STANDARD 1 – REGULATORY FOUNDATION
INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

Program Self-Assessment and Verification Audit Form

The *Standard 1: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the SELF-ASSESSMENT and the VERIFICATION AUDIT process. 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 1 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self-Assessment

Jurisdictions conducting a SELF-ASSESSMENT of the Regulatory Foundation component must indicate on the form if each of the listed Standard 1 criteria are 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 1 criteria listed on this form are available for review.

The *Standard 1: Program Self-Assessment and Verification Audit Form* is divided into four sections:

1. Assessment of the Program's Regulatory Foundation;
2. *Food Code* Interventions and Risk Factors;
3. Good Retail Practices; and
4. Compliance and Enforcement.

The self-assessor must review each Standard 1 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 1: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 1 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the *Standard 1: 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 1: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction must provide the AUDITOR with their completed *Standard 1: Program Self-Assessment and Verification Audit Form* and any worksheets or documents used to support and demonstrate that the Standard 1 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 1: Program Self- Assessment and Verification Audit Form*. The self-assessor must

- Enter their contact information;
- Document if the jurisdiction met the Standard 1 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 1 criteria.

Documenting the Findings from the Verification Audit

The self-assessor must provide their completed *Standard 1: Program Self-Assessment and Verification Audit Form* to the AUDITOR for review. The AUDITOR must indicate on the *Standard 1: 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 an "X" in the "NO" box under the "Auditor's Verification" column on 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 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 1 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 page one of the *Standard 1: Program Self-Assessment and Verification Audit Form*. The AUDITOR must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 1 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 1 criteria if the AUDITOR does not confirm the SELF-ASSESSMENT findings.

STANDARD 1 – REGULATORY FOUNDATION
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 1 Self-Assessment Was Completed:	
Self-Assessment Indicates That the Jurisdiction MEETS the Standard 1 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standard 1 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 1 Was Completed:	
Verification Audit Indicates That the Jurisdiction MEETS the Standard 1 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Standard 1 is true and correct. **Signature of the Verification Auditor:**	

STANDARD 1 – REGULATORY FOUNDATION
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. Assessment of the Program's Regulatory Foundation	a) The jurisdiction has documentation of its side-by-side comparison of its statutes, regulations, rules, and other pertinent requirements against the current published edition of the *FDA Food Code* or one of the two most recent previous editions of the *FDA Food Code*.						
1. Assessment of the Program's Regulatory Foundation	b) The jurisdiction's side-by-side comparison includes an assessment of major Food Code Interventions and Risk Factors, Good Retail Practices, and Compliance/ Enforcement Administrative requirements.						
1. Assessment of the Program's Regulatory Foundation	c) The regulatory foundation assessment clearly identifies the jurisdiction's corresponding requirement to the applicable *Code* section. The assessment provides a determination as to whether a specific provision in the jurisdiction's regulation meets the intent of the corresponding *FDA Food Code* section.						

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. *Food Code* Interventions and Risk Factors	a) The jurisdiction's initial code assessment indicates that the agency's regulatory requirements contain at least 9 of the 11 *FDA Food Code* intervention and risk factor controls. By the third verification audit, the jurisdiction's assessment indicates that the agency's regulatory requirements contain all 11 of the *FDA Food Code* intervention and risk factor controls. ***NOTE**: Auditor's random selection of Food Code Intervention and Risk Factor Control Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's rules, regulations, ordinances, code, or statutes.* *Documentation from:* *Part I - Self-Assessment Worksheet* *Part I - Verification Audit Worksheet*						

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
3. Good Retail Practices	a) The jurisdiction's code assessment indicates that regulatory requirements contain at least 95 percent of the *FDA Food Code* Good Retail Practices Sections. ***NOTE**: Auditor's random selection of Good Retail Practices Code Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's code or statutes.* *Documentation from:* *Part II - Self-Assessment Worksheet* *Part II - Verification Audit Worksheet*						

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. Compliance and Enforcement	a) The jurisdiction's code assessment indicates that regulatory requirements contain ALL the *FDA Food Code* Compliance and Enforcement Sections identified in the Standard, except item 7 and 12 (see note in *Part III – Self Assessment Worksheet*). ***NOTE**: Auditor's random selection of Compliance and Enforcement Code Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's code or statutes.* *Documentation from:* *Part III - Self Assessment Worksheet* *Part III - Verification Audit Worksheet*						
GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT							