

EXECUTIVE CORRESPONDENCE

Manufactured Food Regulatory Program Standards

DRAFT DOCUMENT

This document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing availability of the draft document. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or to the Division of Federal-State Relations (HFC-150), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, rm. 12-07, Rockville, MD 20857. All comments should be identified with the Docket Number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document contact:

Beverly Kent (HFC-150)
Division of Federal-State Relations
Office of Regional Operations
Phone: 716-541-0331
Email: Beverly.kent@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs

July 2006

2006 DRAFT **DO NOT WRITE ON THIS COVER AS IT IS INTENDED FOR RE-USE** *GD 1*
RETURN IT WITH THE FILE COPIES TO ORIGINATING OFFICE

Table of Contents

Introduction	1
Standard No. 1	Regulatory Foundation	3
Standard No. 2	Training Program	5
Standard No. 3	Inspection Program	8
Standard No. 4	Inspection Audit Program	11
Standard No. 5	Food-related Illness and Outbreaks and Food Defense Preparedness and Response	15
Standard No. 6	Compliance and Enforcement Program	18
Standard No. 7	Industry and Community Relations	20
Standard No. 8	Program Resources	21
Standard No. 9	Program Assessment	24
Standard No. 10	Laboratory Support	26
Appendix 1	Self-Assessment Worksheet -- Standard No. 1	28
Appendix 2.1	Self-Assessment Worksheet -- Standard No. 2	32
Appendix 2.2	Individual Training Record	33
Appendix 3.1	Self-Assessment Worksheet -- Standard No. 3	38
Appendix 3.2	Risk Classification Criteria for Food Plants	41
Appendix 4.1	Self-Assessment Worksheet -- Standard No. 4	44
Appendix 4.2	Summary of Field Inspection Audit Findings	45
Worksheet 4.2	Calculation of the performance ratings for the field inspection audits	46
Appendix 4.3	Summary of Inspection Report Audit Findings	48
Worksheet 4.3	Calculation of the performance rating for the inspection report audits	49
Appendix 4.4	Summary of Sample Report Audit Findings	52
Worksheet 4.4	Calculation of the performance rating for the sample report audits	53
Appendix 4.5	Contract Audit -- FDA Form 3610	55
Appendix 4.5a	Guidance for Completing the Contract Audit Form	64
Appendix 4.6	Inspection Report Audit Form	74
Appendix 4.7	Sample Report Audit Form	79
Appendix 4.8	Corrective Action Plan	81
Appendix 5.1	Self-Assessment Worksheet -- Standard No. 5	82
Appendix 5.2	Memorandum of understanding between the department of health and the department of agriculture concerning the investigation of foodborne illnesses associate with food service establishments and food plants	84
Appendix 6.1	Self-Assessment Worksheet -- Standard No. 6	87
Appendix 6.2	Summary of Compliance and Enforcement Activities	89
Worksheet 6.2	Calculation of the level of conformance to compliance procedures	90
Appendix 7	Self-Assessment Worksheet -- Standard No. 7	92
Appendix 8.1	Self-Assessment Worksheet -- Standard No. 8	93
Appendix 8.2	Calculation for determining a required number of inspectors	94
Appendix 8.3	Inspection Equipment	95
Worksheet 9	Self-Assessment and Improvement Tracking	96
Appendix 10	Self-Assessment Worksheet -- Standard No. 10	97

INTRODUCTION

Background

The food safety regulatory system in the United States is a tiered system that involves Federal, State, and local governments. The Food and Drug Administration (FDA) is responsible for ensuring that all foods moving in interstate commerce, except those under United States Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. State agencies conduct inspection and regulatory activities that help ensure that safe food is produced, processed, or sold within their jurisdictions. Many State agencies also conduct food plant inspections under contract with the FDA. These inspections are performed under the States' laws and authorities or the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or both. To maximize the use of resources among the FDA and the State governments, particularly when their jurisdictions overlap, their inspection programs should be equivalent in effect.

In June 2000, the Department of Health and Human Services' Office of the Inspector General (OIG) released a report of FDA's oversight of State contracts. In this report, the OIG recommended that [FDA] take steps to promote "equivalency among Federal and State food safety standards, inspection programs, and enforcement practices."¹ In response to their findings, FDA established a committee to draft a set of quality standards for manufactured food regulatory programs. The committee was comprised of officials from FDA and from State agencies responsible for the regulation and inspection of food plants².

Scope

These draft Manufactured Food Regulatory Program Standards (draft program standards) establish a uniform foundation for the design and management of State programs³ responsible for the regulation of food plants. The elements of the draft program standards describe best practices of a high-quality regulatory program. Achieving conformance with them will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation.

The draft program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. These elements include the program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each standard has corresponding self-assessment worksheets and certain standards have

¹ Office of Inspector General, *FDA Oversight of State Food Firm Inspections: OEI-01-98-00400* (Department of Health and Human Services, 2000), p. 5.

² A building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food as defined by 21 CFR Part 110.3 (k).

³ Program defined as an operational unit(s) that is responsible for the regulatory oversight of food plants.

42 supplemental worksheets and forms for determining a level of conformance with such
43 standards. The State program is not required to use the forms and worksheets contained
44 herein; however, alternate forms should be comparable to the forms and worksheets for
45 draft program standards. These draft program standards do not address the performance
46 appraisal processes that a State agency may use to evaluate individual employee
47 performance.

48

49 When finalized, FDA will use the program standards as a tool to improve contracts with
50 States. The program standards will assist both FDA and the States in fulfilling their
51 regulatory obligations. The implementation of the program standards will be negotiated
52 as an option for payment under the State contract. States that are awarded this option will
53 be expected to implement the program standards to evaluate and improve their
54 manufactured food program. FDA recognizes that full use and implementation of the
55 program standards by those States will take several years. Such States will, however, be
56 expected to implement improvement plans to demonstrate that they are moving toward
57 full implementation.

58

59 The goal is to enhance food safety by establishing a uniform basis for measuring and
60 improving the performance of manufactured food programs in the United States. The
61 development and implementation of these program standards will help Federal and State
62 programs better direct their regulatory activities at reducing foodborne illness hazards in
63 food plants. Consequently, the safety and security of the United States food supply will
64 improve.

65

66

Public Comment

67

68 FDA is seeking input from all interested parties. The draft program standards, which
69 establish a uniform foundation for the design and management of State programs
70 responsible for regulation of plants that manufacture, process, pack, or hold foods in the
71 United States are being distributed for comment purposes only and are not intended for
72 implementation at this time.

73

74

75

76

77
78 **STANDARD No. 1**
79 **Regulatory Foundation**

80 **1.1 Purpose**

81
82 This standard describes the elements of the regulatory foundation⁴ used by a State
83 program to regulate food plants.

84
85 **1.2 Requirement Summary**

86
87 The State program has the legal authority and regulatory provisions to perform
88 inspections and investigations, gather evidence, collect samples, and take enforcement
89 actions under Federal and State laws.

90
91 **1.3 Program Elements**

- 92
93 a. The State program has the legal authority to inspect food plants, gather evidence,
94 collect and analyze samples, and take enforcement actions for adulteration or
95 misbranding of foods equivalent in effect to sections of the FD&C Act specified in
96 appendix 1.
97
98 b. The State program enforces regulatory provisions equivalent in effect to the
99 corresponding Federal regulations specified in appendix 1. In the absence of a
100 corresponding law or regulation, the State program will explain how equivalent
101 regulatory authority is met in appendix 1.
102
103 c. The State program uses its laws and regulations to broaden its scope of regulatory
104 authority.

105
106 **1.4 Outcome**

107
108 The State program has the legal authority and regulatory provisions to protect the public
109 health by ensuring the safety and security of the food supply.

⁴ Laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of a food plant or manufacturing establishment.

110 **1.5 Documentation**

111

112 The State program maintains the records listed here.

113

114 • Appendix 1 Self-assessment worksheet

115 • The statutes, regulations, rules, ordinances, and other prevailing regulatory
116 requirements that: (1) apply to the operation of food plants, (2) delegate authority
117 to the State agency, and (3) stipulate the process by which the State agency
118 establishes its authority, for example, the administrative rulemaking process

119 **STANDARD No. 2**
120 **Training Program**

121
122 **2.1 Purpose**

123
124 This standard defines the essential elements of a training program for inspectors.
125

126 **2.2 Requirement Summary**

127
128 The State program has a training plan that ensures all inspectors receive training required
129 to adequately perform their work assignments. The plan provides for basic and advanced
130 food inspection training as well as continued training for professional development in the
131 field of food processing.
132

133 **2.3 Program Elements**

134
135 The State program maintains a history of the training provided to all inspectors.
136 Appendix 2.1 may be used to document all training provided to inspectors. Or, the
137 training history may be recorded and retained electronically.
138

139 The State program provides, or otherwise makes available, inspection training for all
140 inspectors. A training record similar to appendix 2.2 is maintained.
141

142 a. Basic Food Inspection Training

143
144 The State program requires that each inspector complete a basic food inspection training
145 curriculum that consists of coursework and field training described here.
146

147 Coursework

148
149 The State program requires each inspector to complete coursework in the following areas
150 within 24 months of his or her start date with the State program.
151

- 152 • Prevailing statutes, regulations, and ordinances
- 153 • Public health principles
- 154 • Food defense awareness training
- 155 • Communications skills
- 156 • Microbiology
- 157 • Epidemiology
- 158 • Basics of HACCP
- 159 • Basic labeling
- 160 • Control of allergens

161
162 Coursework is obtained from sources listed here.

- 163
164 • In-house training provided by a government agency
165 • Distance learning, for example, satellite downlinks or web-based training⁵
166 • Colleges, schools, and research centers

167
168 Field training

169
170 The State program requires that each inspector participate in a minimum of ten joint
171 inspections with a qualified trainer and receive a minimum of two acceptable evaluations
172 from the trainer. Joint inspections are conducted in firms that are representative of the
173 food plants in the State program's establishment inventory. Each inspector will complete
174 the minimum field training requirements within 18 months of his or her start date with
175 the State program and prior to conducting independent inspections.

176
177 b. Advanced Food Inspection Training

178
179 The State program requires each inspector who will conduct specialized food inspections
180 to complete an advanced inspection training curriculum that consists of relevant
181 coursework and field training as described here.

182
183 Coursework

184
185 The State program requires each inspector who will perform specialized food inspections
186 to complete coursework listed here for such inspections.

- 187
188 • Applications of epidemiology & foodborne illness investigations
189 • Traceback investigations
190 • Nutrition labeling
191 • Acidified foods
192 • Low acid canned foods
193 • Principles of juice HACCP
194 • Principles of seafood HACCP

195
196 Field training

197
198 The State program requires that each inspector who will conduct specialized food
199 inspections participates in three joint inspections with a qualified trainer and receive a
200 minimum of two acceptable evaluations from the trainer. The joint inspections are
201 conducted in food plants representative of the specialty area. The inspector will complete
202 the minimum field training requirements prior to performing independent inspections.
203

⁵ FDA/ORR U classroom and long distance learning courses are listed at: http://www.fda.gov/ora/training/course_ora.html

204 c. Continuing education

205

206 The State program requires that each inspector participate in continuing education that
207 includes coursework and inspections. Every 36-month interval, each inspector is
208 required to receive 36 contact hours of classroom training and participate in at least two
209 joint inspections with a qualified trainer. These joint inspections are intended to assist
210 the inspector with applying what was learned in the classroom to what should be covered
211 during an inspection.

212 [Note: The 36-month continuing education interval starts when the basic training cycle is
213 complete -- 24 months after the employee's start date.]

214

215 One contact hour is earned for each hour of participation in the continuing education
216 activities from sources described in Section 2.3a.

217

218 **2.4 Outcome**

219

220 The State program has trained inspectors with the knowledge, skills, and abilities to
221 competently inspect food plants.

222

223 **2.5 Documentation**

224

225 The State program maintains the records listed here.

226

- 227 • Appendix 2.1 Self-assessment worksheet
- 228 • Appendix 2.2 Individual training record
- 229 • Documents verifying successful completion of required courses
- 230 • Course description, if necessary
- 231 • Field training and evaluations
- 232 • Continuing education certificates

233

234
235
236

STANDARD No. 3 Inspection Program

237 **3.1 Purpose**

238

239 This standard describes the elements of an effective inspection program for food plants.

240

241 **3.2 Requirement Summary**

242

243 The State program has an inspection system. This system provides the foundation for
244 inspection of food plants to determine compliance with the laws administered by Federal,
245 State, and local governments. In addition, the State program has: (1) an established recall
246 system, (2) a system to respond appropriately to consumer complaints, (3) a system to
247 resolve industry complaints about inspections, and (4) a recordkeeping system for all
248 elements of the inspection program.

249

250 **3.3 Program Elements**

251

252 a. Risk-based inspection program

253 The State program maintains an accurate inventory of its food plants. The inventory is
254 categorized by the degree of risk associated with the likelihood that a food safety or
255 defense incident will occur. Inspections are prioritized, frequencies assigned, and
256 resources allocated based on risk categories assigned to a food plant or product, the
257 manufacturing processes, and the inspection history of the food plant. Appendix 3.2
258 contains examples of factors that may be considered in defining risk categories.

259

260 b. Inspection protocol

261 The State program has written policies and procedures for inspecting food plants that
262 require the inspectors to:

263

- 264 1. Review the previous inspection report and consumer complaints
- 265 2. Have appropriate equipment⁶ and forms needed to conduct inspections
- 266 3. Establish [FDA] jurisdiction
- 267 4. Select an appropriate product for the inspection and, if necessary, make
268 appropriate adjustments based on what the plant is producing
- 269 5. Assess employee activities critical to the safe and sanitary production and storage
270 of food
- 271 6. Properly evaluate the likelihood that conditions, practices, components, and/or
272 labeling could cause the product to be adulterated or misbranded
- 273 7. Recognize significant violative conditions or practices if present and record
274 findings consistent with State program procedures

⁶ Standard number 8, appendix 8.3 Inspection Equipment

- 275 8. Distinguish between significant and insignificant observations, and isolated
- 276 incidents versus trends
- 277 9. Review and evaluate the appropriate records and procedures for the
- 278 establishment's operation and effectively apply the information obtained from this
- 279 review [during the inspection]
- 280 10. Collect adequate evidence and documentation to support inspection observations
- 281 in accordance with State program procedures
- 282 11. Verify correction of deficiencies identified during the previous inspection
- 283 12. Behave professionally and demonstrate proper sanitary practices during the
- 284 inspection
- 285

As appropriate for seafood and juice processors subject to HACCP regulations:

- 286
- 287
- 288
- 289 13. Use the *Fish and Fishery Products Hazards and Controls Guide* or the *Juice*
- 290 *HACCP Hazards and Controls Guide*, when and as appropriate, to identify and
- 291 evaluate the hazards associated with the product and process
- 292 14. Assess the firm's implementation of sanitation monitoring for the applicable eight
- 293 key areas of sanitation
- 294 15. Review the firm's HACCP plan (or necessary process controls in the absence of a
- 295 HACCP plan) and applicable monitoring verification and corrective action
- 296 records, including those related to sanitation
- 297 16. Recognize deficiencies in the firm's monitoring and sanitation procedures through
- 298 in-plant observations

- 299
- 300 17. Make appropriate introductions, and explain the purpose and scope of the
- 301 inspection
- 302 18. Use suitable interviewing techniques
- 303 19. Explain findings clearly and adequately throughout the inspection
- 304 20. Alert the firm's person in charge when an immediate corrective action is
- 305 necessary
- 306 21. Answer questions and provide information in an appropriate manner
- 307 22. Write findings accurately, clearly, and concisely on the State document and
- 308 provide a copy to the firm's person in charge
- 309

310 c. Food recalls

311

312 The State program has a food recall system.

313

314 The State program has written recall procedures for:

- 315
- 316 1. Sharing information about recalls with affected government agencies
- 317 2. Promptly removing recalled food products from the market
- 318 3. Performing recall audit checks
- 319 4. Identifying and maintaining records about essential recall information
- 320

321

322 d. Consumer complaints

323

324 The State program has a system for handling consumer complaints. The system contains
325 written procedures for receiving, tracking, evaluating, answering, closing, and
326 maintaining records of consumer complaints.

327

328 e. Food industry inspection complaints

329

330 The State program has a system to resolve industry complaints about inspections. The
331 system contains written procedures for receiving, evaluating, answering, and maintaining
332 records of industry complaints about inspections.

333

334 3.4 Outcome

335

336 The State program has an inspection program that reduces the occurrence of foodborne
337 illness, injury, or allergic reaction by:

338

- 339 1. Focusing inspection resources on high risk plants, products, and processes
- 340 2. Obtaining immediate corrections and long-term improvements by
341 manufactured food processors
- 342 3. Responding efficiently to prevent unsafe products from reaching consumers or
343 to remove unsafe food from the human food system

344

345 3.5 Documentation

346

347 The State program maintains the records listed here.

348

- 349 • Appendix 3.1 Self-assessment worksheet
- 350 • An official establishment inventory of food plants
- 351 • Written procedures and rationale used for grouping establishments based on food
352 safety risk, including the inspection frequency assigned to each defined risk-based
353 establishment category
- 354 • Inspection policies and procedures including guidelines for performing
355 inspections that require immediate corrective action and re-inspection
- 356 • Written procedures for food recalls, consumer complaints, and industry
357 complaints about inspections
- 358 • Records for the three previous years, including inspection reports and reports
359 pertaining to food recalls and follow-up activities, consumer complaints, and
360 industry complaints about inspections

361

362 **STANDARD No. 4**
363 **Inspection Audit Program**

364
365 **4.1 Purpose**

366
367 This standard describes the basic quality assurance reviews necessary to: (1) evaluate the
368 effectiveness of the inspection program, (2) recognize trends in inspectional coverage,
369 and (3) identify best practices used to achieve quality inspections and sample collections.
370

371 **4.2 Requirement Summary**

372
373 The State program conducts quality assurance reviews to assess the effectiveness of its
374 inspections and sample collections. The data used to determine such performance is
375 obtained from observing an inspector conducting an inspection and the inspector's
376 written reports. This standard is not intended, however, to evaluate individual
377 performance.
378

379 **4.3 Program Elements**

380
381 The State program implements a quality assurance program (QAP) that identifies
382 elements of its inspection and sample collection processes that need improvement.
383 The QAP has two components: (1) a field audit component, which is an on-site
384 performance evaluation of inspections and (2) a desk audit component, which is a
385 performance review of the written reports of inspections and sample collections.
386 Worksheets 4.2, 4.3, and 4.4 will be used to: (1) calculate an overall audit rating for
387 each review (field inspection performance and written reports of inspections and
388 samples collections) and (2) evaluate ratings for a single performance factor.
389 Managers use the ratings to identify specific aspects of its inspection program that
390 need improvement. Performance ratings that fall below 80 percent indicate a need for
391 improvement and require corrective action.
392

393 The State program compiles and summarizes the results of the field and desk audits
394 annually and determines an overall performance rating, which is reported on the self-
395 assessment worksheet (appendix 4.1). The results of the audits are evaluated every
396 36 months to: (1) determine the effectiveness of the food inspection program, (2)
397 recognize trends in inspectional coverage, and (3) identify best practices used to achieve
398 quality inspections and sample collections.
399

400 The worksheets in appendices 4.1-4.8 are used to record and summarize audit findings.
401 Or, the State program may use comparable worksheets to record audit findings.

402

403 a. Field Inspection Audit

404

405 Supervisory inspector, senior inspector, or team leader conducts field inspection
 406 audits to verify that inspections are consistently performed according to the
 407 established policies and procedures. The quality of each inspection is audited
 408 using the performance factors identified on appendix 4.5. An overall rating for
 409 field inspection performance is calculated using worksheet 4.2.

410

411 **Frequency** The QAP requires a minimum of two field inspection audits
 412 of each inspector be conducted every 36 months.
 413 Inspections selected for audit should include high-risk food
 414 firms such as seafood facilities, juice processors, and low-
 415 acid canned food operations.

416

417 **Performance** Appendices 4.5 and 4.2 (including worksheet 4.2)

418 **Documentation**

419

420 **Performance** Inspection procedures and policies described in
 421 **Factors** standard number 3 and appendix 4.5

422

423 b. Inspection Report Audit

424

425 The QAP requires periodic review of inspection reports to verify that inspectional
 426 findings are obtained and reported according to established procedures and policies.
 427 The quality of each inspection report is audited using the performance factors listed in
 428 appendix 4.6. An overall inspection report rating is calculated using worksheet 4.3.

429

430 **Frequency** The State program determines the number of reports for
 431 review based on its inventory of food plants and the number
 432 of inspections completed in the past 12 months. At least
 433 75 reports are randomly selected across inspectors and
 434 supervisors, and geographical locations. If less than
 435 75 inspections were conducted, all inspection reports will be
 436 reviewed.

437

438 **Performance** Appendices 4.6 and 4.3 (including worksheet 4.3)

439 **Documentation**

440

441 **Performance** Performance factors listed on appendix 4.6, and policies
 442 **Factors** and procedures established by the State program.

443

444 c. Sample Report Audit

445

446

447

448

449

450

The QAP requires periodic review of sample reports to verify that samples were properly collected, identified, and submitted according to established procedures and policies and that appropriate information was recorded. The quality of each sample report is audited using the performance factors listed in appendix 4.7. An overall sample report rating is calculated using worksheet 4.4.

451

452

453

454

455

456

457

458

459

Frequency

The State program determines the number of reports for review based on the number of samples collected in the past 12 months. At least 75 reports are randomly selected across inspectors and supervisors, and according to sample type, for example, microbiology, aflatoxin, or low-acid canned foods. If less than 75 samples were collected, all reports will be reviewed.

460

461

462

**Performance
Documentation**

Appendices 4.7 and 4.4 (including worksheet 4.4)

463

464

465

**Performance
Factors**

Performance factors listed in appendix 4.7, and policies and procedures established by the State program.

466

d. Corrective Action Plan

467

468

469

470

471

A corrective action plan is required when an overall audit rating or the rating for an individual performance factor falls below 80 percent. Appendix 4.8 is used to document how the deficiency was corrected.

472

4.4 Outcome

473

474

475

476

477

The State program systematically evaluates and improves its inspection and sample collection systems to ensure that activities and information are accurate, complete, and comply with the jurisdiction's procedures and policies.

478

4.5 Documentation

479

480

The State program maintains the records listed here.

481

482

483

484

485

486

487

- Written procedures that describe the quality assurance program
- Appendix 4.1 Self-assessment worksheet
- Appendix 4.2 Summary of field inspection audit findings (includes worksheet 4.2)
- Appendix 4.3 Summary of inspection report audit findings (includes worksheet 4.3)

488	
489	• Appendix 4.4 Summary of sample report audit findings
490	(includes worksheet 4.4)
491	• Appendix 4.5 Contract Audit - FDA Form 3610
492	• Appendix 4.5a Guidance for completing contract audit form
493	• Appendix 4.6 Inspection report audit form
494	• Appendix 4.7 Sample report audit form
495	• Appendix 4.8 Corrective action plan (includes table 4.8)
496	

STANDARD No. 5
Food-related Illness and Outbreaks
And
Food Defense Preparedness and Response

5.1 Purpose

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate that may result in illness, injury, and outbreaks. It also applies to the collection, analysis, and dissemination of information that may prevent their recurrence.

5.2 Requirement Summary

The State program establishes systems to:

- a. Use epidemiological information supplied by local, State, or Federal agencies to detect incidents or outbreaks of foodborne illness or injury
- b. Investigate reports of illness, injury, and suspected outbreaks
- c. Correlate and analyze data
- d. Disseminate public information
- e. Distribute outbreak reports and surveillance summaries to relevant agencies
- f. Disseminate current guidance to industry on food defense
- g. Provide guidance for immediate notification of law enforcement agencies when intentional food contamination or terrorism is suspected or threatened
- h. Collaborate as necessary with FDA and other Federal authorities under conditions of increased threat of intentional contamination

5.3 Program Elements

A State program complies with this standard either by performing all of the required elements or by contracting (or signing a memorandum of understanding) with another State agency to perform, coordinate, and/or communicate foodborne illness support activities.

If a State program contracts for support of foodborne illness or injury investigations, it will:

- a. Develop and coordinate the operation of written service support agreements between the food program and the epidemiology support program.
- b. Ensure the support service contract or agreement identifies and describes the roles, duties, and responsibilities of each program for: (1) receiving reports of foodborne illness or injury, (2) performing investigational activities to identify the source of the problem, (3) reporting and recording the results of the investigations, (4) containing or mitigating the incident, and (5) preventing recurrence.

- 542 Whether foodborne illness support activities are performed by the State program or under
 543 a contractual agreement, it must have [or contract for] a system to:
 544
- 545 a. Conduct illness or injury investigations and collects information using established
 546 epidemiology procedures similar to those found in the "*International Association for*
 547 *Food Protection Procedures to Investigate a Foodborne Illnesses, Fifth Edition*"
 - 548 b. Provide laboratory support⁷ for investigations of illness, injury, or outbreaks
 - 549 c. Maintain a current list of relevant agencies and emergency contacts
 - 550 d. Coordinate the traceback and trace-forward of food implicated in an illness, injury, or
 551 outbreak
 - 552 e. Identify contributing factors for reports of illness, injury, or incidents implicating
 553 food
 - 554 f. Maintain investigational findings
 - 555 g. Distribute the final report of illness or injury implicating food to relevant agencies,
 556 e.g. the State epidemiologist and Centers for Disease Control
 - 557 h. Immediately notify all relevant agencies if intentional contamination is suspected or
 558 threatened, e.g. tampering or terrorism
 - 559 i. Establish criteria for releasing information to the public (includes identifying a media
 560 person and developing guidelines for coordinating media information with other
 561 jurisdictions)
 - 562 j. Mitigate and contain food-related illness and injury using enforcement activities and
 563 public awareness programs
 - 564 k. Provide guidance to prevent or reduce the incidence of food-related illness, injury,
 565 and intentional contamination, e.g. tampering or terrorism
 - 566 l. Collaborate as necessary with FDA and other Federal authorities under conditions of
 567 increased threat or intentional contamination

568 569 **5.4 Outcome**

570 The State program has a system for surveillance, investigation, response, documentation,
 571 analysis, and communication of alleged food-related illnesses, injuries, and unintentional
 572 or deliberate food contamination.

573 **5.5 Documentation**

574
575 The program maintains the records listed here.

- 576
- 577 • Appendix 5.1 Self-assessment worksheet
 - 578 • A written description of epidemiology support available or an agreement⁸
 579 that outlines epidemiology support
 - 580 • A complaint log or database

⁷ Specific requirements for laboratory support are contained in standard number 10.

⁸ Appendix 5.2 is an example of an agreement for epidemiology support between a State department of agriculture and the State health department.

- 581 • Current emergency contact list for communicating with all relevant agencies
- 582 • Procedure and contact person for releasing information to the public
- 583 • Documented timeframes for responding to complaints
- 584 • The illness, injury, or outbreak response procedures and the data collection forms
- 585 • Policies and procedures for handling incidents and threats of deliberate
- 586 contamination and for collaborations with FDA and other Federal authorities
- 587 under conditions of increased threat or intentional contamination
- 588 • Written agreements that identify and describe sources of supplemental laboratory
- 589 capacity and expertise including laboratory support⁹ to detect contaminants not
- 590 normally found in food
- 591 • Investigation reports and summaries

⁹ Standard number 10 describes the elements of laboratory support for a manufactured food regulatory program.

STANDARD No. 6
Compliance and Enforcement Program

591
592
593
594
595
596
597
598
599
600
601
602
603
604
605
606
607
608
609
610
611
612
613
614
615
616
617
618
619
620
621
622
623
624
625

6.1 Purpose

This standard describes the State agency's strategies, procedures, and actions to enforce the laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program.

6.2 Requirement Summary

The State program has a compliance and enforcement program, which describes its compliance strategy and procedures. It also audits its conformance to established compliance procedures and identifies areas that need improvement and may require procedural changes.

6.3 Program Elements

The State program has a compliance and enforcement program that: (1) contains enforcement strategies, (2) tracks critical and chronic violations and violators, (3) uses a risk-based system to determine when a directed investigation, follow-up, or re-inspection is needed, (4) establishes a timeline for progressive actions, and (5) has a system to communicate verbal and written policy and guidance to managerial and non-managerial staff. Appendix 6.1 is used to describe the compliance and enforcement program.

The State program conducts a performance review of enforcement actions. A summary of enforcement actions¹⁰ is compiled and an overall rating is calculated using worksheet 6.2. Performance ratings that fall below 80 percent indicate a need for improvement and require corrective action.

Frequency

The audit is conducted every 12 months. The results of the audit will be included in the 36 month overall assessment of the State program's performance vis-à-vis the program standards.

¹⁰ Actions in the enforcement strategy may include, but are not limited to:

- Preventive actions such as promoting voluntary compliance through education program and consultation;
- Field actions such as verbal warnings, documented warnings, re-inspections, and product embargos;
- Supervisory/management actions such as warning letters or informal hearings;
- Administrative actions such as complaints and evidentiary hearings to suspend or revoke a business license; and
- Civil or criminal sanctions.

627		
628	Performance	Appendix 6.2 (including worksheet 6.2) or
629	Documentation	equivalent form.
630		
631	Performance	Performance factors listed in appendix 6.1
632	Factors	and policies and procedures established by the State
633		program.
634		
635	6.4 Outcome	
636		
637		The State program has a compliance and enforcement program that provides procedures
638		to ensure that compliance actions are supported by sound judgment, adequate evidence,
639		and appropriate documentation that is submitted in program-prescribed formats and
640		timeframes.
641		
642	6.5 Documentation	
643		
644		The State program maintains the records listed here.
645		
646		• Appendix 6.1 Self-assessment worksheet
647		• Appendix 6.2 Summary of compliance and enforcement activities
648		(includes worksheet 6.2)
649		• Applicable laws, regulations, and guidance documents referenced in
650		standard number 1
651		• Written procedures that describe the compliance and enforcement program
652		• Written enforcement strategy and/or procedures
653		

STANDARD No. 7
Industry and Community Relations

652
653
654
655
656
657
658
659
660
661
662
663
664
665
666
667
668
669
670
671
672
673
674
675
676
677
678
679
680
681
682
683
684
685
686
687
688
689
690
691
692
693

7.1 Purpose

This standard describes the elements of industry and community outreach activities developed and accomplished by the State program.

7.2 Requirement Summary

The State program participates in activities that foster communication and information exchange among the regulators, industry, academia, and consumer representatives.

The State program coordinates or participates in outreach activities that provide educational information on food safety and defense issues.

7.3 Program Elements

The State program interacts with industry and consumers by sponsoring or actively participating in meetings such as task forces, advisory boards, or advisory committees. Topics at such outreach efforts may include food defense, investigation strategies, and regulatory requirements. Representatives from affected food industries, consumers, academia, and other Federal, State, and local food protection agencies are invited to these meetings.

Outreach efforts are tailored to a target population and may include dissemination of information using electronic sources and traditional methods such as mailings.

7.4 Outcome

The State program uses outreach activities to inform varied populations about food-related issues.

7.5 Documentation

The State program maintains the records listed here.

- Appendix 7 Self-assessment worksheet
- Meeting summaries, agendas, or other records documenting interaction with food industries and consumers

696
697
698
699
700
701
702
703
704
705
706
707
708
709
710
711
712
713
714
715
716
717
718
719
720
721
722
723
724
725
726
727
728
729
730
731
732
733
734
735
736
737
738
739

STANDARD No. 8 Program Resources

8.1 Purpose

This standard describes the elements for assessing the adequacy of the resources (staff, equipment, and funding) needed to support a manufactured food regulatory program.

8.2 Requirement Summary

Staff, equipment, and funding are managed to accomplish the elements detailed in these standards.

8.3 Program Elements

Staffing

a. General Administration and Management

The State program has adequate staff to provide the direction, support, and oversight needed to achieve conformance with the program standards. These activities include program management and direction, general administration, clerical support, office services, and coordination with laboratories.

b. Training Program (standard number 2)

The State program has adequate staff to coordinate a training curriculum and ensure it is properly delivered and tracked.

c. Inspection Program (standard number 3)

The State program has adequate staff to inspect all food plants in its establishment inventory at an adequate frequency that is based on the plant's risk classification and the necessary inspection and travel time. Appendix 8.2 provides formulas for calculating an adequate number of inspection staff.

d. Inspection Audit Program (standard number 4)

The State program has adequate staff to administer and monitor its inspection quality assurance program.

e. Food-related Illness and Outbreaks and Food Defense Preparedness and Response (standard number 5)

The State program has adequate staff to prepare for and respond to emergency situations.

- 740 f. Compliance and Enforcement Program (standard number 6)
 741 The State program has adequate staff to implement compliance and enforcement
 742 strategies.
 743
 744 g. Industry and Community Relations (standard number 7)
 745 The State program has adequate staff to participate in outreach and education
 746 activities.
 747
 748 h. Program Assessment (standard number 9)
 749 The State program has adequate staff to conduct self-assessments of the manufactured
 750 food regulatory program.

751
 752 Equipment

- 753
 754 a. Program administration and recordkeeping
 755 The State program has computers, software, and equipment necessary to maintain and
 756 secure records.
 757
 758 b. Communication systems and equipment
 759 The State program has equipment needed for routine and emergency communications.
 760
 761 c. Inspections
 762 The State program provides inspectors with equipment needed to conduct quality
 763 inspections. Appendix 8.3 is a list of inspection equipment.
 764

765 Program funding

766
 767 The State program is adequately funded to cover the following expenses:

- 768 a. Salary and benefits
 769
 770 b. Training costs
 771
 772 c. Travel-related expenses
 773
 774 d. Equipment and supplies
 775
 776 e. Industry and community outreach expenses
 777
 778 f. Laboratory expenses
 779
 780 g. Legal services fees
 781
 782 h. Indirect costs
 783
 784 i. Overhead costs
 785

786 **8.4 Outcome**

787

788 The State program has the resources needed to support a manufactured food regulatory
789 program.

790

791 **8.5 Documentation**

792

793 The State program maintains the records listed here.

794

- 795 • Appendix 8.1 Self-assessment worksheet
- 796 • Document showing the calculations used to determine an adequate number of
797 inspectors such as appendix 8.2
- 798 • Inventory of assigned and available inspection equipment similar to appendix 8.3
- 799 • Document containing the number and function of administrative support staff

STANDARD No. 9
Program Assessment

9.1 Purpose

This standard describes the process a State program uses to assess and demonstrate its conformance with each of the program standards.

9.2 Requirement Summary

Managers conduct periodic self-assessments of its manufactured food regulatory program against the criteria established in each program standard. These self-assessments are designed to identify the strengths and weaknesses of the State program by determining the level of conformance with the program standards. Self-assessments are independently verified using an audit process.

The results of the self-assessments are used to determine areas or functions of the State program that need improvement. The results of the initial self-assessments are used to develop an improvement plan that moves the State program toward conformance with each of the program standards and establishes timeframes for making improvements. Subsequent self-assessments are used to track progress toward meeting and maintaining conformance with the program standards.

9.3 Program Elements

- a. The State program conducts an initial self-assessment of its conformity with each standard. A subsequent self-assessment is conducted every 36 months or less after completion of the initial self-assessment.
- b. When conducting a self-assessment, the State program uses worksheets comparable to those contained in the appendices of each standard.
- c. The State program uses the results of its self-assessments to develop or update an improvement plan. If the elements of the standard are not met, the improvement plan contains specific strategies and timeframes for achieving conformance and maintaining an acceptable level of performance. The improvement plan also contains reviews of the State program's progress in implementing the plan.

835

836

837

838

839

840

841

842

843

844

845

846

847

848

849

850

851

852

853

854

855

856

857

858

859

- d. The State program arranges for a verification audit to confirm and validate the accuracy of each self-assessment. During the verification audit, an auditor reviews the records required by each standard to determine if the self-assessment accurately reflects the State program's level of conformance with each of the standards. Verification audits are conducted within six months of completion of the self-assessment. Audits conducted by FDA for contract purposes satisfy this requirement.
- e. The State program maintains the records required by each standard and records of all self-assessments, improvement plans, and verification audits until superseded.

9.4. Outcome

The State program conforms to the program standards through well-defined evaluation activities and a process for continuous improvement.

9.5. Documentation

The State program maintains the records listed here.

- Worksheet 9 Self-worksheet assessment and improvement tracking
- Completed appendices 1, 2.1-6.1, 7, 8.1, 10
- Supporting operational documents required for each standard
- Verification audit report
- Program improvement plan

860 **STANDARD No. 10**
861 **Laboratory Support**

862
863 **10.1 Purpose**

864
865 This standard describes the elements of laboratory support for a manufactured food
866 regulatory program.

867
868 **10.2 Requirement Summary**

869
870 The State program has access to the laboratory services needed to support program
871 functions and documents its laboratory capabilities including agreements with external
872 laboratories.

873
874 **10.3 Program Elements**

- 875
876 a. The State program has access to a laboratory that is capable of analyzing a variety of
877 samples including food, environmental, and clinical samples.
878
879 b. The State program maintains a record of services for routine and non-routine analyses
880 such as biological hazard determinations.
881
882 c. The State program has a contract or written agreement with its servicing laboratories.
883
884 d. The State program utilizes laboratories that are accredited or certified or that have a
885 written QAP. The QAP will require:
886
887 • Calibration, verification, and maintenance of equipment
888 • Documentation of analytical results
889 • Control and maintenance of documents
890 • Sample accountability
891 • Sample integrity and chain of custody
892 • Qualifications and training of analysts
893 • Audit procedures such as scheduled performance reviews of staff and instrument
894 checks

895
896 **10.4 Outcome**

897
898 The State program has access to laboratory services described in this standard.

899

900

901 **10.5 Documentation**

902

903 The State program maintains records listed here.

904

905 • Appendix 10 Self-assessment worksheet

906 • A list of servicing laboratories used by the State program

907 • Contracts or written agreements with servicing laboratories

Appendix 1 Self-Assessment Worksheet

The State program describes how equivalency is accomplished when it lacks authority to enforce the sections of the FD&C Act and the parts of the CFR listed in the following tables.

For example, the State program may comply with standard number 1 either by identifying its equivalent State authorities or by describing how equivalency is attained through alternative procedures or agreements.

a. Federal Food, Drug, and Cosmetic Act (FD&C Act)

The State law must be equivalent in effect to the sections of the FD&C Act. The language used does not have to be identical if the same outcome is achieved.

Section	Title	State equivalent or alternate provision	"✓" if full intent is met
201	Definitions (f), (k), (m), and (ff)		
301	Prohibited acts (a), (b), (c), (d), (e), (f), (k), and (v)		
303*	Penalties		
304**	Seizure		
401	Definitions and standards for food		
402	Adulterated food		
403	Misbranded food (a)-(s)		
413	New dietary ingredients		
701	Regulations and hearings		
703***	Records of interstate shipments		
704	Factory inspection		

*Penalties may vary from Federal statute.

**Seizure authority is not required under this standard. The agency, however, should have legal authority to stop adulterated and misbranded products from moving in commerce, for example, detention, stop-sale orders, and embargoes.

***This section covers records in interstate commerce. State law should include intrastate records.

b. Code of Federal Regulations (CFR)

The State regulation must be equivalent in effect to the sections listed in the CFR. The language used does not have to be identical if the same outcome is achieved. States may have more stringent regulations unless preempted.

Part	Title	State equivalent or alternate provision	"✓" if full intent is met
1	General enforcement regulations (ONLY § 1.20-1.24)		
7	Enforcement policy (ONLY § 7.1-7.13 and § 7.40-7.59)		
70	Color additives (ONLY § 70.20-70.25)		

Part	Title	State equivalent or alternate provision	“✓” if full intent is met
73	Listing of colors exempt from certification (ONLY § 73.1- § 73.615)		
74	Listing of color additives subject to certification (ONLY § 74.101-706)		
82	Listing of certified provisionally listed colors and specifications (ONLY § 82.3- § 82.706)		
100	General (ONLY § 100.155 and § 101.100)		
101	Food labeling (EXCEPT § 101.69 and § 101.108)		
102	Common or usual name for nonstandardized foods (EXCEPT § 102.19)		
104	Nutritional quality guidelines for foods		
105	Foods for special dietary use		
106	Infant formula quality control procedures (EXCEPT § 106.120)		
107	Infant formula (EXCEPT § 107.200- § 107.280)		
108	Emergency permit control (ONLY § 108.25- § 108.35)		
109	Unavoidable contaminants in food for human consumption and food-packaging materials		
110	Current good manufacturing practice in manufacturing, packing, or holding human food		
111	Current good manufacturing practice for dietary supplements		
113	Thermally processed low-acid foods packaged in hermetically sealed containers		
114	Acidified foods		
115	Shell eggs		
120	Hazard Analysis and Critical Control Point (HACCP) systems		
123	Fish and fishery products		
129	Processing and bottling of bottled drinking water		
130	Food standards: general (EXCEPT § 130.5-6 and § 130.17)		
131	Milk and cream		
133	Cheeses and related cheese products		
135	Frozen desserts		
136	Bakery products		

Part	Title	State equivalent or alternate provision	“✓” if full intent is met
137	Cereal flours and related products		
139	Macaroni and noodle products		
145	Canned fruits		
146	Canned fruit juices		
150	Fruit butters, jellies, preserves, and related products		
152	Fruit pies		
155	Canned vegetables		
156	Vegetable juices		
158	Frozen vegetables		
160	Eggs and egg products		
161	Fish and shellfish		
163	Cacao products		
164	Tree nut and peanut products		
165	Beverages		
166	Margarine		
168	Sweeteners and table syrups		
169	Food dressings and flavorings		
170	Food additives (EXCEPT § 170.6, § 170.15, and § 170.17)		
172	Food additives permitted for direct addition to food for human consumption		
173	Secondary direct food additives permitted in food for human consumption		
174	Indirect food additives: general		
175	Indirect food additives: adhesives and components of coatings		
176	Indirect food additives: paper and paperboard components		
177	Indirect food additives: polymers		
178	Indirect food additives: adjuvants, production aids, and sanitizers		
180	Food additives permitted in food or in contact with food on an interim basis pending additional study		
181	Prior-sanctioned food ingredients		
182	Substances generally recognized as safe		
184	Direct food substances affirmed as generally recognized as safe		
186	Indirect food substances affirmed as generally recognized as safe		
189	Substances prohibited from use in human food		
190	Dietary supplements		

**Appendix 2.1
Self-Assessment Worksheet**

State agency: _____ State program: _____ Year _____

Instructions: Record the name of the employee and the completion date for each training component. Use additional sheets as needed.

Employee name	Start Date	Basic Food Inspection Curriculum		Advanced Food Inspection Curriculum			Continuing Education	
		Course work	Field work	Area of specialty	Course work	Field work	Course work	Field work

Name/title of auditor: _____

Signature: _____ Date: _____

**Appendix 2.2
Individual Training Record**

State agency _____

Name of inspector _____ Inspector's start date _____

Basic Food Inspection Curriculum Coursework			
Please provide the course name and location for the subject areas listed here.	Completion Date	Inspector's Initials	Supervisor's Initials
Prevailing statutes, regulations, and ordinances			
Public health principles			
Communication skills			
Microbiology			
Epidemiology			
Basics of HACCP			
Control of allergens			
Basic food labeling			

Basic Food Inspection Curriculum Fieldwork				
Joint Inspections		Completion Date	Inspector's Initials	Supervisor's Initials
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
Evaluations				
1.				
2.				

Advanced Food Inspection Curriculum Coursework			
Please provide the name and location of the course. Note: <u>Only</u> the juice and seafood HACCP courses listed on this form will meet the training requirement.	Completion Date	Inspector's Initials	Supervisor's Initials
Applications of foodborne illness investigations			
Traceback investigations			
Nutrition labeling			
Acidified foods			
Low acid canned foods			
Principles of Juice HACCP			
Juice HACCP Alliance Training			
<i>Or comparable training</i>			
Juice HACCP for Regulators (FDA video)			
Principles of Seafood HACCP			
Basic Seafood HACCP Class (classroom)			
<i>(Or internet and one day)</i>			
Seafood HACCP Regulators Course (FDA video)			
Seafood HACCP Encore (video)			
Seafood HACCP The Sequel (video)			
Seafood HACCP Hazard Guide Update, 3rd Edition (video)			

**Advanced Food Inspection Curriculum
Fieldwork**

Specialized food inspection:

Joint Inspections		Completion Date	Inspector's Initials	Supervisor's Initials
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
Evaluations				
1.				
2.				

Specialized food inspection:

Joint Inspections		Completion Date	Inspector's Initials	Supervisor's Initials
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
Evaluations				
1.				
2.				

Continuing Education Coursework				
Please provide the name and location of the course.	Completion Date	Contact Hours¹	Inspector's Initials	Supervisor's Initials

Continuing Education Fieldwork				
Joint Inspections		Completion Date	Inspector's Initials	Supervisor's Initials
Please provide the name of the food plant and identification number.				
1.				
2.				

¹ The inspector will earn contact hours at a rate of one contact hour for every course hour.

**Appendix 3.1
Self-Assessment Worksheet**

State agency: _____ State program: _____

Does the State program meet the criteria contained in section 3.3 of the standard number 3?

Program Elements	Yes/No	If no, please specify why criteria are not met.
a. Risk-based inspection system		
1. Is the establishment inventory complete and accurate?		
2. Are establishments grouped based on identified risk factors?		
3. Are risk categories used to prioritize inspections, assign routine inspection frequencies, and allocate resources?		
b. Inspection protocol		
Does the program's inspection protocol require inspectors to:		
1. Review the establishment file, consumer complaints, and other relevant documents prior to inspection?		
2. Use appropriate equipment and forms?		
3. Establish jurisdiction?		
4. Select appropriate product/process (high risk products and processes)?		
5. Assess employee practices critical to the safe production and storage of food?		
6. Properly evaluate the likelihood that conditions, practices, components, and labeling could cause the product to be adulterated or misbranded?		
7. Recognize significant violative conditions or practices, and record findings consistent with program procedures?		
8. Distinguish between significant and insignificant observations, and isolated incidents and trends?		
9. Review and evaluate the appropriate operational records and procedures and apply the information obtained from this review?		
10. Collect adequate evidence and documentation in accordance with program procedures given the nature of the inspectional findings?		
11. Verify correction of deficiencies from a previous inspection?		
12. Behave professionally and demonstrate proper sanitary practices during the inspection?		

13. Use the "Fish and Fishery Products Hazards and Controls Guide" or the "Juice HACCP Hazards and Controls Guide," to identify and evaluate the hazards associated with the product and process?		
14. Assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation?		
15. Review the firm's HACCP plan (or necessary process controls in the absence of a HACCP plan) and applicable monitoring verification and corrective action records, including those related to sanitation?		
16. Recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations?		
17. Identify himself/herself, present credentials, and make appropriate introductions, including explaining the purpose and scope of the inspection?		
18. Use suitable interviewing techniques?		
19. Explain findings clearly and adequately throughout the inspection?		
20. Alert the firm's appropriate management when an immediate corrective action is necessary?		
21. Write findings accurately, clearly, and concisely on the State document?		
22. Answer questions and provide information in an appropriate manner?		
23. And, does the program have an adequate recordkeeping system and does this system contain prescribed records associated with inspections?		
c. Food recalls		
Does the recall system include:		
1. Guidance for sharing information?		
2. Procedures for prompt removal of recalled products?		
3. Procedures for recall audit checks?		
4. And, does the program have an adequate recordkeeping system and does this system contain prescribed records associated with food recalls?		
d. Consumer complaints		
1. Does the program have procedures for receiving, tracking, evaluating, responding to, and closing consumer complaints?		
2. Does the program have a recordkeeping system and are records associated with consumer complaints retained?		

e. Food industry inspection complaints		
1. Does the program have procedures for receiving, evaluating, responding to, and recording food industry complaints about inspections?		
2. Does the program have a recordkeeping system and are records associated with food industry inspection complaints retained?		

Name/title of auditor: _____

Signature: _____

Date: _____

Appendix 3.2

Risk Classification Criteria for Food Plants

Risk management is prioritizing opportunities to reduce risk and allocate food safety efforts and resources. Policymakers must consider the entire production-to-consumption chain and all of the participants (regulators, industry, researchers, health care providers, and consumers) when deciding how to best utilize resources to maximize food safety and reduce costs.

Standard number 3 focuses on one segment of the total food safety system – inspection of food plants. A key requirement of this standard is that the State program uses a science-based and risk-based method for classifying food plants into at least three risk categories with a baseline inspection frequency specified for each category. Although this standard does not prescribe a classification scheme or inspection frequency, frequencies could be established through: (1) risk-based assessment of foodborne hazards, (2) ranking the public health impacts of specific hazards, (3) measurement and valuation of the benefits of reducing risk, (4) evaluation of the effectiveness and cost of risk reduction intervention options, and (5) integration of these analyses to allocate resources.

When categorizing establishments by risk, State programs may consider several factors including: (1) the type of food and ingredients, (2) processing requirements, (3) volume of product manufactured or distributed, (4) intended consumer, and (5) compliance history of the food plant. The factors may be assigned numerical values that are tabulated to rank the food plants and prioritize inspections.

Foods with microbial hazards, especially those that require stringent temperature controls, are usually deemed high risk. Other foods such as unpasteurized juices may be classified as high risk based on epidemiologic implication in foodborne disease outbreaks. In addition to microbial hazards, chemical hazards should also be evaluated.

Complex manufacturing processes with many critical control points such as commercial sterilization, acidification, dehydration, formulation control, or mandatory HACCP systems are generally considered high risk. These operations must be properly controlled to prevent, eliminate, or reduce food safety hazards to acceptable levels. Reconditioning operations including food salvage are often ranked as high risk because improper reconditioning could result in distribution of adulterated or misbranded products to consumers.

High volume manufacturers and distributors have the potential to expose more consumers to food safety hazards if product or process controls fail. When combined with other factors, they may be classified as high risk.

Risk Classification Criteria for Food Plants

Many classification schemes prioritize products intended for use by highly-susceptible populations¹ because these populations are more likely to experience foodborne illnesses compared to the general population.

Inspection or compliance history is commonly considered when establishing inspection frequencies. It is reasonable to expect those firms with a history of compliance to be inspected less frequently than those firms with a history of non-compliance. Some State programs factor the compliance history directly into the risk ranking while others use performance criteria to adjust the inspection frequency from a baseline established by other criteria.

Standard number 3 requires a State program to categorize food plants based on risk and to allocate resources and establish inspection frequencies based on that categorization. Standard number 3 does not prescribe how this must be done. State programs should document their classification system and inspection frequencies. Differences between agencies will exist for many reasons including variable resources, legislative mandates, localized industries and practices, and competing priorities.

The risk classification criteria listed on the next page are intended solely to assist State programs with establishing their own classification system.

¹ Highly-susceptible populations include immuno-compromised persons, preschool age children, or older adults; and persons who obtain food at a facility that provides services such as custodial care, health care, assisted living, a child or adult day care center, kidney dialysis centers, hospital or nursing home, or nutritional or socialization services (senior citizen centers).

Risk Classification Criteria for Food Plants

<u>Risk</u>	<u>Type of processing</u>
High	Canning low acid foods, acidifying foods, vacuum packaging, salvaging, smoking for preservation, curing
Medium	Cooking, cooling, holding under controlled temperatures, pasteurization
Low	Temperature control not required
	<u>Type of foods</u>
High	Potentially hazardous foods frequently implicated in foodborne illness (sprouts, unpasteurized juices, raw shellfish, cream-filled pastries, filled macaroni products)
Medium	Potentially hazardous foods not typically implicated in foodborne illness
Low	Non-potentially hazardous foods
	<u>Volume of product manufactured/distributed</u>
Higher	High volume operations with broad distribution
Lower	Low volume operations or operations with localized distribution
	<u>Target population</u>
Higher	Foods consumed by susceptible populations
Lower	Foods consumed solely or primarily by the general population
	<u>Compliance history</u>
Higher	Businesses with an inconsistent or poor history of compliance with food safety requirements
Lower	Businesses routinely in compliance with food safety requirements

**Appendix 4.1
Self-Assessment Worksheet**

State agency: _____ State program: _____

The results of the field inspection and desk audits are summarized below. Performance ratings that fall below 80 percent indicate a need for improvement and require corrective action. Worksheets 4.2 – 4.4 can be used to identify the specific aspects of the inspection program that need improvement.

Overall Audit Rating (based on three-year averages)	
<i>Circle one:</i>	<i>Performance rating criteria:</i>
Acceptable	All performance rating averages \geq 80 percent.
Needs improvement	One more performance rating averages < 80 percent.

	Audits		
	Field inspection	Inspection report	Sample report
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Three-year average	<input type="text"/>	<input type="text"/>	<input type="text"/>

Recommendations:

Name/title of auditor: _____

Appendix 4.2

Summary of Field Inspection Audit Findings

The summary of the performance factor ratings for all field inspection audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Worksheet 4.2 is used to calculate an overall rating for the performance period and identify single performance factors rated as “needs improvement” in multiple audits. The performance factors are described in appendix 4.5. A rating below 80 percent indicates a need for improvement and requires corrective action.

INSTRUCTIONS: (1) For each field inspection audited, record the auditor’s initials and date of audit in the box.

(2) For each field inspection audited, record the rating for each performance factor listed in appendix 4.5.

A = acceptable; NI = needs improvement.

(3) Record the A_t and NI_t for each performance factor.

A_t = horizontal total of acceptable ratings.

NI_t = horizontal total of needs improvement ratings.

(4) Calculate the overall rating for the field inspection audits.

Record the rating in the space provided in the box located at the top of worksheet 4.2.

FORMULA:

Field inspection audit performance rating =

$$\left[\frac{\sum A_t}{(\sum A_t + \sum NI_t)} \times 100 \right]$$

NOTE: \sum is the statistical symbol for the sum of all numbers.

$\sum A_t$ = vertical sum of acceptable ratings.

$\sum NI_t$ = vertical sum of needs improvement ratings.

(5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of worksheet 4.2 to identify and make notes about single performance factors rated as “needs improvement” in multiple audits.

Worksheet 4.2 Calculation of the performance rating for the field inspection audits.

State program: _____	Performance period: _____
Field inspection audit performance rating (4): _____	
Name/title of reviewer: _____	Office: _____ Date: _____

Performance factors (5)	Auditor's initials and date of audit (1)														A _t (3)	NI _t (3)		
	Performance ratings (2)																	
I.1																		
I.2																		
II.1																		
II.2																		
II.3																		
II.4																		
II.5																		
II.6																		
II.7																		
II.8																		
II.9																		
II.10																		
IIA.1																		
IIA.2																		
IIA.3																		
IIA.4																		
III.1																		
III.2																		
III.3																		
III.4																		
III.5																		
III.6																		
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																	
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																	

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

State program: _____ Performance period: _____

Performance factors (5)	Auditor's initials and date of audit (1)																A _t (3)	NI _t (3)	
	Performance ratings (2)																		
I.1																			
I.2																			
II.1																			
II.2																			
II.3																			
II.4																			
II.5																			
II.6																			
II.7																			
II.8																			
II.9																			
II.10																			
IIA.1																			
IIA.2																			
IIA.3																			
IIA.4																			
III.1																			
III.2																			
III.3																			
III.4																			
III.5																			
III.6																			
Total	<i>Enter the sums of (3).</i>																		

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Appendix 4.3

Summary of Inspection Report Audit Findings

The summary of the performance factor ratings for all inspection report audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Worksheet 4.3 is used to calculate an overall rating for the performance period and identify single performance factors rated as “needs improvement” in multiple audits. The performance factors are described in appendix 4.6. A rating below 80 percent indicates a need for improvement and requires corrective action.

- INSTRUCTIONS:**
- (1) For each inspection report audited, record the firm identification number and date of the inspection in the box.
 - (2) For each inspection report audited, record the rating for each performance factor listed in appendix 4.6.
A = acceptable; NI = needs improvement.
 - (3) Record the A_t and NI_t for each performance factor.
 A_t = horizontal total of acceptable ratings.
 NI_t = horizontal total of needs improvement ratings.
 - (4) Calculate the overall rating for the inspection report audits.
Record the rating in the space provided in the box located at the top of worksheet 4.3.

FORMULA:

$$\text{Inspection report audit performance rating} = \left[\frac{\sum A_t}{(\sum A_t + \sum NI_t)} \times 100 \right]$$

NOTE: Σ is the statistical symbol for the sum of all numbers.

$\sum A_t$ = vertical sum of acceptable ratings.

$\sum NI_t$ = vertical sum of needs improvement ratings.

- (5) Evaluate audit ratings for a single performance factor. Use the blank page of worksheet 4.3 to identify and make notes about single performance factors rated as “needs improvement” in multiple audits.

Worksheet 4.3 Calculation of the performance rating for the inspection report audits.

State program: _____ Performance period: _____
 Inspection report audit performance rating (4): _____
 Name/title of reviewer: _____ Office: _____ Date: _____

49

Performance factors (5)	Firm identification number and date of inspection (1)																								A _i (3)	NI _i (3)								
	Performance ratings (2)																																	
I.1																																		
I.2																																		
II.1																																		
II.2																																		
II.3																																		
II.4																																		
II.5																																		
II.6																																		
II.7																																		
II.8																																		
II.9																																		
II.10																																		
II.11																																		
II.12																																		
III.1																																		
III.2																																		
III.3																																		
III.4																																		
IV.1																																		
IV.2																																		
IV.3																																		
IV.4																																		
IV.5																																		
IV.6																																		
V.1																																		
V.2																																		
V.3																																		
V.4																																		
V.5																																		
V.6																																		
V.7																																		
V.8																																		
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																																	
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																																	

Worksheet 4.3
Continuation sheet

State program: _____ Performance period: _____

Performance factors (5)	Firm identification number and date of inspection (1)																A _t (3)	NI _t (3)	
	Performance ratings (2)																		
I.1																			
I.2																			
II.1																			
II.2																			
II.3																			
II.4																			
II.5																			
II.6																			
II.7																			
II.8																			
II.9																			
II.10																			
II.11																			
II.12																			
III.1																			
III.2																			
III.3																			
III.4																			
IV.1																			
IV.2																			
IV.3																			
IV.4																			
IV.5																			
IV.6																			
V.1																			
V.2																			
V.3																			
V.4																			
V.5																			
V.6																			
V.7																			
V.8																			
Total	<i>Enter the sums of (3).</i>																		

50

Worksheet 4.3

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Appendix 4.4

Summary of Sample Report Audit Findings

The summary of the performance factor ratings for all sample report audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Worksheet 4.4 is used to calculate an overall rating for the performance period and identify single performance factors rated as “needs improvement” in multiple audits. The performance factors are described in appendix 4.7. A rating below 80 percent indicates a need for improvement and requires corrective action.

- INSTRUCTIONS:**
- (1) For each sample report audited, record the sample report identification number and date of sample collection in the box.
 - (2) For each sample report audited, record the rating for each performance factor listed in appendix 4.7.
A = acceptable; NI = needs improvement.
 - (3) Record the A_t and NI_t for each performance factor.
 A_t = horizontal total of acceptable ratings.
 NI_t = horizontal total of needs improvement ratings.
 - (4) Calculate the overall rating for the sample report audits.
Record the rating in the space provided in the box located at the top of worksheet 4.4.

FORMULA:

$$\text{Sample report audit performance rating} = \left[\frac{\sum A_t}{(\sum A_t + \sum NI_t)} \times 100 \right]$$

NOTE: Σ is the statistical symbol for the sum of all numbers.

$\sum A_t$ = vertical sum of acceptable ratings.

$\sum NI_t$ = vertical sum of needs improvement ratings.

- (5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of worksheet 4.4 to identify and make notes about single performance factors rated as “needs improvement” in multiple audits.

Worksheet 4.4 Calculation of the performance rating for the sample report audits.

State program _____	Performance period: _____
Sample report audit performance rating (4): _____	
Name/title of reviewer: _____	Office: _____ Date: _____

Performance factors (5)	Sample report identification number and date of sample collection (1)															A, (3)	NI, (3)	
	Performance ratings (2)																	
I.1																		
I.2																		
I.3																		
I.4																		
I.5																		
II.1																		
II.2																		
II.3																		
II.4																		
II.5																		
II.6																		
II.7																		
III.1																		
III.2																		
III.3																		
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																	
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																	

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

53

Worksheet 4.4
Continuation sheet

State program: _____ Performance period: _____

Performance factors (5)	Sample report identification number and date of sample collection (1)																		A, (3)	NI, (3)		
	Performance ratings (2)																					
I.1																						
I.2																						
I.3																						
I.4																						
I.5																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
III.1																						
III.2																						
III.3																						
Total	<i>Enter the sums of (3).</i>																					

54

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CONTRACT AUDIT		
FDA AUDITOR	STATE INSPECTOR	
FIRM	CFN / FEI NUMBER	
FIRM ADDRESS		
PRODUCT(S) COVERED		
TIME IN	TIME OUT	OVERALL RATING <input type="checkbox"/> Acceptable Improvement <input type="checkbox"/> Needs
I. PREINSPECTION ASSESSMENT		
1. DID THE INSPECTOR REVIEW THE STATE'S ESTABLISHMENT FILE FOR THE PREVIOUS INSPECTION REPORT AND POSSIBLE COMPLAINTS OR ACCESS OTHER AVAILABLE RESOURCES IN PREPARATION FOR THE INSPECTION? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement COMMENTS <i>(required for Needs Improvement)</i>		
2. DID THE INSPECTOR HAVE THE APPROPRIATE EQUIPMENT AND FORMS TO PROPERLY CONDUCT THE INSPECTION? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement COMMENTS <i>(required for Needs Improvement)</i>		

II. INSPECTION OBSERVATIONS AND PERFORMANCE

1. WAS FDA JURISDICTION ESTABLISHED?

- Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. DID THE INSPECTOR SELECT AN APPROPRIATE PRODUCT FOR THE INSPECTION AND, IF NECESSARY, MAKE APPROPRIATE ADJUSTMENTS BASED ON WHAT THE FIRM WAS PRODUCING?

- Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. DID THE INSPECTOR ASSESS THE EMPLOYEE PRACTICES CRITICAL TO THE SAFE PRODUCTION AND STORAGE OF FOOD?

- Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

4. DID THE INSPECTOR PROPERLY EVALUATE THE LIKELIHOOD THAT CONDITIONS, PRACTICES, COMPONENTS, AND/OR LABELING COULD CAUSE THE PRODUCT TO BE ADULTERATED OR MISBRANDED?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

5. DID THE INSPECTOR RECOGNIZE SIGNIFICANT VIOLATIVE CONDITIONS OR PRACTICES IF PRESENT AND RECORD FINDINGS CONSISTENT WITH STATE PROCEDURES?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

6. DID THE INSPECTOR DEMONSTRATE THE ABILITY TO DISTINGUISH BETWEEN SIGNIFICANT VERSUS INSIGNIFICANT OBSERVATIONS AND ISOLATED INCIDENTS VERSUS TRENDS?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

7. DID THE INSPECTOR REVIEW AND EVALUATE THE APPROPRIATE RECORDS AND PROCEDURES FOR THIS ESTABLISHMENT'S OPERATION ANDEFFECTIVELY APPLY THE INFORMATION OBTAINED FROM THIS REVIEW?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

8. DID THE INSPECTOR COLLECT ADEQUATE EVIDENCE AND DOCUMENTATION IN ACCORDANCE WITH STATE PROCEDURES GIVEN THE NATURE OF THE INSPECTIONAL FINDINGS?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

9. DID THE INSPECTOR VERIFY CORRECTION OF DEFICIENCIES IDENTIFIED DURING THE PREVIOUS STATE INSPECTION?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE (Continued)	
<p>10. DID THE INSPECTOR ACT IN A PROFESSIONAL MANNER AND DEMONSTRATE PROPER SANITARY PRACTICES DURING THE INSPECTION?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS (required for Needs Improvement)</p>	
II. A. INSPECTION OBSERVATIONS AND PERFORMANCE FOR 'HACCP-REGULATED' FACILITIES	
<p>Note to Auditor: These four questions apply to only firms subject to HACCP regulations. These four questions should be left blank for firms not subject to HACCP regulations.</p>	
<p>1. DID THE INSPECTOR USE THE "FISH AND FISHER PRODUCTS HAZARDS AND CONTROLS GUIDE" OR THE "JUICE HACCP HAZARDS AND CONTROLS GUIDE," AS APPROPRIATE, TO IDENTIFY AND EVALUATE THE HAZARDS ASSOCIATED WITH THE PRODUCT AND PROCESS?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS (required for Needs Improvement)</p>	
<p>2. DID THE INSPECTOR ASSESS THE FIRM'S IMPLEMENTATION OF SANITATION MONITORING FOR THE APPLICABLE EIGHT KEY AREAS OF SANITATION?</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement</p> <p>COMMENTS (required for Needs Improvement)</p>	

3. DID THE INSPECTOR REVIEW THE FIRM'S HACCP PLAN (OR NECESSARY PROCESS CONTROLS IN THE ABSENCE OF A HACCP PLAN) AND APPLICABLE MONITORING, VERIFICATION AND CORRECTIVE ACTION RECORDS, INCLUDING THOSE RELATED TO SANITATION?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

4. DID THE INSPECTOR RECOGNIZED EFFICIENCIES IN THE FIRM'S MONITORING AND SANITATION PROCEDURES THROUGH IN-PLANT OBSERVATIONS?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION

1. DID THE INSPECTOR IDENTIFY HIMSELF/HERSELF AND MAKE APPROPRIATE INTRODUCTIONS, WHICH INCLUDE EXPLAINING THE PURPOSE AND SCOPE OF THE INSPECTION?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

2. DID THE INSPECTOR USE SUITABLE INTERVIEWING TECHNIQUES?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

3. DID THE INSPECTOR EXPLAIN FINDINGS CLEARLY AND ADEQUATELY THROUGHOUT THE INSPECTION?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

4. DID THE INSPECTOR ALERT THE FIRM'S APPROPRIATE MANAGEMENT WHEN AN IMMEDIATE CORRECTIVE ACTION WAS NECESSARY?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

5. DID THE INSPECTOR ANSWER QUESTIONS AND PROVIDE INFORMATION IN AN APPROPRIATE MANNER?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

6. DID THE INSPECTOR WRITE THEIR FINDINGS ACCURATELY, CLEARLY AND CONCISELY ON THE STATE FORM/DOCUMENT LEFT WITH THE FIRM?

