inspection forward to the current date to determine if follow-up action was taken and documented for each RISK FACTOR and public health intervention that was out of compliance on the "start-point" inspection.

- The self-assessor must review the follow-up actions for each RISK FACTOR and public health intervention violation documented on the "start-point" inspection. The self-assessor must determine if the follow-up actions complied with the jurisdiction's written procedures.
  - The self-assessor must place an "X" in the "File Meets the Standard 6 Criteria" box if:
    - The completed Worksheet shows at least one follow-up action in each column where a foodborne illness RISK FACTOR or public health intervention violation was marked on the "start-point" inspection; and
    - The jurisdiction's written procedure was followed.
  - The self-assessor must place an "X" in the "File Does NOT Meet the Standard 6 Criteria box." if:
    - The completed Worksheet shows that one or more of the "start-point" violations do not have at least one follow-up activity; or
    - The jurisdiction's written procedure was not followed for one or more follow-up activities.

- When the review for each randomly selected establishment file is completed, the self- assessor must indicate his or her findings on the Self-Assessment Summary Worksheet. Under the "Status of Reviewed File" column, the self-assessor must check one of the following boxes:
  - "YES" – indicating that the reviewed file meets the Standard 6 criteria.
  - "NO" – indicating that the reviewed file does not meet the Standard 6 criteria.
  - "D.N.Q." – indicating that the establishment file did not qualify for the assessment and a substitute file will need to be randomly selected and reviewed.

STEP 4 – Determine if the Standard 6 criteria are met

Standard 6 requires that 80 percent of the reviewed files 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 included in the calculation for this percentage. The self-assessor must determine if 80% of the establishment files reviewed met the Standard 6 criteria.

STANDARD 6 – COMPLIANCE AND ENFORCEMENT
SELF-ASSESSMENT SUMMARY AND WORKSHEET

Establishment Files

Jurisdiction Name:

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
1						
2						
3						
4						
5						
6						
7						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
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	Self-Assessor's General Comments
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
28						
29						
30						
31						
32						
33						
34						
35						
36						
37						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
38						
39						
40						
41						
42						
43						
44						
45						
46						
47						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
48						
49						
50						
51						
52						
53						
54						
55						
56						
57						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
58						
59						
60						
61						
62						
63						
64						
65						
66						
67						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
68						
69						
70						

STANDARD 6 – COMPLIANCE AND ENFORCEMENT
SELF-ASSESSMENT SUMMARY AND WORKSHEET

Substitute Establishment Files

Jurisdiction Name:

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
1						
2						
3						
4						
5						
6						
7						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
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	Self-Assessor's General Comments
18						
19						
20						