

**STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND
HUMAN SERVICES
FOOD PROTECTION SECTION
PERFORMANCE AUDIT REPORT
JULY 2015**



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To The Fiscal Committee Of The General Court:

We conducted a performance audit of the Department of Health and Human Services, Food Protection Section to address the recommendation made to you by the joint Legislative Performance Audit and Oversight Committee. We conducted the audit in accordance with generally accepted government auditing standards. Those standards require we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. The evidence we obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The purpose of the audit was to determine how efficient and effective the Food Protection Section was in preventing foodborne illness during State fiscal years 2013 and 2014.

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July 2015

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ABBREVIATIONS AND GLOSSARY OF TERMS

Accreditation	An encompassing term that may include licensure, certification, permitting, and registration of an establishment.
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BIDC	Bureau Of Infectious Disease Control
Board	Milk Sanitation Board
BTU	Bulk Tank Unit
CAP	Corrective Action Plan
<i>Cold Storage</i>	RSA 145, <i>Cold Storage</i>
Committee	Dairy Practices Committee
CY	Calendar Year
<i>Dairy</i>	RSA 184, <i>Inspection And Sale Of Dairy Products</i>
DAMF	Department Of Agriculture, Markets, And Food
DES	Department Of Environmental Services
DHHS	Department Of Health And Human Services
DPHS	Division Of Public Health Services
Establishment	Any facility engaged in food production, processing, distribution, storing, selling, and service.
F&G	Fish And Game Department
FDA	U.S. Food And Drug Administration
Food Processing Plant	A type of food service establishment that is a commercial operation that processes food for human consumption and provides processed food for sale and distribution to other business entities such as other food establishments. The term does not include an operation that processes food under the oversight of the DAMF.
FPS	Food Protection Section
<i>Food Code</i>	The FDA's 2009 <i>Food Code</i>
Food Service Establishment	Any fixed or mobile, attended or unattended restaurant; coffee shop; cafeteria; short order cafe; luncheonette; grill; tearoom; sandwich shop; soda fountain; tavern; bar; cocktail lounge; nightclub; roadside stand; industrial feeding establishment; food processing plant; food vending operation; private or public organization or institution, whether profit or nonprofit, which routinely serves food; catering kitchen; commissary, or similar place in which food or drink is prepared for sale or for service on the premises or elsewhere; and any other eating and drinking establishment or operation in which potentially hazardous food is served or provided for the public with or without charge.
FTE	Fulltime Equivalent
HACCP	Hazard Analysis And Critical Control Point
IT	Information Technology
IMS	Interstate Milk Shipper
<i>Inspectors</i>	RSA 130, <i>Sanitary Inspectors</i>
JLCAR	Joint Legislative Committee On Administrative Rules
LG	Labor Grade
<i>Licensure</i>	RSA 143-A, <i>Food Service Licensure</i>

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MOA	Memorandum Of Agreement
<i>Model Ordinance</i>	The FDA's 2005 <i>National Shellfish Sanitation Program Model Ordinance</i>
PMO	The FDA's 2011 <i>Grade "A" Pasteurized Milk Ordinance</i>
<i>Pure Food</i>	RSA 146, <i>Purity And Branding Of Foods And Drugs; Immature Veal</i>
Retail Store	Any establishment or section of an establishment where food or food products intended for off-premise consumption are offered to the public. The term includes delicatessens offering prepared food in bulk quantities only. It does not include establishments handling only prepackaged, not potentially hazardous foods; roadside markets or farm stands; food service establishments; or food and beverage vending machines.
RSA	Revised Statutes Annotated
<i>Sanitary Production</i>	RSA 143, <i>Sanitary Production And Distribution Of Food</i>
SFY	State Fiscal Year
SHIP	<i>State Health Improvement Plan, 2013-2020</i>
SJD	Supplemental Job Description
SOP	Standard Operating Procedure

**STATE OF NEW HAMPSHIRE
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FOOD PROTECTION SECTION**

EXECUTIVE SUMMARY

A well-designed food safety regulatory program can increase the likelihood the public health will be adequately protected. We found systemic inadequacies in the Department of Health and Human Services, Food Protection Section (FPS) programs and practices intended to help ensure food safety. We also observed most measures related to food safety indicated ineffectiveness, including increases in reports of foodborne illness. While limitations of data and science prevent attributing these trends solely to FPS activities, the FPS nonetheless had a key role. Concurrently, the risks facing the public food supply increased, making effective FPS action increasingly important.

Comprehensive food protection takes a systems approach to address risks during production, processing, transportation, distribution, and storage, and at retail. The FPS improperly operationalized certain State laws for which it was responsible, compromising its effectiveness by limiting food safety inspections to accredited establishments, leaving other segments of the public food supply insufficiently regulated or unregulated. Further, inspection scheduling was inconsistently risk-based, and significant portions of the highest risk, accredited establishments were not inspected during the audit period.

During the audit period, FPS inspections of establishments decreased, and complaints and the percent of follow-up inspections increased, indicating increases in deficient food establishments. Systematic inadequacies in accreditation, inspection, sampling, complaint, and sanctions management systems further compromised the effectiveness of the FPS. Complaint investigations were inconsistently timely, and some were not closed-out. Sanctions were applied inconsistently. The lack of control exerted by the FPS over self-inspecting towns further contributed to a fractured statewide food safety network. During State fiscal year 2014, systemic inefficiencies and ineffectiveness in FPS practices and procedures resulted in the estimated loss of the equivalent of more than one full-time field inspector, or 600 inspections, to administrative tasks, and the inefficient expenditure of nearly \$48,500. Improper collection of required fees and management of a dedicated fund during the audit period resulted in an estimated net loss to the General Fund of \$1,163,677.

The FPS lacked the organization structure, policies, procedures, and other controls to fulfill its role effectively and efficiently. We found rules, policies, and practices were at times noncompliant with the statutes they purportedly implemented, policies and practices were at times noncompliant with rules, memoranda of agreement with self-inspecting towns were not complied with, and the regulatory structure was obsolete and unnecessarily complex. Management controls over information transmission to the public, agency risk management, performance measurement, ethics, delegation of authority, records and information management, human resource management, and information technology were either missing or functioning improperly. Information technology controls and resources were so unreliable: 1) the FPS had to abandon online posting of food establishment status, 2) inspectors performed data entry and were displaced from their primary purpose of conducting field inspections, and 3) we were compelled to qualify each aspect of this report relying on agency data.

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**STATE OF NEW HAMPSHIRE
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FOOD PROTECTION SECTION**

RECOMMENDATION SUMMARY

Observation Number	Page	Legislative Action Required?	Recommendation	Agency Response
1	10	No	Food Protection Section (FPS) management review policies, procedures, practices, and its role in helping ensure a safe public food supply and reducing the occurrence of impure foods, unsanitary establishments, and risky practices statewide; coordinate with other State agencies and self-inspecting jurisdictions to develop a reporting system; centralize reporting of all food safety complaints, illness and outbreak data, sampling results, and noncompliant establishment data; analyze performance measures; and develop and publicize a time-phased strategic plan for improving effectiveness.	Concur
2	19	No	FPS management expand its scope of operation to reflect the full extent of its statutory obligations.	Concur
3	22	YES	The Legislature consider repealing six chapters of statute and replacing them with a comprehensive food safety statute. The Commissioner consolidate and standardize common elements of rules such as administrative fines, accreditation procedures, and fees.	Concur
4	29	YES	The Commissioner seek changes to statute to standardize and simplify the accreditation structure, migrate applicable licensing cycles to a biennial schedule, and promulgate changes to rule. FPS management adopt policies and procedures to ensure accreditations are not issued improperly and licensing inspections occur as required.	Concur In Part
5	32	No	FPS management require applicants submit a plan review application and required documentation, review the number of copies of documentation required, improve management oversight, and decentralize the plan review process.	Concur
6	33	No	The Commissioner promulgate rules for granting and processing variances to ensure licensees have consistent access to variances.	Concur

Recommendation Summary

Observation Number	Page	Legislative Action Required?	Recommendation	Agency Response
6 (Continued)			FPS management develop written policies for managing variances, ensure variances granted to grandfathered establishments are recorded, and ensure performance information is recorded and timeliness and other performance goals are achieved.	
7	36	No	The Commissioner amend rules to include detailed inspection practices as required by statute. FPS management develop and implement a risk-based inspection scheduling system focused on high-risk establishments, develop a quality assurance program, incorporate the distribution phase of the food production cycle into the scope of inspection practices, ensure repeat risks are addressed in inspections, and ensure establishments are regulated uniformly.	Concur In Part
8	43	No	FPS management ensure unlicensed establishments are systemically inspected based on risk, incentivize violation corrections, ensure Hazard Analysis and Critical Control Point (HACCP) plans are checked, require assignment of risk categories, formalize policy and procedure, and improve violation tracking and resolution.	Concur
9	46	No	FPS management comply with rules, annually reregister out-of-State non-commercial producers, and ensure out-of-State non-commercial producers are aware of registration requirements.	Concur In Part
10	48	YES	The Commissioner promulgate rules regulating cold storage establishments and consider seeking statutory changes to simplify their regulation. FPS management annually inspect each cold storage establishment.	Concur In Part
11	50	No	The Commissioner formally delegate authority to the FPS administrator. FPS management standardize and update Memoranda of Agreement (MOA), ensure self-inspecting towns comply with relevant State laws and MOAs, require all complaints and their resolution be provided timely, assess training needs and develop a training program, document	Concur

Observation Number	Page	Legislative Action Required?	Recommendation	Agency Response
11 (Continued)			transactions, develop performance measures, collect data, and regularly evaluate local program effectiveness and compliance.	
12	53	YES	<p>The Legislature consider updating and amending statute to transfer elements of dairy industry regulation under the Department of Agriculture, Markets, and Food (DAMF) to the Department of Health and Human Services (DHHS) and consider updating fees to reflect actual administrative cost.</p> <p>The Commissioner promulgate or revise rules for inspecting milk distributors and accrediting transfer stations.</p> <p>FPS management inspect all licensed and permitted establishments, consider redefining the sanctions for non-critical violations, accredit transfer stations, seek a formal agreement with the DAMF for shared regulatory responsibilities over bulk milk tankers and bulk milk haulers and samplers, and formalize policy and procedures for interacting with Bulk Tank Units.</p>	Concur In Part
13	57	YES	<p>The Legislature consider disestablishing the Milk Sanitation Board and transferring any unique responsibilities to the DHHS.</p> <p>The Milk Sanitation Board, should it continue, amend rules to comply with statute and disestablish the Dairy Practices Committee (Committee). Should the Committee continue, no longer include FPS inspectors on the Committee.</p>	Concur In Part
14	59	NO	FPS management timely comply with corrective action plans, require establishments author HACCP plans, create a contingency plan, increase management oversight, and improve control of enforcement activities.	Concur
15	63	NO	<p>The Commissioner amend rules to establish a risk-based inspection frequency.</p> <p>FPS management ensure annual inspections for each in-State beverage and bottled water establishment are completed, conduct a risk analysis to establish the needed inspection</p>	Concur

Recommendation Summary

Observation Number	Page	Legislative Action Required?	Recommendation	Agency Response
15 (Continued)			frequency, process applications for licensure and registration according to rule, improve oversight of license and registration processing, and enforce sanctions.	
16	67	NO	FPS management reinstitute food sampling as required by statute, develop comprehensive risk-based policies and procedures, and collect and analyze sampling results.	Concur
17	68	NO	FPS management improve complaint management processes, guidelines, and requirements.	Concur In Part
18	72	YES	The Commissioner seek statutory changes to the sanctions regime and amend rules to establish a graduated sanctions regime. FPS management use specified sanctions when required by statute and rule, and improve management oversight of noncompliance and sanctions.	Concur
19	79	YES	The Commissioner revise rules to comply with food safety laws. FPS management develop policies and procedures to ensure inspections are completed as required in statute.	Concur In Part
20	82	NO	The Commissioner promulgate comprehensive rules. FPS management develop policies and procedures to ensure timely responses to applications and complaints.	Concur In Part
21	85	NO	The Commissioner formally delegate authority.	Concur
22	86	NO	The Commissioner amend food safety-related rules.	Concur
23	89	NO	The Commissioner analyze program costs, ensure subprogram revenue neutrality, expend dedicated funds on subprogram expenses, ensure fund balances brought forward are not general funds, amend rules, and balance accreditation revenues with inspection revenues. FPS management charge inspection fees, undertake subprogram revenue and cost accounting, and comply with rules.	Concur In Part

Observation Number	Page	Legislative Action Required?	Recommendation	Agency Response
24	93	No	FPS management develop organizational goals, objectives, and sub-objectives; establish specific and measurable organizational and individual performance levels; collect and routinely analyze relevant data; assess whether measurable improvements in food safety are being achieved; develop, implement, and enforce a formal records management policy; integrate and simplify information management systems; and improve the completeness, accuracy, and validity of records and data.	Concur
25	96	No	FPS management communicate public health risks identified during inspections, publicize program outcomes, and regularly obtain industry and customer feedback.	Concur
26	97	No	FPS management conduct an entity-wide risk assessment and develop a strategic plan.	Concur
27	99	No	<p>The Commissioner facilitate improved efficiency by coordinating for routine FPS field staff use of DHHS District Offices.</p> <p>FPS management increase inspector output by improving human resource management, simplify practices, seek to increase the FPS fleet size, ensure employees comply with their Supplemental Job Descriptions (SJD), review and amend SJDs, add performance measures and quality improvement mechanisms to SJDs, ensure SJDs have responsibilities compatible with the corresponding job classifications, and create succession plans for key roles.</p>	Concur In Part
28	103	No	FPS management improve information technology controls, improve systems designs, and reduce field staff data entry requirements.	Concur
29	106	No	FPS management develop written policies and procedures detailing practices and ensure staff have a common understanding of the ethics policy.	Concur

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FOODBORNE ILLNESS PREVENTION

Enteric illnesses, those affecting the intestines, spread in various ways. Food-related hazards can be posed by eating food contaminated with pathogens, foreign material, or allergens. Annually, foodborne illnesses in the U.S. afflicted an estimated 48 million people, hospitalized 128,000, and killed 3,000, costing at least \$14.1 billion. Over 700 cases, costing an estimated \$681,000, were reported in New Hampshire in 2012. Food supply safety risks are increasing with globalization of the supply chain, changes in diet, increases in consumption of commercially prepared food, and emerging infectious agents and trends in transmitting known agents through food, and among the most vulnerable segments of society.

A well-designed regulatory program can increase the likelihood of adequately protecting the State's citizens and uniformly regulating the industry. The Food Protection Section (FPS), within the Division of Public Health Services of the Department of Health and Human Services (DHHS), was primarily responsible for protecting the safety and security of the State's public food supply and for preventing foodborne illness. These responsibilities spanned producing, processing, packaging, branding, labeling, transporting, storing, distributing, serving, and selling or giving food intended for human, or other animal, consumption. To accomplish this, the FPS's primary tasks included inspecting establishments, sampling food, accrediting many establishments in the industry, reviewing the construction and renovation of establishments, investigating certain food-related complaints, sanctioning non-conforming establishments, educating the public on food safety practices, and overseeing recalls.

The FPS relied on six primary statutes, four chapters of rule, and three sets of federal standards regulating food safety and distributed responsibilities to four subprograms. Rules incorporated significant elements of the U.S. Food and Drug Administration's (FDA): 1) 2009 *Food Code*, with amendments, to regulate food service establishments; 2) 2011 *Grade "A" Pasteurized Milk Ordinance*, to regulate interstate milk and milk-related product commerce; and 3) 2005 *National Shellfish Sanitation Program Model Ordinance*, to regulate interstate molluscan shellfish commerce. Beverage and bottled water establishments were regulated based primarily on State regulations.

The FPS did not regulate, or exclusively regulate, certain portions of the State's food supply. Other entities with a role in regulating food produced and sold within the State included the:

- Department of Environmental Services (DES), which regulated the sources of bottled water, public water supplies, and recreation camps, and established safe areas for shellfish harvesting;
- Department of Agriculture, Markets, and Food (DAMF), which helped ensure safe and healthy food supplies from agricultural operations and meat producers;
- Fish and Game Department (F&G), which regulated inland and marine aquaculture, game, finfish, and shellfish;

- Milk Sanitation Board, which was responsible for advising the DHHS Commissioner, conducting hearings, and adopting rules related to the production of milk and related products;
- 16 municipalities operating their own food protection programs and licensing and inspecting local establishments directly; and
- FDA and U.S. Department of Agriculture.

Additionally, statute exempted segments of the State's food supply from licensure and, in limited cases, inspection. In practice, many more types of establishments and food were effectively exempted from State regulation.

Program Effectiveness

Enhancing food safety was a State priority, integral to an effective public health system, and a key determinant of public health. No single activity could achieve this. A well-designed, science-based food safety regulatory program required a system of systems, including inspection, sampling, accrediting, responding to complaints, and sanctioning the noncompliant, to improve food safety and reduce the incidence of foodborne illness. Understanding the performance of each system can provide an understanding of overall program effectiveness.

Observation No. 1

Improve Effectiveness

In the aggregate, trends in indicator data demonstrated the State lost ground on food safety during the audit period.

Food-associated Illness

Foodborne illness was a common, reportedly preventable, public health problem. Many enteric illnesses possibly transmitted by food were tracked by the Bureau of Infectious Disease Control (BIDC), the component of the DHHS responsible for investigating and evaluating reported, suspected, or probable cases and clusters of foodborne illness, and the ongoing monitoring of trends in foodborne illness. However, several factors generally limited full and complete understanding of foodborne illness:

- Food safety science was not settled; it was evolving.
- More than 250 different foodborne diseases caused by a variety of bacteria, viruses, and parasites could contaminate food.
- Many microbes could spread in more than one way, so confirming a disease was foodborne was difficult.
- Poisonous chemicals and other harmful substances, when present in food, could also cause foodborne disease.
- Confirmation of foodborne illness, regardless of cause, could only be accomplished by laboratory testing.

In New Hampshire, attributing an illness or outbreak to food or a food establishment was difficult, and in many instances the source of illness was unknowable, because:

- While, according to unaudited BIDC data, 1,222 enteric illness cases were reported in State fiscal years (SFY) 2013 and 2014, the BIDC estimated as many as 22,544 cases actually occurred, translating into a 94.6 percent underreporting and under-diagnosing rate during the audit period.
- Reporting all potential foodborne illnesses was not required by State laws and rules.
- Foodborne illness cases may not have been closed due to limitations in the investigation.
- Foodborne illness outbreak investigations may have been limited or impossible to complete.
- Data collection changed over time and technical definitions varied by illness.
- The FPS was not exclusively responsible for aspects of food safety, such as within self-inspecting cities.

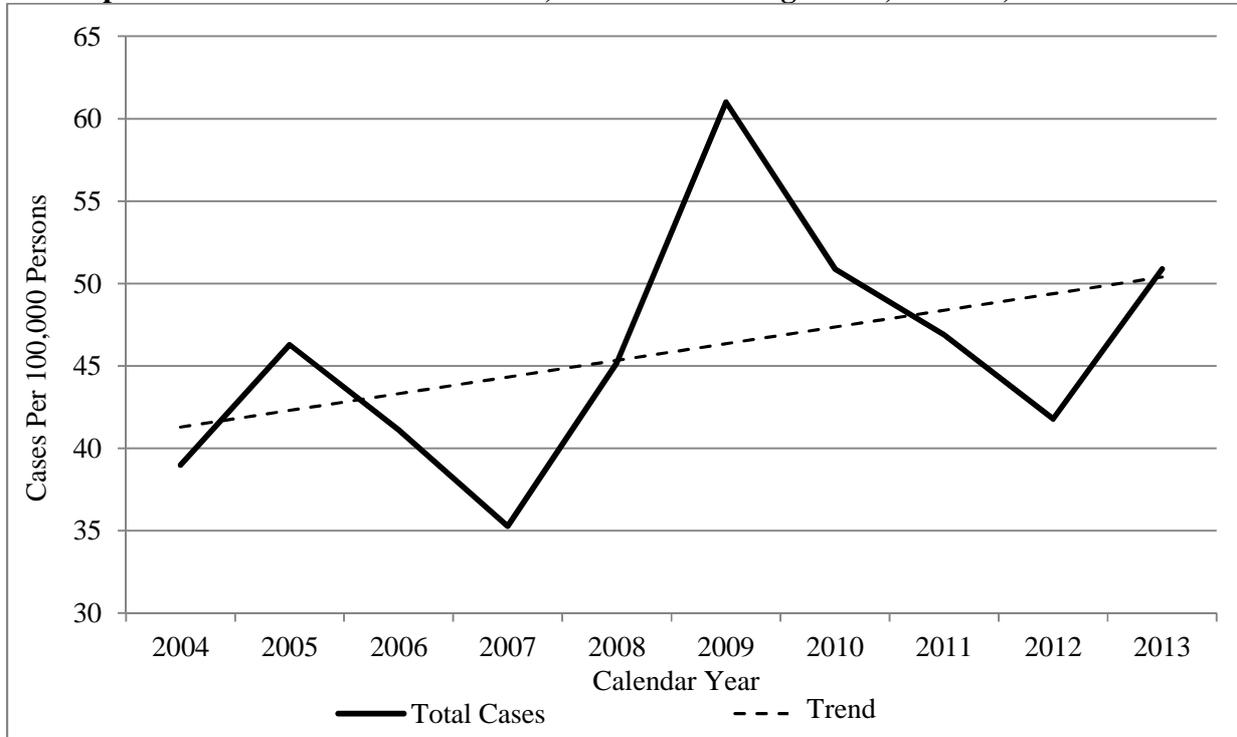
Consequently, the available data presented *a view* of aspects of foodborne illness, not necessarily the *full view* of foodborne illness statewide. These limitations and lack of demonstrated causation prevented attributing foodborne illness outcomes, positive or negative, to the FPS. Illness data could only be correlated to FPS activities.

Reported Illness Cases

As Figure 1 demonstrates, reported cases of enteric illnesses, calendar year (CY) 2004 through CY 2013, and during the two calendar years for which data were available and encompassing the audit period, increased. Most reportedly *involved* food, but were not necessarily transmitted by food. The stated FPS mission was to protect the safety and security of the State's food supply and reduce foodborne illness statewide. Correlating illness increases to the FPS mission suggests the FPS was not effective in reducing foodborne illness during the audit period.

Figure 1

Reported Cases Of Enteric Illnesses, CYs 2004 Through 2013, Per 100,000 Persons



Comments:

- ¹ DHHS data are based upon information provided under statutory and regulatory requirements.
- ² The numbers reported may represent an underestimate of the true absolute number and incidence rate of cases in the State.
- ³ The DHHS disclaims responsibility for any duplication or misrepresentation of surveillance data.
- ⁴ Data were complete as of March 20, 2015.
- ⁵ Data were only available through CY 2013 because CY 2014 data were scheduled for quality assurance review in the second quarter of CY 2015.
- ⁶ Enteric disease data includes all confirmed and probable cases of *Campylobacter*, *Cryptosporidiosis*, *Cyclosporiasis*, *Giardia*, Hepatitis A, *Listeriosis*, *Salmonellosis*, Shiga toxin-producing *Escherichia coli* (*E. coli*), *Shigellosis*, *Trichinosis*, Typhoid Fever, *Vibriosis*, and *Yersiniosis* reported to the BIDC. Data are presented as rates per 100,000 residents and rates were calculated using N.H. population estimates from the U.S. Census from 2004 through 2009 at <http://www.census.gov/popest/data/intercensal/state/state2010.html> and for 2010 through 2014 at <http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk>.
- ⁷ Other food-associated illnesses such as Botulism and *Brucellosis*, while reportable, were excluded due to infrequent occurrence and lack of recent cases. Cases of Noroviruses were excluded because cases were not reportable under State law and rule, but outbreaks were reportable and were contained in those data.
- ⁸ Data encompass 1) a significant change in the method of tracking *Giardia*; 2) *Giardia* and *Cryptosporidium*, infrequently transmitted by food; and a 3) Hepatitis A outbreak unrelated to food, all of which skew case counts.

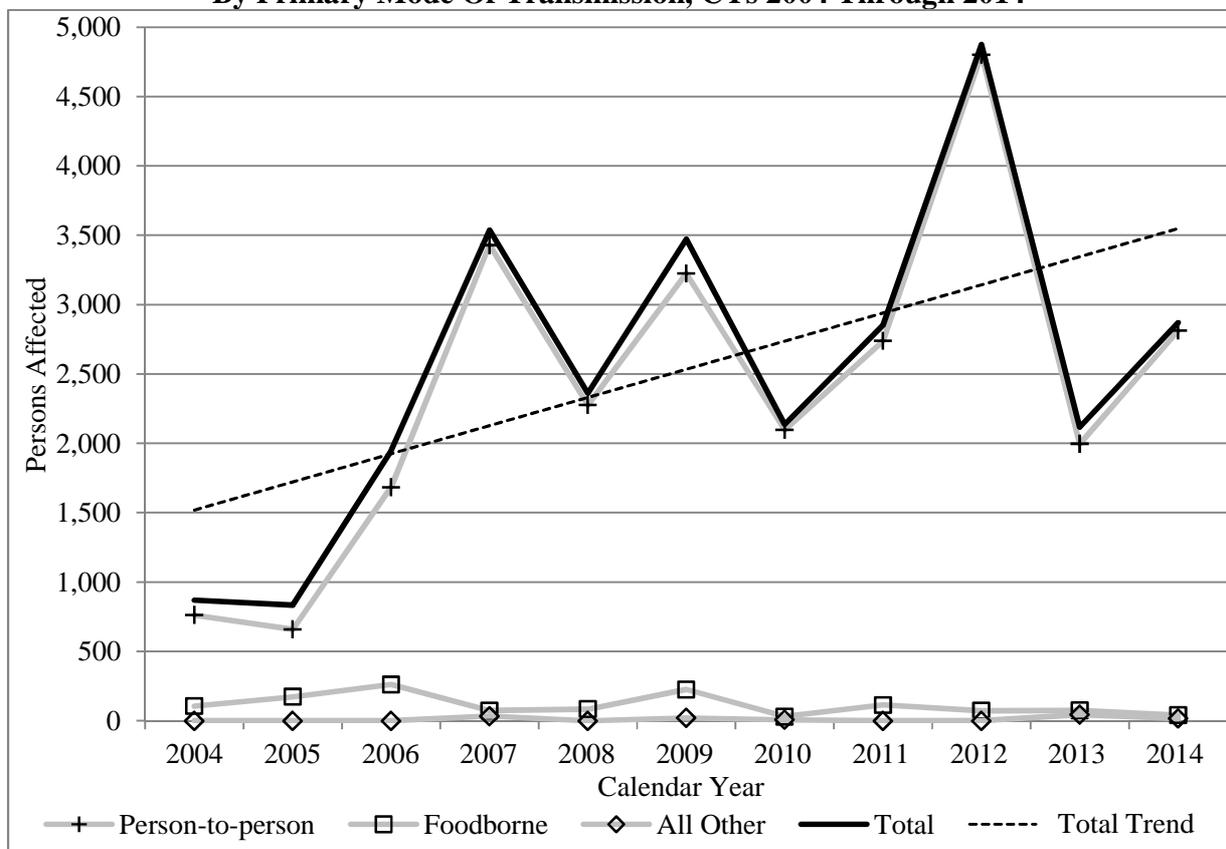
Source: LBA analysis of unaudited DHHS, BIDC data.

Reported Outbreaks

Outbreaks were the occurrence of two or more cases of a similar illness resulting from a common source. Outbreaks encompassed illness cases. Figure 2 illustrates the numbers of reported outbreaks, and the number of people reportedly affected by them, increased between 2004 and 2014, while outbreaks definitely attributable to foodborne illness decreased over the same period. Correlating outbreak data with the FPS mission of reducing foodborne outbreaks suggested some degree of effectiveness.

Figure 2

Number Of Persons Reported Affected By Acute Gastroenteritis Outbreaks, By Primary Mode Of Transmission, CYs 2004 Through 2014



Comments:

- ¹ For CYs 2004 and 2005, outbreak data for transmission modes other than foodborne were not consistently or robustly tracked, skewing trends.
- ² Data from CYs 2006 through 2008 were obtained from a separate database, and recorded and tracked differently than the data for CYs 2009 through 2014; therefore, it may be difficult to compare trends between these two periods.
- ³ All enteric, or gastrointestinal, outbreaks occurring from CYs 2004 through 2014, were by one of the following modes of transmission: foodborne, waterborne, animal contact, person-to-person, environmental, and unknown.

Source: LBA analysis of unaudited DHHS, BIDD data.

Unaudited BIDC data indicated food establishments, but not necessarily FPS-accredited food establishments, accounted for 34.7 percent of foodborne outbreaks and 33.7 percent of illness associated with a foodborne outbreak during CYs 2004 through 2014. However, 50.0 percent of foodborne outbreaks and 77.2 percent of illnesses associated with an outbreak occurred during CYs 2012 through 2014, the years encompassing the audit period. Correlating these data to the FPS mission suggested limited effectiveness. However, data did not permit disaggregation of food establishment data to determine whether an establishment was FPS-accredited, accredited by a local jurisdiction, accredited by another agency, or unaccredited.

Inspections And Priority Violations

Inspections were a key component of a food safety surveillance system. Federally assembled national data indicated outbreaks that could be traced to a contributing factor were often tied to food handling and processing practices subject to FPS inspection. Inspection and co-occurring education, and sampling, were preventative measures. An inspection program focused on risk, establishing compliance status, and targeting systemic correction of deficiencies through active managerial control could help prevent foodborne illness.

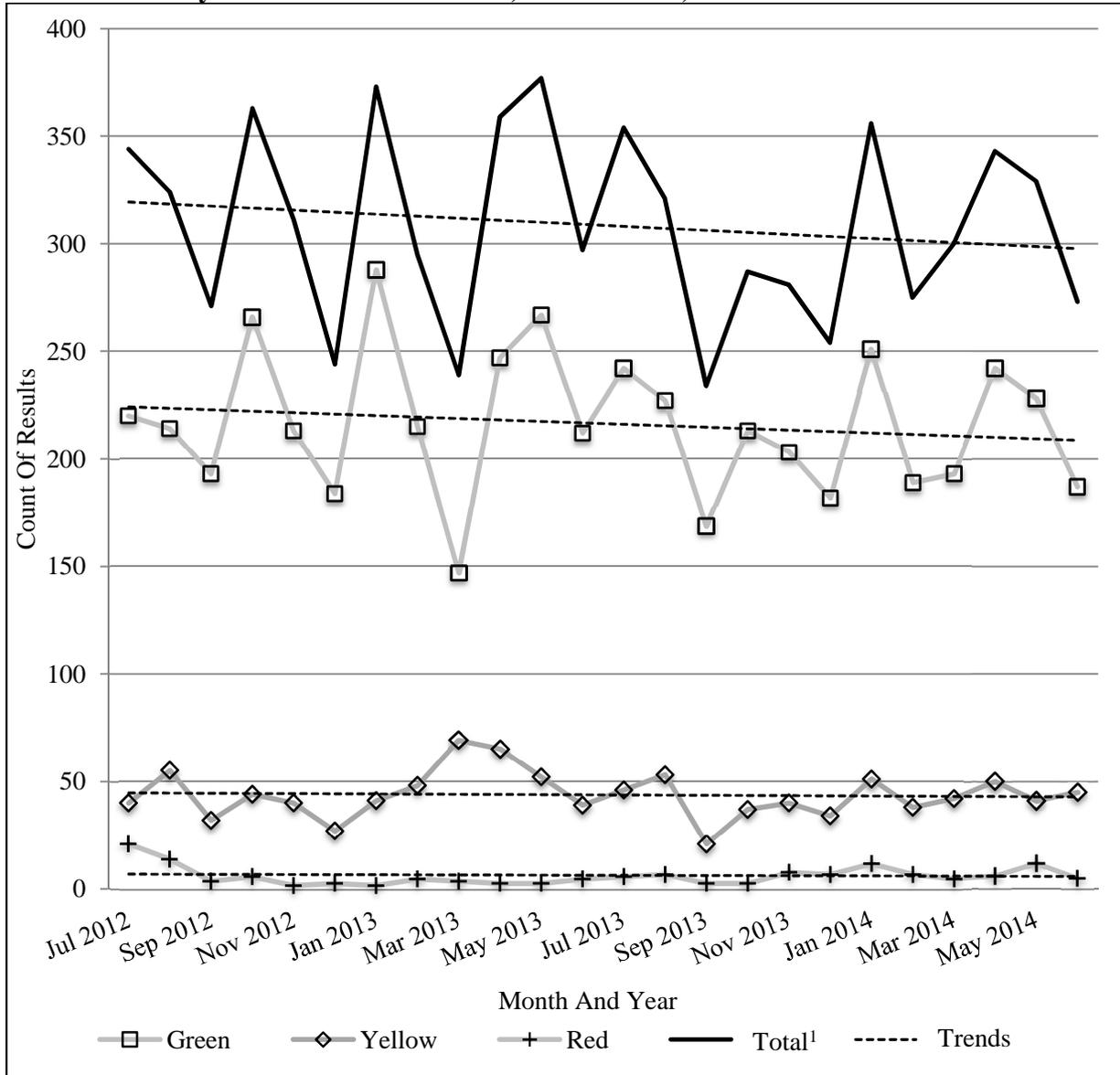
While risk was a reported factor in FPS inspection scheduling, in practice, FPS inspection scheduling practices were inconsistently focused on risk. Based on unaudited FPS data, of the 474 highest-risk licensed food establishments, the average number of days since the last inspection was 427, the maximum number of days since last inspection was 5,270, and 17.9 percent were not inspected during the two-year audit period.

Under rules, licensed food establishment inspection results were coded: *green* for no priority violations, or if all priority violations were permanently corrected at the time of inspection; *yellow* if priority violations were not permanently corrected at the time of the inspection; and *red* if an imminent health hazard existed or if the establishment was operating without a current, valid license at the time of the inspection. A *priority item* was a provision contributing most directly to eliminating, preventing, or reducing hazards associated with foodborne illness or injury. Two categories of lesser importance also existed but did not determine establishment status: a *priority foundation item*, a provision supporting, facilitating, or enabling one or more priority items; and a *core item*, a provision related to general sanitation, operational controls, facilities or structures, equipment design, or general maintenance.

An effective regulatory program should reduce priority violations over time. The FPS set one goal, reducing priority violations, or the frequency of *yellow* inspection results, in licensed food establishments. As Figure 3 indicates, food establishment inspections have decreased during SFYs 2013 and 2014, as have the number of resulting *green*, *yellow*, and *red* evaluations. However, *green* evaluations decreased at a greater rate than did both *red* and *yellow* evaluations, resulting in a greater proportion of inspected licensed food establishments having one or more ongoing priority violations. Additionally, the percent of re-inspections required increased, also indicating an increase in the number of unresolved deficiencies. This negative correlation suggests FPS activities were ineffective.

Figure 3

Monthly Counts Of Green, Yellow, And Red Inspection Results, By Color Code And Month, With Trends, SFYs 2013 And 2014



Note:

¹ Total includes all inspection result codes.

Source: LBA analysis of unaudited FPS data.

Additionally, the FPS had no mechanism to obtain self-inspecting jurisdiction reports on deficient establishments. Further, several hundred fixed establishments serving hundreds of thousands of meals annually, and dozens of events serving an additional half-million or more meals annually, fell outside the limits of accreditation statutes, and consequently outside the

bounds of effective State regulation. These conditions were due to the FPS mis-operationalizing statutory requirements. The degree to which these entities posed an ongoing risk to the State's food safety was unknown.

Complaints

Effective regulatory oversight should result in decreases in complaints. Complaint monitoring helped identify foodborne illness and possible outbreaks, but improved safety was ex post facto in nature, and only contributed to preventing further spread of disease. As illustrated in Figure 4, unaudited FPS data indicated food safety complaints submitted to the FPS increased during the audit period. Illness and injury complaints decreased, suggesting the FPS may have been effective in reducing those types of complaints. However, data quality undermined reliability. Also, the FPS did not ensure self-inspecting towns reported complaints and had no oversight responsibilities over self-inspecting cities, meaning complaints, illness, and outbreaks might have been locally investigated and not fully reported to the State.

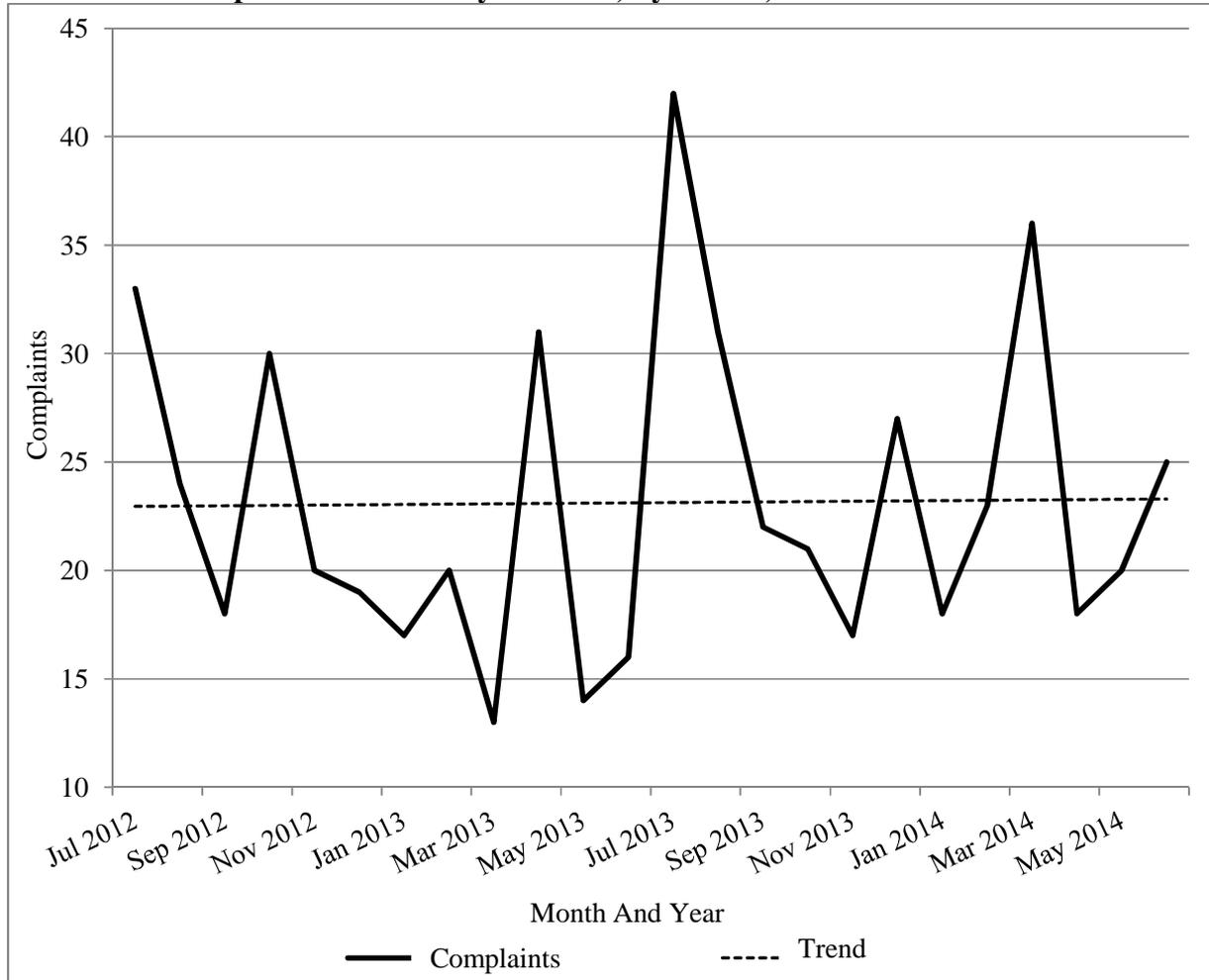
Unaudited FPS data indicated the State received 558 complaints of all types during the audit period; 255 in SFY 2013 and 303 in SFY 2014. This included 148 complaints in self-inspecting jurisdictions. However, the 12 self-inspecting jurisdictions responding to our 2015 survey indicated they received 247 sanitation and 85 foodborne illness complaints, or 332, in 2014 alone. The FPS data included some, but likely not all, of the self-inspecting jurisdictions' complaints reported via our survey. Thus, the full scope of foodborne illness complaints statewide, and food safety complaints in general, remained unquantified.

Sampling

Sampling was successful in identifying impure food and was increasingly important given the nature of the food supply chain. Since the FPS did not undertake comprehensive food sampling during the audit period, and there was no reporting mechanism in place to aggregate the results of sampling for those jurisdictions that did sample systematically, the FPS lacked data on food quality statewide.

Figure 4

Complaints Received By The FPS, By Month, SFYs 2013 And 2014



Source: LBA analysis of unaudited FPS data.

Recommendations:

We recommend FPS management:

- undertake a systematic, strategic review of its policies, procedures, practices, and role in helping ensure safety of the public food supply and reducing the occurrence of impure foods, unsanitary establishments, and risky practices statewide;
- coordinate with responsible elements of State government to develop a reporting system ensuring centralized reporting of all food safety complaints, illness and outbreak data, sampling results, and noncompliant establishment data;

- **coordinate with each self-inspecting jurisdiction to develop a reporting system ensuring centralized reporting of all food safety complaints, illness and outbreak data, sampling results, and noncompliant establishment data;**
- **ensure analysis of performance measures for factors and systems contributing to food safety statewide are completed, and FPS contributions to each is measured to identify trends and definitively establish outcomes of FPS interventions; and**
- **develop and publicize a time-phased strategic plan for improving effectiveness.**

Agency Response:

The Department concurs.

The Department recognizes that there is a need for the continual development, revision, and distribution of standards to achieve its mission to protect the safety of New Hampshire's food supply. Not only is this important to maintain compliance with the two FDA Cooperative Programs that the FPS participates in relative to the regulation of milk plants and dairy farms, and molluscan shellfish plants and growing waters but also to apply the most current science and standards to regulating retail and food service establishments. To achieve the latter objective, the FPS enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards in 2012. The Department completed its self-assessment as a requirement of enrolling in the program standards in 2013 and was independently audited to have met three of the nine standards with regard to Regulatory Foundation, Complaint Management and Customer Relations. As part of future strategic planning, the FPS aims to systematically meet additional standards that have been determined by the FDA to be elements of an effective retail food program. Timelines for meeting additional standards will be determined through a strategic planning process that the Department plans to engage in early 2016.

The Division of Public Health Services, which includes the FPS, is pursuing Public Health Department accreditation. This involves measurement of health department performance against a set of nationally recognized, practice-focused and evidenced-based standards. The goal of the voluntary national accreditation program is to improve and protect the health of the public by advancing the quality and performance of Tribal, state, local, and territorial public health departments. The public health department accreditation process seeks to advance quality and performance within public health departments. Accreditation process has already been initiated with review and collection of required documents that demonstrate compliance as well as gaps. The process is targeted for completion July 2018.

Compliance with the federal cooperative programs and self-improvement initiatives have been ongoing in the face of staff reductions and within NH legislation environment that has modified food safety laws (HB 1402 in 2012; HB 608 in 2013; HB 200 in 2014) towards less regulation.

Improving the FPS licensing and inspection database was identified as a necessity to improve program management as early as 2003. Authorization to procure the software for this database was granted by Governor and Council in March 2015. The FPS is actively implementing this new database and anticipates completion in November 2015. This new database will offer

electronic inspections, an online application and payment portal for licensees that will reduce paperwork, real time data for managers to set and monitor performance metrics and a press feature which will allow the public to access inspection results.

While the FPS recognizes that there would be value to a centralized complaint tracking system to complement current infectious disease surveillance, there is a concern that other agencies and self-inspecting cities and towns will be reluctant to comply with reporting into this system. Therefore, there has been little interest in acquiring the reporting system. The FPS agrees to explore regulatory changes needed to require centralized reporting and to explore acquiring a database to be used for collection of this data.

The FPS will utilize its new database system in concert with the Performance Management Application that is being developed by the Department. Test data has been entered but the FPS will not be using the Performance Management Application until the new FPS licensing and inspection database goes live in the Fall of 2015.

The FPS agrees there is a need for the continual development, revision, and distribution of standards to achieve its mission to protect the safety of New Hampshire's food supply. The FPS agrees to develop a strategic plan with annual milestones for a 5-year period using this audit report and a contracted facilitation in early 2016.

Program Scope

The public expects the food they purchase will be safe and government-regulated. Most elements of a comprehensive food protection system were specified in statute to be broad and encompassing, except for accreditation, which was intended to be narrow in scope with limited objectives. Regardless, State food safety laws were designed and intended to work in concert.

Observation No. 2

Expand Scope Of Operation To Reflect Statutory Obligations

FPS practices did not reflect the statutory scope of the DHHS's responsibilities intended to protect public health from impure food and unsanitary food production. The FPS was responsible for regulating and enforcing:

- food purity and branding standards to prevent the manufacture, delivery, holding, receipt in commerce, sale, or offering for sale of adulterated, misbranded, poisonous, or deleterious food; and
- prohibitions against unclean, unhealthful, or unsanitary conditions or practices in any establishment, place, or vehicle where food was produced, manufactured, transported, stored, or sold.

To accomplish this, statute provided the powers to inspect, sample and test food, make rules, issue corrective orders, compel establishment closure, levy penalties and administrative fines, embargo food from sale, seal food from use, and seize food articles as evidence without warrant. These powers applied throughout the State's food supply. Additionally, the FPS was required to accredit some, but not all, establishments. These requirements and powers were designed and intended to work in concert to achieve public health goals.

Inspections and sampling were generally accepted as interventions helping to improve food safety. Inspections helped to verify preventive measures were implemented and working as intended, to predict outbreaks, and to ensure the public health was protected. Sampling and subsequent testing helped establish food purity and also could verify preventative measures were implemented and effective. Statutes required the FPS to inspect food, facilities, and processes, and to take samples throughout the State's food supply. FPS inspectors had the necessary power and authority to enter any place at all times.

Accreditation and inspection were inconsistently dependent functions. Accreditation was required by several statutes affecting different, but not all, segments of the food-related industry. Some statutes required an inspection before an accreditation could be issued, but others did not, and statute also provided inspection requirements and authority independent of accreditation requirements. Accreditation laws usually required compliance only with specific accreditation standards, not compliance with other chapters of law related to food safety. To ensure compliance with these other food safety laws, procedures other than accreditation were required. Also, exemptions from accreditation pertained only to accreditation requirements. Exemptions were understood to waive the *additional* benefit accreditation would provide exempt establishments, leaving them to pose a greater relative health and safety risk, albeit the same risk they posed before accreditation. This was predicated upon other generally applicable mechanisms being consistently applied, such as inspection, sampling, closure, and enforcement procedures.

No statutory accreditation requirement waived or limited requirements in other chapters of law related to food safety, such as inspecting and sampling food for purity and proper branding, seizure, or embargo. Accreditation was not to replace or supplant existing statutes and the contemporary food safety regulatory scheme, rules, and related agency practices. Accreditation was intended as an additional measure and to work in concert with other requirements to help ensure food safety, but only within certain segments of the public food supply. Additionally, food service establishment and retail store licensing was requested by the DHHS to better enable it to achieve public health protection objectives as an *additional* tool and applicable to only a *subset* of food establishments.

However, when licensing food service establishments and retail stores became required in the late 1980s, deliberate administrative action made licensed establishments the focus of FPS inspections and other enforcement activities. The FPS discontinued broad regulation of the public food supply, including inspections of establishments other than those to which it issued an accreditation, and sampling of most food. Rules and practices that operationalized the broad scope of regulation were repealed and replaced with rules and practices focused on accredited establishments. This was contrary to apparent legislative intent and testimony attributed to the

agency at the time food service licensing was being considered. The decision to circumscribe the regulatory construct was not risk-based, but rather for administrative convenience and counter to evidence higher risks might no longer be regulated. In effect, the agency substituted one *tool*, accreditation, designed to *help* better achieve an organizational objective, protecting the public food supply, for the objective itself.

Statutory and regulatory compliance is a basic element of management control, and agencies must conduct activities according to applicable laws and rules. Some DHHS managers reported general awareness some statutory requirements were not enforced, and of some of the FPS's authorities and obligations within under-enforced statutes. Some FPS practices and procedures also relied directly or indirectly on authorities within under-enforced statutes. Prior FPS administrations established the current system and, while oversight and periodic review should exist, the FPS never had an in-depth review and the system has not been altered.

Comprehensive food protection addresses risks throughout processing, distribution, transport, storage, and at retail. Successful food protection should be science-based to determine optimal interventions, such as inspection and sampling, not be the result of administrative convenience. The State food supply faced increased risk and at least several hundred fixed establishments serving hundreds of thousands of meals annually, and dozens of events serving an additional half-million or more meals annually, fell outside the limits of accreditation statutes, and consequently outside the bounds of effective State regulation as implemented by the FPS.

Recommendation:

We recommend FPS management expand its scope of operation to reflect the full extent of its statutory obligations to achieve its mission. This would necessarily include risk-based inspection, sampling, and other regulatory activities not only at accredited establishments but also throughout the entirety of the State's food supply.

Agency Response:

The Department concurs.

The Department agrees to examine the meaning and operational implications of this recommendation. There will be a related review of staff resources and costs associated with expanded inspection and sampling. As previously noted, the program has lost staff (3 positions since 2008 - Shellfish Supervisor, Food Inspector, Food Emergency Response Specialist/Inspector). As it relates to risk assignment and staffing levels for food inspections, the Department will use the guidance of the 2013 FDA Voluntary National Retail Food Regulatory Program Standards. Standard 3 and Standard 8 address risk based inspections and resources. Even with maximizing staff by addressing reported inefficiencies described throughout this report and through gained efficiencies by the improved data collection with the new database, there are several factors that need to be considered. First, if FPS operations were expanded, an assessment needs to be done to determine what the establishment inventory would be, assign a risk to all food establishments based on risk, establish a frequency of inspection based on risk

assignment, and determine number of staff needed to meet inspection frequency. A timeline for this process will be vetted in strategic planning in 2016.

The FPS agrees that there is value to a systematic food sampling program with related sampling criteria, standards and enforcement actions. There is a concern with the feasibility of expanding sampling without additional resources. The FPS agrees to explore the level of additional resources needed to develop a systematic sampling program. The program will include the administrative and public health lab personnel that would be required for this sampling program. There is also the concern of sampling products that may also have federal oversight. Collaboration with federal partners to prevent duplicity of sampling efforts would need to be considered as part of a systematic sampling program.

Statute

Compliance with law and rule was a fundamental element of management control and aids agencies in achieving their objectives. FPS food safety responsibilities were included in six chapters of State law:

- RSA 130, *Sanitary Inspectors (Inspectors)*;
- RSA 143, *Sanitary Production and Distribution of Food (Sanitary Production)*;
- RSA 143-A, *Food Service Licensure (Licensure)*;
- RSA 145, *Cold Storage (Cold Storage)*;
- RSA 146, *Purity and Branding of Foods and Drugs; Immature Veal (Pure Food)*;
and
- RSA 184, *Inspection and Sale of Dairy Products (Dairy)*.

Observation No. 3

Improve Statutory Construct

Several gaps existed within and among food safety statutes. Some gaps were the result of the FPS improperly operationalizing the whole of its statutory obligations. Others gaps had statutory underpinnings.

State License-exempt

Even though State law established operating without a license was a danger to the public health, statute exempted several types of establishments from State food service licensing to avoid duplication at establishments regulated under certain other statutes, or to avoid unduly burdening small establishments. Due to erroneous operationalization of its statutory responsibilities, the FPS also exempted these establishments from inspection, sampling, and other regulation, although a food safety risk was recognized. The record did not support the Legislature intended this outcome, and it resulted in risks to food safety statewide and foodborne illness and outbreaks which diminished FPS effectiveness in achieving its mission to protect the safety and security of

the State's food supply. Inconsistency also created an irregular environment for the food industry and regulators.

Temporary And Occasional

Temporary and occasional food service establishments and events not regulated by a self-inspecting jurisdiction were exempt from State food service licensure. This type of setting included food concessions at agricultural fairs, food-centered events or festivals, and community-based events. We found no practical way to quantify the overall risk exposure presented by these types of establishments and events. Based on available data, dozens of these types of establishments and events existed or occurred regularly and predictably, and annually served over one-half million meals statewide. The risk category of these establishments and events was indeterminate, but was likely moderate- to high-risk, depending on the nature of the food produced or procedures used, and the clientele served. Unaudited BIDD data from 2004 through 2014 indicated 18 outbreaks affecting 119 people occurred in a temporary and occasional setting.

Recreational Camps

The 152 recreation camps licensed and inspected by the DES in 2014 were exempt from food service licensure when operating within the scope of a recreation camp license. Although DES rules required compliance with the *Food Code*, inspections focused on 17 food-safety related points which did not equate to FPS *Food Code*-based inspection criteria, nor were inspectors standardized *Food Code* inspectors. Attendance and food service data were not available, but likely thousands of meals were served in this type of setting annually. Unaudited BIDD data from 2004 through 2014 indicated five outbreaks affecting 244 people occurred in a recreational camp setting, including the worst single outbreak recorded during this period, which affected 133 people.

Health Facilities

Licensed health care facilities were exempt from food service licensure. Kitchen facility inspections were inconsistently accomplished, were not documented using a standardized inspection checklist, and were only subjected to generalized food safety requirements, not *Food Code*-equivalent standards. In 2013, 350 health facilities with nearly 17,000 beds were licensed by the DHHS, and served an indeterminate number of meals to some of the highest risk populations. Unaudited BIDD data from 2004 through 2014 indicate seven outbreaks affecting 80 people occurred in a health care facility setting.

Soup Kitchens

Statute permitted the Commissioner to exempt soup kitchens from food establishment licensure, and DHHS rule formalized the exemption. The FPS in practice also excluded them from inspection, sampling, and any other regulation. In 2014, as many as 237 charitable food distribution entities existed in the State, with about 160 entities within State food safety jurisdiction. Likely, several hundred thousand meals were served annually statewide in this type

of setting, and were likely served to a higher-risk clientele. Further, while soup kitchens were defined as “a food service establishment operated by a charitable organization...that prepares and serves meals to the poor without charge,” food banks and pantries only provided unprepared foodstuffs to their clientele which may categorize them as a food service establishment or retail food store. They were not treated as such by the FPS.

Self-inspecting Jurisdictions

Food service establishments and retail food stores licensed in self-inspecting cities were independent of State control and oversight. Food service establishments and retail food stores licensed in self-inspecting towns were a shared responsibility, but during the audit period the FPS exerted no effective oversight of self-inspecting town food safety programs. At least two outbreaks during the audit period occurred in self-inspecting jurisdictions, affecting 61 people, one of whom was hospitalized and five others sought medical care.

Cold Storage

The State’s three cold storage establishments were regulated under a separate chapter of law and part of rules. While the rules will reportedly be incorporated into licensed food establishment rules, aspects of the *Cold Storage* law may unnecessarily complicate the regulatory environment and the administration of food safety requirements, and may have exacerbated FPS statutory noncompliance in this area.

State Agency Interactions

The FPS’s purpose and activities intertwined with those of the DAMF, F&G, DES, and other State agencies. While the DAMF regulated agriculture and the quality and grade of agricultural crops and food products, the DHHS also had jurisdiction over agricultural commodities and food. In practice, the DAMF regulated commodities and some food articles to quality standards rather than safety standards, although some quality standards related to food safety. This resulted in overlapping regulation for certain articles and at certain establishments. It also resulted in gaps, including pet treats, which neither the DAMF nor the FPS regulated, registered, or inspected. During the audit period, one outbreak was attributed to this article type and led to 43 illnesses, including 16 hospitalizations of an average 2.7 days, and 14 other visits to medical care providers. Inadequate processing procedures were found to underpin the outbreak, procedures routinely examined by FPS inspectors at establishments it inspected and on which it provided education to operators. While FPS inspectors must examine the sanitary condition of places where meats were kept and the methods of preparing meat products for sale, for humans or other animals, this establishment remained unregulated.

We also noted introducing new products or commodities to the State’s food supply may be problematic. Fermented teas and wild-picked mushrooms were cited as articles and commodities producers sought to introduce, but because of regulatory inadequacies and unclear regulatory responsibility, had reportedly been unable to do so.

Statutes Outdated

While aged statutes are not necessarily obsolete, food safety science has changed substantially since many State food safety laws were originally promulgated. The major food safety statutes date to 1907 and 1911, and sections date back to 1878 and 1881. Food safety laws were amended piecemeal, many chapters were not substantively altered from their original form, and some contained outmoded provisions. For example, *Sanitary Production*, using language unchanged from 1911, provided “[u]nclean, unhealthful or unsanitary conditions or practices shall be deemed to exist if...any employer shall knowingly permit or suffer any person who is affected with tuberculosis or any other communicable disease to work” in “any place where food is prepared for sale, stored, served or sold...” While communicable disease risks remain, exemplified by the 2013 confirmed case of a Hepatitis A-infected food service worker, which led to preventative inoculations being administered to over 1,200 potentially exposed individuals, progress since 1911 has made many communicable diseases controllable.

Definition Of Food

Statutes upon which food safety was predicated had multiple definitions of fundamental elements, including food itself. At least eight sections or paragraphs in five chapters of statute defined one or more aspects of food. Some were narrow, such as definitions of oleomargarine, milk, shellfish, and beverages. Others were broader, but limited to items for human consumption, while others still had no such limitation, such as the definition provided in *Sanitary Production*: “food shall include all articles used for food, drink, confectionery or condiment, whether simple, mixed or compound, and all substances and ingredients used in the preparation thereof” or *Pure Food*: food “means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” The FPS was responsible for each definition. It was not clear each definition was necessary, and some were not applied in practice because the FPS operationalized a restrictive definition, limiting the scope of the FPS’s purview.

Takings

State law provided varied authorities to take both property and the opportunity to engage in public commerce in the food industry. Statutes placed authority with various officials, including the Commissioner, field inspectors, and the courts, while recourse to due process was inconsistently explicit. With an inadequate control structure and lack of formal delegations, it was unclear whether and how Commissioner-held authority was delegated to FPS staff.

- Thirteen sections and paragraphs in four chapters of law provided for inconsistent authority to take property, including seizure, forfeiture, embargo, condemnation, detention, and restraint. Statute also authorized or required inspectors take samples of articles, with or without compensating the owner.
- Twenty-nine sections and paragraphs in five chapters of law provided for inconsistent mechanisms to take the privilege of engaging in commerce in the food industry, including injunction, closure, suspension, revocation, cancelation, and denial.

Internal Conflicts And Other Inconsistencies

Several provisions of food safety law appeared inconsistent or to conflict:

- Licensed, permitted, or certified Dairy, Shellfish, or Beverage and Bottled Water subprogram establishments and cold storage facilities were not exempted from duplicate licensure as a food service establishment or under another subprogram, leading to ten establishments we could identify as being licensed, inspected, and otherwise regulated under two subprograms for similar operations.
- At least eight sections or paragraphs in five chapters of law provided for administrative fines for noncompliance. The maximum fines for violating statute or rules varied, ranging from \$100 to \$2,000, and contained inconsistent maximum fines for similar offenses.
- Eleven sections in five chapters of law provided inconsistent authority to issue administrative orders on different topics.
- As we depict in Table 2, in Observation No. 18, criminal sanctions were inconsistent across food safety laws. Further, the Commissioner was statutorily obligated to prosecute intentional noncompliance under one chapter but not others, and it was unclear whether every instance of noncompliance with this law warranted prosecution.
- Thirty-three paragraphs in five chapters provided for promulgating rules or regulations, an obsolete term for rules.
- Statutorily-required fees were inconsistent among the chapters regulating food safety. This led to inconsistent funding mechanisms, inconsistent application of fees, and created confusion and inappropriate General Fund allocations.
- In some chapters, inspections were required but only permitted in others, often for the same act, such as accreditation.
- Both the Milk Sanitation Board and the DHHS have rule-making authority related to the dairy industry. Having two entities adopting two sets of rules based on a single statute and regulating the same industry appeared inefficient.

Optimally, the desired outcome of a regulatory program should be efficient and uniform regulation of the industry. However, the FPS was a small unit within the DHHS and operationalizing six chapters of dated and at times conflicting laws, along with four chapters of rules and three federal ordinances or codes, created an unduly complex regulatory structure. Many of the chapters of law created distinctions among food establishments, but without sufficient difference to warrant stand-alone chapters of law. Further, the FPS maintained four separate subprograms to operationalize this regulatory structure, leading to different practices for similar processes, compartmentalized data collection, and other boundaries. While FPS practices changed over time to reflect current food safety practices, statute did not keep pace. To ensure lawful operations, statutes and practices must be consistent. Management controls include oversight and periodic review, which the FPS lacked. These factors exacerbated inconsistencies and led to inefficiency and reduced effectiveness.

Recommendations:

We recommend the Legislature consider repealing *Inspectors, Sanitary Production, Licensure, Cold Storage, Pure Food, and Dairy* statutes and replacing them with a new comprehensive food safety statute, disposing of those elements which are obsolete, inconsistent, and contradictory while retaining those elements of existing law with ongoing or future value, such as:

- a single, broad and all-encompassing definition of food, such as the one found in *Pure Food*, to ensure the FPS continues to be ultimately responsible for food safety statewide;
- administrative accreditation requirements and exemptions separate and distinct from inspection, sampling, and other general food safety-related requirements;
- clearly established food safety-related inspection, sampling, and other requirements not hinged upon an establishment's accreditation status, such as those found in *Pure Food*;
- required fees, such as inspection fees as required in *Licensure*, which may be useful for other subprograms; and
- clear descriptions of any exemptions from all aspects of State regulation, if any category of establishment is truly expected to be outside any State food safety regulation.

We recommend the Commissioner consolidate elements of the various chapters of rules and standardize common elements, such as administrative fines, accreditation procedures, and fees.

Agency Response:

The Department concurs.

The FPS agrees to review current statutes and to consolidate definitions, accreditation processes and fee and fine structure where feasible. Many of the points noted in this section have been addressed in our response to Observation No. 2. Rather than repeat, the FPS will reference that response. A timeline will be established during strategic planning in 2016.

It is important to note that when food entities are not licensed with related rules established, they have no required sanitation guidelines to follow other than what is in current law for general food sanitation standards. The FPS could develop rules to require registration and more defined standards for some of these venues, while others are currently exempt from licensure, which would make it more difficult to locate them to inspect them. The FPS has experienced in practice that accreditation in concert with inspection is integral to safety and implementation of quality standards, as the requirements are known in advance rather than discovered via random inspections. To depict registration and licensing as only an administrative revenue generating activity does not give recognition to the advantages of registration requirements, which includes identification of products, locations, hours of operation, and size of a venue – all of which helps to determine risk and prioritization for inspection.

The FPS agrees to seek clarification on legislative intent of ‘exemption from licensing’ if that is to be expanded in practice to ‘exemption from inspection.’ Based on FPS experience with the legislative process over the past four years, the trend has been to weaken regulatory oversight of food in favor of market freedom for New Hampshire producers.

The Department agrees to work on a strategy relative to rulemaking of food safety for food establishments not previously accredited. The Department agrees that there is some degree of food safety risk where all food is served whether at accredited or non-accredited food establishments. Study will be given to situations where accreditation and inspection have been reported dissociated and to examine best practices to maximize food establishment compliance through an enforcement schedule that may or may not be linked to accreditation status.

It should be noted that the FPS is currently in the process of rulemaking to address the expired cold storage rules. These rules passed the Joint Legislative Committee on Administrative Rules (JLCAR) on June 19, 2015.

The conditional approval was based on need for DAMF to create rules surrounding the registration of poultry and rabbit producers and was not based on the Cold Storage statute. As Cold Storage facilities accreditation and inspection standards have been incorporated into He-P 2300, and we have included for cold storage the same requirements as for a food processing plant. The Department will seek to repeal RSA 145, Cold Storage, as the statute is obsolete.

Accreditation

Mandatory accreditations facilitated developing an inventory of establishments subject to regulation. Accreditation practices should have been standardized and systematized, and ensured regulated establishments follow applicable requirements and the public was adequately protected. To operate many types of establishments providing food for public consumption in New Hampshire, some form of accreditation was required. Additionally, to ship food for public consumption across State lines, compliance with federal and other states’ requirements was necessary. This may have been a license, permit, certification, or registration as specified in State law or federal ordinance. During the audit period, the FPS accredited approximately 5,925 operations within, or selling products within, the State, 5,290 (89.3 percent) of which were licensed as food service establishments. This excluded:

- approximately 3,000 establishments accredited, inspected, and otherwise regulated during SFY 2014 by self-inspecting municipalities;
- establishments falling within one of the 12 statutory exemptions; and
- bulk samplers, haulers, and others accredited by the DAMF.

Two of 15 (13.3 percent) FPS employees were primarily responsible for managing accreditations, although other staff also had a role in accrediting certain establishments. Statute established ten types of licenses, certifications, registrations, and permits issued by the FPS and required for legal operations of certain types of establishments, including:

- licenses for nine classes with 34 categories for food service establishments;
- licenses for four classes for milk plants, distributors, and producer-distributors based on the volume of production;
- licenses for five classes of beverage and bottled water establishments;
- licenses for cold storage establishments;
- permits for dairy farms;
- certificates for five classes of shellfish establishments; and
- registrations of out-of-State producers of bottled water and beverages, out-of-State dairy plants, and non-commercial out-of-State kitchens.

With the exception of the dairy permit, issued on a one-time-basis and valid as long as the dairy farm operated according to law and rule, accreditations were valid for one year. Food service establishment licenses were issued throughout the year and renewals were based on the day the previous license expired, shellfish certificates expired on December 31, and beverage and bottled water licenses and registrations and dairy licenses expired on January 1 annually.

Observation No. 4

Improve Accreditation Practices

We found instances where the FPS improperly issued licenses, did not inspect establishments as required by law before issuing licenses, and was burdened by and did not properly implement some elements of the complex accreditation structures prescribed by rule and law.

Improperly Issued Accreditations

Statute and rule required compliance with their requirements before an expiring accreditation could be renewed. Our review of 182 establishment files indicated at least nine instances (4.9 percent) of licenses or certifications being issued or renewed while the establishment had known priority or critical violations, but only one example (0.5 percent) of a license withheld for a violation. Unaudited FPS data indicated at least 62 food service establishments were relicensed after inspections during the audit period found them violating State requirements.

Our file review also indicated:

- two of 182 establishments (1.1 percent) were issued licenses erroneously, including one license (0.5 percent) which was issued under the wrong subprogram;
- thirteen of 93 (14.0 percent) food establishment license renewals did not include water supply information required by rule;
- 23 of 43 (53.5 percent) Beverage and Bottled Water subprogram license applications and seven of 29 (24.1 percent) registration applications did not appear to indicate water source or test results;
- licensing information was not included in 11 of 24 (45.8 percent) in-State milk plant, distributor, and producer-distributor files;
- approval of accreditation applications did not include supervisory review;

- the dates license renewals were approved were inconsistently recorded; and
- electronic records were inconsistently completed and contained unreliable information.

Erroneously-issued accreditations appeared to be due to a disconnect between accreditation operations and inspection outcomes, and limited analytical and quality assurance procedures. Compliance with statute and rule was a fundamental element of management control, and continuing to accredit establishments without resolving noncompliance at those establishments or ensuring complete applications risked public health.

Missed Licensing Inspections

Statute and rule required new license applicants under the Food and Beverage and Bottled Water subprograms be inspected prior to issuing a provisional license, to receive a 90-day provisional license prior to full licensure, and to be inspected again within 45 days of provisional licensing to determine compliance before issuing a full license. Our file review indicated 53.6 percent of food establishments issued new licenses did not have two inspections prior to licensure as required by rule. FPS files and unaudited data indicated 84.6 and 87.8 percent, respectively, did not have any inspections within 45 days as required by law, and 38.5 and 65.3 percent, respectively, were not inspected by the time the 90-day provisional licensed had expired. FPS records did not indicate provisional license expirations affected establishment operations, or full licensure.

The FPS reportedly did not track subsequent licensing inspections after sending application requests to inspectors. Proper licensing with required inspections can help ensure establishment compliance with public health requirements.

Standardization Of Structure

The FPS issued 72 different types of licenses, certifications, registrations, or permits and inspected holders of three additional accreditation types issued by the DAMF. The federal Dairy and Shellfish subprogram ordinances imposed some of these categorization requirements, and others were primarily internal FPS identifiers. However, the complexity of the accreditation structure created administrative inefficiencies and improper tracking and implementation of some program elements, such as cold storage facilities licensed as food establishments, incomplete out-of-State non-commercial kitchen re-registrations, and unlicensed transfer stations.

Federal ordinances did not require routine reaccreditation of any establishment except in the Shellfish subprogram. State law required routine annual reaccreditation of food, dairy, and beverage and bottled water establishments, creating an administrative burden. Accreditation without inspection rendered an annual relicensing schedule arbitrary without a unique demonstrable public health benefit and kept inspectors out of the field in order to perform administrative work. Further, specific statutory expiration dates created a surge in demand for administrative time and required inspections ahead of those deadlines for some programs.

Statute required timely responses to applications, including the provision of contact information, notice of errors, and application resolution. The FPS did not comply with these requirements in six instances we identified in file review.

Recommendations:

We recommend the Commissioner seek changes to statute to standardize and simplify the accreditation structure, promulgate changes to rule to standardize and simplify the accreditation structure, and pursue a change in statute to migrate all subprogram accreditation cycles, except for the Shellfish subprogram, to a biennial schedule.

We recommend FPS management:

- **adopt policies and procedures to ensure accreditations are not issued improperly, including supervisory review and approval;**
- **adopt policies and procedures to help ensure licensing inspections occur as required in statute and rule; and**
- **communicate with applicants in a systemic and timely manner to help ensure compliance with statutory response and decision timelines.**

Agency Response:

The Department concurs in part.

While the Department acknowledges the value of improved oversight and policy development to include enhanced supervisory review, the FPS will seek legislative change to the provisional licensing process to align with reasonable practice. It should be noted that two of the four subprograms do currently have supervisory review of applications. Performance metrics with regard to accreditations issuance and response to applicants will be further developed with implementation of the new licensing and inspection database. Currently only one computer in the program can be used to access the current licensing database.

The Department is reluctant to agree in advance to adopting a biennial schedule without further study and will study the feasibility of the biennial schedule but reserves doing so until SFY 2017. The efficiency effect of the new database with enhanced ability to process online applications will begin in the Fall of 2015. Assessment of the potential efficiency gains will be more feasible within one year of running the new system and at that time a review of the potential benefits of a two-year cycle can be better assessed.

Plan Review

The FPS was responsible for pre-approving construction and major structural changes. Food establishment plan review was an important food protection function as it helped ensure establishments met code and rules. An effective plan review process helps minimize risk and

avoid future problems, allows for changes to be made before construction and installation occurred, and should be consistently applied.

Observation No. 5

Improve Management Of The Food Service Establishment Plan Review Process

The FPS plan review process for food service establishments was inefficient and inconsistent. Unaudited FPS data indicated 209 plan reviews of new and renovated food service establishments occurred during the audit period.

Inconsistency

A plan review should mimic inspection processes by reviewing menus, determining the flow of food through the facility, and identifying contamination risks. Rules required a plan review application be used, but in practice, the FPS conducted some plan reviews without an application. The application required a proposed menu; two copies of plans depicting refrigeration equipment, plumbing equipment and fixtures, and locations of poisonous or toxic materials; and other documentation. In practice, these documents reportedly were inconsistently required or reviewed and the process focused on the number of sinks. The FPS reported this focus resulted in improvements within the industry. It may have also elevated risks within other areas of sanitation and food safety, such as pest control or locations of poisonous or toxic materials which can result in *Food Code* violations. Also, some duplicate documentation was required but disposed of due to a lack of storage space, indicating this may be an unnecessary requirement.

Inefficiency

The food establishment plan review process was centralized at the Concord office and accomplished by a single field inspector taken off field inspection duties. During the audit period, this resulted in a loss of an estimated 236 food establishment inspections. A decentralized process could increase the efficiency by allowing the field inspector with plan review duties to conduct normal inspection duties, while distributing the burden of plan reviews among all inspectors and also placing the review responsibility on the inspectors who will have to inspect the establishment in the future. The Dairy subprogram relied on a decentralized plan review process.

While management should periodically review control activities to ensure continued relevance and effectiveness in achieving the entity's objectives, the FPS had no formal management oversight or review of the plan review process.

Recommendations:

We recommend FPS management:

- **require applicants submit a plan review application as established in rule;**

- **require all documentation requested in the application before processing the request;**
- **review the number of copies of documentation required by rule to ensure the requirement to submit multiple copies of documents remains valid and seek necessary changes to rules to lessen the burden on the applicant;**
- **improve management oversight over the plan review process to help ensure consistency and efficiency; and**
- **decentralize the plan review process.**

Agency Response:

The Department concurs.

Changes to the administrative rules to change the plan review process will streamline the application process for the applicant. These rules passed JLCAR on June 19, 2015.

The FPS agrees that there is benefit for policy development for metrics and quality control over the plan review process. The FPS agrees to create a Standard Operating Procedure (SOP) for this and update the supplemental job description of the plan reviewer to include performance metrics.

We disagree with decentralization as this would shift staff time from inspection to plan review, require additional staff training and oversight and would promote inconsistency. Instead of decentralizing plan reviews, the FPS agrees to explore electronic submission of plan reviews, so that this function could be done remotely.

Variances

Statute permitted variances to food service establishment licensing requirements. Variances were also permitted by food service establishment, shellfish, and expired cold storage rules. Other subprograms had no provisions for variances or waivers in statute or rule. Similar processes within the same organization should be standardized when possible to promote efficiency, performance measurement, and equity.

Observation No. 6

Improve Variance Management

The FPS ineffectively managed variances during the audit period, which according to unaudited FPS data included 44 food service establishment variances issued or renewed.

Rules provided the Commissioner authority to approve or deny waivers for the food, shellfish, and cold storage subprograms and statute required written delegations of authority from the Commissioner to subordinates. In practice, the FPS Administrator decided whether to grant

variances based on consultation with relevant food inspectors, but without delegated authority. Formally assigned responsibilities within an organization enable efficient and effective operations, compliance with statutes and regulations, and reduce risk of abuse and ad hoc decision-making.

Further, FPS inspectors appeared to frequently accept compliance with past regulatory requirements during inspections conducted under new regulatory requirements, allowing establishments to be “grandfathered” with an exception from current rules. These individual decisions did not appear to be recorded as variances or provided for in statute or rule, except for existing dairy establishments’ plumbing. Additionally, uncodified FPS policy, which did not comply with rule, provided food establishments exemptions from plumbing requirements. Grandfathered deviations from rule should be processed and recorded as variances to provide consistency among all regulated establishments and to provide for management oversight and approval.

The FPS lacked a formal, written policy governing the variance management process, lacked adequate data collection, and had no process to help ensure variances were granted timely. Statute required the FPS to respond to and act on applications timely, but receipt dates for variance requests and rationales for awarding or denying them were not recorded. Effective management control relies on relevant and reliable data, including performance measurement, information, and records. Agency management should monitor, document, and evaluate performance against objectives and written policies provide management control structures and help reduce risk.

Recommendations:

We recommend the Commissioner promulgate rules for granting and processing variances to ensure accredited establishments across all FPS subprograms have consistent access to variances when not otherwise prohibited.

We recommend FPS management develop written policies and procedures for managing variances and ensure:

- **variances granted to grandfathered establishments are recorded as variances,**
- **performance information is recorded, and**
- **timeliness and other performance goals are achieved.**

Agency Response:

The Department concurs.

The FPS will prioritize development of a variance management process as part of the development of an SOP manual, and/or as a quality improvement step in strategic planning. The new database will have enhanced capability for recording and tracking variances issued. The FPS will also plan to structure related performance measures for staff in the performance evaluation process.

Inspections

Regulatory oversight of food establishment operations emphasizes recognizing and correcting food safety violations during or following inspections. Inspections were a key component of the State's food safety system. While inspections were a snapshot of establishment practices and may not represent a true picture of establishment operations, an inspection program focused on risk, establishing compliance status, and targeting systemic correction of deficiencies through active managerial control can help prevent foodborne illness. Inspection processes should be standardized and systematized, and ensure regulated establishments follow applicable requirements and the public was adequately protected. Consistency can increase compliance and consumer confidence and reduce regulatory risk among industry. Routine management review of inspector activities can help ensure consistency.

Inspections were the primary function within each FPS subprogram. Eleven of 15 FPS employees were primarily field staff. Some had other responsibilities in addition to field inspection work.

- Ten had varying degrees of food establishment inspection responsibilities, equaling 7.5 full-time equivalent (FTE) food establishment inspectors, and were assigned one of nine specific districts of the State. Unaudited FPS data indicated 7,404 food establishment inspections occurred during the audit period.
- Three had varying degrees of dairy establishment inspection responsibilities, equaling 2.25 FTE, and were assigned to one of two regions within the State. Unaudited FPS data indicate 991 Dairy subprogram inspections occurred during the audit period.
- Two had varying degrees of shellfish establishment inspection responsibilities, equaling 0.75 FTE, and were assigned statewide responsibility for all shellfish establishments. Unaudited FPS data indicated 146 Shellfish subprogram inspections were completed during the audit period.
- Two had some degree of beverage and bottled water establishment inspection responsibilities, equaling 0.25 FTE, and regions were coterminous with Dairy subprogram regions. Our file review indicated 11 inspections of beverage and bottled water establishments were completed during the audit period.

Inspections were categorized as routine, construction, follow-up, change-of-ownership, or complaint-based. Priority was given to inspections associated with illness and injury complaints, disasters, and accrediting new establishments. Inspection and accreditations were not codependent functions. Six statutes either permitted or required inspections, but not all required accreditation. For example, while renewing establishments must pay a fee to the FPS for application processing, an inspection was not necessary for each accreditation renewal to occur. Additionally, FPS practices further dissociated the inspection function from establishment accreditation.

Observation No. 7

Improve Inspection Practices

The FPS lacked controls to ensure inspection practices were compliant with rules, consistent, and risk-based. A quality assurance program, formal policies on inspection practices, and ongoing standardization of inspectors were either lacking or inconsistent. Lack of controls resulted in gaps within the regulatory structure designed to minimize public health risks and ensure safe practices within the food industry.

Risk-based Inspections

A well-designed and implemented science-based food safety regulatory program can increase the likelihood that State regulation will adequately protect the public health. Risk assessments allow agencies to efficiently allocate resources to the highest-risk establishments. The FPS lacked a comprehensive risk-based approach to inspections for the Beverage and Bottled Water and Food subprograms. Additionally, non-Interstate Milk Shipper establishments regulated under the Dairy subprogram were inspected sporadically, not twice annually as established in law, and beverage and bottled water establishments were inspected upon request, not annually as required by rule. Both subprograms experienced resource challenges and neither undertook a risk assessment to help prioritize resource allocations towards high-risk establishments.

The Food subprogram partially implemented a risk-based inspection system. Most establishments were assigned a risk category, but some appeared to not match the established guidelines for risk categories. The FPS set the informal goal of prioritizing food establishment inspection scheduling on risk, but lacked the management control, formal policies, and inspection goals for inspectors to implement it. The food establishment inspection schedule was determined by each individual inspector without a formal schedule or a hierarchy of priorities.

Food establishment risk categories were numbered one to four, with one being the lowest risk and four being the highest risk. Although the FPS adopted this methodology, 18.1 percent of establishments were not assigned a valid risk category. Table 1 depicts the median, the maximum, and the average number of days since last inspection as of December 30, 2014, and the number and percent of licensed food establishments uninspected during the audit period. Higher risk establishments were inspected more frequently and were less likely to have been uninspected during the audit period. However, 17.9 percent of the highest risk establishments were uninspected during the audit period. Meanwhile, 50.9 percent of the lowest risk establishments were inspected, demonstrating mis-prioritization of inspections resources. Additionally, many high-risk establishments serving highly susceptible populations, or using specialized food production processes, were not required by statute to be licensed by the FPS, which opted to not inspect or otherwise regulate them.

Table 1

Licensed Food Establishment Inspections

Risk Category Assignment And Number Of Days Since Last Inspection, As Of December 30, 2014						
	Unassigned	Risk One	Risk Two	Risk Three	Risk Four	Total
Number of establishments	1,008	111	1,386	2,373	474	5,352
Median	347	615	505	317	291	n/a
Maximum	7,782	5,649	7,180	5,727	5,270	n/a
Average	495	921	777	447	427	n/a

Uninspected Establishments By Risk Category, SFYs 2013 And 2014¹						
	Unassigned	Risk One	Risk Two	Risk Three	Risk Four	Total
Number of establishments	265	54	542	493	85	1,439
Percent	29.5	49.1	39.1	20.8	17.9	27.5

Note:

¹ Excludes 50 establishments licensed during the audit period but not included in the FPS inspection database.

Source: LBA analysis of unaudited FPS data.

Risk was reportedly considered in an inspector's schedule, but it was considered secondary to licensing and complaint inspections. Statute required provisionally-licensed establishments be inspected within 45 days after license issuance. However, unaudited FPS data indicated 87.8 percent of these inspections were not completed and the FPS did not meet its goal of following-up within 24 hours of receiving an illness complaint receipt 44.8 percent of the time.

Inconsistent Inspection Practices

FPS management did not ensure consistent inspection practices among inspectors. In three of the four subprograms, we identified inconsistencies related to:

- thoroughness;
- responses to similar violations;
- enforcing rules, the *Food Code*, and law;
- coding a food establishment as *yellow* without an uncorrected priority violation;
- checking for current license or certification;
- inspecting vehicles;
- correcting violations on-site;
- accepting testimonial evidence or requiring direct observation to verify a deficiency corrected; and
- discretion in not issuing a fine and not recording an observed deficiency.

Training And Standardization

Standardization was a training and co-inspection process intended to help improve uniformity when: 1) applying and interpreting regulations, 2) conducting inspections, and 3) writing reports. The Food subprogram did not formalize its approach to, or regularly conduct, standardization. Food inspectors were last standardized in 2011, and some reported never completing the process. The FPS set the informal goal of standardizing inspectors every three years, but has not re-standardized any inspectors. Although Shellfish and Dairy subprogram inspectors met federal standards, no standardization or review of inspection practices by FPS management occurred for these subprograms as the FPS lacked a quality assurance program to ensure uniformity among inspection staff. Control activities like reviewing inspection reports were limited in scope. A quality assurance program should verify risk categories, ensure required sanctions are levied, review past inspection findings for trends, and otherwise ensure compliance with rules and laws.

Inspectors reported they received training through individual study of regulations, team meetings, occasional FDA classes, on-the-job co-inspections, and standardization efforts. Some inspectors reported infrequent or incomplete co-inspections and standardization efforts with inconsistent application and no formal policy existing. Inconsistent standardization and training efforts may have contributed to developing inconsistent practices and rule interpretations. Training helps employees become and remain competent, reinforces standards of conduct, and helps meet changing organizational needs.

Follow-up

Follow-up inspections were essential to ensuring noncompliance was rectified and provisionally licensed establishments met requirements for full licensure, but follow-up inspection scheduling practices did not ensure follow-up inspections were conducted timely, or at all.

- Inspections following provisional licensure were reportedly missed by the FPS in the Food subprogram. During the audit period, unaudited FPS data and our file review indicated provisional licensees did not receive the required follow-up inspection within 45 days 87.8 and 84.6 percent of the time, respectively.
- Our file review of 72 licensed Food subprogram establishments found three (4.2 percent) had missed follow-up inspections after a routine inspection identified noncompliance.
- Follow-up inspections in the Shellfish subprogram were typically scheduled for the next routine inspection, but when they were scheduled outside of the next routine inspection, they were inconsistently completed.
- During the audit period, the Beverage and Bottled Water subprogram did not perform any follow-up inspections, although three of 16 establishments (18.8 percent) recorded chronic deficiencies requiring follow-up.
- Follow-up inspections on complaints were inconsistently completed and inconsistently timely when they occurred.

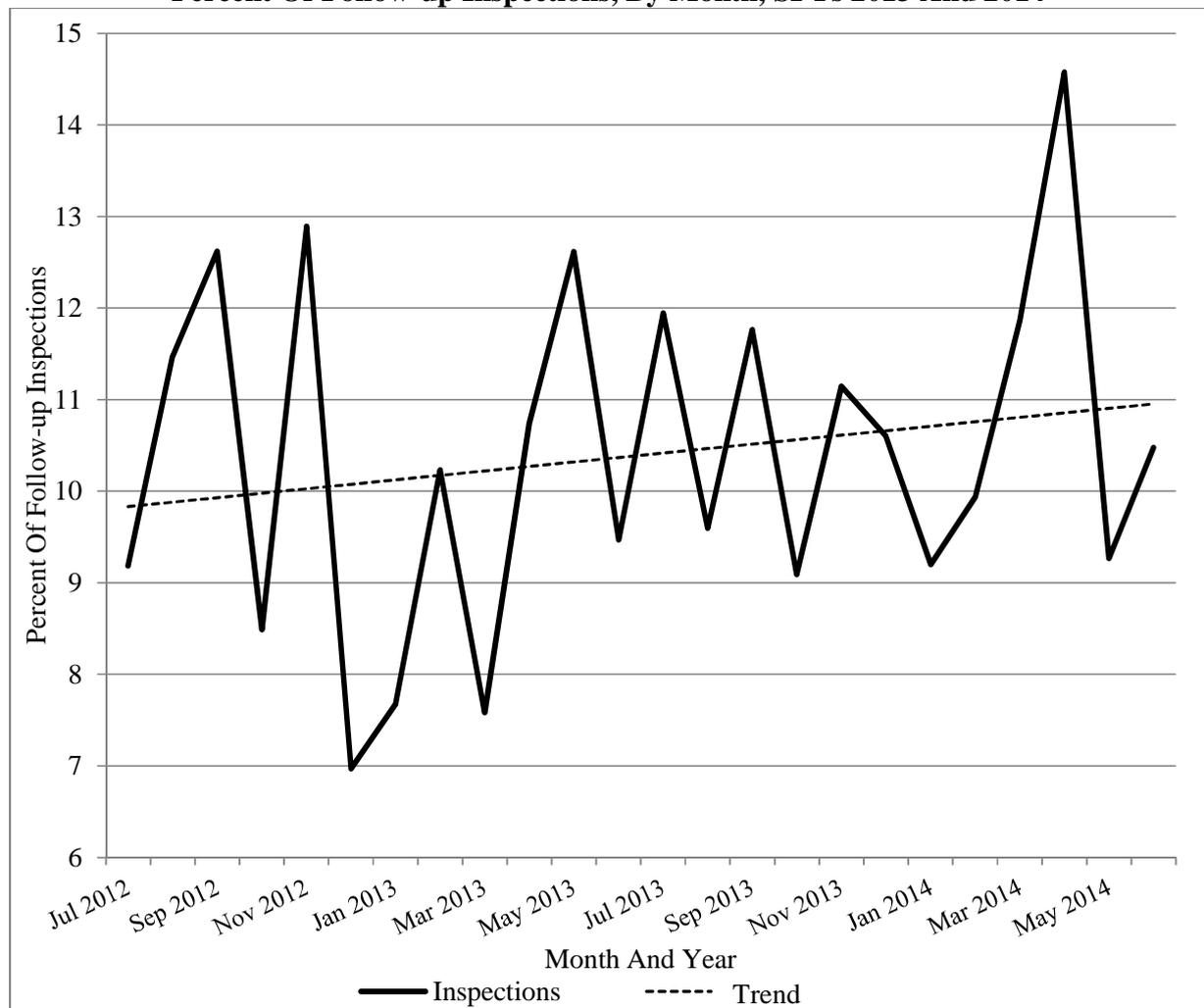
Lack of follow-up created a gap in the regulatory system. We found one establishment received four complaints during the audit period, including two for inadequate food temperature control.

Two inspections were conducted and both identified priority violations related to potentially hazardous food temperature controls. The food temperature control priority violation still remained when a third inspection was conducted, but no additional follow-up was conducted to ensure this public health risk was corrected.

Also, follow-up inspections were an indication a public health risk existed in an inspected establishment and required follow-up. As compliance with the *Food Code* increased, the percentage of follow-up inspections should have decreased. However, as Figure 5 illustrates, follow-up inspections as a percentage of total inspections by month increased during the audit period.

Figure 5

Percent Of Follow-up Inspections, By Month, SFYs 2013 And 2014



Source: LBA analysis of unaudited FPS data.

Vehicle And Vessel Inspections

While the DHHS was required and empowered by statute to ensure sanitary production and distribution of food, the FPS inconsistently inspected and accredited vehicles and vessels. Although required by rule, the FPS reported not inspecting vehicles transporting shellfish product every six months and Food subprogram inspectors usually did not enter delivery trucks or other vehicles to perform inspections. Inspectors avoided going into some vehicles due to perceived legal barriers or risks, despite recognized public health concerns. Further, Food and Shellfish subprogram inspections inconsistently focused on shipping and receiving food, and inconsistently tracked vehicle and vessel inspections. Food was exposed to potential risks throughout its life cycle, from production, distribution, and consumption. Contaminated products distributed to hundreds or thousands of locations were more difficult to eliminate from the food supply, so preventing foodborne illness during distribution was essential. The FPS reported a need to include food product transportation into the scope of inspection work, but lacked necessary procedures.

Establishment History

Inspectors should have studied all available data before conducting inspections, including previously noted deficiencies. The Food subprogram rarely brought up prior violations during an inspection or reviewed files prior to an inspection. Without reviewing past inspection findings, potential trends in noncompliance might not be observed.

Unannounced Inspections

The FPS inconsistently conducted unannounced inspections. Inspections of food processing plants and beverage and bottled water establishments were typically announced, shellfish inspections were inconsistently unannounced, and dairy inspections were unannounced, but were scheduled in a manner permitting the industry to predict routine inspection schedules. Unannounced inspections prevent establishments from altering their true practices and altering inspection results.

Rule

Dairy and *Licensure* required inspection practices be codified in rule, while other statutes did not. Comprehensive inspection rules for all subprograms did not exist. Those rules that did exist inconsistently provided information on the scope of routine, follow-up, and complaint inspections; inconsistently included a risk-based methodology to scheduling; and lacked details on inspection scheduling. Adopting detailed, transparent rules communicates requirements to the industry and the public and minimizes discretion.

Recommendations:

We recommend the Commissioner amend rules to include detailed inspection practices.

We recommend FPS management:

- **develop and implement a risk-based inspection scheduling system focused on ensuring high-risk establishments are identified, prioritized, and regularly inspected regardless of their accreditation status;**
- **develop a quality assurance program to ensure inspection practices are consistent and the standardization process is formalized and conducted according to an established frequency;**
- **ensure repeat food risks are addressed in inspections by consistently reviewing an establishment's file before an inspection;**
- **incorporate statutorily-required vehicle and vessel inspections and the distribution phase of the food production cycle into the scope of inspection practices, systemically regulate vehicles, and develop formal policies and procedures; and**
- **ensure establishments are regulated uniformly by consistently conducting unannounced inspections and all required follow-up inspections.**

Agency Response:

The Department concurs in part.

The FPS believes that inspection and accreditation should go hand-in-hand due to standards being known and enforcement.

The FPS agrees to develop procedures and policies and metrics. The new database implementation is critical to supporting this recommendation so that data surrounding these metrics can be captured.

Repeat food risks will be tracked with the new database. The current database does not have the ability to reliably track risk information. The new database will allow for work prioritization based on risk.

Within the Shellfish program, due to seasonal activity, it is accepted and required practice (as noted in the guidance document for the National Shellfish Sanitation Program Model Ordinance (NSSP MO)), to schedule these inspections so that inspection frequency is met.

The FPS does not agree that dairy inspections are predictable. They are conducted at a prescribed frequency based on the federal Pasteurized Milk Ordinance (PMO).

Per FPS practice for food establishments, inspections are unannounced. The exception is food processing plants where scheduled inspections are sometimes required due to the variability of operation schedules at this type of facility.

The FPS agrees to seek legal guidance as to whether follow up inspections are deemed required by rule. If needed, the FPS would seek to change the rule because this practice is not reflective of public health risk and would require more resources.

The FPS agrees to follow the guidance set forth in the FDA Voluntary National Retail Food Regulatory Program Standards regarding standardization of inspectors. A timetable for meeting this standard will be developed within FPS strategic planning. Performance metrics for food inspectors will be developed within an SOP manual.

It should also be noted that an additional FPS food inspector completed standardization with the FDA Regional Retail Food Specialist in June 2015. This means the FPS now has two inspectors standardized by the FDA and they are available to standardize inspectors across the state.

It should also be noted that the FPS food sanitation supervisor does maintain a file of standardization inspections and the documentation is maintained. The FPS agrees to develop an SOP for tracking this training and standardization.

The FPS suggests the report reflect that dairy inspection reductions are attributable to a year-long hiring freeze imposed on the FPS when a dairy inspection position became vacant.

Food Service Establishment Sanitation Subprogram

Regulators seek to manage foodborne illness by minimizing the use of food from unsafe sources, inadequate cooking practices, improper holding temperatures, contaminated equipment, and poor personal hygiene at food establishments. The FPS used the 2009 edition of the *Food Code*, incorporated with amendments into rule to structure inspections and guide priorities. The *Food Code* was designed to focus on the highest risks to consumer health.

Establishments were divided into classes based on the scope of their operations and included specific establishment types with limited scopes, such as homesteads and food processing plants. FPS management reported a goal of inspecting each establishment once every two years. Higher-risk establishments were to receive more frequent inspections. State law did not require routine inspections to occur at a defined frequency for most establishments. However, inspections must occur when an application for a new establishment was received or when a change of ownership occurred. These inspections were required before operations began under a provisional license and before a new regular license was granted. Inspections were also required within ten days of a request from an establishment with a revoked license seeking reinstatement. Food service establishments paid a fee to the FPS for renewal processing, but an inspection was not necessary for license renewal to occur. Violations of selected *Food Code* items during a defined period were a key measure of food safety performance. Repeat violations occurring at an establishment was direct evidence an establishment had not responded effectively to previous violations. Unaudited FPS data indicated the Food subprogram licensed 5,290 food establishments and conducted 7,404 inspections during the audit period.

Observation No. 8

Improve Management Of The Food Sanitation Subprogram

The Food subprogram did not regularly inspect unlicensed establishments, incentivize non-priority violation corrections, consistently check establishment Hazard Analysis and Critical Control Point (HACCP) plans intended to help ensure food safety, or ensure risk assignment and enforcement activities were consistent.

Unlicensed Establishment Inspections

Statute authorized the FPS to inspect all buildings, rooms, and other places used for producing, storing, selling, or distributing food and provided the responsibility to inspect and sample food quality, condition, and branding. However, the FPS rarely inspected unlicensed establishments. Of the 7,404 inspections recorded in the unaudited Food subprogram inspection database, 7,355 (99.3 percent) were of food establishments licensed during the audit period. Licensed establishments did not include food establishments in self-inspecting jurisdictions; temporary food service establishments, such as fairs and other events; recreation and youth camps; health care facilities; child care facilities; small homestead operations; federally-exempt poultry producers; and soup kitchens. Some of these unlicensed establishments were reportedly a potential public health risk, and some caused substantial foodborne illness outbreaks in the past.

Lingering Violations

The DHHS had a publicly-stated goal to reduce the number of priority violations. Rule required food establishments with uncorrected priority violations be coded *yellow*. These establishments had to either correct deficiencies within ten days, implement a Corrective Action Plan (CAP), or face fines and license revocation. Rules permitted food establishments with lesser violations to be coded *green*, but required priority foundation violations be fixed within ten days and core violations within 90 days. However, priority foundation and core violations were inconsistently followed-up or were inconsistently addressed in follow-up inspections assessing priority violation corrections. No policy established when priority foundation or core violations warranted follow-up inspections, leaving unclear the relative severity of these violations and the necessity for corrective action. Priority foundation and core violations were not recorded in the FPS inspection database. This limited the FPS's ability to track and understand which violations were allowed to persist, or to evaluate risk and measure performance. Further, rule required the FPS to use CAPs to correct all deficiencies not addressed within ten days. As the FPS operationalized rule, food establishments earning a *green* rating had little or no incentive to correct priority foundation and core violations, and priority foundation and core violations were permitted to persist. Lack of follow-up could suggest to food establishment operators that identified violations were unimportant.

Inconsistent Enforcement

We found inspectors did not assign risk categories to establishments in 14.0 percent of FPS files we reviewed and in 18.1 percent of unaudited FPS data. We also found inconsistent enforcement of statutory and regulatory requirements and violation resolution.

- One establishment was inspected twice in the 13 months after its license expired but was allowed to operate without a license. It did not renew its license until it was inspected a third time and ordered to close after 53 months of unlicensed operation. Statute required this establishment to hold a valid license to operate.
- An establishment with a priority violation was subsequently the subject of a complaint and completed three license renewals and four routine or follow-up inspections with the same priority violation noted, and fines threatened but not imposed, before achieving compliance after 43 months. Statute and rule provided re-licensure should only occur if an establishment was compliant with law and rule and had addressed deficiencies cited in the most recent licensing inspection. Rule required establishments with the same priority violations on more than two consecutive inspections to pay a \$500 fine.
- An establishment received one routine and 11 follow-up inspections during 17 months due to failure to correct the same priority violation. The establishment was fined twice, and the license renewal was withheld until fines were paid, after which the license was renewed. A CAP was not closed. Rule required license applications be denied if the establishment did not correct an identified deficiency, did not complete a CAP, or was cited two or more times for the same priority violation within the last 12 months or the previous five inspections.
- A food processing plant was allowed to operate without a rule-required HACCP plan for over one year. No CAP was implemented nor was a \$500 fine levied after two inspections identified the lack of a HACCP plan.
- An establishment received a routine and six follow-up inspections for the same priority violation during eight months. No fines were levied or CAPs implemented even though rule required fines for failures to correct priority violations after more than two consecutive inspections and required CAPs when an establishment could not correct deficiencies within ten days.

HACCP Plan Inspections

Federal law required HACCP plans in schools. Rules and policy required the FPS to inspect school HACCP plans, but inspectors did so inconsistently. Eight of the 43 (18.6 percent) routine inspection reports we reviewed should have included a HACCP check but did not, and 11 inspection reports (25.6 percent) did not indicate whether a HACCP check occurred or was considered necessary.

Recommendations:

We recommend FPS management:

- **ensure unlicensed establishments are systemically inspected based on their public health risk;**
- **ensure compliance policies and procedures are formalized, comply with law and rule, incentivize priority foundation and core violation corrections, and guide follow-up inspection decisions;**
- **ensure HACCP plans are consistently checked where they are required by law; and**
- **require consistent assignment of risk categories to each establishment and improve violation tracking and resolution to help ensure compliance with rule and law, and reduce the public health risk.**

Agency Response:

The Department concurs.

As stated previously under Observation No. 2, the FPS agrees to examine the meaning and operational implications of this recommendation. There will be a related review of staff resources and costs associated with expanded inspection and sampling. As previously noted, the program has lost staff (3 positions since 2008 - Shellfish Supervisor, Food Inspector, Food Emergency Response Specialist/Inspector).

The Department agrees to work on a strategy relative to rulemaking of food safety for food establishments not previously accredited. The Department agrees that there is some degree of food safety risk where all food is served whether at accredited or non-accredited food establishments.

The FPS agrees to seek guidance from the Legislature to clarify which types of establishments the FPS is expected to inspect. Further review is needed regarding the role and reach of the FPS regarding un-licensed establishments that are not specifically exempted by statute; examples include farmer's markets, short-term events such as public fairs, and other types of food vendors that currently are without oversight such as pet food manufacturers. The FPS perspective is the entity should be required to have a permit to operate, which includes standards of sanitary practice. This allows the FPS to register, track and inspect within a regulatory context, rather than ad hoc such as dropping by a farmer's market which has few defined standards of operation. This shift would require expansion of FTEs, which we would assess via a study commissioned from an objective party. This observation is being repeated throughout the audit, however the FPS is addressing concerns within response to Observation No. 7 and here. Further study on the feasibility is needed as the workload implications are substantial. For example, consider if the FPS added child-care facilities – how many FTE hours would be required for an annual inspection, given the number of these types of establishments? Should they be required to have a food license? Do we charge an inspection fee for each inspection and use that to cover our FTE costs? Would the option of offering food safety training to child care administrators or food inspection training to child care licensing workers be more efficient? Would the state budget system allow any funds collected through expanded inspections by the FPS to be used to support expanded FTEs? Currently any funds brought in are sent to the general fund except a fixed amount - \$300,000.

As it relates to risk assignment and staffing levels for food inspections, the Department will use the guidance of the 2013 Voluntary National Retail Food Regulatory Program Standards. Standard 3 and Standard 8 address risk based inspections and resources. Other related comments are provided under the FPS response to Observation No. 2. The FPS agrees to align rules and follow up practices to be reflective of public health risk. We do not agree with the requirement to correct all violations of lesser public health risk (priority foundation and core items) because this could be to the detriment of the compliance with priority items which are the most critical in correcting due to the increased risk of foodborne illness associated with these items. For example, not properly cooking raw animal food has a higher food safety risk associated with it versus a broken floor tile. Each violation should not carry the same weight when determining a follow up schedule and current practice is to focus on priority items. The FPS agrees that a timeline for correction as delineated in its current administrative rules should remain in place, however current rule does not require a re-inspection to confirm correction of such deficiencies. FPS agrees to study the merits of follow up inspection requirement if certain level of non-priority violations is reached.

The FPS agrees to develop a formal policy and SOP with regard to Hazard Analysis Critical Control Point (HACCP) plan review and tracking.

The FPS agrees that consistent risk assignment is needed. An SOP will be developed to ensure consistent assignment of risk categories and the new database will be used to track risk and schedule inspections based on risk.

Out-of-State Non-commercial Kitchens

Out-of-State non-commercial kitchens were a subset of food processing plants. No State inspections of these establishments occurred, the State instead relied on documented local inspections occurring. Requiring out-of-State non-commercial kitchens be registered was intended to hold out-of-State vendors to the same standard as in-State vendors in promoting sanitary food production and distribution. Registration also supported product tracing so the State could quickly trace-back contaminated articles to their origin in the case of an outbreak or contamination and prevent further illness. Unaudited FPS data indicated eight out-of-State non-commercial kitchens were registered to permit importing food articles into the State.

Observation No. 9

Improve Management Of Out-of-State Producers In Residential, Non-commercial Kitchens

The FPS did not annually reregister out-of-State producers in residential, non-commercial kitchens selling food articles in New Hampshire as required by rule. Controls over establishment records appeared to be nonexistent, and the FPS lacked oversight of this segment of the industry.

Rules required out-of-State non-commercial producers register by submitting an application, verifying local health code compliance, and paying a fee. Registrations expired on December 31

annually, and establishments must have reregistered by submitting an application and verifying continued local health code compliance. FPS staff reported being unaware of the annual reregistration requirement until we discussed the matter with them.

An inventory of producers supplying food articles to retail establishments in New Hampshire was important to enabling trace-back, should any such articles be implicated in foodborne illness or injury. The FPS had no process to identify entities requiring registration to operate and to notify them of operating requirements. A primary public disclosure means could have been the FPS's web presence, but no information related to out-of-State non-commercial producers, or the application forms, were present. Only eight out-of-State non-commercial producers were listed as registered, with some registrations dating back to 2008. This may not represent all out-of-State non-commercial producers selling product in New Hampshire.

Recommendations:

We recommend FPS management:

- **comply with rules and annually reregister out-of-State non-commercial producers selling food articles in New Hampshire;**
- **send expiration notices and renewal applications to these establishments as is done for other establishment types;**
- **ensure out-of-State non-commercial producers are aware of registration requirements and include information and forms for these establishments on the FPS's web presence; and**
- **ensure staff are aware of, and enforce, all food safety and security program requirements.**

Agency Response:

The Department concurs in part.

The FPS agrees that study is needed to determine if the FPS should continue registration of Out-of-State Producers. Due to recent legislative changes relative to homestead products produced within NH, the FPS agrees to seek clarification of legislative intent to continue to register these out of state producers of homemade products. Because these products are also under the regulatory jurisdiction of the state in which they are based, more study needs to be done regarding the types of foods and number of producers that are actually being shipped into NH. Based on these findings the FPS may move to change statute and rules to make them align with legislative intent and FPS practice.

Cold Storage

Cold storage establishments were a subset of licensed food establishment but regulated under the *Cold Storage* statute. Cold storage establishments employed refrigeration in the storage of food

articles for 30 or more days at or below a temperature of 40 degrees Fahrenheit. Unaudited FPS data indicated three cold storage establishments were licensed during the audit period.

Observation No. 10

Improve Management Of Cold Storage Establishments

The FPS lacked adequate controls over cold storage establishments, rules for cold storage establishments were expired, and rules did not reflect statute.

Inspections

Three cold storage establishments were licensed by the FPS and they received a total of four inspections during the audit period, all in SFY 2013. Statute and expired DHHS rules required annual licensure and inspection of cold storage establishments prior to licensure.

Statutes And Rules

Cold storage establishment-related rules, except for licensing fees and an administrative fine schedule, expired on June 14, 2014 and erroneously defined the storage temperature for cold storage as 41 degrees Fahrenheit or lower, while State law provided cold storage was 40 degrees Fahrenheit or lower. The FPS reported seeking to replace the expired rules and incorporate them into food service establishment rules promulgated under the *Licensure* statute.

During the audit period, the FPS administered cold storage establishment licensing and records like they were food service establishments, even using the same license form which indicated cold storage establishments were regulated under the *Licensure* statute. However, cold storage establishments were regulated under the industry-specific *Cold Storage* statute dating to 1917 and cold storage establishment-like operations were not explicitly contained in the definition of food establishment in the *Food Code* adopted by the State. Neither was a 40 degrees Fahrenheit threshold accommodated in the *Food Code* for food service establishments.

The *Cold Storage* statute had several similarities to the *Licensure* statute, including requiring establishments be licensed annually, requiring an inspection before initially issuing a license, and providing authority to promulgate rules for fees and administrative fines. These may make the chapters amenable to combination in rule.

The *Cold Storage* statute also differed from the *Licensure* statute.

- Food was defined differently.
- Unsanitary cold storage establishments may be temporarily closed by the Commissioner to correct deficiencies, and have their licenses suspended for extended noncompliance; while food service establishments can have licenses revoked after repeated violations or for posing an imminent health hazard, and suspension was only for non-payment of fees.

- The Commissioner had a duty to inspect cold storage establishments annually, while food service establishments had no routine annual statutory inspection requirement, inspection only being required in two instances: 45 days after a provisional license was issued to approve a full license, and within 10 days of a request to reinstate a revoked license.
- The Commissioner had a duty to inspect food entering cold storage establishments to prevent unwholesome food articles from entering them while no corresponding requirement existed for food service establishments.
- Food articles may be stored for no more than one year in cold storage establishments unless an approved extension was applied for and granted by order, while food service establishments had no similar requirements.
- Rules were required to operationalize unique elements of both chapters, such as cold storage establishment closure and license suspension and food service establishment license revocation.
- Nonconformity with *Cold Storage* and rules could result in a misdemeanor charge, while noncompliance with food service licensing laws and rules could result in a violation for the first offense and a misdemeanor or felony subsequently.
- Cold storage was defined as 40 degrees Fahrenheit or lower. Food service establishments had no similar requirement in statute and were held to 41 degrees Fahrenheit or lower for cold holding by rule.

Incorporating cold storage establishments into food service establishment rules would require accommodating each statutory difference. However, with only three regulated cold storage establishments, aspects of *Cold Storage* may unnecessarily complicate the regulatory environment and the administration of food safety requirements. Repealing *Cold Storage* and incorporating essential elements into the *Licensure* chapter may better serve the public interest.

Recommendations:

We recommend the Commissioner promulgate rules for regulating cold storage establishments as required by statute, and consider seeking statutory changes to simplify regulating cold storage establishments while preserving necessary elements of existing statute.

We recommend FPS management ensure each cold storage establishment is inspected annually as required by statute.

Agency Response:

The Department concurs in part.

The FPS is in the process of revising the administrative rules to incorporate cold storage facilities into the Rules for the Sanitary Production and Distribution of Food (He-P 2300) instead of creating a separate rule for cold storage facilities. These rules were passed by JLCAR on June 19, 2015.

The Department will seek to change the statute so that cold storage facilities are inspected on a frequency based on risk and not annually as required by statute.

The conditional approval was based on need for DAMF to create rules surrounding the registration of poultry and rabbit producers and was not based on the Cold Storage statute. As Cold Storage facilities accreditation and inspection standards have been incorporated into He-P 2300, the Department will seek to repeal RSA 145 as the statute is obsolete. See comments for Observation No. 3.

Self-inspecting Jurisdictions

During the audit period, 16 municipalities opted to license and inspect local food establishments. We surveyed the 15 jurisdictions still managing local programs in 2015. The aggregated responses of the 12 that responded are in Appendix C. They reported regulating 2,997 local food establishments. Nine cities independently operated food safety programs, but seven self-inspecting towns were subject to DHHS oversight and, except for one, had to seek approval of the Commissioner to operate local programs. The one exception had a chapter law authorizing it to operate its local program. The DHHS retained concurrent enforcement authority in self-inspecting towns.

Observation No. 11

Improve Oversight Of Self-inspecting Town Food Safety Programs

During the audit period, the FPS exerted no effective oversight of self-inspecting town food safety programs. The framework for oversight of six self-inspecting towns was structured in memoranda of agreement (MOA) between the State and locality, while the seventh was regulated only by State laws. The requirements were inconsistent across the seven sets of standards found in the MOAs and State law.

Inspector Qualifications

The MOAs with three towns (42.9 percent) addressed local inspector qualifications. Each town reported some form of inspector certification and some local inspectors were reportedly standardized by State or federal officials, but no FPS records existed demonstrating who was certified or standardized, or whether the credentials were current. The FPS reportedly discontinued routine standardization of local inspector competencies prior to the audit period.

Inspection Frequency

Five of seven towns (71.4 percent) were required to complete an inspection of each establishment twice annually. No FPS records documented any evaluation as to whether towns achieved this standard. Data reported by self-inspecting towns completing our survey indicated this standard was inconsistently met.

Complaints And Deficient Establishments

Four of seven towns (57.1 percent) were required to submit complaints to the FPS. However, FPS policy only encouraged self-inspecting jurisdictions to report consumer complaints to the DHHS. Unaudited FPS data indicate the FPS directly received 44 complaints in self-inspecting towns. FPS data contained inspection results for 11 (25.0 percent). We found no complaints or reports of violations from self-inspecting towns in FPS hardcopy records, and were unable to determine whether the remaining 75.0 percent of complaints originating in a self-inspecting town were acted upon. Survey data indicated at least 247 sanitation and 85 illness complaints occurred in self-inspecting jurisdictions during 2014 alone.

State law also required one town (14.3 percent) to submit copies of inspection reports with deficiencies to the State. FPS records did not contain such inspection reports.

Meetings And Technical Assistance

Four of seven towns (57.1 percent) were required to attend quarterly State meetings open to all self-inspecting jurisdictions, but the meetings were inconsistently attended and the FPS lacked attendance records. The FPS also reportedly provided technical assistance upon request but there was no documentation demonstrating how often requests were received, whether the requests were responded to, and were responded to timely, or whether technical assistance or quarterly meetings were effective.

Training

The FPS was obligated to provide four training sessions per year but they were inconsistently scheduled or executed. Five towns (71.4 percent) reported attending at least one quarterly meeting instead. The FPS did not document measuring the effectiveness of this approach, and three of 12 self-inspecting jurisdictions (25.0 percent) indicated this venue did not provide training value. Further, the FPS did not document an assessment of what training needs existed, but reported self-inspecting towns lacked expertise and training equivalent to FPS field staff.

Evaluation Of Local Programs And Annual Reports

Four towns (57.1 percent) were required to submit an annual statistical report. FPS records did not contain annual reports or other indications oversight occurred. Reportedly, formal FPS program evaluation and analysis were discontinued. Four of six towns (66.7 percent) responding to our survey indicated never having an evaluation, while two (33.3 percent) reported annual or less frequent evaluations.

Outdated Standards

MOAs were outdated despite reported FPS efforts to update at least one. One of six (16.7 percent) was signed in 2014, three (50.0 percent) were signed in 2011, and two (33.3 percent) were signed in 1998. Each town was required to adopt State food sanitation rules and provide copies of regulations to the DHHS. The FPS did not ensure towns provided regulations or

adopted current rules. Consequently, some jurisdictions relied on outdated sanitation standards dating back to 1998. Four MOAs lacked expiration dates, perpetuating inconsistent and outdated requirements.

By allowing outdated and inconsistent requirements to continue in force and not adhering to statutory and MOA-based requirements, the FPS lacked a full understanding of the scope and nature of food safety in self-inspecting towns. This undermined its effectiveness in achieving its mission to protect the safety and security of the State's food supply, and prevent foodborne illness and injuries. Inconsistency also created an irregular environment for the food industry and regulators. Further, the DHHS provided no formal, written delegations of authority related to self-inspecting town oversight to any FPS employee, and no employee was explicitly responsible for oversight of self-inspecting towns and ensuring compliance with the terms and conditions of MOAs and applicable laws. Only one employee had any related responsibilities: to supervise the development and implementation of training programs for self-inspecting towns.

Recommendations:

We recommend the Commissioner formally delegate authority to the FPS administrator, including authority to:

- **negotiate the terms and condition of MOAs,**
- **enter into MOAs,**
- **oversee self-inspecting town compliance, and**
- **require localities submit necessary materials.**

We recommend FPS management improve self-inspecting town oversight by:

- **updating MOAs to reflect current food safety practice;**
- **standardizing the terms and conditions of the MOAs;**
- **ensuring self-inspecting towns comply with relevant State laws and the terms and conditions of the MOAs;**
- **requiring all complaints and their resolution be provided timely;**
- **assessing training needs and developing a training program to ensure local inspectors are sufficiently trained;**
- **documenting transactions with self-inspecting towns; and**
- **developing performance measurements, collecting data, and regularly evaluating local program effectiveness and compliance.**

Agency Response:

The Department concurs.

The FPS would work closely with our legal department regardless of the Commissioner's delegated authority to negotiate the terms and conditions of MOAs as is our current practice. The FPS would continue this practice of legal review to provide proper checks and balances. We suggest authorizing the Division of Public Health Services (DPHS) Director to sign MOAs.

The FPS agrees to review its current authority within current RSA structure to oversee towns with MOAs. The program will also strive for greater consistency within the MOAs. The FPS will need to estimate and then request adding additional FTE to provide more oversight for this area.

The FPS agrees to the recommendations concerning improving management of self-inspecting town oversight. The FPS wants to document that the level of resources to implement this would need to be assessed for feasibility.

Dairy Sanitation Subprogram

Milk and milk product safety began at the farm level. The Dairy subprogram regulated production, preparation, and transport of milk and other dairy products in the State. According to unaudited FPS data from the audit period, the Dairy subprogram inspected 144 farms, 48 milk plants and producer-distributors, 41 milk haulers and 21 bulk milk tanker trucks co-regulated by the DAMF, and one transfer station. The FPS conducted 991 inspections of dairy establishments in total during the audit period. The Dairy subprogram also licensed eight in-State milk distributors and 144 out-of-State milk plants, distributors, and producer-distributors. Permits were issued without charge to farms passing inspection and supplying milk to plants or producer-distributors.

During our file review, we examined files from 21 farms; 23 in-State milk plants, distributors, and producer-distributors; five out-of-State milk plants, ten milk haulers; ten bulk milk tankers; and the State's single transfer station. We also examined related databases.

Dairy subprogram activities were driven by the FDA's 2011 *Grade "A" Pasteurized Milk Ordinance* (PMO) adopted by the Milk Sanitation Board (Board), with amendments, in rules. The FPS was the authorized State agent of the FDA and was responsible for ensuring federal requirements were met. The State's program was reviewed every three years by the FDA. Dairy operations must comply with federal requirements to sell milk across state borders legally and qualify as interstate milk shippers (IMS). Non-IMS establishments were those only selling their products within the borders of the State. State law and rule regulated IMS and non-IMS establishments similarly, with modifications for certain raw milk and yogurt producers. The FDA did not regulate non-IMS dairy establishments.

Observation No. 12

Improve Management Of The Dairy Sanitation Subprogram

The Dairy subprogram did not inspect non-IMS licensed and permitted operations as often as rule required, did not sample non-IMS products as often as rule required, had conflicting rules and bifurcated regulatory responsibility, and had inefficient administrative practices. Missed inspections, sampling, and tests potentially permitted improperly produced or prepared milk products to be sold to the public, increasing the risk of foodborne illness.

Inspection And Sampling Frequency

Staff reallocations during the audit period led the FPS to focus on IMS plants and farms which shipped to bulk tank units (BTU), private organizations which collected milk from dairy farms for testing, processing, shipping, and sale, even though inspection frequency requirements did not differ between IMS and non-IMS establishments. Resources allocated to inspections of non-IMS milk plants and producer-distributors and non-BTU farms were insufficient to meet requirements under State rules.

Rules required in-State licensed milk plants and producer-distributors be inspected every three months, and statute required all licensees be inspected at least twice per year. Our review of FPS files and databases indicated each of the seven in-State IMS milk plants received required inspections. However, according to unaudited FPS data, 40 of 41 (97.6 percent) of non-IMS milk plants and producer-distributors did not. Further, FPS files indicated inspection requirements were not met for ten of 18 (55.6 percent) of both IMS and non-IMS milk plants and producer-distributors.

FPS files also indicated:

- 51 of 127 (40.2 percent) of both IMS and non-IMS routine milk plant and producer-distributor inspections did not occur; and
- 51 of 67 (76.1 percent) of required routine non-IMS plant and producer-distributor inspections did not occur.

Additionally, one non-IMS milk plant and two non-IMS producer-distributors did not receive any inspections.

Rules required in-State dairy farms be inspected every six months, and statute required inspections at least twice per year. Our review of unaudited FPS data indicated the required number of routine inspections did not occur during the audit period at 2.5 percent of BTU-affiliated farms and at 100 percent of non-BTU farms.

Rules required certain pasteurization equipment tests at applicable milk plants every three months. Unaudited FPS data indicated the 12 pasteurizers at IMS plants received all required inspections during the audit period, but at least ten of the 20 (50.0 percent) non-IMS pasteurizers inspected at least once during the audit period did not appear to receive the required inspections.

Statute and rule required product samples be collected and analyzed monthly from milk and raw yogurt producers and milk bottlers. Our file review indicated 20.4 percent of required samples from non-BTU farms were collected during the audit period.

Milk Distributor Inspections

Statute required licensees, including milk plants, milk distributors, and producer-distributors, to be inspected at least twice per year. However, the Dairy subprogram appeared to inspect distributors in response to complaints or inconsistently in response to license applications. Of

eight licensed distributors listed in the FPS database, six files were available for our review. These six distributors were required to receive 24 inspections, but we found only one inspection, a complaint-based inspection, occurred during the audit period.

Federal Noncompliance

State rules conflicted with the PMO regarding the types and frequency of violations which triggered suspension of a producer permit. State rules modified the PMO by defining both critical and non-critical violations. Only critical violations resulted in automatic follow-up inspections before establishments were allowed to continue operating, and without consideration of other violations. However, the PMO treated all repeat violations the way the State treated repeat critical violations. By defining non-critical violations, the Dairy subprogram allowed some violations at regulated establishments to persist through multiple inspection cycles with little incentive for correction. Also:

- the PMO and State rules required transfer stations to be permitted, but the State's single transfer station was not;
- the PMO required permit suspension after two successive instances of any repeated violations, but State rules did not require permit suspensions until three successive instances of repeated critical violations; and
- State rules required a second dairy farm follow-up inspection to be conducted by two inspectors, but file review indicated only one inspector was present at such a follow-up.

Inspection Of DAMF-regulated Operations

Statute required the DAMF to biennially license bulk milk haulers and samplers collecting milk and milk samples from farms by tanker truck, or sampling milk at plants. The DAMF was also required to annually permit and inspect bulk milk tanker trucks. However, the Dairy subprogram tested operators and inspected these operations to comply with the PMO. The Dairy subprogram lacked enforcement authority and did not collect the \$5 licensing and permitting fees set in 1977. The Dairy subprogram required general fund contributions to operate, partially due to low fees. Dairy subprogram inspectors reported completing these inspections required substantial time investments, and required inspections were inconsistently completed.

Organizations should be structured on a functional basis to enable agencies to achieve their objectives and assign responsibilities to efficiently and effectively complete their operations. Fees should defray the cost of completing regulatory activities. Compliance with law and rule was a fundamental element of management control and missed inspections increased the risk of foodborne illness in the State.

Bulk Tank Units

Several BTUs employed private field inspectors who participated in enforcement and inspection activities. The BTUs and the FPS shared inspection reports and the results of milk sample analyses. Usually, the public must submit a Right-to-Know request to obtain inspection reports.

Interactions with the BTUs were not formalized by a policy. Policies and procedures should be written and communicated to employees to ensure management controls are properly implemented.

Recommendations:

We recommend the Legislature consider updating and amending statute to transfer responsibilities related to regulating dairy industry activities under the DAMF to the DHHS and consider updating, or delegating to the DHHS via rulemaking authority, licensing and permitting fees to reflect the actual cost of required regulatory activities.

We recommend the Commissioner promulgate or revise rules related to inspecting milk distributors and accrediting stations.

We recommend FPS management:

- **inspect all licensed and permitted establishments, including milk distributors, as required by law and rule;**
- **treat all violations in the same manner as the PMO requires or seek promulgation of sanctions for repeat non-critical violations;**
- **accredit transfer stations;**
- **seek a formal agreement with the DAMF for shared regulatory responsibilities over bulk milk tankers and bulk milk haulers and samplers until legislative changes occur; and**
- **formalize policy and procedures for interacting with BTUs.**

Agency Response:

The Department concurs in part.

The FPS reserves comments on the recommendation to the Legislature and leaves it to their consideration.

The FPS agrees to review the licensing and inspection fee structure.

The FPS agrees to further study the recommendation related to transfer of dairy industry under DAMF.

The FPS agrees to promulgate rules for milk distributors if determined, after legal consultation, that the responsibility of inspecting transfer stations (deemed to be a milk plant) is the responsibility of the FPS. The Department will seek legal clarification with regard to milk transfer stations as to whether or not they are considered within the definition of a Milk Plant, per RSA 184:79, III, and license or not license accordingly.

The FPS agrees to inspect all licensed and permitted facilities assuming the subprogram has the appropriate resources.

The FPS disagrees with the recommendation that all violations be treated in the same manner as the PMO. The Milk Sanitation Board has deleted those sections of the PMO that require the FPS to treat all violations the same and substituted its own rules dealing with violations of critical and non-critical nature. The rationale for this difference is the incorporation of assessment of public health significance when determining sanctions.

The FPS disagrees with the need for a formal agreement as there have been no operational issues with the current arrangement.

The FPS agrees to formalize policy and procedures for interacting with BTU's.

Observation No. 13

Simplify Dairy Regulatory Structure

The Milk Sanitation Board (Board) appears to be needed no longer. Established by statute in 1963, the Board consisted of the DAMF Commissioner, the DHHS Commissioner or a designee, a representative from the College of Life Sciences and Agriculture at the University of New Hampshire, an individual holding a milk plant license, and three individuals holding producer permits. The Board was responsible for updating certain dairy sanitation rules, advising the DHHS Commissioner on matters related to milk supplies and sanitation, holding enforcement hearings against license and permit holders, and approving sanitation and enforcement ratings.

Necessity Of The Board

The Board's authority paralleled the DHHS Commissioner's and was primarily advisory. The Board reportedly met infrequently and rarely was involved in enforcement actions, with appeals hearings reportedly occurring once every three or four years. Statute provided the DHHS Commissioner the authority to deny or revoke a permit or license, with the Board providing advice on these decisions and providing a parallel process to the existing DHHS appeals process used by other FPS subprograms. The Board was responsible for one set of dairy sanitation rules, while the DHHS was responsible for a second set, creating parallel means to promulgate dairy sanitation rules, and adding an additional step to the process. Agency operations should efficiently produce intended results, and regulations and oversight boards should be merged where practical to promote efficiency. Given parallel processes existed within the DHHS and the Board was advisory, the existence of alternative or additional venues for enforcement hearings and rulemaking appeared unnecessary and inefficient.

Dairy Practices Committee

The New Hampshire Dairy Practices Committee (Committee), established in Board rules and separate from the Board itself, reportedly provided information for farmers in the State and organized a dairy industry trade show. The Committee reportedly met quarterly, the Dairy subprogram inspectors were automatic members of the Committee, and the Dairy subprogram supervisor was the Committee treasurer.

Since 2009, law required all boards, commissions, councils, advisory committees, and task forces to cease operations unless established by law or extended and reinstated by the Governor. The Committee was neither extended in 2011 by the Executive Order which re-instated 23 other DHHS committees, nor was the Committee provided for in statute. The Committee required diverting inspector and supervisor time from other Dairy subprogram duties and created a potential conflict of interest. Regulators should avoid developing relationships with the regulated industry which may compromise objectivity.

Improve Rules

The Board's organizational rules required Board meeting minutes be a public record and made available 144 hours after a meeting or vote, but statute required minutes of meetings be recorded and open to public inspection not more than five business days, or 120 hours, after a meeting.

Statute also required the Board to promulgate rules related to approving equipment or facilities, but rules only required establishments adding new or remodeled milk pipeline systems to submit plans to the DHHS. Plan approval was not required, and rules did not direct the DHHS to review or respond to the submitted plans.

Recommendations:

We recommend the Legislature consider disestablishing the Milk Sanitation Board and transferring any unique responsibilities to the DHHS.

We recommend the Milk Sanitation Board, should it continue to operate, amend rules to comply with statute.

We recommend the Milk Sanitation Board disestablish the New Hampshire Dairy Practices Committee. Should the Committee continue, we recommend no longer including FPS staff on the Committee.

Agency Response:

The FPS concurs in part.

The FPS reserves comments on the first recommendation and leaves it to the Legislature to consider.

The FPS agrees that if the Milk Sanitation Board continues to operate that it should amend its rules to reflect statutory timeline for posting meeting minutes.

If the New Hampshire Dairy Practices Committee is not disestablished, FPS continued presence on the committee is important as it facilitates interaction with regulators and stakeholders. This opportunity for exchange of information, challenges and best practices builds communication and can ultimately lead to better compliance of the regulated industry. We believe our presence

as a member of such a committee is not inconsistent with other committees which have Commissioner's designees as participating members.

Shellfish Sanitation Subprogram

Although shellfish was a food article and establishments producing shellfish were food processors, New Hampshire's shellfish industry was required to meet national requirements before the interstate sale of their products was allowed. Shellfish sanitation was a responsibility shared by DHHS with the DES and F&G, with responsibilities outlined in five MOAs. DHHS rules incorporated by reference the 2005 *National Shellfish Sanitation Program Model Ordinance (Model Ordinance)*, with amendments. The State's 37 shellfish-related establishments fell into three different classes with different scopes of operation, including production, transport, and packaging of shellfish. Rules required certifications and inspections be conducted in accordance with the *Model Ordinance*, and occur when changes or renewals in certifications occurred and at differing regular intervals for different classes of certifications, ranging from monthly to every six months. Unaudited FPS data indicated 146 inspections of shellfish establishments were completed during the audit period, and 29 more were attempted. Federal reviews of the Shellfish subprogram have found significant FPS noncompliance with the *Model Ordinance*. We examined 25 of the 37 Shellfish subprogram establishment files and select subsets of corresponding data.

Observation No. 14

Improve Management Of The Shellfish Sanitation Subprogram

We found the Shellfish subprogram lacked adequate management controls to ensure compliance with federal standards and related to program management, processing shellfish certifications, and enforcing sanctions. Further, supervisory review to ensure regulatory activities complied with laws and regulations was effectively held by the FDA, no effective State management review occurred, and no in-depth review of the FPS occurred. Effective management controls include oversight and periodic review by management.

Major Nonconformance With Federal Requirements

Federal reviews of the Shellfish subprogram were based on seven criteria. In November 2012, the FDA found the Shellfish subprogram in major nonconformance with federal requirements, which jeopardized the State's ability to export shellfish product. The FPS and the FDA entered into a corrective action plan in December 2012 to rectify the subprogram's major nonconformity. The State improved from complying with three criteria in 2012 to five criteria in 2013. The two outstanding criteria were 1) enforcement mechanisms triggered when any inspection detects a critical deficiency and 2) field inspections.

- Enforcement mechanisms in rule were inadequate because the enforcement mechanism was only triggered once three consecutive critical deficiencies occurred.

The Shellfish subprogram had to develop a federally-compliant enforcement mechanism and reportedly did not until October 2014.

- Federal inspection standards required all establishments have an accepted HACCP plan, no critical deficiencies during inspections, and a limited number of key and other deficiencies. In 2012, the FDA evaluated nine shellfish establishments and found five (55.6 percent) did not meet federal standards. In 2013, it evaluated 11 shellfish establishments and found four (36.4 percent) did not meet federal standards.

Segregation Of Duties

During the audit period, the Shellfish subprogram authored HACCP plans while also reviewing these plans for accuracy. The Shellfish subprogram started authoring HACCP plans to increase industry compliance with HACCP plans, but also placed two incompatible duties under one person. Segregation of duties reduces risk of error, misuse, or fraud and one individual should not control all aspects of compliance processes or any control activity. Further, regulators should avoid developing relationships with the regulated industry which may compromise their objectivity.

Contingency Planning

During the audit period, the FPS had two FDA-qualified shellfish inspectors. However, resources dedicated to maintaining two standardized inspectors were re-allocated to another FPS subprogram, and in July 2014, one inspector's credentials lapsed without a back-up plan in place. Without a certified shellfish inspector, exporting shellfish to other states could be jeopardized. Agencies should have contingency plans that include ongoing assignment of responsibilities when key positions are vacated to improve responses to personnel changes.

Certification Processes

Shellfish subprogram establishments were required to submit a complete application but file review revealed 33.9 percent of renewal applications were not fully completed. Further:

- 58 of 59 (98.3 percent) of recertification applications were submitted after the required November 1 submission date;
- applications needed to identify the name of the public water system or conduct a water quality test 30 days prior to the submission of the application and six months after the application had been submitted, but none identified the name of the public water system being used, four of five (80.0 percent) using a private water system did not provide water test results within 30 days of a submitted application, and four of five (80.0 percent) did not provide water test results six months after a submitted application;
- applications needed to document the sewage and water disposal system was approved, but no application did;
- applications needed to document compliance with local health laws, rules, and ordinances, but none did; and

certification or recertification required no critical deficiencies be identified during inspection, but one recertification (1.7 percent) was issued to an establishment with an outstanding critical deficiency.

The FPS did not request a resubmission or deny any applications for being incomplete as required by rule. The shellfish application form used did not inform applicants of requirements in rule, which likely facilitated the high degree of noncompliance. The shellfish inspection and certification process also lacked adequate management review.

Enforcement

Rules required certificate suspension for 90 days if: 1) more than two key deficiencies were detected during an inspection and remained uncorrected for 30 or more days, or 2) more than three other deficiencies were detected and remained uncorrected at the next inspection. Rules required revocation of a certificate if a second instance of the same violation causing a suspension occurred within one year after the initial violation. File review indicated two instances where a certification suspension was warranted and one instance where a certification revocation was warranted, but none occurred. Four of six (66.7 percent) key deficiencies which warranted a certification suspension remained deficient in the next inspections and one key deficiency (16.7 percent) remained for five months after certification suspension should have occurred.

Rules also required the FPS impose:

- a \$1,000 fine for the same critical deficiency cited during more than two consecutive inspections and a \$1,000 fine for each additional occurrence, but no fines were levied in the two instances we found where this condition occurred;
- a \$500 fine for the same key deficiency cited three times within any 12 month period and a \$500 fine for each additional occurrence, but fines were only levied for 25.0 percent of these occurrences; and
- a \$500 fine for not complying with a compliance agreement, but no fines were levied in the single instance we found where this deficiency occurred.

We also found one establishment was under-fined by \$5,500 and three other establishments were not fined a total of \$1,500 for sanitation violations. Had FPS applied statutorily-required fines, it would have collected \$7,000 more in fines during the audit period. Further, in one instance, the fine was issued four months after the fine-eligible violation was identified by the FPS, permitting continued unsafe production of shellfish product until the establishment corrected the violation one month after the fine was issued.

Finally, compliance schedules were infrequently met. Inspection practices allowed deficiencies to be either re-inspected during the next scheduled inspection, three- to six-months later depending on the certification type, or on another schedule. When a compliance schedule other than the next inspection was established, the inspection did not occur timely 64.3 percent of the time.

Supervisory review was required to ensure regulatory activities were consistent. However, violation tracking and compliance enforcement was not routinely reviewed by management.

Recommendations:

We recommend FPS management:

- **comply with corrective action plans and improve response time in addressing deficiencies;**
- **require HACCP plans be authored by shellfish establishments;**
- **create a contingency plan to ensure continuity in key roles within the Shellfish subprogram;**
- **improve control over the certification process by amending the application form to better align with rule requirements and increasing management review and oversight; and**
- **improve enforcement activity control by adding another layer of review to the tracking of violations and enforcement mechanisms.**

We further recommend the FPS implement supervisory control for the Shellfish subprogram designed to ensure day-to-day operations are routinely monitored and ensure compliance with State and FDA requirements.

Agency Response:

The Department concurs.

The FPS agrees that responses to corrective action plans should be timely, however would note that the description in the recommendation regarding response time in addressing deficiencies noted by the FDA's evaluation should take into account that the timeline within the corrective action plan was agreed to by the FDA. This timeline was created due to feasibility. The Shellfish rules are subject to review by JLCAR which has a three month process. The original intent was to adopt the 2011 NSSP Model Ordinance which expected to be published in the Fall 2012 but was not actually released until 2013. The timeline took these factors into consideration.

The FPS agrees to assess the recommendation of creating the requirement that the shellfish establishments author the HACCP plans based on the capacity of the FPS staff. The NSSP MO and the Guidance Document does not require that the dealer has to be the entity to author the HACCP plan, however we do acknowledge the point that establishments should be the authors and the FPS be the reviewers of such plans as a matter of well-balanced practice and clear roles between the regulated and the regulators.

The FPS concurs that a contingency plan should be created for the shellfish subprogram; however, this needs to account for feasibility based on available FTEs.

Regarding the recommendation that alignment with rules and the application is needed, this has already been addressed when the revised Shellfish Rules were approved by JLCAR in October 2014.

In response to the recommendation for increased oversight, the FPS plans to use the new database as a tool to develop program metrics and measure performance against these metrics. The FPS agrees to work on policies and SOPs for guidance and development of program metrics to aid supervisors in tracking performance.

The FPS concurs that enforcement activity needs better tracking. The new database will be tracking this upon implementation in the Fall of 2015.

Beverage And Bottled Water Subprogram

The State regulated beverage and bottled water based largely on State standards, although DHHS rules required all finished bottled water products meet FDA standards for water quality. Beverage and Bottled Water subprogram staff were shared with the Dairy subprogram, and inspectors reportedly scheduled visits to beverage and bottled water establishments around required dairy inspections. Rules required inspections at least once annually or more frequently when noncompliance was suspected. Inspections were an opportunity for surveillance and education. Licensure was also required to allow New Hampshire establishments to export to certain states. As of SFY 2014, there were three water bottling plants, two bulk water transfer loading facilities, and 13 beverage and cider manufacturers. The FPS also registered 228 out-of-State beverage manufacturers to ensure those manufacturers were regulated or evaluated by other recognized governing bodies or organizations. We examined 16 in-State and 10 out-of-State establishment files and selected subsets of corresponding data. FPS records indicated 11 routine and three equipment inspections occurred during the audit period.

Observation No. 15

Improve Management Of The Beverage And Bottled Water Subprogram

We found the FPS did not ensure establishments were inspected as frequently as required, licensing and registration activities were consistent, enforcement of sanctions complied with rule, or information and records management was adequate. Further, the FPS did not take a public health risk-based approach to inspections, but focused on economic risk by ensuring establishments could continue to export product.

Inspections

Rules required establishments renew their license annually on a calendar-year basis and receive an annual inspection. Annual inspections included equipment such as pasteurizers. CY 2013 was the only full licensing cycle during the audit period and the FPS conducted inspections at six of the 13 (46.2 percent) in-State establishments that year. Also, a seventh establishment (7.7 percent) received a partial inspection, which only tested the operation of specific equipment. The

FPS reported the limited inspections were attributable to resources normally dedicated to this subprogram being shifted to another subprogram. Incomplete inspections, or inspections not conducted, created gaps in the State's food safety surveillance system.

Risk Management

Inspections should be random and risk-based, instead of relying on a blanket policy of inspecting all establishments within a designated time frame and regardless of the risk posed. Risk-based inspection practices can help direct regulatory resources for maximum impact on outcomes, help regulators identify inspection priorities, reward compliant businesses, and penalize noncompliant businesses.

The Beverage and Bottled Water subprogram used neither a risk-based nor random approach to inspection scheduling. Rule established a blanket policy of annually conducting inspections for all establishments and in practice inspectors focused on ensuring in-State establishments could continue to ship product to other states. However, inspection scheduling was initiated by an establishment's request. This resulted in food safety risks being monitored irregularly. For example, four in-state establishments which were documented as having private wells, which potentially posed a higher risk than government-regulated water sources, received no routine inspections and only one pasteurization equipment test inspection in 11 licensing periods during SFYs 2013 and 2014.

Health Risks And License Revocation

The Beverage and Bottled Water subprogram sanction regime was incomplete and unused. The Beverage and Bottled Water subprogram relied on voluntary correction of deficiencies between inspections, but voluntary compliance was inconsistent. During SFYs 2013 and 2014, no potential sanctions were communicated to noncompliant establishments, no fines imposed, and no compliance agreements were developed.

Rules provided a license must be revoked if an inspection uncovered an imminent public health risk, a violation of water quality standards occurred, or an establishment failed to follow a compliance agreement. Rule required an establishment with two consecutive inspections finding the same non-imminent health hazard enter into a compliance agreement documenting what must be corrected and when. Of the 16 establishments active during the audit period, three (18.8 percent) had chronic violations documented:

- one establishment with a prior history of contamination complaints was allowed to operate with the same deficiency since 1997,
- one establishment had the same deficiency since 2007, and
- one establishment had no documented water test results since 2006.

The Beverage and Bottled Water subprogram also lacked operational definitions of what constituted an imminent public health hazard, such as those found in the *Food Code* and applicable to Food establishments, instead relying on the discretion of the inspector, and did not define an unacceptable length of time for gaining voluntary compliance.

Licensing

In-State establishments seeking license renewal were required to submit a complete application providing contact information, a list of products, and water source information. Only 26.8 percent of in-State license renewal applications were completely filled-out. Water test results were not provided in 51.2 percent of license renewal applications.

In-State new license applicants must provide water source test results and product labels. One of the two new in-State establishments seeking licensure during the audit period was approved without submitting an application and both were approved without providing product labels or water test results.

Water test results, required by rule to be submitted for an in-State application to be complete, were instead examined during the inspection process. The four in-State establishments with private water systems provided water test results 18.2 percent of the time and did not receive a complete inspection during the audit period. Given the low frequency of inspections, this may not adequately protect the public health.

Registration

Out-of-State renewal applications were required to include an inspection report from a regulatory authority or a recognized national third-party audit organization, and a certificate or letter from a local regulatory authority confirming compliance. Out-of-State establishments registered with the FPS did not completely fill out 58.6 percent of renewal application forms, 55.2 percent did not provide inspection results, and 41.4 percent did not provide a certificate from a local regulatory agency. One of 29 renewal applications (3.4 percent) contained an inspection conducted by an organization with an expired credential. Rule required incomplete applications be denied or not processed and returned for correction. Our review of ten FPS files demonstrated the FPS did not request applicants resubmit missing materials or deny any applications for being incomplete.

Administrative Noncompliance Issues And Fines

Administrative fines primarily pertained to licensing and registration activities and not deficiencies found during an inspection. Five of 41 in-State renewal applications (12.2 percent) were not submitted timely, and while operating with an expired license should have resulted in an initial \$1,000 fine and an additional \$500 fine for each day of unlicensed operation, no fines were issued.

Recommendations:

We recommend the Commissioner amend rules to establish a risk-based inspection frequency.

We recommend FPS management:

- **ensure complete inspections are annually conducted for each in-State beverage and bottled water establishment as required by rule;**
- **conduct a risk analysis to establish the needed frequency of inspections based on public health risk;**
- **process applications for licensure and registration according to rule and use the application process to help ensure compliance and not rely solely on the inspection process;**
- **improve oversight of license and registration processing; and**
- **enforce sanctions in rule and establish policies to limit the amount of discretion used in implementing sanctions.**

Agency Response:

The Department concurs.

The FPS reported the limited number of inspections was attributable to resources normally dedicated to this subprogram being shifted to another subprogram.

The FPS concurs with the recommendation that rules be amended to establish a risk-based inspection frequency.

The FPS agrees that the best approach is to modify the current rules to create a risk-based inspection approach for this subprogram.

The FPS agrees to review the application process for in-state and out-of-State beverage applicants. The FPS agrees to only collect and review information that has meaning to public health and is not reviewed in duplicity by another public health agency.

The FPS agrees with the need to improve the oversight of the license and application process. The database will provide more transparency to supervisors in the Fall of 2015.

The FPS agrees with the need to develop policies regarding the enforcement of sanctions. These will be incorporated as SOPs by the program. The database will provide more transparency to supervisors with regard to issuing of sanctions.

Sampling

Sampling is an industry-recognized intervention used to verify preventative measures were implemented and effective, can successfully identify impure food, is a useful tool for education to show the benefits of sanitation and the effects of poor procedures, and is an element of foodborne illness investigation and FPS food embargo practices. Sampling and subsequent testing can help establish food purity and supported an embargo or adulterated food seizures.

Observation No. 16

Reinstitute Statutorily-required Systematic Sampling Of Food Articles

During the audit period, the FPS lacked a comprehensive food sampling policy and related practices.

The Dairy subprogram sampled finished dairy product monthly for IMS listed plants as required by the PMO. The subprogram also sampled: 1) bottled raw milk and non-IMS products, such as yogurt and raw milk yogurt, monthly as required by rule, and 2) cheese, ice cream, and similar articles, randomly without requirement but to address public health risks. Four articles were reportedly sampled for testing from licensed and unlicensed dairy-related establishments monthly. Unaudited FPS data indicated 75 of these samples were taken during the audit period statewide.

State inspectors were statutorily empowered to examine and sample any article of food but no other FPS subprogram routinely sampled food articles, having either discontinued the practice before the audit period or never having undertaken sampling. Reportedly, prior FPS management discontinued sampling efforts over concerns with how to respond to positive results and State liability. Consequently, the DHHS was noncompliant with State law which required sampling food on sale, possessed for sale, or in process of manufacture or distribution for analysis. The FPS also lacked formal policy and procedures for FPS sampling, and for how to deal with self-inspecting jurisdictions, some of which had active sampling programs, with positive test results. Self-inspecting towns were under FPS oversight.

Sampling was increasingly important given the nature of the food supply chain. Sampling should have been risk-based to focus limited resources. By not sampling, the FPS's ability to ensure food being manufactured or on sale was unadulterated and produced, manufactured, stored, and sold under sanitary conditions was limited. The State may have also assumed increased risk due to the food supply chain being globalized and other emergent or developing risks, such as pathogens newly associated with foodborne illness.

Recommendations:

We recommend FPS management:

- **reinstitute food sampling beyond select dairy products;**
- **develop comprehensive policies and procedures to support risk-based sampling and focus limited resources;**
- **develop policy and procedure for dealing with self-inspecting jurisdictions' results; and**
- **collect and analyze sampling results.**

Agency Response:

The Department concurs.

As mentioned previously in Observation No. 2, the FPS agrees that there is value to a systematic food sampling program with related sampling criteria, standards and enforcement actions. There is a concern with the feasibility of expanding sampling without additional resources. The FPS agrees to explore the level of additional resources needed to develop a systematic sampling program, which would include the administrative portion of executing a sampling program as well as the staffing levels for food inspectors and public health lab personnel that would be required for this sampling program. There is also the concern of sampling products that may also have federal oversight. Collaboration with federal partners to prevent duplicity of sampling efforts would need to be considered as part of a systematic sampling program.