Acceptable Needs Improvement

COMMENTS *(required for Needs Improvement)*

NOTE: EVERY ITEM MARKED "NEEDS IMPROVEMENT" MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS JUDGED AS NEEDING IMPROVEMENT.

Overall Rating:

If three or less items are marked "needs improvement," the overall rating is "acceptable." If four or more items are marked "needs improvement," the overall rating is "needs improvement." The overall rating must be marked in the space provided in the header on the first page.

All questions must be answered "acceptable" or "needs improvement," except for section II.A. *Inspection Observations and Performance for 'HACCP-Regulated' firms.* **If the establishment is not subject to Seafood or Juice HACCP regulations, leave the scoring for these four questions blank.**

If four or more evaluated items are marked as "needs improvement," the state program manager must be notified by the appropriate FDA liaison that additional training or other performance improvement measures for then inspector being audited should be initiated. All contract inspectors who receive an overall audit score of "needs improvement" shall receive remedial training in deficient areas or as agreed upon by the FDA Project and Co-Project Officers prior to resuming contract inspection duties.

ADDITIONAL COMMENTS

SIGNATURE OF FDA AUDITOR

DATE

Appendix 4.5a
Guidance for Completing the Contract Audit Form (FDA Form 3610)

This document provides guidance on assigning ratings during an audit for each of the performance factors listed on the Contract Audit Form. For each performance factor examples of actions and observations that would likely result in a “needs improvement” rating are provided.

I. Pre Inspection Assessment

1. Did the inspector review the State’s establishment file for the previous inspection report and possible complaints or access other available resources in preparation for the inspection?

References:

- State program’s establishment files
- FDA compliance programs referenced in the contract

Examples of a “needs improvement” rating

- a. The inspector does not review the State’s previous inspection report and follow-up on previously cited deficiencies.
- b. The inspector does not review a firm’s response letter to the State’s previous establishment inspection where corrective actions were promised.
- c. The inspector does not verify the firm’s normal days of operation or seasonal hours.
- d. The inspector does not follow-up on a consumer complaint contained in the State’s establishment file.

2. Did the inspector have the appropriate equipment and forms to properly conduct the inspection?

References:

- FDA compliance programs referenced in the contract
- FDA inspection guides

Examples of a “needs improvement” rating:

- a. During an inspection of a cream-filled pie manufacturer, the inspector does not have a calibrated thermometer to check the temperature of the pie.
- b. During an inspection of a cooked, ready-to-eat food processor, the inspector does not have a method to test the concentration of iodine sanitizer in the hand dip station.

- c. The inspector does not have a flashlight to examine poorly lit raw material storage areas in the plant.

II. Inspection Observations and Performance

1. Was FDA jurisdiction established?

References:

- FDA Investigations Operations Manual (IOM), subchapter 432 - Documenting Interstate Shipments
- IOM, subchapter 701 – Statutory Authority

Examples of a “needs improvement” rating

- a. The inspector fails to confirm interstate movement of a product or ingredients.
- b. The inspector fails to verify interstate shipment of food by a manufacturer that has not shipped product in interstate commerce during the past 24 months nor has the manufacturer received interstate shipments of ingredients or packaging components.

2. Did the inspector select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the firm was producing?

References:

- FDA compliance programs referenced in the contract

Examples of a “needs improvement” rating

- a. The inspector covers only a low-risk product while the firm is producing a high-risk product on the day of the inspection.
- b. The inspector does not cover a small ready-to-eat sandwich operation in a large frozen dinner processing plant.
- c. While inspecting a beverage bottling plant whose primary product is institutional-sized root beer syrup, the inspector ignores a bottled water processing operation on the premises.

3. Did the inspector assess the employee practices critical to the safe production and storage of food?

Examples of a “needs improvement” rating:

- a. The inspector fails to evaluate the hygienic practices of employees working in a food processing area.
- b. The inspector is unaware of the need for employees who are processing cooked, ready-to-eat foods to wash and sanitize their hands every time they touch an unclean surface.
- c. The inspector notices that the firm has a trash bin and a reclaim bin in the same area. He/she does not, however, recognize the potential hazard. Consequently, the inspector misses an employee placing trash in the reclaim bin that contains product reintroduced into the manufacturing process.

4. Did the inspector properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?

References:

- FDA compliance programs referenced in the contract
- NLEA inspection guide

Examples of a “needs improvement” rating:

- a. The inspector fails to recognize when a firm’s finished product labeling does not contain a sulfite declaration, even though the raw material does contain a sulfite declaration.
- b. The inspector fails to note the significance of “back hauling” raw eggs in a tanker used to carry pasteurized ice cream mix.
- c. During an inspection of a baby food manufacturer, the inspector observes a belt moving rapidly, glass jars rattling, and shards of glass on the belt. The inspector fails to determine if such observations are related to a recent increase in complaints of glass in baby food.
- d. The inspector fails to recognize the addition of an allergen during the production of a breaded product, and he/she doesn’t review the product label.

5. Did the inspector recognize significant violative conditions or practices, if present, and record findings consistent with State procedures?

Examples of a “needs improvement” rating:

- a. The inspector fails to recognize that the food residues and mold growth on food contact surfaces are violations.
- b. The inspector does not recognize that employees handling cooked, ready-to-eat product with soiled hands is a deficiency.
- c. The inspector fails to notice that WD-40™, observed in the processing area, is being used to lubricate machine parts above food contact surfaces.
- d. The inspector fails to recognize that condensate dripping from a freezer onto finished product may cause cross contamination.

6. Did the inspector demonstrate the ability to distinguish between significant versus insignificant observations and isolated incidents versus trends?

References:

- FDA compliance programs referenced in the contract

Examples of a “needs improvement” rating:

- a. The inspector notes minor deficiencies such as chewing gum and nail polish while failing to note places where cross contamination of cooked and raw product might occur.
- b. The inspector identifies record keeping deficiencies in records that are two months old. The inspector objects to these deficiencies without appropriately considering that the firm’s weekly management review of the records has identified the deficiencies, which have not been repeated within the last seven weeks.
- c. During an inspection of a ready-to-eat salad processor, the inspector focuses primarily on filthy, non-food contact surfaces.
- d. During the inspection of a warehouse, the inspector focuses primarily on products being stored against the walls but fails to notice several pallets of rice infested with moths.

7. Did the inspector review and evaluate the appropriate records and procedures for this establishment's operation and effectively apply the information obtained from this review?

Examples of a "needs improvement" rating:

- a. During a review of the processing records, the inspector fails to detect that cooking times are outside the scheduled process.
- b. The inspector fails to detect possible evidence of record falsification such as inconsistencies among different types of records, unrealistic and repetitive data, and inconsistencies in signatures.
- c. Can teardown records are reviewed, but the inspector doesn't recognize that teardown measurements were not done at appropriate intervals.

8. Did the inspector collect adequate evidence and documentation in accordance with State procedures given the nature of the inspectional findings?

Examples of a "needs improvement" rating

- a. The inspector fails to adequately document findings according to State requirements when violations are found in the firm.
- b. The inspector fails to follow State requirements when collecting samples of processed food necessary to document violative conditions.
- c. In an acidified food processing plant, the pH of the final product is questionable. The inspector does not, however, collect a sample of the product for pH determination.

9. Did the inspector verify correction of deficiencies identified during the previous State inspection?

Examples of a "needs improvement" rating:

- a. Although significant time and temperature abuse of coconut cream pies was identified during the previous inspection, the inspector does not determine if these deficiencies were corrected.
- b. In the previous inspection, the inspector reported that a private well was not equipped with a sanitary seal. During the current inspection, the manager tells the inspector that the well was repaired, and the lab results were acceptable. The inspector reviews the microbiological lab results, but does not go to the well to verify that the sanitary seal was installed.

- c. The inspector fails to follow up on deficiencies from the previous inspection for cooked, ready-to-eat product because that product was not being made at the time of the inspection. Nor does the inspector review process records for the product to determine if the firm took appropriate corrective actions.

10. Did the inspector act in a professional manner and demonstrate proper sanitary practices during the inspection?

Examples of a “needs improvement” rating:

- a. The inspector does not use the boot bath when entering in the firm's processing areas.
- b. The inspector fails to sanitize his/her thermometer prior to probing product.
- c. The inspector fails to wear protective clothing when entering an aseptic processing area.
- d. The inspector wears jewelry, which is prohibited by the firm, in the manufacturing areas.

II. A. Inspection Observation and Performance for ‘HACCP-Required’ Facilities

[Note: These four questions may be left blank if the firm is not required by regulations to have a HACCP plan.]

References:

- FDA compliance programs referenced in the contract
- Title 21 Code of Federal Regulations (21 CFR) parts 110, 120, 123, and 1240
- Fish and Fishery Products Hazards & Controls Guide
- HACCP Regulation for Fish & Fishery Products: Questions and Answers
- Juice HACCP Hazards and Controls Guide

- 1. Did the inspector use the “Fish and Fishery Products Hazards and Controls Guide” and the “Juice HACCP Hazards and Controls Guide”, as appropriate, to identify and evaluate the hazards associated with the product and process?**

Examples of a “needs improvement” rating:

- a. In a tuna processing plant, the inspector fails to identify histamine as a hazard inherent to the incoming raw material and fails to question its absence in the firm’s HACCP plan. (Failure to identify a hazard reasonably likely to occur.)

- b. A firm is producing fresh, raw, refrigerated fish in cryovac packaging. The inspector is not aware that *C. botulinum* is a significant hazard.
 - c. An inspector incorrectly identifies aquaculture drugs as a significant hazard for a secondary processor of a product that it receives from the primary processor. (Identification of a hazard not reasonably likely to occur.)
 - d. The inspector fails to recognize that a batter tank in a breaded shrimp processing operation is a possible CCP. (Failure to recognize an appropriate CCP.)
- 2. Did the inspector assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation?**

Examples of a "needs improvement" rating:

- a. The inspector insists on the need for the firm to perform medical check-ups for crabmeat pickers.
 - b. The inspector is unaware of which of the eight areas of sanitation are relevant to the firm's operations.
 - c. The inspector fails to inquire about the firm's SSOPs and monitoring practices.
- 3. Did the inspector review firm's HACCP plan (or necessary process controls in the absence of a HACCP plan) and applicable monitoring, verification, and corrective action records, including those related to sanitation?**

Examples of a "needs improvement" rating:

- a. After conducting a brief walk through a crabmeat processor, the inspector relies on a review of the firm's records to assess the firm's implementation of its HACCP plan. The inspector does not return to the crab picking room to determine if picking and packing critical limits are being met or if the firm has the equipment to properly monitor the critical limits as specified in the plan.
- b. The inspection reveals that the firm is processing a product that requires a HACCP plan. The inspector cites the firm's failure to have a HACCP plan, but the inspector does not determine if the necessary controls were put into place without a HACCP plan.
- c. Although the inspector is told that the firm uses well water, not potable water, as its source for ice, the inspector does not verify that the firm has the water tested for coliforms to ensure its safety.
- d. The inspector does not ask the plant manager for records of pest control after learning that the service is contracted to a private company.

- e. The inspector fails to accompany the firm's sanitarian on a pre-operation inspection when there were indications that sanitary practices may be inadequate.

4. Did the inspector recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations?

Examples of a "needs improvement" rating:

- a. The inspector fails to recognize that cumulative times and temperatures for cooling, holding, and picking of cooked crabs were substantially above such times and temperatures specified in the firm's HACCP plan.
- b. The inspector fails to recognize that a firm's finished product labeling does not contain a sulfite declaration even though an ingredient contains a sulfite declaration.
- c. The inspector fails to recognize that the presence of food residues and mold growth on processing equipment immediately prior to processing is evidence of unsanitary conditions.
- d. The inspector does not recognize that food-contact surfaces are being sanitized with a product that is not approved for use on food contact surfaces.

III. Oral and Written Communication

1. Did the inspector identify himself/herself and make appropriate introductions, which include explaining the purpose and scope of the inspection?

Examples of a "needs improvement" rating:

- a. The inspector fails to explain why he/she is at the firm.
- b. The inspector enters through the back door and begins examining a storage area without notifying anyone at the firm.

2. Did the inspector use suitable interviewing techniques?

Examples of a "needs improvement" rating:

- a. The inspector requests for information are vague; consequently, the firm provides documents that are unrelated to the inspection.
- b. Because the inspector's requests for information contain jargon, the employees are confused and unable to respond to his/her requests.

- c. When the plant manager's responses are evasive, the inspector does not ask follow-up questions to obtain the necessary information. Consequently, the answers to the questions are incomplete.

3. Did the inspector explain findings clearly and adequately throughout the inspection?

Examples of a "needs improvement" rating:

- a. The inspector does not discuss the inspection observations with the firm managers at the end of the inspection.
- b. The inspector does not discuss with the general manager a significant deficiency observed in the processing area before going to the packing area of the cannery.
- c. The inspector is vague during his discussion with the managers at the end of the inspection. Therefore, the managers are unaware of the significance of the observations and that corrective actions are needed.

4. Did the inspector alert the firm's appropriate management when an immediate corrective action was necessary?

Examples of a "needs improvement" rating

- a. The inspector fails to alert the appropriate manager that food containing undeclared FD&C Yellow #5 is being packaged, and, if shipped, could result in a health hazard.
- b. The inspector fails to tell the appropriate manager about blood dripping from boxes of boneless beef onto raw carrots.
- c. After witnessing product being contaminated with a toxic chemical, the inspector immediately notifies the cleaning lady to clean up the toxic chemical to prevent further product contamination.

5. Did the inspector answer questions and provide information in an appropriate manner?

Examples of a "needs improvement" rating:

- a. The inspector tells the plant manager about FDA's legal action against a competitor.
- b. The inspector gives a competitor's product formula to a friendly plant manager.

- c. The inspector fabricates an answer to a policy question, which may lead the firm to take an inappropriate corrective action.
 - d. The inspector dictates an inappropriate corrective action for a deficiency.
- 6. Did the inspector write their findings accurately, clearly, and concisely on the State form/document left with the firm?**

References:

- FDA compliance programs referenced in the contract

Examples of a “needs improvement” rating:

- a. The inspector fails to write that the firm has a significant process deviation on the list of findings.
- b. The inspector fails to write on the list of findings that he/she observed excreta pellets in bags of rice.
- c. The list of findings shows that the “Firm did not control hazards” with no further explanation.

Appendix 4.6

Manufactured Food Regulatory Program Standards Inspection Report Audit Form	
Auditor	Date of audit
Firm identification number	Date of inspection
I. Introduction	
<p>1. FORMAT OF THE INSPECTION REPORT FOLLOWED THE STATE PROGRAM'S CURRENT PROCEDURES AND POLICIES.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>	
<p>2. REQUIRED FIELDS ON INSPECTION REPORT OR RELATED REPORT FORMS ARE COMPLETED.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>	
II. Evidence Development	
<p>1. IDENTIFIED FIRM MANAGERS AND KEY PERSONNEL AND DESCRIBED THEIR RESPONSIBILITIES.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>	
<p>2. VERIFIED LEGAL STATUS OF FIRM AND CORPORATE OFFICERS.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>	
<p>3. DOCUMENTED INDIVIDUAL RESPONSIBILITY.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>	
<p>4. REVIEWED QUALITY ASSURANCE PROGRAM AND FIRM'S PROCEDURES FOR IDENTIFYING RISK AND MAINTAINING CONTROLS.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>	
<p>5. IDENTIFIED VIOLATIONS.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>	

Page 2	
6. DOCUMENTED SIGNIFICANT FINDINGS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement	
COMMENTS (<i>required for needs improvement</i>)	
7. DOCUMENTED POSSIBLE CAUSES OF CONTAMINATION. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement	
COMMENTS (<i>required for needs improvement</i>)	
8. COLLECTED SUFFICIENT SAMPLES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement	
COMMENTS (<i>required for needs improvement</i>)	
9. COLLECTED EXHIBITS, PHOTOGRAPHS, OR PHOTOCOPIES TO DOCUMENT FINDINGS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement	
COMMENTS (<i>required for needs improvement</i>)	
10. DESCRIBED FIRM'S SYSTEM FOR PRODUCT AND LOT CODING. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement	
COMMENTS (<i>required for needs improvement</i>)	
11. REPORTED PRODUCT DISTRIBUTION. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement	
COMMENTS (<i>required for needs improvement</i>)	
12. REVIEWED RECORDS OF COMPLAINTS RECEIVED BY FIRM. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement	
COMMENTS (<i>required for needs improvement</i>)	
III. Discussions With Management	
1. DISCUSSED FINDINGS AND VIOLATIONS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement	
COMMENTS (<i>required for needs improvement</i>)	

Page 3	
2.	<p>REPORTED RESPONSES OR REPLIES FROM THE FIRM.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
3.	<p>RECORDED ANY WARNINGS OF POSSIBLE FURTHER ACTIONS (REINSPECTION, EMBARGO, REVOCATION OF LICENSE, OR LEGAL CONSEQUENCES OF VIOLATIVE CONDITIONS) GIVEN TO THE FIRM.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
4.	<p>RECORDED ANY REFUSALS ENCOUNTERED DURING THE INSPECTION.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
IV. Organization of the Report	
1.	<p>REFERENCED EXHIBITS IN THE REPORT.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
2.	<p>WRITTEN OBSERVATIONS WERE CLEAR AND CONCISE.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
3.	<p>OBSERVATIONS WERE FACT BASED AND SUPPORTED BY LAWS AND REGULATIONS.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
4.	<p>EMPHASIZED SIGNIFICANT OBSERVATIONS.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>
5.	<p>OBSERVATIONS WERE REPETITIOUS.</p> <p><input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS (<i>required for needs improvement</i>)</p>

Page 4	
6.	SUBMITTED REPORT WITHIN TIMEFRAMES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
V. Supervisory Review	
1.	STATED THE REASON FOR THE INSPECTION, A BRIEF HISTORY OF THE FIRM, AND FOLLOW-UP TO THE PREVIOUS INSPECTION, IF NECESSARY. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
2.	A SUMMARY OF FINDINGS AND DISPOSITION OF INSPECTION WERE RECORDED IN THE REPORT. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
3.	REINSPECTION SCHEDULE AND RECOMMENDATION FOR COMPLIANCE FOLLOW UP WERE GENERATED AND RECORDED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
4.	CLASSIFICATION AND FOLLOW-UP WERE CONSISTENT WITH THE LAW, CURRENT POLICIES, AND INSPECTIONAL FINDINGS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
5.	SUPERVISORY REVIEW AND ACTION WERE DONE WITHIN ADMINISTRATIVE TIMEFRAMES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)
6.	VERIFIED AND DESCRIBED CORRECTIVE ACTIONS FROM PREVIOUS INSPECTION FINDINGS. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (<i>required for needs improvement</i>)

Page 5

7. DATES IN REPORT, COVERSHEET, AND CODING OR OTHER ADMINISTRATIVE DATA WERE RECORDED ACCURATELY.

Acceptable Needs improvement

COMMENTS (*required for needs improvement*)

8. DISTRIBUTION OF REPORT WAS RECORDED ACCURATELY ON THE COVERSHEET.

Acceptable Needs improvement

COMMENTS (*required for needs improvement*)

Appendix 4.7

Manufactured Food Regulatory Program Standards Sample Report Audit Form	
Auditor	Date of audit
Sample identification number	Date of collection
I. Introduction	
<p>1. REASON FOR SAMPLE COLLECTION WAS RECORDED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (required for needs improvement)</p>	
<p>2. SAMPLE SIZE WAS DESCRIBED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (required for needs improvement)</p>	
<p>3. LOT AND PRODUCT CODING WERE RECORDED ON SAMPLE REPORT. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (required for needs improvement)</p>	
<p>4. MANUFACTURER, SHIPPER, DEALER, AND THE RESPONSIBLE FIRM WERE RECORDED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (required for needs improvement)</p>	
<p>5. REQUIRED FIELDS ON THE SAMPLE REPORT (SR) OR RELATED REPORT FORMS ARE COMPLETED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (required for needs improvement)</p>	
II. Evidence Development	
<p>1. METHOD OF COLLECTION WAS APPROPRIATE FOR TYPE OF PRODUCT. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (required for needs improvement)</p>	
<p>2. METHOD OF COLLECTION, INCLUDING SAMPLE SIZE, WAS APPROPRIATE FOR THE LABORATORY ANALYSES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (required for needs improvement)</p>	
<p>3. SAMPLE, LABELS, AND LABELING, BEAR IDENTIFICATION MARKS AND WERE ACCURATELY REPORTED ON THE SR. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement COMMENTS (required for needs improvement)</p>	

Page 2	
4.	<p>PRODUCT LABEL AND LABELING WERE SUBMITTED WITH SR. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>
5.	<p>RECEIPT FOR SAMPLE WAS OBTAINED. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>
6.	<p>AFFIDAVITS WERE CLEAR, LEGIBLE, AND COMPLETE. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>
7.	<p>SR WAS SUBMITTED WITHIN TIMEFRAMES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>
III. Sample Integrity	
1.	<p>SAMPLE WAS HANDLED, PACKAGED, AND SHIPPED TO PREVENT COMPROMISING THE CONDITION OR INTEGRITY OF THE SAMPLE. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>
2.	<p>SAMPLE WAS DELIVERED OR SHIPPED TO THE APPROPRIATE LABORATORY WITHIN ACCEPTABLE TIMEFRAMES. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>
3.	<p>SAMPLE DELIVERY (DATE AND CUSTODIAN) WAS RECORDED ON SR. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs improvement</p> <p>COMMENTS <i>(required for needs improvement)</i></p>

Appendix 4.8
Corrective Action Plan

The corrective action for each deficiency reported during an audit should be described in the table below. Supporting documents should be referenced and maintained by the State program.

State agency: _____ State program: _____

Type of audit: **FIELD INSPECTION** **INSPECTION REPORT** **SAMPLE REPORT**
(circle one)

Performance factor (record number from audit form)	Description of deficiency	Corrective action(s)	Date of next audit

Appendix 5.1
Self-Assessment Worksheet

State agency: _____ State program: _____

Does the State program meet the criteria contained in standard number 5, section 5.3?

Program Elements	Yes/ No	If no, specify why criteria are not met.
The State program uses epidemiological information from other agencies.		
1. Is the State program responsible for epidemiological investigations identified?		
2. Is there a system to coordinate agreements between the food and epidemiology programs and that clearly identifies the roles, duties, and responsibilities of each program?		
The State program has an established system to investigate reports of illness, injury, and suspected outbreaks.		
1. Are complaints alleging food-related illness, injury, or terrorism maintained in a log or database?		
2. Does the State program initiate a response to reports of illness or injury within established timeframes?		
3. Does the State program use established epidemiology procedures to conduct illness or injury investigations and collect information?		
4. Are the factors that caused the illness, injury, or incidents reported?		
The State program disseminates information to the public.		
1. Is a procedure in place that outlines criteria for releasing information to the public?		
2. Does the State program provide food safety education to the public and regulated industry?		
3. Are enforcement tools utilized to reduce and contain illness and injury?		

Program Elements	Yes/ No	If no, specify why criteria are not met.
Outbreak reports and surveillance summaries are distributed to the appropriate agencies.		
1. Does the State program maintain a current list of communication links with the appropriate agencies?		
2. Is a coordinator designated to guide investigative efforts of all agencies involved?		
3. Are investigations coordinated with the appropriate agencies?		
4. Is a procedure in place to conduct tracebacks of food implicated in an illness, injury, or outbreak, including coordination with the appropriate agencies?		
5. Are final reports of the State program's findings of foodborne illness and injury investigations maintained and shared with the appropriate agencies?		
The State program provides guidance for immediate notification of appropriate law enforcement agencies when intentional food contamination or terrorism is suspected or threatened.		
1. Is a written policy in place for handling reports or threats of intentional food contamination or terrorism?		
2. Has the State program identified a coordinator to lead investigations of suspected or threatened intentional food contamination and terrorism?		
3. Has the State program identified the appropriate agencies to be contacted and the name and phone number of designated contact persons in such agencies?		
4. Does the State program collaborate as necessary with FDA and other Federal authorities under conditions of increased threat of intentional contamination?		

Name/title of auditor: _____

Signature: _____

Date: _____

Appendix 5.2**Memorandum of understanding between the department of health and the department of agriculture concerning the investigation of foodborne illnesses associated with food service establishments and food plants**

I. GENERAL

This Memorandum of Understanding (MOU) replaces the MOU dated _____, and effective on _____, between the Department of Health (Health) and the Department of Agriculture and (Agriculture).

The purpose of this MOU is to clarify the respective responsibilities of Agriculture and Health in the surveillance for, and investigation of, foodborne illnesses, and in furtherance of such purpose, to broaden cooperative efforts between the two agencies.

