

Appendix H

STATE IMPLEMENTATION AGREEMENT And YEAREND EVALUATION

Background

The Contract Inspection Audit Program (hereafter known as the Audit Program) is described in FDA Field Management Directive No. 76 (FMD-76). The FMD-76 provides procedures for auditing all contract inspection programs. State agencies have the opportunity to assume responsibility for auditing their human food and animal food contract inspections. The transition to a state-based Audit Program occurs in two phases (Phase II and Phase III) after the District has completed Phase I of the Audit Program. Phases II and III are described in FMD-76. This option does not apply to other contract inspection programs including egg, tissue residue, and medical device.

Planned Resources

- a. Funding
 1. FDA/OP will provide funding for state inspectors to attend the audit courses.
 2. FDA/OP will provide funding to the state agency for implementation of the Audit Program.
- b. Personnel
 1. The Program Division or state agency will provide auditors to train and verify the performance of state auditors assigned to audit human food and animal food contract inspections.
 2. The state agency will provide state supervisors, team leaders, or senior inspectors to be trained as auditors.

Reporting

Refer to Appendix B.2 in FMD-76 for specific reporting instructions.

PRINT

RESET

APPENDIX H

STATE IMPLEMENTATION AGREEMENT and YEAREND EVALUATION

I. CONTACT INFORMATION

1. Program Division/District:	2. Program Division/District Contact:
3. State Agency:	4. State Agency Contact:

II. CONTRACT INFORMATION

1. Period of Performance: start date: _____ end date: _____
2. Audit Phase: Phase II <input type="checkbox"/> Phase III <input type="checkbox"/>
3. Commodity: Human Food <input type="checkbox"/> Animal Food <input type="checkbox"/>

III. STATE BASED AUDIT PROGRAM

The State agency has provided the training required by the human food or animal food inspection contract and the FMD-76 to the State inspectors designated as auditors for the Audit Program. Qualifications for auditors are stated in FMD-76. The Program Division/District agrees that the State program is ready to implement the Audit Program.

Under this agreement, the FDA and the State agency will:

- a. Follow the requirements in the FMD-76 and human food or animal food contract Statement of Work (SOW).
- b. Develop a plan to train and verify the performance of State auditors assigned to audit contract inspections.
- c. Develop an audit plan based on the firms assigned for inspection by the State agency to verify the performance of State inspectors. The firm selection should be based on the inspection priorities listed in the "Statement of Work" section of the contract and the contract obligation of the State.
- d. Develop a plan for State inspectors who require remedial training to resume conducting inspections or audits under FDA contract.
- e. Complete separate forms for Human Food and Animal Food programs using either page 3 or page 4 as appropriate.
- f. Complete Section VII, Yearend Evaluation, of this form for the contract performance period.

IV. PLANNED AND COMPLETED AUDITS

	Planned	Completed*
1. Total number of contract inspections		
2. Total number of contract audits		
3. Number of training audits for State auditor trainees completed by State and/or District		
4. Number of verification audits for State auditor trainees completed by State and/or District		
5. Number of verification audits for State auditors completed by State		
6. Number of verification audits for State auditors completed by District		
7. Number of contract audits completed by District		
8. Number of contract audits completed by State agency		
9. Number of joint inspections completed by District		
10. Number of contract audits rated as acceptable		
11. Number of contract audits rated as needs improvement		

* To be completed by Program Division/District.

V. STATE AUDITORS

List all state auditors. Identify the program area(s) in which the state auditors are trained to conduct audits by placing a check mark in the appropriate box. Additional State auditors should be listed on the Continuation Sheet.

If requested by the District, the state agency will provide records to verify the state auditors completed the training requirements in FMD-76.

Human Food State Auditor	GMP	LACF	Acidified Food	Seafood HACCP	Juice HACCP
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

VI. SIGNATURE SECTION

Signatures of Responsible Parties (To be signed prior to contract award and submitted with contract proposal)

For the State Agency:

Name:	Title:
Signature:	Date:

For the U.S. Food and Drug Administration:

Name:	Title:
Signature:	Date:

V. STATE AUDITORS

List all State auditors. Identify the program area(s) in which the State auditors are trained to conduct audits by placing a check mark in the appropriate box. Additional State auditors should be listed on the Continuation Sheet.

If requested by the District, the State agency will provide records to verify the State auditors completed the training requirements in FMD-76.

Animal Food State Auditor	BSE	Licensed Medicated Animal Food	Unlicensed Medicated Animal Food
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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For the State Agency:

Name:	Title:
Signature:	Date:

For the U.S. Food and Drug Administration:

Name:	Title:
Signature:	Date:

VII. YEAREND EVALUATION

This section will be completed by the Program Division/District. The state will be evaluated on its overall work performance during the contract year, not the outcome of one contract audit. The Program Division/District and State agency should follow the procedures in FMD-76 when program or performance deficiencies occur. An unacceptable audit will not cause a contract to be altered or unpaid nor will payment for the contract inspection be withheld.

1. Evaluation (*record strengths/weaknesses*):

2. Date yearend evaluation was discussed between Program Division/District and state agency:

3. Names and titles of persons who participated in yearend evaluation: