

## STANDARD 1 – REGULATORY FOUNDATION

### INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

#### Part I – *Food Code* Interventions and Risk Factor Controls

##### STEP 1 – Confirm Completion of the Self-Assessment for the Program’s Regulatory Foundation

The jurisdiction’s review of its code against the *FDA Food Code* should include documentation that a that a side-by-side comparison of its prevailing statutes, regulations, rules, and other pertinent requirements was completed.

The jurisdiction’s side-by-side comparison must include an assessment of the following items:

1. The major *Food Code* Public Health Intervention and Risk Factor control measures;
2. Good Retail Practices;
3. Compliance and Enforcement Administrative Provisions.

The side-by-side comparison should clearly identify the jurisdiction's corresponding requirements to the applicable *FDA Food Code* section.

*NOTE: If a jurisdiction adopted the current published edition or one of the two most recent editions of the FDA Food Code by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.*

##### STEP 2 – Determine *Food Code* Interventions and Risk Factor Controls Sections to Review

The verification AUDITOR must randomly select *FDA Food Code* sections to review. The AUDITOR should only review public health interventions and risk factor control categories that the jurisdiction reported as meeting on Part I of their *Standard 1: Self-Assessment Worksheet*. Part I of the jurisdiction's *Standard 1: Self-Assessment Worksheet* contains 94 *FDA Food Code* sections pertaining to Public Health Interventions and Risk Factor Controls. Each of these *FDA Food Code* sections has been assigned a number from 1 to 94.

For Part I, the verification AUDITOR must randomly select 15 *FDA Food Code* sections for the review. A list of random numbers can be obtained from the following web link: [www.randomizer.org](http://www.randomizer.org). Using the jurisdiction's *Standard 1: Self-Assessment Worksheet*, the verification AUDITOR must identify the *FDA Food Code* sections that correspond to the randomly selected numbers recorded on the Verification Audit Worksheet. This worksheet is included at the end of these instructions.

The AUDITOR should only review those *FDA Food Code* sections that the jurisdiction indicates were met. If a Public Health Intervention or Risk Factor Control *Food Code* section is selected that the jurisdiction did not meet, the verification AUDITOR should select a substitute *FDA Food Code* section to review.

### STEP 3 – Confirm Findings for *Food Code* Interventions and Risk Factor Controls

For each of the randomly selected regulatory requirements, the AUDITOR must compare the language in the jurisdiction's code to the corresponding *FDA Food Code* section to verify it's at least as stringent.

Record an "X" in the appropriate box on the *Standard 1: Verification Audit Worksheet* based on the determination.

**Yes** - Full Intent is Met or

**No** - Full Intent is not Met

In instances where the verification AUDITOR determines that the jurisdiction's language does not meet the criterion, they must explain on the *Standard 1: Verification Audit Worksheet*. Record the explanation under the column "If No, Auditor is to specify why the criterion is not met."

### STEP 4 – Document the Verification Audit Results for Part I

Part I of the *Standard 1: Self-Assessment Worksheet*, included at the end of these instructions, contains 11 public health interventions and risk factor controls:

1. Demonstration of Knowledge
2. Employee Health
3. Consumer Advisory
4. Approved Source
5. Time/Temperature
6. Protection from Contamination
7. Control of Hands as a Vehicle of Contamination
8. Good Hygienic Practices
9. Chemical
10. Conformance with Approved Procedures
11. Highly Susceptible Population

To meet any one of the 11 public health intervention and risk factor controls identified under the SELF-ASSESSMENT process, the SELF-ASSESSMENT must indicate that the jurisdiction's regulatory requirements address all *FDA Food Code* sections listed for that area. For initial listing, the jurisdiction's regulatory foundation must contain at least nine of the 11 public health interventions and risk factor controls. In order to fully meet the requirement of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third VERIFICATION AUDIT cycle.

If four or more of the 15 selected code sections reviewed during the audit process do not meet the stringency of language criteria, the Standard 1, Part I element fails to meet the criteria, and no further sampling is necessary. If one, two or three of the 15 selected code sections do not meet the stringency of the language criteria, but the jurisdiction continues to meet the required number of interventions and risk factor controls to meet the Standard, then randomly select an additional 15 *FDA Food Code* sections. No more than three total disagreements are acceptable in the 30 Code sections drawn for comparison in order for the audit to confirm the Part I element of Standard 1 as met. In addition, at least nine out of the 11 interventions and risk factor controls must still be met at the end of the first audit after the disagreements are taken into account, and the jurisdiction must meet 11 out of the 11 interventions and risk factor controls by the third regular audit in order to meet the Standard 1 criteria.

Examples of documents that may be reviewed:

- The jurisdiction's statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that govern the operation of its food establishments;
- Version of the *FDA Food Code* that was used for the SELF-ASSESSMENT;
- Completed *Standard 1: Self-Assessment Worksheet, Part I – Food Code Interventions and Risk Factor Controls*; and
- If applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

## STANDARD 1 – REGULATORY FOUNDATION VERIFICATION AUDIT WORKSHEET

### Part I – *Food Code* Interventions and Risk Factor Control

Number of Sections Reviewed	Randomly Selected Number	Corresponding <i>FDA Food Code</i> Chapter from Part I Interventions and Risk Factors Self-Assessment Worksheet	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	NO Full Intent is Not Met	If no, auditor must specify why criterion is not met
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

**NOTES**

1. If there is Agreement that ALL 15 selected code sections meet the stringency of the language criteria in the *FDA Food Code*, proceed to Part II.
2. If one, two or three of the 15 selected code sections do not meet the stringency of the language criteria in the *FDA Food Code*, then complete the Supplemental Part I Section of the worksheet by randomly selecting another 15 Interventions and Risk Factor code sections to review.
3. If four or more of the 15 selected code sections do not meet the stringency of the language criteria in the *FDA Food Code*, then the jurisdiction does not meet the Standard 1 criteria for *Food Code* Interventions and Risk Factors.

## STANDARD 1 – REGULATORY FOUNDATION VERIFICATION AUDIT WORKSHEET

### Supplement to Part I – *Food Code* Interventions and Risk Factor Control

Number of Sections Reviewed	Randomly Selected Number	Corresponding <i>FDA Food Code</i> Chapter from Part I Interventions and Risk Factors Self-Assessment Worksheet	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	<u>NO</u> Full Intent is Not Met	If no, auditor must specify why criterion is not met
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

**NOTES**

- If more than three of the 30 total selected code sections do not meet the stringency of the language criteria in the FDA Food Code, then the jurisdiction does not meet the Standard 1 criteria for Food Code Interventions and Risk Factors.*