FDA's Recommended National Retail Food Regulatory Program Standards

Formulated by FDA
with input from federal, state, and local regulatory officials,
industry, trade associations, academia, and consumers.

INTRODUCTION

The aspect of national uniformity has long been a point of contention among the industry, regulators and consumers. Adoption of the Food Code has historically been the keystone in achieving that uniformity. However, a missing piece has been an agreed upon national standard or foundation for regulatory programs that administer the Food Code. The attached DRAFT Voluntary National Retail Food Regulatory Program Standards were formulated by FDA from ideas and input from federal, state, and local regulatory officials, industry, trade and professional associations, academia and consumers.

In March of 1996, the FDA met to explore ways in which the retail food program could be improved. Included in that meeting were the FDA Retail Food Specialists, FDA headquarters personnel, and state/local regulatory officials from the six FDA regions, the Association of Food & Drug Official's president, and representatives of industry. As a result of that meeting, FDA established a National Retail Food Specialist Team comprised of all the Regional Retail Food Specialists and set up an agency Retail Food Program Steering Committee representing all agency components involved with retail food. The Steering Committee was tasked with responding to the direction from the participants in the meeting, i.e. providing national leadership, being equal partners, being responsive, and providing communication and promoting uniformity.

The Steering Committee was charged with developing a five-year Operational Plan for the FDA's retail food program. As the President's Food Safety Initiative began to form, the committee was recharged with formulating an operational plan in keeping with the Food Safety Initiative's goals and mission. The Operational Plan involved soliciting input from the regulatory community, industry and consumers. The resultant Operational Plan describes the future of the National Retail Food Program and involves reassessing the respective roles of all stakeholders and how best to achieve program uniformity.

The broad goals of the plan involve two basic principles to build a new foundation for the retail program:

1. Active managerial control of the CDC identified risk factors that are known to cause foodborne illness, and
2. Establishment of a recommended retail food program framework within which the active managerial control of the risk factors can be realized.

The broad goals led to the drafting of program standards that would involve voluntary participation by the regulatory agencies. The draft standards were developed after significant input from all the stakeholders at the 1996 meeting, FDA Regional Seminars, subsequent meeting held with the states by the Retail Food Specialists, and six Grassroots Meetings held around the country in 1997. Also included were the written comments provided by industry associations, associations of regulatory officials, and others. The draft document is the result of that two-year process. As promised at the Grassroots Meetings, the draft document is being provided to the Conference for Food Protection for further input, defining, and consensus from all the stakeholders.

One of the challenges in developing and agreeing on program "standards" lies in the recognition that the overarching goal of instituting them is ultimately reducing illnesses and deaths from food produced at the retail level and that there are likely several ways to get to that point. Currently, federal, state, local, and tribal agencies have various mechanisms with varying levels of sophistication trying to achieve that goal.

The challenge in this draft document is not to capture the level of food safety to which we may ultimately aspire, but to begin to construct a standard from which is the foundation for all regulatory programs. Standards that reinforce sanitation (good retail practices), operational and environmental prerequisite programs; standards that provide direction and focus to regulatory agencies and industry on the causative factors of foodborne illness and the contributing factors; and to improve and build upon existing mechanisms and programs.

These standards constitute a framework designed to accommodate both traditional and emerging approaches and a process for continuous improvement via future standards revisions through the Conference for Food Protection process that will allow for constant program enhancement and promote uniformity.

PURPOSE AND INTENT

The purposes of these standards are to serve as a guide to regulatory retail food program managers in the design and management of a retail food program as described below in "SCOPE" and to provide a means of recognition for those programs that meet these standards.

The intent in the development of these standards is to establish a basic foundation in design and management of a retail food program. Program management may add additional requirements to meet individual program needs.

The appendices are intended to assist in the collection of information necessary for an assessment of a retail program. Alternative forms that capture the same information may be used, including those developed by a regulatory agency or jurisdiction.

SCOPE

The standards apply to the operation and management of a regulatory retail food program focused on the reduction of risk factors known to cause foodborne illness as well as other factors

that may contribute to foodborne illness and on the promotion of active managerial control of all factors that may cause foodborne illness. The results of a self-assessment based on these Standards may be used to evaluate the effectiveness of food safety interventions imposed by government and implemented by industry. The Standards provide a procedure for establishing a database against which to measure regulatory and industry efforts by measuring trends in the occurrence of risk factors over time

NEW DEVELOPMENTS
In developing these standards, FDA intends to allow for and encourage new and innovative approaches to the reduction of factors that are known to cause foodborne illness. Program managers and other health professionals participating in this voluntary program who have demonstrated means or methods other than those described here may submit those to FDA for consideration and inclusion in this program.

In fact, the draft Program Standards were pilot tested in each of the five FDA regions during 1999, and each regulatory participant reported the results at the April 2000 Conference for Food Protection. Comments from the pilot participants were reviewed and incorporated into the document dated January 2001.

IMPACT ON PROGRAM RESOURCES
Jurisdictions that pilot tested the 2/6/98-draft document reported that the initial use of the self-assessment was time consuming and could significantly impact an agency's resources. Collection, analysis and management of information for the database were of special concern. Advance planning is recommended before beginning the process. However, they also commented that the resource commitment was worthwhile, and that the results of the self-assessment were or were expected to be beneficial to the retail food protection program.

INTERPRETATIONS
To provide a uniform and reasonable application of these standards, interested persons are invited to submit comments and inquiries to the FDA Regional Retail Food Specialists or Retail Food and Interstate Travel Team (RFITT), Center for Food Safety and Applied Nutrition.

Voluntary National
Retail Food Regulatory Program Standards
DEFINITIONS

A. The following definitions apply in the interpretation and application of these Standards.
B. Terms defined.
   1) **Active Managerial Control** - Implementation and supervision of food safety practices to control risk factors by the person-in-charge.
   2) **Auditor** - An FDA Certified Evaluation Officer (CEO), or any authorized city, county, district, state, federal, tribal or other third party person who has no responsibilities for the day-to-day operations of that jurisdiction and is charged with conducting a verification audit.
   3) **Baseline Survey** - Establishment of a database that measures the occurrence of the CDC-identified foodborne illness risk factors within the retail segment of the food industry in accordance with the "FDA Retail Food Program Database of Foodborne Illness Risk Factors Report" and FDA Baseline Data Collection Form.
   4) **Baseline Survey Update** - data collected to update the initial baseline survey.
   5) **Candidate** - a regulatory officer whose duties include the inspection of retail food establishments.
   6) **Compliance and Enforcement** – Compliance includes all voluntary or involuntary conformity with provisions set forth by the regulatory authority to safeguard public health and ensure that food is safe. Enforcement includes any legal and/or administrative procedures taken by the regulatory authority to gain compliance.
   7) **Direct Regulatory Authority (DRA)** - the organizational level of government that is immediately responsible for the management of the retail program. This may be at the city, county, district, state, federal or tribal level.
   8) **Enforcement Actions -** actions taken by the regulatory authority such as warning letters, revocation or suspension of permit, court actions, monetary fines, hold orders, destruction of food, etc., to correct a violation found during an inspection.
   9) **FDA Certified Evaluation Officer (CEO) -** A person, usually a state employee, who has successfully completed the FDA requirements for certification as an evaluator of retail food safety programs.
   10) **Follow-up Inspection -** an inspection conducted after the initial routine inspection to confirm the correction of a violation(s).
   11) **Food Code Interventions** – the preventive measures to protect consumer health stated below:
      1. management's demonstration of knowledge;
      2. employee health controls;
      3. controlling hands as a vehicle of contamination;
      4. time / temperature parameters for controlling pathogens; and
      5. consumer advisory.
   12) **Good Retail Practices (GRP's)** - preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and

are not addressed by the *Food Code* interventions or risk factors.

13) **Hazard** - a biological, chemical or physical property that may cause an unacceptable consumer health risk.
14) **National Registry of Retail Food Protection Programs (National Registry)** - A listing of retail food safety programs that have voluntarily enrolled as participants in the *Voluntary National Retail Food Regulatory Program Standards*.
15) **Person in charge (PIC)** - the individual present at a food establishment who is responsible for the operation at the time of inspection.
16) **Program Element** - One of the program areas for which a National Standard has been established such as regulations, training, inspection system, quality assurance, foodborne illness investigation, compliance and enforcement, industry and consumer relations, and program resources.
17) **Program Manager** - the individual responsible for the oversight and management of a regulatory retail food program.
18) **Quality Records -** Documentation of specific elements of program compliance with the National Standards as specified in each Standard.
19) **Risk Control Plan (RCP)** - a short plan based on HACCP principles designed to control a specific risk factor.
20) **Risk Factors** - improper practices or procedures stated below which are most frequently identified by epidemiological investigation as a cause of foodborne illness or injury:
    1. improper holding temperature;
    2. inadequate cooking;
    3. contaminated equipment;
    4. unsafe source; and
    5. poor personal hygiene.
21) **Routine Inspection -** a full review and evaluation of a food establishment's operations and facilities to assess its compliance with Food Safety Law, at a planned frequency determined by the regulatory authority. This does not include reinspections and other follow-up or special investigations.
22) **Self-Assessment** - An internal review by program management to determine whether the existing program meets the National Standards.
23) **Standardization Inspection** - an inspection used to demonstrate a candidate's knowledge, communication skills, and ability to identify violations of all regulatory requirements and to develop a risk control plan for identified, uncontrolled risk factors.
24) **Trainer** - an individual who has successfully completed the training elements outlined in Standard No 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.
25) **Training Standard** - a person who has successfully completed the training elements outlined in Standard No 2; has received further training by an FDA Standardized Inspection or Training Officer; and represents the regulatory agency position on all issues.
26) **Verification Audit** - A systematic, independent examination by an external party to confirm the accuracy of the Self-Assessment.

STANDARD NO. 1
REGULATORY FOUNDATION

This standard applies to the regulatory foundation used by a retail food program. Regulatory foundation includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment.

Requirement Summary

The regulatory foundation includes provisions for:

1. The public health interventions contained in the *Food Code;*
2. Control measures for the risk factors known to contribute to foodborne illness;
3. Good Retail Practices (GRP's) at least as stringent as the *Food Code*; and
4. Compliance and enforcement at least as stringent as the selected provisions from *Food Code* and Annex 1 of the *Food Code*.

Description of Requirement

A. *Food Code* Interventions and Risk Factor Control Measures

The regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the *Food Code*. To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed in Appendix A, Table A-1 and summarized in Table A-2, from #1 "Demonstration of Knowledge" through #11 "Highly Susceptible Populations." For initial listing, the regulatory foundation must contain at least 9 of the 11 interventions and risk factor controls. In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the second audit.

B. Good Retail Practices

The regulations contain provisions that address Good Retail Practices that are at least as stringent as those described in the *Food Code*. To meet this element of the Standard, regulations must have a corresponding requirement for 95 percent of the *Food Code* sections as listed in Appendix A, Table A-3 and summarized in Table A-4, from #12 "Personnel" through #37 "Variance for Smoking."

C. Compliance and Enforcement

The regulations contain provisions that address Compliance and Enforcement requirements that are at least as stringent as those contained in the *Food Code*. To meet this element of the Standard, regulations must have a corresponding requirement for each of the *Food Code* sections

as listed in Appendix A, Table A-5, items 1 through 15.

Outcome

The desired outcome of this standard is the adoption of a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry.

Documentation

The quality records needed for this standard include:

1. The statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of a retail food establishment; and

2. The completed Appendix A and its accompanying tables.

STANDARD NO. 2
TRAINED REGULATORY STAFF

This standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory staff shall have the knowledge, skills, and ability to adequately perform their required duties.

Description of Requirement

One hundred percent (100 Percent) of the inspection staff shall comply with each of the following items.

1. Curriculum

Within 18 months of employment or assignment to the retail food program, the regulatory staff conducting inspections of retail food establishments must satisfactorily complete of training that includes the following components:

1. prevailing statutes, regulations, ordinances;
2. public health principles;
3. communication skills;
4. microbiology;
5. epidemiology;
6. HACCP.

Credit for each component may be gained by providing documentation of previous training (college courses, military training, etc.). Satisfactory completion of each training component is documented in the individual's training plan. (See www.fda.gov for a Example Training Plan.)

2. Field Training and Experience

Within 12 months of employment or assignment to the retail food program, the regulatory staff conducting inspections of retail food establishments must satisfactorily complete initial field training as described below. Initial field training includes:

1. Twenty five joint training inspections; and

2. Twenty five independent inspections

Field training consists of at least twenty-five joint training inspections with a trainer who has successfully completed all training elements required by this standard. After completing the joint training inspections, the candidate completes at least twenty-five independent inspections of the various types of retail food establishments regulated by the jurisdiction.

3. Field Standardization

Within 18 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete eight joint inspections with a "training standard" using a process similar to the *FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officer*. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas: 1) Good Retail Practices, 2) Risk-based inspections, 3) Application of HACCP, 4) Inspection equipment, and 5) Communication.

Continuing standardization shall be maintained by performing six joint inspections with the "training standard" every three years.

4. Continuing Education and Training

Each employee conducting inspections accumulates 20 contact hours of continuing education every 36 months after the initial training (18 months) is completed. The candidate qualifies for 1 contact hour for each hour's participation in any of the following activities:

1. Attendance at regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Workshops;
4. Food-related training provided by government agencies.

See Appendix B, Trained Regulatory Staff, as an example of a self-assessment tool containing all the essential information for documenting compliance with this Standard.

Outcome

The desired outcome of this standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates earned from the successful completion of course elements of the uniform curriculum;
2. Contact hour certificates for continuing education;
3. Procedures for standardization;
4. Standardization certificates or other records showing proof of satisfactory standardization;
5. Field inspection reports for twenty-five each joint and independent inspections;
6. Date of hire records or assignment to the retail food program; and
7. Summary record of employees' compliance with the Standard (For an example see Appendix B).

STANDARD NO. 3
INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

Requirement Summary

An inspection program that focuses on the status of risk factors, determines and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

1. Implements the use of an inspection form that is designed for the identification of risk factors and intervention, documentation of the compliance status of each risk factor and intervention (i.e. in compliance, out of compliance, not observed, or not applicable for risk factors), and documentation of all compliance and enforcement activities.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk.
4. Develops and implements a program policy that requires:
   a) On-site corrective actions* as appropriate to the type of violation.
   b) Discussion of long-term control** of risk factor options, and
   c) Follow-up activities.
5. Establishes and implements written polices addressing code variance requests related to risk factors and interventions.
6. Establishes written polices regarding the verification and validation of HACCP plans when a plan is required by the code.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:

1. Inspection form,
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category,
3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections.

*Note: **On-site** corrective action as appropriate to the violation would include such things as:

a. Destruction of foods that have experienced extreme temperature abuse,
b. Embargo or destruction of foods from unapproved sources,
c. Accelerated cooling of foods when cooling time limits can still be met,
d. Reheating when small deviations from hot holding have occurred,
e. Continued cooking when proper cooking temperatures have not been met.
f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

STANDARD NO. 4
UNIFORM INSPECTION PROGRAM

This standard applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance / enforcement procedures.

Requirement Summary

Program management has established a quality assurance program to ensure uniformity among regulatory staff in the interpretation and application of laws, regulations, policies, and procedures.

Description of Requirement

1) Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff. The quality assurance program shall:

   A. Be an on-going program.

   B. Assure that each inspector:

      1. Determines and documents the compliance status of each risk factor and intervention through observation and investigation;
      2. Completes an inspection report that is clear, legible, concise, and accurately records findings, observations and discussions with establishment management;
      3. Interprets and applies laws, regulations, policies and procedures correctly;
      4. Cites the proper local code provisions for CDC-identified risk factors and Food Code interventions;
      5. Reviews past inspection findings and acts on repeated or unresolved violations;
      6. Follows through with compliance and enforcement;
      7. Obtains and documents on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation;
      8. Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of control risk factor occurred on consecutive inspections. Options may include but are not limited to risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans;
      9. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met; and

10. Files reports and other documentation in a timely manner.

C. Describe the actions that will be implemented when the program analysis identifies deficiencies in quality or consistency in any program aspect listed in 1) B.

2) The quality assurance program must achieve an overall inspection program performance rating for each of the ten measured aspects [Items1-10] of at least 75% using the following self-assessment procedure and the appropriate Table in Appendix D.

An assessment review of each inspector's work shall be made during at least two joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports of the same inspected establishments, during every self-assessment period.

Outcome

A quality assurance program exists that ensures uniform, high quality inspections.

Documentation

The quality records needed for this standard include:

1. A written procedure that describes the jurisdiction's quality assurance program, including corrective actions for deficiencies, and
2. Documentation that the program achieves a 75 percent performance rating on each aspect using the self-assessment procedures described above and in Appendix D.

STANDARD NO. 5
FOODBORNE ILLNESS INVESTIGATION & RESPONSE

This standard applies to the investigation and subsequent review of alleged foodborne illness incidents and outbreaks.

Requirement Summary

The program has an established system to collect and investigate complaints of food-related illness and injury; and investigate foodborne disease outbreaks.

Description of Requirement

The retail food program and the appropriate epidemiological investigation program or other department or agencies have an established operating procedure or, if appropriate a Memorandum of Understanding (MOU) for conducting investigations of foodborne illness. The operating procedure or the MOU clearly identifies the roles, duties and responsibilities of each party.

Food program management, alone or in cooperation with another department or agency, maintains a log or database of all complaints alleging food-related illness or injury. Follow up on complaints that involve alleged illness or injuries are conducted by the regulatory agency within 24 hours of receiving the complaint. At the conclusion of the complaint investigation, the findings are recorded in the log or database, and the investigation reports are filed in or linked to the establishment record for retrieval purposes. The final report of the investigation is shared with the state epidemiologist and Centers for Disease Control and Prevention.

During illness or injury investigations, procedures used and information collected are similar to those found in the *International Association for Food Protection Procedures to Investigate A Foodborne Illness, Fifth Edition* and include the possible contributing factors to the illness or injury.

The laboratory support for illness or injury investigations, follow-up sampling and surveillance activities related to foodborne illness investigation is identified and described in writing by the food program and, if appropriate, MOU's between the food program and a laboratory are developed. Laboratory support includes in-house capability or access to external sources. Laboratory support includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis. The types of pathogens, chemical agents, or other food adulterants that can be identified by the laboratory are also described.

Program management has an established procedure to address the trace-back of food implicated in an illness or outbreak. These procedures include provisions for the coordinated involvement of the appropriate agencies as well as the identification of an appropriate coordinator to guide the investigation efforts of all the agencies involved. A final report is shared with the agencies

involved, including CDC.

Recall of a product is initiated based on conclusions of the illness or injury investigation. Recall procedures equivalent to *21 CFR, Part 7*, are utilized when the jurisdiction has the responsibility to request or monitor a recall. Written procedures are established for conducting effectiveness checks of actions by firms when requested by cooperating agencies.

Procedures are established that define criteria for when information is provided to the public regarding a FBI outbreak. The media person for the agency is identified.

An annual review of the data in the log or data base and the illness or injury investigations is conducted to identify the trends and possible contributing factors that are most likely to cause illness or injury. The review focuses on, but is not limited to:

1. Multiple complaints on the same establishment;

2. Multiple complaints on the same establishment type;

3. Multiple complaints implicating the same food;

4. Multiple complaints associated with similar food preparation processes;

5. Number of laboratory-confirmed, food-related outbreaks;

6. Number of non-laboratory-confirmed but epidemiologically linked, food-related outbreaks;

7. Contributing factors most often identified.

Outcome

A food regulatory program has a systematic approach for the investigation, documentation and analysis of alleged food-related illness and injury.

Documentation

The quality records required to meet this standard include:

1. That the log or database of alleged food-related illness or injury complaints is maintained and findings recorded.

2. The illness, injury, outbreak investigation procedures and the data collection instrument

utilized.

3. Investigation reports of alleged foodborne illness. Reports are retrievable by implicated establishment name.

4. A written description of laboratory support available or the MOU that outlines laboratory support and includes the types of samples that can be analyzed and the analysis that can be conducted.

5. The procedure addressing the trace-back of food products implicated in an illness or outbreak.

6. *21 CFR, Part 7*, or a document comparing the food program's recall procedures to the recall procedures outlined in *21 CFR, Part 7*. Procedures for monitoring or conducting effectiveness checks of a firm's actions when requested by cooperating agencies.

7. The annual report of the review of the log or database and the report of the review of illness or injury investigations.

8. Procedure and contact person for release of public information.

STANDARD NO. 6
COMPLIANCE AND ENFORCEMENT

This standard applies to all compliance and enforcement activities used by a jurisdiction to achieve compliance with regulations.

Requirement Summary

Compliance and enforcement activities result in follow-up actions for out-of-control risk factors and timely correction of code violations

Description of Requirement

Compliance and enforcement encompasses all voluntary and regulatory actions taken to achieve compliance with regulations. Voluntary corrective action includes, but is not limited to, such activities as on-site corrections at time of inspection, voluntary destruction, risk control plans and remedial training. Enforcement action includes, but is not limited to, such activities as warning letters, re-inspection, citations, administrative fines, permit suspension and hearings. Compliance and enforcement options may vary depending on state and local law.

The program must demonstrate credible follow-up for each violation noted during an inspection, with particular emphasis being placed on risk factors that most often contribute to foodborne illness and *Food Code* interventions intended to prevent foodborne illness. The resolution of out-of-compliance risk factors and/or food code interventions must be documented in each establishment record. The essential program elements required to meet this standard are:

1. A written step-by-step procedure that describes how compliance and enforcement tools are to be used to achieve compliance.
2. Inspection report form(s) that record and quantify the compliance status of risk factors, interventions and other serious code violations.
3. Documentation on the establishment inspection report form or in the establishment file that compliance and/or enforcement action was taken to achieve compliance at least 80 percent of the time when out-of-control risk factors or interventions are recorded on a routine inspection measured using the procedures in Appendix F.
4. Compliance and enforcement actions that follow the step-by-step procedure.

Outcome

The desired outcome of this standard is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

Documentation

The quality records needed for this standard include:

1. A copy of the written step-by-step enforcement procedures.

2. Documentation that compliance and enforcement action was taken 80 percent of the time using the worksheet and procedures in Appendix F when out-of-control risk factors or code interventions are recorded on routine inspections.

3. A reference "Key" which identifies the major risk factors and *Food Code* interventions on the jurisdiction's inspection report form. [Note: A jurisdiction will not be penalized under Standard No. 6 for sections of the *Food Code* which have not yet been adopted.]

STANDARD NO. 7
INDUSTRY AND COMMUNITY RELATIONS

This standard applies to industry and community outreach activities utilized by a regulatory program to solicit a broad spectrum input into a comprehensive regulatory food program, communicate sound public health food safety principles, and foster and recognize community initiatives focused on the reduction of foodborne disease risk factors.

Requirement Summary

The jurisdiction documents participation in forums that foster communication and information exchange among the regulators, industry and consumer representatives.

The jurisdiction documents outreach activities that provide educational information on food safety.

Description of Requirement

1. Industry and Consumer Interaction

   The jurisdiction sponsors or actively participates in meetings such as food safety task forces, advisory boards or advisory committees. These forums shall present information on food safety, food safety strategies and interventions to control risk factors. Offers of participation must be extended to industry and consumer representatives.

2. Educational Outreach

   Outreach encompasses industry and consumer groups as well as media and elected officials. Outreach efforts may include industry recognition programs, web sites, newsletters, FightBAC™ campaigns, food safety month activities, food worker training, school-based activities, customer surveys or other activities that increase awareness of the risk factors and control methods to prevent foodborne illness. Outreach activities may also include posting inspection information on a web site or in the press.

Agency participation in at least one activity in each of the above categories annually is sufficient to meet this standard.

Outcome

The desired outcome of this standard is enhanced communication with industry and consumers through forums designed to solicit input to improve the food safety program. A further outcome is the reduction of risk factors through educational outreach and cooperative efforts with

stakeholders.

Documentation

Quality records needed for this standard reflect activities over the most recent three-year period and include:

1. Minutes, agendas or other records that forums were conducted,

2. For formal, recurring meetings, such documents as by-laws, charters, membership criteria and lists, frequency of meetings, roles, etc.,

3. Documentation of performed actions or activities designed with input from industry and consumers to improve the control of risk factors, or

4. Documentation of food safety educational efforts.

Statements of policies and procedures may suffice if activities are continuous, and documenting multiple incidents would be cumbersome, i.e., recognition provided to establishments with exemplary records or an on-going web site.

STANDARD NO. 8
PROGRAM SUPPORT AND RESOURCES

This Standard applies to the program resources (budget, staff, equipment, etc.) necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors known to contribute to foodborne illness.

Requirement Summary

The program provides funding, staff and equipment necessary to accomplish compliance with the Voluntary National Retail Food Regulatory Program Standards.

Description of Requirement

The program budget provides the necessary resources to develop and maintain a retail food safety program that meets the following criteria:

1. A staffing level of one full-time equivalent (FTE) devoted to food for every 280 - 320 inspections performed*. Inspections for purposes of this calculation include routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews and other direct establishment contact time such as on-site training.

   A process should exist for the regulated food establishments to be grouped into at least three categories based on food safety risk (See Standard 3). The number of inspections assigned per FTE should be adjusted within the 280-320 range depending upon the composition of low- to high-risk establishments in the assigned inventory. When an FTE is divided between program areas, the total number of food inspections planned for that FTE should be adjusted to compensate for the additional training time required to maintain competency in multiple program areas. An adjustment of planned inspections per FTE should also occur when food establishments are geographically dispersed due to increased travel time.

2. Inspection equipment of each inspector to include head covers, thermocouples, flashlights, sanitization test kits, heat sensitive tapes or maximum registering thermometers, necessary forms and administrative materials. The following equipment must be available for use by inspectors when needed: computers, cameras, black lights, light meters, pH meters, foodborne illness investigation kits, sample collection kits, data loggers and cell phones.

3. Equipment for administrative staff to include computers, software and/or items necessary to support the record keeping system utilized by the program. A system is in place to collect, analyze, retain and report pertinent information.

4. Training and training documentation for all regulatory staff to meet the level specified in Standard No. 2.

5. Staff to meet all of the requirements in Standard No. 3, inspection based on HAACP principles.

6. Administrative and supervisory staff to administer and monitor a uniform inspection program based on HACCP principles that meet Standards No. 3 and 4.

7. Staff and resources to maintain a foodborne illness investigation and response system that meets Standard No. 5.

8. A program that demonstrates follow-through on all compliance and enforcement actions initiated according to the written step-by-step procedures required in Standard No. 6.

9. An industry and consumer relations program as specified in Standard No. 7.

10. Sufficient staff and resources to conduct regular program self-assessment and risk factor surveys as specified in Standard No. 9.

11. Funds to provide access to accredited laboratory resources in support of the program as specified under these nine Standards.

The essential program elements required to demonstrate compliance with this standard are:

A. Full-time equivalent (FTE) personnel to inspections accomplished ratio as described in element 1.
B. Inspection equipment assigned or available as described in element 2.
C. Equipment and/or supplies required for administering the program as described in element 3.
D. A full and accurate completion of Appendix H for Standards 1-7 and Standard 9 whether or not those standards are met.

Outcome

The desired outcome of this standard is that resources are available to support a risk-based retail food safety program designed to reduce the risk factors known to contribute to foodborne illness.

Documentation

The quality records needed for this standard include:

1. Documentation of FTE to inspections ratio,
2. Inventory of assigned and available inspection equipment,

3. Documentation and demonstration of records system and adequacy of support
4. The completed Appendix H

*NOTE: An average workload figure of 300 inspections per year was originally recommended in the *1976 Food Service Sanitation Manual*, the standard originating from a book entitled, "Administration of Community Health Services." This approximate figure was recently reaffirmed by a study of inspection times for five risk categories performed by the Ohio Department of Agriculture in cooperation with the Ohio Department of Health. Their study resulted in a median time of 4.18 hours per establishment.

STANDARD NO. 9
PROGRAM ASSESSMENT

This standard applies to the process used to measure the success of jurisdictions in meeting the *Voluntary National Retail Food Regulatory Program Standards 1 through 8* (hereafter referred to as the National Standards) and their progress in reducing the occurrence of foodborne illness risk factors. Additionally, it applies to the requirements for recognition by the Food and Drug Administration of those jurisdictions meeting the National Standards.

Requirement Summary

1. That the program manager conducts an initial *self-assessment* within 12 months of the date of enrollment in the National Registry and every 36 months thereafter;

2. That a baseline survey and report on the occurrence of risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit. The baseline information is updated at least once within every 3-year audit interval to measure trends; and

3. That a *verification audit* is conducted within 36 months of the initial *self-assessment* and following the initial baseline survey report. Subsequent verification audits are conducted every 36 months thereafter.

Description of Requirement

1. Self-Assessment: The program manager, or a designated representative, conducts an initial *self-assessment* of the retail food safety program within 12 months of the date of enrollment in the National Registry and every 36 months thereafter. The *self-assessment* will determine:

   A. The compliance status with each of the National Standards by completing the Appendix documents (hereafter referred to as the worksheets) for each Standard, and

   B. Whether the *quality records* specified as requirements in each of the National Standards have been established, identified, and maintained. If the quality records for a specific program element are incomplete or provide inadequate information upon which to make a determination, that standard is not met.

2. A baseline survey and report on the occurrence of risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit. The baseline information is updated at least once in every 3-year audit interval to measure trends. The subsequent surveys and reports will determine whether there has been a net change in the occurrence of the risk factors and use *Food Code* interventions. A survey tool similar to Appendix J is required.

3. Verification audit: The first *verification audit* is conducted within 36 months the initial *self-assessment* and following the initial baseline survey report. An individual as defined in the definitions shall complete the verification audit. Subsequent verification audits are conducted every 36 months thereafter. Verification audits confirm and report on the accuracy of the *self-assessment* and the survey reports. During the *verification audit*, the auditor will:

   A. Review the *quality records* and confirm that the *self-assessment* accurately reflects the current program compliance status in each of the program elements, and

   B. Confirm that the baseline data collection procedures and survey tools similar to Appendix I have been used and that the conclusions are supported by the data.

4. Reporting: The FDA National Registry Report will be completed and submitted to the appropriate FDA Regional office within 30 days following completion of the self-assessment, baseline surveys, verification audits, and/or baseline update. The FDA National Registry will be updated using data contained in this report. A current Release and Permission to Publish Form must accompany each FDA National Registry Report

OUTCOMES

The desired outcome of this Standard is to enable managers to measure their program against national criteria. The process identifies program elements that may require improvement or be deserving of recognition.

DOCUMENTATION

The quality records required for this standard include:

1. The completed Appendices (worksheets) for each Standard and supporting records,
2. Baseline survey report,
3. Verification audit report,
4. FDA National Registry Report, and
5. Affidavit of Permission to Publish.