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 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 Program Division 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 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 experienced (qualified) staff to be trained as auditors. This could include supervisors, team leaders or inspectors.

Reporting

Refer to Appendix B.2 (Human Food) and C.2 (Animal Food) in FMD-76 for specific reporting instructions.

APPENDIX H

STATE IMPLEMENTATION AGREEMENT
and
YEAREND EVALUATION

1. Program Division	2. Responsible FDA Division Contact
3. State Agency	4. Responsible State Agency Contact

1. Period of Performance:	Start date		End date	
2. Audit Phase:	Phase II	☐	Phase III	☐
3. Commodity:	Human Food	☐	Animal Food	☐

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 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 Section VII, Yearend Evaluation, of this form for the contract performance period. Complete separate forms for Human Food and Animal Food programs.

IV. PLANNED AND COMPLETED AUDITS

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

* To be completed by Program Division.

V. HUMAN FOOOD 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 applicable Continuation Sheet.

If requested by the division, 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
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*referenced as Food Inspections on the contract (includes Limited Scope PC and Modified Req)

VI. SIGNATURE SECTION

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

For the State Agency - Director of state inspection program signs

Name:	Title:
Signature:	Date:

For the U.S. Food and Drug Administration – Program Division Director signs

Name:	Title:
Signature:	Date:

V. ANIMAL FOOD 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 Program Division, the state agency will provide records to verify the state auditors completed the training requirements in FMD-76.

Animal Food State Auditor	BSE	Medicated Animal Food	PC - Animal Food	PCAF Part 507 CGMP
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VI. SIGNATURE SECTION

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

For the State Agency - Director of state inspection program signs

Name:	Title:
Signature:	Date:

For the U.S. Food and Drug Administration – Program Division Director signs

Name:	Title:
Signature:	Date:

VII. YEAREND EVALUATION

This section will be completed by the program division. The state will be evaluated on its overall work performance during the contract year, not the outcome of one contract audit. The program division 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 and state agency:

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

V. HUMAN FOOD CONTINUATION SHEET

Human Food State Auditor	GMP	LACF	Acidified Food	Seafood HACCP	Juice HACCP
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Additional Notes:

V. ANIMAL FOOD CONTINUATION SHEET

Animal Food State Auditor	BSE	Medicated Animal Food	PC - Animal Food	PCAGF Part 507 CGMP
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Additional Notes: