# Chapter 5
# Regulatory Program Foundations: Program Standards

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**Learning Objectives**

- Discuss the overarching concepts of national program standards.
- Discuss the interdependencies of various program standards.
- Illustrate a systems approach using the program standards.

## Introduction

Model program standards provide foundations upon which regulatory programs can be built and continuously improved and are important in the development of an integrated food safety system (IFSS). Standards for federal, state, or local agencies

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do not carry the legal authority of laws, statutes, ordinances, or regulations. Rather, standards serve as a guide for agency managers in the design and management of a food safety regulatory program. As a result, regulatory agencies can measurably improve their existing programs and better focus on those factors that contribute to foodborne illness. Food protection professionals (FPPs) should be aware of the role that program standards play in the overarching goal of food safety. This, in turn, can help improve industry and consumer confidence in food protection programs and enhance uniformity within and between regulatory agencies.

The standards addressed in this chapter include national standards created by the US Food and Drug Administration (FDA, www.fda.gov) for various regulatory programs (retail food regulatory programs, manufactured food regulatory programs, and animal feed regulatory programs), public health-related standards from the US Centers for Disease Control and Prevention (CDC, www.cdc.gov) and the Public Health Accreditation Board (PHAB), the International Comparability Assessment Standards (ICAT), and standards proposed by the Food Safety Modernization Act (FSMA) related to third-party auditors.

## National Program Standards

### *Voluntary National Retail Food Regulatory Program Standards (VNRFRPS)*

In the US, state, local, tribal, and territorial agencies are responsible for the regulation of the retail food industry—restaurants, grocery stores, schools, and hospitals—while FDA provides technical assistance to these agencies. In the late 1990s, FDA held a series of meetings with several agencies, along with industry and consumer groups, to gather feedback and ideas on how to increase uniformity in retail food regulation, a primary need identified by FDA and all stakeholder groups (FDA 2013a), along with a way for regulatory programs to measure improvement and be recognized for that improvement. Encouraging regulatory agencies to adopt the FDA Food Code (www.fda.gov/FoodCode/) remains one of the primary goals of FDA, but in this case, the goal was even broader. FDA sought to develop a mechanism that could be universally implemented and that was inclusive of every major function (e.g., regulations, training, quality assurance, foodborne illness investigation, etc.) of a retail food protection program. Out of these meetings and information sharing, the VNRFRPS began to take shape and were developed into the model that is largely still in practice today.

The VNRFRPS serve as a guide to regulatory food program managers in the design and management of a retail food regulatory program and provide a means of recognition for those programs that meet these standards. Program managers and administrators may establish additional requirements to meet individual program needs (FDA 2013a).

The VNRFRPS are designed to help food regulatory programs enhance the services they provide to the public. When applied in the intended manner, the program standards should:

- Identify program areas where an agency can have the greatest impact on retail food safety.
- Promote wider application of effective risk factor intervention strategies.
- Assist in identifying program areas most in need of additional attention.
- Provide information needed to justify maintenance of or increase in program budgets.
- Lead to innovations in program implementation and administration.
- Improve industry and consumer confidence in food protection programs by enhancing uniformity within and between regulatory agencies (FDA 2013a).

The VNRFRPS consist of nine (U.S. Food and Drug Administration 2013c) individual standards, each encompassing a major aspect of a regulatory retail food safety program. Jurisdictions can enroll in the program and then measure themselves against each of the standards to determine their strengths, as well as identify gaps in their food safety program. This self-assessment and gap analysis provides the program with a measuring stick that can be used to plan program improvement. The standards do not have to be accomplished in order; progress toward the standards can be tailored to the specific needs of the jurisdiction. As of October 2014, more than 630 jurisdictions in the US—at the state, territory, district, county, city, town, or other level—had enrolled in the VNRFRPS (FDA 2014a).

## *VNRFRPS Standard 1: Regulatory Foundation*

Standard 1 applies to the regulatory foundation used by a retail food regulatory program. The regulatory foundation includes any statute, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment. In order to achieve conformance with Standard 1, a jurisdiction must examine its own food safety regulations to determine if the regulations are comparable to the FDA Food Code. The jurisdiction's regulations do not have to be exactly the same as the Food Code, but must establish an equivalent level of protection. The desired outcome of this standard is the adoption of a sound, science-based regulatory foundation for the food safety regulatory program and the uniform regulation of industry (FDA 2013a).

## *VNRFRPS Standard 2: Trained Regulatory Staff*

Standard 2 applies to the essential elements of a training program for food safety regulatory staff. The essential elements in this standard include new employee initial training, coursework, field inspection work (conducted both with a trainer and

individually), standardization, and continuing education. A jurisdiction has flexibility in how its training program is structured. FDA online courses or a combination of equivalent courses could be utilized by FPPs. The courses must cover topics such as prevailing regulations, food microbiology, communication skills, and foodborne illness investigation. As indicated above, Standard 2 also incorporates a process for "standardization." Standardization is an assessment of the employee in the field to evaluate his or her inspection techniques, communication abilities, and rule interpretation/application. The desired outcome of this standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections (FDA 2013a).

### *VNRFRPS Standard 3: Inspection Program Based on HACCP Principles*

Standard 3 is intended to focus a jurisdiction's inspection program on hazard analysis and critical control points (HACCP) principles. In order to achieve conformance with this standard, the program must focus inspections on the status of risk factors, determine and document compliance with the risk factors, and target corrective actions, both on-site and long-term (e.g., embargo or destruction of foods from unapproved sources, temperature controls, handwashing, prevention of hand contact with ready-to-eat foods, etc.). In addition, a jurisdiction must have a way to categorize food establishments based on risk and assign them an inspection frequency related to that categorization.[1] 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 (FDA 2013a).

### *VNRFRPS Standard 4: Uniform Inspection Program*

Standard 4 is intended to guide program management in the implementation of an ongoing quality assurance (QA) program. In order to achieve conformance with this standard, there must be an ongoing QA program that ensures a minimum level of competency in ten quality elements. These quality elements focus on areas such as proper completion of inspection reports, correction and follow-up regarding risk factor violations, and taking appropriate compliance and enforcement actions. This standard is also intended to guide program staff in the documentation of corrective action when problems are noted during the evaluations (e.g., remedial staff training).

[1] For example, a nursing home that prepares food for the elderly (a population highly susceptible to foodborne illness) would be inspected more frequently than a convenience store that sells hot dogs.

The desired outcome of this standard is to ensure high-quality inspections during which inspection personnel are uniform in their interpretation and application of laws, rules, and policies (FDA 2013a).

### *VNRFRPS Standard 5: Foodborne Illness and Food Defense Preparedness and Response*

Standard 5 is intended to guide a program in the establishment and implementation of a system to detect, collect, investigate, and respond to complaints and emergencies that involve foodborne illness, injury, and intentional or unintentional food contamination. The criteria in this standard address the jurisdiction's relationship with epidemiologists and communicable disease personnel, laboratory support, emergency responders, and others who could be involved in foodborne illness and food defense response situations. This standard also addresses the jurisdiction's understanding of jurisdictional lines and responsibilities, particularly as they relate to food recall and trace-back procedures, the policies and procedures in place regarding the investigation of food-related complaints, recalls, and media management. This standard requires that a foodborne illness and/or defense exercise be conducted by the jurisdiction if any actual event has not occurred in the previous year. The desired outcome of this standard is that the program has a systematic approach for the detection, investigation, response, documentation, and analysis of food-related incidents that involve illness, injury, or unintention, or deliberate food contamination (FDA 2013a).

### *VNRFRPS Standard 6: Compliance and Enforcement*

Standard 6 is intended to guide a retail food regulatory program in the establishment and implementation of compliance and enforcement activities. Compliance and enforcement activities include all voluntary and regulatory actions taken to achieve compliance with regulations. In order to achieve conformance with this standard, a program must establish policies and procedures for compliance and enforcement. This standard does not dictate which tools the jurisdiction should have available, but only that the jurisdiction has step-by-step procedures to use certain tools along with a mechanism to ensure that the tools are being used appropriately. Examples of compliance and enforcement tools that a jurisdiction might implement include the closure of establishments, embargo of food, and administrative and/or civil penalties. In addition to establishing policies and procedures, program staff must assess whether FPPs are consistently implementing the jurisdiction's compliance and enforcement policies and procedures. The desired outcome of this standard is an effective compliance and enforcement program that is implemented consistently and progressively to achieve compliance with regulatory requirements (FDA 2013a).

### *VNRFRPS Standard 7: Industry and Community Relations*

Standard 7 examines the jurisdiction's activities with its regulated industry and community. Conformance with this standard is achieved by implementation of education and outreach activities such as food safety task forces (which include regulatory, industry, and consumer representatives), industry training initiatives, and other activities designed to educate and solicit feedback from various stakeholder groups. The desired outcome of this standard is enhanced communication with industry and consumers through forums designed to solicit input to improve the food safety regulatory program. Another desired outcome of this standard is the reduction of food safety risk factors through educational outreach and cooperative efforts with stakeholders (FDA 2013a).

### *VNRFRPS Standard 8: Program Support and Resources*

Standard 8 applies to a jurisdiction's staffing and resources. This standard includes an assessment of the amount of inspection staff needed for the number of inspections conducted within the jurisdiction. A staffing level of one employee or full-time equivalent should be devoted to food protection work for every 280–320 inspections performed. Standard 8 also assesses the resource needs, such as funding and equipment, necessary to effectively implement the food safety program. The desired outcome of this standard is that sufficient resources are available to support a risk-based retail food regulatory program (FDA 2013a).

### *VNRFRPS Standard 9: Program Assessment*

Standard 9 is an assessment of program effectiveness. There are two components incorporated in Standard 9: the risk factor study and the intervention strategy. The risk factor study provides a method to assess the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors. A risk factor study is an analysis of the occurrence of foodborne illness risk factors in regulated establishments. Foodborne illness risk factors are those conditions which are most likely to lead to foodborne illness if left uncontrolled. The top five foodborne illness risk factors are food from unsafe sources, time/temperature abuse, improper cooking temperatures, contaminated equipment and cross-contamination of food, and poor personal hygiene.

The risk factor study serves two primary purposes. The first purpose is to identify risk factors that are in need of priority attention and develop appropriate intervention strategies to reduce the occurrence of those risk factors (FDA 2013a). For example, if a jurisdiction conducts a risk factor study and finds that a high number of establishments have problems with cooling foods, an intervention strategy could

be implemented to address the problem. That intervention strategy could include the development of educational tools (brochures, reminder signs, etc.), stronger emphasis during inspections, training courses for workers, and the purchase of demonstration tools (e.g., chill sticks) that could be used by FPPs during inspections. Future risk factor studies could then be used to evaluate the effectiveness of those intervention strategies.

The second purpose of the risk factor study is to evaluate trends over time (FDA 2013a). Standard 9 requires that risk factor study data be collected at least every 5 years to provide sufficient data to analyze. For example, the FDA conducted nationwide risk factor studies in 1998, 2003, and 2008 with the goal of seeing a 25 % reduction in risk factor occurrence over the 10-years period. While this goal was not achieved overall, the trend analysis provided detailed information regarding areas where improvement is being made and where additional attention is needed (FDA 2009).

A risk factor study can be conducted either through an evaluation of regularly -conducted inspection data or through a special survey of randomly-selected establishments in the jurisdiction. In either case, having a staff that is properly-trained in collecting the data is of the utmost importance.

## *Changing/Revising the VNRFRPS: Conference for Food Protection (CFP)*

Changes/revisions to the VNRFRPS are made through the Conference for Food Protection (CFP, www.foodprotect.org), a parliamentary-style organization that operates through committees, councils, and a general assembly and comprises representatives from the food industry, government, academia, and consumer organizations. Any stakeholder can submit an "issue" to the biennial CFP meeting and ask that the conference consider a change to the standards. Issues related to the Retail Program Standards are debated in council 2—administration, education, and certification. Council 2 is comprised of appointees from all stakeholder groups with equal representation from the regulatory and industry sectors. FDA, CDC, and USDA representatives have non-voting, consultant status on this council. Issues submitted to the Conference for Food Protection, and debated within a council, can be accepted as submitted, accepted after amendments made by the council, or rejected by the council by majority vote. The issues then go before the general assembly, which represents regulators from all the 50 states and territories. If the general assembly agrees with the council's recommendation, the issue is sent to the FDA for further consideration. If the general assembly does not agree with the council's recommendation, then the issue may be revisited by an ad hoc committee formed by the executive board of the CFP, which comprises members from federal, state, and local food regulatory agencies, along with industry, consumer, and academia representatives. More information about the CFP Councils can be found at www.foodprotect.org/administration/councils/.

## *Manufactured Food Regulatory Program Standards (MFRPS)*

The VNRFRPS were written for retail food regulatory programs and are a voluntary set of standards. In contrast, the Manufactured Food Regulatory Program Standards (MFRPS) were developed by FDA, along with selected state program managers, and are used as a guide for continuous improvement for state food manufacturing programs (FDA 2014b). Although the MFRPS were patterned after the VNRFRPS—and there is significant overlap—differences between the respective sets of standards do exist. There are nine VNRFRPS, yet ten MFRPS. This is because, in the MFRPS, *laboratory support* is its own standard (MFRPS Standard 10). In the VNRFRPS, laboratory support is a component of VNRFRPS Standard 5—Foodborne Illness and Food Defense Preparedness and Response. The requirements, the documentation necessary to demonstrate compliance, and the intended outcomes are similar for some VNRFRPS and MFRPS standards; however, differences between the standards also exist due to the differences in administering a manufactured food regulatory program versus a retail food regulatory program. The MFRPS were first published and piloted in 2007 and updated in 2010 and 2013 (FDA 2013b). Like the VNRFRPS, the MFRPS represent a platform that facilitates integration between states and FDA, establishes a uniform basis for measuring and improving the performance of regulatory programs, and helps agencies direct their regulatory activities to reduce foodborne illness hazards. Additionally, the MFRPS are used as a contracting/auditing tool by FDA for states performing contract FDA inspections.

## *MFRPS Standard 1: Regulatory Foundation*

Standard 1 is a cataloging standard for state regulatory programs to inventory which authorities in the Food, Drug, and Cosmetic Act (FD&C Act, Public Law 75-717) and the Code of Federal Regulations (CFR, www.ecfr.gov) and the state may have adopted, by reference or directly, and to inventory any authorities held within the state that are not found in the FD&C Act or the CFR (FDA 2013b). For example, in Oregon there is a state regulation addressing blue green algae. FDA, however, does not have blue green algae in its regulations.

## *MFRPS Standard 2: Training Program*

Standard 2 provides foundational, specialized, and continuing education requirements for a state manufacturing regulatory program field staff. The three-level approach provides for natural progression for all employees, from new hires to fully-trained staff. The standard combines online courses, face-to-face classroom training, and joint inspections as training methods. In Standard 2, earning certificates and

demonstrating competencies ensure that an investigator/inspector has the knowledge, skills, and abilities to conduct manufactured food inspections (FDA 2013b).

### *MFRPS Standard 3: Inspection Program*

Standard 3 addresses the elements of an effective inspection program for food plants. The standard calls for:

- A risk-based inspection program, where plants are inspected based upon their manufacturing processes and compliance history.
- Written inspection protocols for conducting manufacturing inspections.
- A written recall plan.
- Methods to capture and catalog consumer complaints.
- A process for industry to file complaints about an inspection/inspector.

By fully developing each of these five requirements in Standard 3, a state food program should have some level of confidence that the program focuses inspection resources on high-risk plants, products, and processes and prevents unsafe products from reaching consumers (FDA 2013b).

### *MFRPS Standard 4: Inspection Audit Program*

Standard 4 is the quality assurance (QA) arm of the manufactured food regulatory program. The standard provides for the state program to monitor and document its own activities, identify gaps, and take corrective actions. Three activities are monitored for quality: field inspections, inspection reports, and sampling. The standard also provides specialized forms and worksheets to help rate these three activities. A written correction action plan, developed by the state program and tailored to its specific needs, can help address any deficient areas (FDA 2013b).

### *MFRPS Standard 5: Food-Related Illness and Outbreak Response*

Standard 5 describes how a state program investigates food-related illnesses, outbreaks, and other hazards related to manufactured foods. Standard 5 provides an opportunity to coordinate roles and responsibilities with other jurisdictions that may have authority to investigate and resolve food-related illnesses and outbreaks. This standard may be implemented in one of three ways: contracting for the work with a third party, having the authorities assigned via state statute, or creating a

memorandum of understanding (MOU) with the lead agency in the state if the authority is not assigned to the one seeking to meet the standard.

The first option is rare, even though the option is mentioned in the standard. The second implementation option is considered direct authority and is usually assigned to a State Department of Health. The third option occurs when the State Department of Agriculture is enrolled in the MFRPS and not the lead agency in an illness or outbreak investigation that resulted from a manufacturing facility. An MOU would be needed to outline the roles and responsibilities of both agencies (FDA 2013b).

### *MFRPS Standard 6: Compliance and Enforcement Program*

Standard 6 addresses a state program's strategies, procedures, and actions to enforce compliance with laws and regulations. The secondary objective for Standard 6 includes monitoring and evaluating the effectiveness of these enforcement actions by tracking and trending chronic and critical violators. By outlining what authorities a state may have, integration efforts can be harmonized, and duplication of efforts can be eliminated. Compliance and enforcement is one area where integration generally succeeds, due to states and FDA having different authorities and strategies (FDA 2013b).

### *MFRPS Standard 7: Industry and Community Relations*

Standard 7 directs the state manufactured food regulatory program to provide targeted outreach to affected industries, consumers, academia, and other food protection agencies. There is no prescriptive format for this outreach, only that the outreach takes place, is documented, and evaluated for impact on the community and industry stakeholders. Examples of outreach include, but are not limited to, an agency website, a food safety task force, a monthly newsletter, providing a guest lecturer at a local college or university, providing a speaker at a meeting related to food manufacturing, or organizing a food safety conference (FDA 2013b).

### *MFRPS Standard 8: Program Resources*

Standard 8 addresses a program's resource shortages by systematically identifying constraints to meeting any of the standards. The constraints can include lack of funding, equipment, or staff. Standard 8 helps state programs assess whether resources are adequate to fully implement the standards; resources are sufficient to promulgate rules to protect public health; resources are adequate to fully train staff to conduct inspections in accordance with Standard 3; and resources are sufficient to implement the QA program outlined in Standard 4 (FDA 2013b).

### *MFRPS Standard 9: Program Assessment*

Standard 9 is the self-assessment standard for the MFRPS. The requirements for Standard 9 include the initial self-assessment, a written strategic plan identifying gaps in all of the MFRPS, target dates for eliminating the gaps, and an annual progress review (FDA 2013b).

### *MFRPS Standard 10: Laboratory Services*

Standard 10 describes elements needed by regulatory laboratories to fully support a manufactured food regulatory program. If the state laboratory has QA programs accredited by the International Organization for Standardization (ISO, www.iso.org), the laboratory is automatically considered fully compliant with Standard 10. If the laboratory is not ISO accredited, it must have current accreditation from the American Association for Laboratory Accreditation (A2LA, www.a2la.org). State laboratories must be able to analyze a variety of samples (food, environmental, and clinical). If using a servicing laboratory, an MOU is required with the companion lab. Generally, agriculture department food safety laboratories analyze inputs (food and environmental samples), and health departments analyze outputs (clinical specimens) (FDA 2013b).

### *Changing/Revising the MFRPS*

Changes to the MFRPS are considered by the MFRP Alliance, which was formed through a cooperative agreement grant between the FDA and the Association of Food and Drug Officials (AFDO, www.afdo.org). The MFRP Alliance has an executive board, elected by state manufactured food regulatory program managers who are enrolled in the standards, and appointed committees that consider recommendations for changes to the standards. Industry plays a much lesser role in changing the manufactured standards compared to changing the retail standards. The MFRPA also includes staff members from FDA's Office of Regulatory Affairs (ORA), who serve as non-voting technical advisors. A state food laboratory manager is also appointed to serve as a technical advisor to facilitate collaboration and coordination with food laboratories. Similar to the retail program standards, any recommendations from the MFRP Alliance on changing the standards—based on evolving science or needed changes—are sent to the FDA for consideration, and the FDA will determine whether to accept or reject the recommendation or look further into the issue. The MFRPS are an official FDA document and must be approved by the Office of Management and Budget (OMB, www.whitehouse.gov/omb) every 3 years to remain viable. (To illustrate, the 2010 standards were reviewed and updated in 2013.) This process makes the standards document itself a *continuous improvement system*, which will be discussed later in this chapter.

### *Animal Feed Regulatory Program Standards (AFRPS)*

The FDA, in partnership with the Association of American Feed Control Officials (AAFCO), developed the Animal Feed Regulatory Program Standards (AFRPS) in order to establish a uniform foundation for the design and management of state programs responsible for the regulation of animal feed (FDA 2014c). By implementing the feed standards, a state program will be able to achieve and maintain programmatic improvements that help ensure the safety and integrity of the US animal feed supply.

The AFRPS are composed of eleven standards that serve as an objective framework to evaluate and improve components of a state feed program. The standards cover the state feed program's regulatory foundation, training, inspection program, auditing, feed-related illness or death and emergency response, enforcement program, outreach activities, budget and planning, laboratory services, sampling program, and assessment and improvement of standards implementation.

### *Centers for Disease Control and Prevention (NPHPS and EnvPHPS)*

The CDC National Public Health Performance Standards (NPHPS) provide a framework to help public health bodies assess their capacity and performance, identify areas for improvement, strengthen state and local partnerships, and ensure that a strong system is in place for addressing public health issues (CDC 2014). The CDC's Environmental Public Health Performance Standards (EnvPHPS) are a set of standards that describe the optimal performance and capacity for *environmental public health systems and programs* (CDC 2013). The EnvPHPS complement the NPHPS, with both sets of standards helping health departments focus their efforts on identifying the strengths/weaknesses of the programs and determining gaps between the current services provided and the optimal level of service described in the standards.

Both the NPHPS and the EnvPHPS are informed by CDC's 10 Essential Public Health Services. These 10 services identify the actions necessary to protect and improve environmental public health programs and systems:

1. Monitor environmental and health status to identify and solve community environmental public health problems.
2. Diagnose and investigate environmental public health problems and health hazards in the community.
3. Inform, educate, and empower people with regard to environmental public health issues.
4. Mobilize community partnerships and action to identify and solve environmental public health problems.
5. Develop policies and plans that support individual and community environmental public health efforts.

6. Enforce laws and regulations that protect environmental public health and ensure safety.
7. Link people to needed environmental public health services and ensure the provision of environmental public health services when otherwise unavailable.
8. Ensure a competent environmental public health workforce.
9. Evaluate effectiveness, accessibility, and quality of personal and population-based environmental public health services.
10. Research for new insights and innovative solutions to environmental public health problems (CDC 2011).

## *Public Health Accreditation Board (PHAB)*

Public health departments may become "accredited" by the Public Health Accreditation Board (PHAB, www.phaboard.org). Public health department accreditation is defined as the development of a set of standards, a process to measure health department performance against those standards, and reward or recognition for those health departments who meet the standards. Accreditation documents a public health department's ability to deliver the 10 Essential Public Health Services. Like the 10 Essential public Health Services, public health accreditation is broadly related to the entire public health program, whereas, for example, the VNRFRPS are related specifically to retail food regulatory programs.[2]

One health department that received PHAB accreditation is the Hennepin County (MN) Public Health Department. Having completed continuous improvement projects in meeting the VNRFRPS, the Environmental Health unit was able to apply the processes to satisfy the PHAB requirements. Table 5.1 provides examples of how Hennepin County aligned the FDA VNRFRPS with specific provisions required for PHAB accreditation, and how this alignment can serve as a model for other regulatory agencies across the nation.

**Table 5.1** Aligning retail standards with PHAB standards

| VNRFRPS | PHAB |
|---|---|
| Standard 2: Trained regulatory staff "Trained regulatory staff with skills and knowledge necessary to conduct quality inspections" | Domain 8: maintain a competent public health workforce |
| Standard 7: Industry and community relations "Enhanced communications with industry and consumers through forums designed to solicit input" | Domain 4: engage with community to identify and address health problems |
| Standard 8: Program support and resources "Resources available to support risk-based retail food safety program" | Measure 11.2.4: seek resources to support agency infrastructure and processes, programs, and interventions |

[2] FDA, in collaboration with the National Association of County and City Health Officials (NACCHO, www.naccho.org), published, in 2014, a comprehensive cross-walk of the retail program standards and the PHAB standards.

### *FSMA's Proposed Rule on Third-Party Auditors*

In July 2013, the FDA published a proposed rule (Docket # FDA-2011-N-0146) to help implement Section 307 of the Food Safety Modernization Act (FSMA), which addresses the accreditation of third-party auditors and the certification of foreign food facilities. The FDA will use certification from accredited auditors to determine whether to admit certain imported foods into the USA and to determine whether an importer qualifies for a voluntary program allowing for expedited review and entry of food. Under the proposed rule, the FDA would recognize accreditation bodies, which would in turn accredit third-party auditors to conduct food safety audits and issue certifications for foreign food facilities. This process will help ensure the safety of FDA-regulated food moving in international trade in a more efficient manner. The FDA plans to draft model accreditation standards, including education and experience requirements for third-party auditors and their audit agents. Third-party auditors can include foreign governments, foreign cooperatives, and other third parties. The FDA will make the draft standards available for public comment. Although the use of accredited third-party auditors is not required by the FDA, the agency anticipates that the accreditation system will increase reliance by importers on audits by accredited third parties.

### *International Comparability Assessment Tool (ICAT)*

FDA has developed a process for determining whether a foreign food safety system is comparable to that of the USA, through a self-assessment tool (the International Comparability Assessment Tool or ICAT) that can be completed by countries requesting systems recognition. FDA used the MFRPS as a model in creating the draft ICAT, which includes US references corresponding to each element and describes the US system with respect to each of the elements under each of the ten standards. Countries are given the opportunity, through submitting an ICAT assessment, to demonstrate how the country's system may differ from that of the USA and how the country's system, though different, provides similar food safety outcomes with respect to each element (FDA 2013c).

Analysis of a country's ICAT assessment will be combined with an in-country systems recognition assessment in order to validate the information presented in the ICAT. During the in-country assessment, a team of FDA scientists, auditors, and investigators will visit government agencies and food processing facilities to conduct interviews, review records, observe the implementation of written policies, and observe the enforcement of food safety regulations. These efforts will allow FDA to ensure that a country's food safety program offers the same level of public health protection as the system implemented by FDA in the US (FDA 2013c).

In late 2012, New Zealand became the first country to have its system recognized by the US (FDA 2012).

## Interdependencies Among Program Standards

Some standards are interrelated, and progression toward one will lead to progression toward another, either directly or indirectly. For example, the basic structure of the jurisdiction's inspection form is referenced in both VNRFRPS Standard 3 and Standard 6. Other standards build on each other in a logical order. For instance, development of a strong training and standardization program (VNRFRPS Standard 2) would be logical to implement prior to the implementation of a quality assurance program (VNRFRPS Standard 4).

Similar interdependencies can be seen among the MFRPS. To illustrate:

- MFRPS Standard 6 cannot be fully implemented until MFRPS Standard 3's risk-based inspection program is developed. The evaluation of the critical and chronic violators and the reduction in enforcement actions would suggest the risk-based inspection program is working as needed to protect public health.
- MFRPS Standard 4 should not be implemented prior to the staff training addressed in MFRPS Standard 2. There is no benefit to auditing inspectors who have not been fully trained. What is more, the audit findings in MFRPS Standard 4 should feed back into the training in MFRPS Standard 2 so any gaps in knowledge can be identified.
- MFRPS Standard 7 has an outreach requirement that should be implemented (at least partially) by evaluating MFRPS Standard 6 statistics and target industries with compliance and enforcement issues.
- MFRPS Standard 5 should have a complete look through an "MFRPS lens" after each outbreak, i.e., the state program should assess whether the program has the regulatory foundation to prevent another outbreak, whether new regulations are needed, and whether staff is sufficiently trained to respond to the next outbreak or illness.
- MFRPS Standard 1, after new rule promulgation, should be used to update and modify the inspection program and protocol in MFRPS Standard 3.
- The laboratory analysis conducted via MFRPS Standard 10 should reflect the industries inspected under MFRPS Standard 3.

Interrelationship across program standards can also be seen. To illustrate, environmental health programs that do not have nationally-recognized standards in place may find the VNRFRPS the best place to begin. The VNRFRPS provide a step-by-step tool to identify program gaps, develop strategies for addressing gaps, and measure the progress and impact of program improvements. Once this approach is underway, it can be used as an example or model for other environmental health programs. In a similar fashion, retail food regulatory programs that are already enrolled or considering enrollment in the VNRFRPS may find it beneficial to consider the 10 Essential Environmental Public Health Services. Besides being complementary, these two initiatives encourage people working in food safety programs to think more holistically and could be a catalyst for career advancement and leadership opportunities. Table 5.2 demonstrates the interrelationship between the 10 Essential Environmental Public Health Services and the VNRFRPS.

**Table 5.2** 10 Essential Environmental Public Health Services and the corresponding FDA VNRFRPS (source: unpublished FDA white paper)

| 10 Essential Environmental Public Health Services | Corresponding VNRFRPS Standard |
|---|---|
| 1. Monitor environmental and health status to identify community environmental public health issues | • Standard 5—Foodborne Illness and Food Defense Preparedness and Response<br>• Standard 3—Inspection Program Based on HACCP (Principles)<br>• Standard 8—Program Resources |
| 2. Diagnose and investigate environmental public health problems and health hazards in the community | • Standard 3—Inspection Program Based on HACCP<br>• Standard 5—Foodborne Illness and Food Defense Preparedness and Response<br>• Standard 8—Program Resources |
| 3. Inform, educate, and empower people about environmental public health issues | • Standard 7—Industry and Community Relations |
| 4. Mobilize community partnerships to identify and solve environmental public health problems | • Standard 7—Industry and Community Relations |
| 5. Develop policies and plans that support individual and community environmental public health efforts | • Standard 3—Inspection Program Based on HACCP<br>• Standard 7—Industry and Community Relations |
| 6. Enforce laws and regulations that protect environmental public health and safety | • Standard 1—Regulatory Foundation<br>• Standard 3—Inspection Program Based on HACCP<br>• Standard 4—Uniform Inspection Program<br>• Standard 6—Compliance and Enforcement |
| 7. Link people to needed environmental public health services and assure the provision of these services when otherwise unavailable | • Standard 7—Industry and Community Relations |
| 8. Assure a competent environmental public health workforce | • Standard 2—Trained Regulatory Staff<br>• Standard 4—Uniform Inspection Program<br>• Standard 6—Compliance and Enforcement<br>• Standard 8—Program Resources |
| 9. Evaluate effectiveness, accessibility, and quality of personal and population-based environmental public health services | • Standard 9—Program Assessment |
| 10. Research for new insights and innovative solutions to environmental public health concerns | • Self-assessment against all eight standards, development of strategic plan to address identified gaps, and Standard 9 foodborne illness risk factor study to measure effectiveness of interventions |

## A Systems Approach to Using National Program Standards

Meeting national program standards creates a more consistent and accountable approach to inspections. However, the ability to achieve the standards may depend on factors related to the type of agency (state, local, tribal, or territorial), the size of the agency staff, internal agency policies and procedures, agency resources, support from management or legislative bodies, and training of field staff.

### *Systems Approach at State Agencies*

State agencies generally have a larger staff and more resources to devote to national program standards as compared to local, tribal, or territorial agencies. In many cases, upper management will expect the state agency to comply with the standards and will provide appropriate directives and resources. Generally, FPPs who are lead workers are assigned to work on specific sections of the standards. Generally, one staff person is designated the coordinator, or point person, and reports directly to management. The coordinator identifies the specific work needed to be accomplished, sets up meetings, delegates assignments, and checks in on workers assigned to different sections of the standards. For small agencies, it is difficult to keep up with routine work when a portion of the staff is performing work to meet standards.

A state program may be enrolled in multiple sets of standards depending upon the program's responsibilities. Many state food safety programs regulate retail food and manufactured food facilities. Consequently, program staff may inspect both types of facilities, and program managers may participate in the governance for the VNRFRPS and MFRPS. A program may also have environmental health responsibilities and are strives to meet the 10 Essential Public Services, or state feed regulatory programs may strive to meet the AFRPS. Some food and feed regulatory programs are housed in the same agency and are sometimes managed by the food regulatory programs. These states are challenged to develop programs that achieve all standards in an efficient and effective manner.

In 2013, the Partnership for Food Protection (PFP) National Standards Workgroup published a National Standards Crosswalk Resource Paper (http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/UCM369991.pdf) that identified and summarized standards that applied to the grade "A" milk and milk products, manufactured foods (excluding meat and poultry), retail foods, and molluscan shellfish. The resource paper provides a side-by-side comparison of how program elements are addressed by each program. The paper is a resource for states that are responsible for implementing multiple programs and for identifying opportunities to harmonize standards where possible, across programs (PFP 2013).


**Fig. 5.1** Plan-do-check-act model (source: US Department of Energy https://ecenter.ee.doe.gov/EM/SPM/Pages/Step4.aspx)

## *Systems Approach at Local Agencies*

Some local agencies may have difficulty in pursuing national standards due to staff size, limited resources, or other local challenges. In other local agencies, the management may expect staff to meet the standards despite a lack of dedicated resources and an already full workload. Some larger cities and counties will have adequate resources to meet the standards.

## *Success Strategies for Both State and Local Agencies*

One approach that can be used by agencies is a model of continuous or quality improvement. One of the more commonly used continuous improvement models is called the plan-do-check-act model or PDCA (Fig. 5.1). Although this chapter is not a complete guide to PDCA, the chapter does provide a short overview that can help agencies as they approach the adoption of national program standards.

Utilizing the PDCA model allows for a thorough, 360° analysis of a problem that can identify potential solutions. During the "plan" phase, objectives are clarified, predictions are made, and decisions are made about what needs to be done. During the "do" phase, decisions made during the planning phase are carried out and observed. During the "check" phase, results and observations are analyzed, and preparations are made for the "act" phase, where adjustments are made and a new cycle of planning begins.

The PDCA model can be used for entire national program standards or for a single part of the standards. However, the model is often used to make a small improvement first, leading up to larger improvements in the future. An incremental approach can lessen the burden on already-stressed agency resources. Using the strategic model allows for efficiency and structure, allows management to check in and get the "broad picture" of a current status, and helps an agency see both where the agency has to go and where the agency has been.

## Conclusion

National program standards serve the important function of helping food regulatory programs—whether at the state, local, tribal, or territorial level—adopt best practices, form partnerships, and make efficient use of resources, which all help in the achievement of a truly nationally-integrated food safety system. National standards have been developed for retail regulatory programs, manufactured food regulatory programs, animal feed programs, environmental public health agencies, and regulatory laboratories. A systems approach is recommended to help regulatory programs tailor policies and procedures to the national set(s) of standards.

## Take-Home Message

A food protection professional (FPP) may work for a state or local jurisdiction that is enrolled in national program standards related to food safety (manufactured food, retail food, animal feed, etc.). Enrollment in these national programs helps develop uniformity among food regulatory programs and helps promote the continuous improvement of participating agencies.

## Activity

Which VNRFRPS or MFRPS applies to each of the following scenarios?

1. A food program manager puts a new ongoing quality assurance program in place to ensure that all staff members are uniform in the way they conduct inspections.
2. A food program manager implements new policies regarding how inspections are conducted to ensure that inspectors are requiring corrective actions of risk factor violations, e.g., inadequate cooking temperatures, improper handwashing, etc.
3. A food program manager is interested in upgrading state food regulations. She uses the current version of the FDA Food Code as a basis for the changes that are made.
4. A food program manager would like to evaluate the regulatory actions taken by inspectors in that state. The actions include establishment closures, food embargoes, and warning letters.
5. A state laboratory receives accreditation from the International Organization for Standardization (ISO) for its quality assurance (QA) programs.
6. A county environmental health director implements a new program to ensure that all staff members meet a minimum standard in the courses they take per year for continuing education.

7. A food program manager would like to conduct an evaluation of risk factor occurrence in the establishments within the state. The data will be used to implement new training strategies for operators.
8. A food program manager is interested in the implementation of a new advisory group that would provide feedback on proposed food safety educational materials and rule changes. This group would include representatives from industry and consumer groups.
9. A food program manager is concerned that the number of inspectors for the establishments in the county is inadequate. The program manager is looking for a way to calculate the number of staff needed per inspections conducted.
10. An environmental health director seeks to upgrade the program's response to foodborne illness investigation and response. The director works with the health department's communicable disease staff to implement new memorandums of understanding between the agencies.

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## Answer Key

1. Standard 4
2. Standard 3
3. Standard 1
4. Standard 6
5. MFRPS Standard 10
6. Standard 2
7. Standard 9
8. Standard 7
9. Standard 8
10. Standard 5