Responsible Agencies

Agriculture and Health are the responsible agencies for the implementation of this MOU. Under the authority of Sections _____ of the Public Health Law and pursuant to the power granted to the State Commissioner of Health by Agriculture Law to certify and approve service food establishment permit and inspection programs of local health agencies, the State Commissioner of Health, by execution of this instrument, binds all city and county health departments and State district health offices (local health units) to its terms and conditions.

For purposes of this agreement, Health and Agriculture will be responsible for its implementation.

Jurisdiction

This MOU applies to the entire State and includes all city and county health departments.

Effective Date

This agreement will be effective _____.

Legal Authority

The _____ provides requisite authority for Agriculture and Health to enter into this MOU. Section _____ of the Public Health Law and Section _____ of the Agriculture Law also authorize this MOU.

II. RESPONSIBILITIES AND IMPLEMENTATION**Determination of Responsibility**

When a food-related illness from a manufactured food product regulated by Agriculture, Health, and local health departments is reported, Health will be responsible for conducting the epidemiologic investigation. Agriculture will be responsible for investigating the food preparation areas and conducting an investigation at the food plant. Agriculture will send a copy of these reports to Health. Agriculture will also coordinate any resulting actions to remove the contaminated food from distribution. Laboratory support for investigations will be coordinated by each agency under separate existing agreements.

Implementation

Agriculture will inform its field representatives of their areas of responsibility. Health will define areas of responsibility among its local health units. Responsibilities of other State and Federal agencies also will be specified.

Health, Agriculture, and local health units will provide or sponsor joint training sessions in the interpretation and application of principles, regulations, standards, and techniques of common concern or interest.

III. MECHANISMS FOR INFORMATION EXCHANGE

Health, Agriculture, and each local health unit shall maintain rosters of regional and local Health officials and Agriculture food program supervisors and make such rosters available to each other.

If Agriculture becomes aware of actual or suspected cases of foodborne illness, it shall report such cases by telephone--without delay--to the local health unit having jurisdiction for that locality. Health and Agriculture will jointly investigate and complete final reports involving illnesses that occur at, or due to, establishments regulated by Agriculture. These reports will be forwarded to Agriculture and to Health.

Whenever one agency learns of an FDA Class I or similar recall of food or food products, it shall immediately notify the other agency of such recall. Throughout the recall process, both agencies at all levels will make a maximum effort to keep the other agency informed and cooperate in every way possible to expedite the removal of hazardous food from the marketplace.

IV. MECHANISMS FOR EMBARGO/SEIZURE OF FOOD SOURCES IMPLICATED IN EPIDEMIOLOGIC INVESTIGATIONS

Epidemiologic Investigation

Health will investigate foodborne disease outbreaks. These investigations are conducted by county, city health departments, and/or State health departments following procedures outlined in the "Environmental Health Manual." Health will notify Agriculture of all on-going investigations where a contaminated food source is the suspected cause of a disease outbreak. Agriculture will provide assistance in the investigation and may play the lead role in tracing contaminated foods back to their source by visiting retailers, wholesalers, and producers to review and obtain records that document the chain of distribution for the products. Health will analyze the findings of the epidemiologic and source investigations and make a determination as to the likelihood of an association between the illness outbreak and its cause being one or more sources. When warranted, based on the evaluation of the investigation data and analysis, the Commissioner of Health will certify to the Commissioner of Agriculture that food from the source(s) constitute(s) a danger to the health of the people of the State and that such source(s) is/are unapproved source(s) for food service establishments in the State.

Embargo, Seizure, Recall, and Public Notification

After receiving certification from the Commissioner of Health, the Commissioner of Agriculture shall direct the seizure quarantine and/or destruction of the food in question pursuant to the provisions of Section ____ of the Agriculture Law, following his or her determination that said food is adulterated within the meaning of Section ____ of the Agriculture Law and, as such, that the manufacture, processing, possession, sale, offering, or exposure for sale of such food would violate Section ____ of the Agriculture Law. Where they deem it appropriate, the Commissioners of Health and Agriculture shall direct that a recall of such adulterated food be implemented and that the public be notified of such recall. Health shall assist in cases involving such seizures, quarantines, destructions, and recalls by assuring the removal of any remaining contaminated food from food service establishments and food plants and by making available witnesses for any administrative proceedings and/or litigation associated with such actions.

Nothing herein contained shall be construed to restrict the power of the Commissioner of Health to take Summary Action under Public Health Law Section ____ to require the discontinuance of conditions or activities constituting a danger to public health when such action is deemed appropriate under the circumstances.

V. REVIEW OF AGREEMENT

This agreement between the two departments shall be submitted annually to the Governor's Office and the Division of the Budget for their review of effectiveness and to solicit their recommendations to both Agriculture and Health as to changes of policies and procedures with respect to this agreement.

For the Department of Agriculture

Signature _____

Title _____

Date _____

For the Department of Health

Signature _____

Title _____

Date _____

Appendix 6.1
Self-Assessment Worksheet

State agency: _____ State program: _____

The State program will provide an overview of its compliance and enforcement program. References to sources such as laws, regulations, and manuals are acceptable.

1. Describe the compliance and enforcement program and include references to sources.

2. Describe how the State program uniformly applies enforcement strategy(ies).

3. Describe the methods (including electronic systems) used by the State program to track critical and chronic violations and violators.

4. Describe the risk-based process used to determine when a directed investigation, follow-up, or a re-inspection is needed.

5. Provide the established timeline for progressive compliance actions including but not limited to license revocation, embargoes, warning letters, and injunctions.

6. Describe how the State program delivers verbal and written policy and guidance impacting compliance decisions to non-operational and operational staff.

Name/title of auditor: _____

Signature: _____

Date: _____

Appendix 6.2

Summary of Compliance and Enforcement Activities

Worksheet 6.2 is used to: (1) record the enforcement actions recommended in the past 12 months and (2) calculate the State program's rating for conformance to compliance procedures. Supporting documents should be referenced and maintained by the State program. It should also be indicated when an action was taken when voluntary compliance was not achieved.

It is recommended that all cases be reviewed and compiled. State programs with a volume of cases, however, may use a statistical approach and review representative cases. Use continuation sheets as necessary.

- INSTRUCTIONS:**
- (1) Record the food firm identification number in column A and the enforcement action recommended in column B.
 - (2) For each type of enforcement action, record the level of conformance to compliance procedures in column C.
A = acceptable; NI = needs improvement
 - (3) Record the A_t and NI_t .
 A_t = vertical total of acceptable ratings.
 NI_t = vertical total of needs improvement ratings.
 - (4) Calculate the audit rating for State program's conformance to compliance procedures.

FORMULA:

$$\text{Performance factor rating} = [A_t / (A_t + NI_t) \times 100]$$

- (5) Record the rating at the top of the worksheet 6.2.

Worksheet 6.2

Calculation of the level of conformance to compliance procedures

State agency: _____ State program: _____

Rating for conformance to compliance procedures (5):

A	B	C		D
Food firm identification number (1)	Enforcement action recommended (1)	Compliance procedures followed? (2) <i>(If "NI", explain in column D).</i>		
Subtotal^a (3)	<i>Enter total number of ratings from this worksheet.</i>	A_t^a =	NI_t^a =	
Subtotals^b(3)	<i>Enter total number of ratings from all continuation sheets.</i>	A_t^b =	NI_t^b =	
TOTAL (4)	<i>Enter total of all ratings:</i> A_t = (A_t^a + A_t^b) NI_t = (NI_t^a + NI_t^b)	A_t =	NI_t =	

Name/title of auditor: _____

Signature: _____

Date: _____

Worksheet 6.2
Continuation sheet

A	B	C		D
Food firm identification number (1)	Enforcement action recommended (1)	Compliance procedures followed? (2) <i>(If "NI", explain in column D).</i>		
Subtotal^b	<i>Enter total number of ratings from this worksheet.</i>	A_t^b =	NI_t^b =	

**Appendix 7
Self-Assessment Worksheet**

State agency: _____ State program: _____ Year _____

List all industry and community outreach activities in the following table.

Date	Topic	Description	Audience Type	Number of Attendees	Location

Name/title of auditor: _____
Signature: _____ Date: _____

**Appendix 8.1
Self-Assessment Worksheet**

State agency: _____ State program: _____

Does the State program have sufficient funds, staff, equipment, and resources necessary to meet the program standards? Answer yes or no in each block. If no, please explain. Use additional pages as needed.

	Standard	Funding	Staffing	Equipment	Other resources needed
1	Regulatory Foundation				
2	Training Program				
3	Inspection Program				
4	Inspection Audit Program				
5	Food-related Illness ...Outbreaks...Food Defense...				
6	Compliance and Enforcement				
7	Industry and Community Relations				
8	Program Resources				
9	Program Assessment				
10	Laboratory Support				

Name/title of auditor: _____

Signature: _____

Date: _____

Appendix 8.2

Calculation for determining a required number of inspectors

This appendix provides a sample calculation for the number of field staff required to conduct inspections¹ of food plants. The data in the following table will vary significantly based on local or regional conditions.

Risk category	Number in inventory	Inspection frequency	Average inspection time (include travel) ²	Reinspection frequency
High	1,000	12 months	7.2 hours	10%
Medium	2,000	18 months	5.7 hours	10%
Low	1,000	24 months	4.2 hours	10%

1. Calculate available annual inspection time per full time equivalent (FTE).

For example, the State agency determines that after allowances for annual leave, sick leave, holidays, training, administrative time, and other activities each State program FTE has 1200 hours available for conducting inspections.

2. Calculate the number of hours required to inspect establishments in each risk category.

Formula for high risk establishment inspection time:

1000 firms x 100% coverage = 1000 inspections + 10% reinspection = 1100 total inspections per year x 7.2 hours = 7920 hours

Formula for medium risk establishment inspection time:

2000 firms x 66.6% coverage = 1333 inspections + 10% reinspection = 1466 total inspections per year x 5.7 hours = 8356 hours

Formula for low risk establishment inspection time:

1000 firms x 50% coverage = 500 inspections + 10% reinspection = 550 inspection total inspections x 4.2 hours = 2320 hours

3. Calculate the number of FTE's required.

Formula:

7920 hours for high risk + 8356 hours for medium risk + 2320 hours for low risk = 18596 inspection hours required / 1200 inspection hours available per FTE = **15.5 FTEs**

¹ Includes routine surveillance, reinspections, complaint or outbreak investigations, compliance follow-up investigations, risk assessment reviews, process reviews, and other direct establishment contact time such as on-site training.

² Inspection times based on calculations presented in "DHHS Office of Inspector General's FDA Oversight of State Food Firm Inspections" dated June 2000.

Appendix 8.3 Inspection Equipment

Equipment	Assigned	Available	Wish list
Computer and printer			X
Camera	X		
Digital camera			X
Credentials	X		
Important phone numbers (supervisor and servicing laboratory)	X		
Regulation and policies	X		
Paper, pen, masking tape, and permanent marker	X		
Clipboard	X		
Required forms ¹	X		
Alcohol swabs and wipes	X		
Flashlight and holder	X		
Blacklight		X	
Light meter		X	
Thermometer	X		
Infrared thermometer	X		
Exacto knife and scissors	X		
Putty knife and scraper	X		
Sampling devices (sieves, triers, and swabs)		X	
Sampling equipment (sterile containers and scoops)		X	
Coolant (ice and freezer paks)		X	
Shipping containers		X	
Appropriate sanitizer test strips	X		
Official seals	X		
Protective clothing (lab coat, gloves, and boots)	X		
Eye protection	X		
Hair restraint	X		
Hearing protection	X		
Hard hat	X		
Safety shoes			X
Respirator		X	

¹ States will attach to appendix 8.3 a list of its required inspection forms.

Worksheet 9

Self-Assessment and Improvement Tracking

State agency: _____ State program: _____ Year: _____

Standard	Initial self-assessment	Verification audit	Program improvement plan	Subsequent self-assessment
1 Regulatory Foundation	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
2 Training Program	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
3 Inspection Program	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
4 Inspection Audit Program	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
5 Food-related Illness...Outbreaks ...Food Defense...	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
6 Compliance and Enforcement	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
7 Industry and Community Relations	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
8 Program Resources	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
9 Program Assessment	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:
10 Laboratory Support	Date completed: Conformance status: Assessor initials:	Date of audit: Conformance status: Auditor initials:	Date completed: Date implemented:	Date completed: Conformance status: Assessor initials:

96

Name/title of auditor: _____

Signature: _____ Date: _____

**Appendix 10
Self-Assessment Worksheet**

State agency: _____ State program: _____

Does the State program meet the assessment criteria?

Program Elements	Yes/No	If no, please specify why criteria are not met.
Does the program have:		
a. A current list of servicing laboratories		
b. A list of analytical capabilities for each servicing laboratory		
c. A servicing laboratory to analyze samples that may contain biological hazards.		
d. Contracts or written agreements with servicing laboratories.		
e. Verification of the servicing laboratory's accreditation or certification		
The servicing laboratory's QAP contains the requirements listed here:		
a. Calibration, verification, and maintenance of equipment		
b. Documentation of analytical results		
c. Recordkeeping (worksheets, sample records)		
d. Sample accountability		
e. Sample integrity and chain of custody		
f. Qualifications of analysts (training included)		
g. Audit procedures		

Name/title of auditor: _____

Signature: _____

Date: _____