Complaints

Complaints help determine whether regulated establishments conform to industry standards and regulations. Complaint handling should be systematized and formalized, and help ensure the public is adequately protected and incorporate detection, investigation, response, documentation, and analysis. Complaint tracking is a nationally recommended measure and helps identify foodborne illness and possible outbreaks. Effective regulatory oversight should result in decreases in complaints.

The FPS received food-related complaints from inspectors, consumers, the food service industry, federal agencies, local health officials, and law enforcement. Complaints included illness and injury, contamination, sanitation, and disaster. By policy, the FPS triaged complaints, interviewed the complainant, and, when warranted, conducted an inspection of an implicated establishment, usually within 24 hours of the receipt of an illness complaint. Investigations were a collaborative undertaking that included other components of the DHHS, such as the Infectious Disease Prevention, Investigation, and Care Section; the Public Health Laboratories; and the Communicable Disease Surveillance Section, and other agencies, such as the DES and F&G. Each agency had defined roles during an investigation.

Observation No. 17

Improve Complaint Management

FPS management control of complaints did not consistently meet its own standards or policies where they existed. We also found the policies and goals related to complaint management were insufficient. Complaint handling practices should include a systematic process with guidelines and requirements detailing which complaints need action, and how quickly action was required; assigning complaints for review or investigation; investigating complaints to determine whether problems exist; re-investigating when warranted; tracking complaints to ensure they are addressed; providing feedback to the complainant; and maintaining complete records.

FPS policy identified four categories of complaint: illness and injury, sanitation, contamination, and disaster. FPS data included a fifth category of complaint, “other,” which included licensing and product branding complaints but was not reflected in policy. FPS policy gave priority to illness complaints, and established a goal of following-up on most illness complaints within 24 hours. Other goals related to complaints were nonexistent and the FPS did not report an upper bound to complaint closure time in policy or practice. According to unaudited FPS data, during the audit period, the FPS received 558 complaints, 360 (64.5 percent) of which were referred to an FPS inspector for follow-up, 192 (34.4 percent) cases were referred to another agency for follow-up, and six (1.1 percent) had no referred agency indicated.

Timeliness And Final Closure

Unaudited FPS data indicated the FPS was inconsistent in closing cases, and closing them timely during the audit period. Nineteen of 558 complaints (3.4 percent), including illness, sanitation, and disaster complaints, lacked data and supporting documentation demonstrating investigation and closure, and had been open an average of 334 days at the end of the audit period. This included 17 of the 360 cases (4.7 percent) referred to the FPS for follow-up.

Unaudited FPS data indicated 127 complaints (35.3 percent) referred to the FPS were responded to in one day or less. Five of 127 complaints (3.9 percent) were responded to as many as 19 days *before* the intake date of the complaint, and while three cases may have been attributable to data quality controls issues, two cases appeared to have been closed based on inspections that *preceded* the complaint.

Unaudited FPS data also indicated the FPS responded to 198 of 360 complaints (55.0 percent) more than one day after receipt, averaging 8.4 days and taking as many as 200 days to respond. Fifty-eight of 360 complaints (16.1 percent) were illness complaints, and the FPS inconsistently met its goal to follow-up within 24 hours of complaint receipt. Also:

- eight (13.8 percent) illness complaints lacked inspection data, three (5.2 percent) of which also lacked closure data;
- 26 (44.8 percent) illness complaints were responded to in one day or less, including two responded to *before* the complaint was received; and
- 24 (41.4 percent) illness complaints were responded to in more than one day, averaging 3.8 days for closure and taking as long as 38 days to receive a response.

Additionally, FPS hardcopy files contained at least four records alleging unlicensed food establishment operations which were not included in the complaint database and for which we found no documented follow-up or outcome.

Self-inspecting Jurisdictions

Valid complaints outside FPS jurisdiction should have been referred to the appropriate jurisdiction. Four self-inspecting towns were required to provide the FPS with all complaints received and a fifth was required to provide inspection reports with violations of the State sanitary food code to the FPS. Two towns and the nine self-inspecting cities had no requirement

to report complaints to the FPS. While the FPS was responsible for overseeing self-inspecting towns, policy only encouraged towns to report consumer complaints to the DHHS. FPS policy did not assign oversight of complaints in self-inspecting jurisdictions to any employee.

Unaudited FPS data indicated the FPS directly received 148 complaints originating in self-inspecting jurisdictions, 44 of which were in self-inspecting towns. FPS data contained inspection results for 11 (25.0 percent). We found no complaints or reports of violations from self-inspecting towns in FPS hardcopy records, and were unable to determine whether the remaining 33 (75.0 percent) complaints originating in a self-inspecting town were acted upon.

Complainant Feedback

FPS policy was to provide complainants with feedback on the results of their investigation only upon request. However, statute required responses to applications, petitions, and requests, including the provision of contact information and notice of errors, within 60 days, and application resolution within 120 days. The 19 complaints that lacked data and supporting documentation demonstrating investigation and closure, had been open an average of 334 days at the end of the audit period.

Gaps in data, as well as data quality control issues in subsets of data we examined and compared to hardcopy records, compromised the reliability of the complaint database. Without accurate and complete records, the relevance and value of FPS records was undermined, and it was not clear whether appropriate follow-up was undertaken or whether the FPS was effectively accomplishing its mission. Without feedback to complainants on the outcome of the FPS investigation into their complaints, the complainants may not be adequately informed as to the disposition of their complaints. Without central collection of food-related complaints from self-inspecting towns, and without FPS follow-up to ensure resolution, the State lacked data necessary to operate a statewide surveillance system.

Recommendations:

We recommend FPS management:

- **establish complaint management guidelines and requirements detailing which complaints need action, and how quickly action is required for each type of complaint;**
- **include unaccredited operation allegations in the complaint management system;**
- **consistently assign complaints for review or investigation, and assign supervisory staff the responsibility to review and formally close each case;**
- **investigate in-jurisdiction complaints to determine whether problems exist and re-investigate when warranted;**
- **develop a management reporting system to help track complaints to ensure each is fully addressed and properly closed, to identify trends and contributing factors, and to identify any further investigation needed;**

- **maintain complete records for all complaints and analyses, and improve complaint data quality;**
- **ensure complaints in self-inspecting towns are submitted timely to the FPS, that each is properly closed-out by the responsible jurisdiction, and the results reported to the FPS;**
- **formally assign responsibility for overseeing complaints in self-inspecting towns to ensure proper resolution;**
- **obtain a commitment from self-inspecting cities to timely provide FPS with each complaint received and its final disposition; and**
- **develop policy and implement procedures to ensure each complainant timely receives contact information and final resolution of their complaint.**

Agency Response:

The Department concurs in part.

The FPS concurs that the complaint management protocol should be revised to address noted items.

The FPS agrees that this should be included in the complaint management system and SOP will be modified to reflect this.

The FPS agrees that complaints should require supervisory review. The new database will have an enhanced capability to track complaints.

As part of enrollment in the FDA Voluntary National Retail Food Regulatory Program, the FPS has been tracking complaint trends. The FPS has been deemed by an independent auditor, as required by the FDA Voluntary National Retail Food Regulatory Program, to have met this standard relative to complaint management - Standard 5-Foodborne Illness and Food Defense Preparedness and Response.

FPS acknowledges that Voluntary National Retail Food Regulatory Program standards for complaint management applied only to retail food establishments and does not include all New Hampshire laws and rules. FPS agrees to expand the scope of its complaint tracking and evaluation to include NH statutes and all subprograms.

The FPS was not aware of the requirement to report results of a complaint inspection. The FPS will seek legal guidance on what the FPS is obligated to track and report relative to consumer complaints and address in policy if changes are needed.

The FPS agrees to explore the feasibility of ensuring that self-inspecting towns submit complaints timely to the FPS.

The FPS disagrees with the need to obtain complaint information from self-inspecting cities. Cities have legal jurisdiction to regulate and inspect food establishments, and thus there is an

expectation that cities are managing complaints. Cities do report the required list of incidences of foodborne illness to the state through other surveillance methods.

Sanctions

The public expects the food they purchase will be safe and government-regulated, and providers who demonstrate an inability or unwillingness to comply with administrative and food safety requirements will be dealt with through appropriate administrative or judicial proceedings. Regulatory agencies should take enforcement action when regulated entities do not voluntarily comply with regulations. Sanctions should be sufficient, documented, communicated, reviewed by management, tracked, and allow for a clear appeal process. Sanctions should be consistently applied. The DHHS had statutory authority to establish fines in rules. The FPS levied over \$20,000 dollars in administrative fines in each SFYs 2013 and 2014, encompassing 84 transactions in SFY 2013 and 126 transactions in SFY 2014. Receipts from fines were deposited in the General Fund. Fines for late applications and operating without an accreditation were levied more often than other categories of fines. Due process procedures were available and included an opportunity to appeal, notice requirements, an opportunity for hearing, and an opportunity to present evidence.

The State may also embargo or condemn food when probable cause exists that it was adulterated, otherwise unsafe, or a nuisance. The DHHS may petition a court to condemn or destroy unsuitable items once their altered state was confirmed. The DHHS may also order immediate closure of establishments endangering public health and safety. In the event of any closure, the owner was entitled to a hearing. No such actions occurred in SFYs 2013 or 2014. Additionally, the FPS may revoke, suspend, and otherwise affect an accreditation held by an establishment.

Observation No. 18

Improve Sanctions Management

The FPS lacked adequate controls over its use of sanctions to help achieve its mission to ensure compliance with food safety laws, rules, and protocols. The FPS primarily focused sanctions on administrative violations related to establishments' accreditations and not on known public health risks observed by inspectors. Sanctions were used infrequently by the FPS to address public health risks and their use inconsistently complied with rules. Further, the FPS did not use all of the compliance tools available and the ones used were at times ineffective. Inconsistencies also existed within the statutory and regulatory structure of the sanctions regime.

Sanctions And Public Health Risks

Rules provided several enforcement mechanisms designed to obtain compliance from establishments creating a public health risk, but the FPS infrequently used sanctions for public health violations. Unaudited FPS data indicated 1,050 food establishment inspections during the audit period resulted in a *yellow* status, indicating uncorrected priority violations and an ongoing risk to the public health. At least seven establishments remained deficient throughout the audit

period without any corrections. These seven establishments received a total of 21 inspections, but no license denials or revocations. A total of \$19,000 in fines should have been levied as the result of violations uncovered during inspections, but none were levied. Further, of the \$46,855 in administrative fines the FPS levied, only \$4,000 (8.5 percent) dealt with public health risks observed during inspections. The majority of fines levied were for expired licenses (34.1 percent) or late applications (33.0 percent).

Inconsistent Sanction Application

A sanctions regime designed to obtain compliance must establish certainty within the regulated industry that a noncompliant establishment will receive a sanction when warranted. This certainty can be established through effective operationalization of the sanctions regime as established in rules. However, in some instances where warranted, the FPS applied sanctions to establishments in three subprograms for noncompliance with food safety codes, but did not in other instances when warranted.

The Food subprogram sanctions regime was inconsistently implemented due to conflicting internal policy. Rule required priority violations and priority foundation violations be corrected within ten days. In practice, the FPS focused follow-up efforts only on priority violations, and follow-up consistently exceeded the ten-day limit set in rule. This allowed priority foundation violations to persist without correction or the follow-up required by rule to ensure corrective actions occurred and the public's health was protected. During the audit period, one establishment was fined twice in 18 months for having a priority violation directly linked to the risk of causing foodborne illness. Rules demonstrated the fine for this establishment should have been \$4,500, and initiating the license revocation process was required after the first instance of a consecutive priority violation. However, \$1,000 in fines were levied and no action was taken against the establishment's license. Our review of unaudited FPS data found nine other food establishments were allowed to operate for an average of 220 days with three or more consecutive inspections finding priority violations, but no fines issued or action taken against the licenses. We estimated \$8,500 in fines should have been levied under rules.

Similar inconsistencies were noted in the Shellfish subprogram sanctions regime. Rules required fines for repeated critical deficiencies, and key deficiencies in more limited circumstances. However, one establishment continued to operate with a critical violation for four months without a timely response from the FPS, and a total of \$7,000 in fines which were required under rule were not levied during the audit period.

All subprograms had codified an agreement process with noncompliant establishments designed to compel deficiency resolution within a certain timeline.

- Rules required noncompliant food establishments to enter into CAP with the FPS to correct deficiencies which would take more than ten days to correct. CAPs were inconsistently operationalized, used much more infrequently than required by rule, and were both extended and unenforced by inspectors contrary to rule. Our file review indicated CAP documentation was inconsistently retained, and eight of ten

(80.0 percent) CAPs we examined were either revised, extended and revised, not closed, or not addressed timely.

- Rule required establishments certified under the Shellfish subprogram to use compliance schedules, prior to re-certification, for a single key deficiency, or for fewer than three other deficiencies. The Shellfish subprogram extended a compliance schedule without authority to do so, and the compliance schedule process was implemented inconsistently with rule.
- Rules required Beverage and Bottled Water subprogram licensees to enter into compliance agreements to correct non-imminent health hazards which had been out-of-compliance for two consecutive inspections. The Beverage and Bottled Water subprogram did not use these agreements or any other sanctions established in rule to prevent consecutive offenses, even though three establishments recorded the same non-imminent health hazard deficiency, one as far back as 1997 and the most recent since 2007.
- Dairy subprogram compliance agreements had narrow applicability and none were observed during the audit period.

We found one case where a sanitation complaint resulted in an inspection which uncovered multiple priority foundation violations. A CAP was entered into, and subsequent inspections found minimal progress on meeting the terms and conditions of the CAP. Ninety days after the initial sanitation complaint, the establishment was still noncompliant but the FPS closed the CAP. The FPS never levied a fine, took action against the license, or charged inspection fees. If statute and rules had been followed, the establishment would have been fined \$500 for not complying with a CAP and a license revocation initiated.

Lack of follow-up and sanctions for noncompliance with binding agreements could have signaled to food establishment operators that violations noted were unimportant and agreements were subject to renegotiation.

The FPS also inconsistently used sanctions for administrative offenses, those not related to food safety. By rule, an administrative fine paid more than 30 days after being imposed was subjected to a \$500 fine, and each day thereafter constituted a separate offense. During the audit period, 85.4 percent of fines paid after 30 days were not charged late fines, a potential net loss to the General Fund of \$20,500. Additionally, in one instance, an establishment was found operating after license expiration and by rule should have received a \$1,000 initial fine and \$500 for each subsequent day, but instead received a \$75 fine for filing a late application.

Inconsistent Selection Of Sanction Type

The FPS inconsistently used CAPs, charged inspection fees and denied licenses, and never sought criminal charges or revoked accreditations during the audit period. By not using available sanctions, the FPS compromised the effectiveness of the sanctions regime and allowed noncompliant establishments to serve the public while potentially producing unsafe food.

- Statute and rules required the Food subprogram deny a license renewal application to a noncompliant establishment. However, according to unaudited FPS data, at least

seven food establishments remained in deficient, *yellow* status for inspections conducted during the audit period. No action against these establishments' licenses was taken. The FPS did deny, at least temporarily, five of 13 (38.5 percent) initial license applications or renewals in instances identified in file review and qualifying for denial or revocation, including one which continued to have similar compliance issues after renewal of its license was granted. No renewals were denied solely for a public health risk identified during an inspection.

- Rules also required Food subprogram license denials or revocations for food establishments if an applicant or licensee failed to: 1) pay a fine or fee, 2) correct a deficiency identified in an inspection report, 3) implement or continue to implement a CAP, or 4) implement an approved HACCP plan. Rule also required license revocation if a licensee was cited two or more times for the same priority violation in the prior 12 months or during the last five inspections. We found all of these events occurred, but no licenses were revoked.
- The Food subprogram inconsistently charged statutorily-required inspection fees to help deter noncompliant establishments from requesting multiple inspections to achieve compliance.
- Shellfish subprogram rules required certificate suspension if more than two key deficiencies or three other deficiencies remained uncorrected, and revocation if a suspension-inducing violation occurred again within a year. Of the 25 files we reviewed, no suspensions or revocations occurred, despite two certificate holders (8.0 percent) qualifying for a suspension and one (4.0 percent) for a revocation.
- Beverage and Bottled Water subprogram rules required licenses to be revoked if an inspection indicated contamination of product might occur which might cause a threat to public health and immediate steps to achieve compliance were not taken. We observed no steps toward revocation in our file review, despite ongoing deficiencies indicated in three of 16 (18.8 percent) files we reviewed.
- No criminal charges were sought, as provided for in statute, for violations in any subprogram.

Graduated Sanctions

Sanctions should have been graduated and progressively more stringent as noncompliance persisted. Sanction processes should have started with a warning; progressed through increased administrative fines, accreditation suspensions, and accreditation revocations; and, as a last resort, resulted in criminal punishment. The number and severity of violations should have directly correlated to the level of sanctions enforced. Table 2 depicts the convoluted statutory sanctions regime, illustrating which of the six primary food safety statutes provided for sanctions, and the gaps and overlap which existed among the statutes.

The inconsistent statutory sanction structure was reflected in rule. For example, Food subprogram rules required a \$500 administrative fine for three consecutive priority violations uncovered during inspections, but two priority violations in 12 months or in the last five inspections resulted in denying a renewal application or revoking the license.

Recommendations:

We recommend the Commissioner seek statutory changes to add consistency to the sanctions regime and amend rules to establish a graduated sanctions regime.

We recommend FPS management consistently comply with statute and rule by using the sanctions specified under the established circumstances, and improve management tracking and oversight of noncompliance to ensure establishments warranting sanctions consistently receive them.

Agency Response:

The Department concurs.

Regarding the point of fines being threatened but not imposed, the FPS practice has been to use the fine option as leverage to obtain compliance, but have allowed some flexibility depending on circumstances.

The Department agrees to study all sanctions across all subprograms and to revise with the idea of keeping sanctions consistent and also practical in execution based on the types of enforcement actions that are regularly encountered. The work will be completed by the end of SFY 2016.

The FPS understands that it has discretion to levy a fine. In cases where fines are appealed, it is more likely that a fine will be upheld if required by statute.

Table 2

Statutory Sanction Regimes

Statute And Establishments Impacted By Sanctions:

Sanction Type	Statute And Establishments Impacted By Sanctions:						
	<i>Licensure</i> (RSA 143-A)	Beverage (RSA 143:9 through 143:19-a) and Shellfish (RSA 143:20 through 143:28)	<i>Dairy</i> (RSA 184)	<i>Cold Storage</i> (RSA 145)	<i>Sanitary Production Any Location</i> (RSA 143:1 through RSA 143:8)	<i>Pure Food Any Food</i> (including pet food) (RSA 146)	<i>Inspectors Any Food</i> (RSA 130)
Administrative Fine	Yes	Yes	Yes ¹	Yes	Yes	Yes	No
Suspension	Limited ²	Yes	Yes	Yes	No	No	No
Closure	No	No	No	No	Yes	No	No
Revocation	Yes	Yes	Yes	Yes	No	No	No
First Offense	Violation	Misdemeanor	Violation	Misdemeanor	Violation	Violation or Misdemeanor ³	Violation
Second Offense	Misdemeanor	Misdemeanor	Violation or Misdemeanor ³	Misdemeanor	Violation	Misdemeanor or Felony ⁴	Misdemeanor
Third Offense	Misdemeanor or Felony ⁴	Misdemeanor	Misdemeanor	Misdemeanor	Violation	Misdemeanor or Felony ⁴	Misdemeanor
Seizure And Restraint	No	No	No	No	No	No	Yes
Injunctions	Yes	No	Yes	No	No	No	No
Embargo	No	No	Yes ⁵	No	No	Yes	No
Corrective Orders	No	No	No	No	Yes	No	No

Notes:

¹ Administrative fines did not include a sanction for unsanitary conditions uncovered during an inspection.² Food establishment license suspension was limited to instances where an establishment did not pay a fee.³ A violation if a natural person, or a misdemeanor if any other person.⁴ A misdemeanor if a natural person, or a felony if any other person.⁵ *Dairy* relied upon embargo procedures in *Pure Food*.

Source: LBA analysis.

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**STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD PROTECTION SECTION**

MANAGEMENT CONTROL

Management control: 1) includes the plans, policies, methods, and procedures adopted by management to meet its missions, goals, objectives, and sub-objectives; 2) includes processes for planning, organizing, directing, and controlling program operations; 3) encompasses systems for measuring, reporting, and monitoring program performance; 4) helps safeguard assets; and 5) can prevent and detect errors, fraud, abuse, and noncompliance with provisions of laws, regulations, contracts, or grant agreements. Effective management control is systematized and increases the likelihood an agency will be effective. By linking objectives throughout the entity to the mission, management can improve program effectiveness and efficiency. Effective operations achieve intended results; efficient operations achieve intended results and minimize waste. Ineffective or unintegrated controls undermine management control effectiveness. Effective management control includes oversight and periodic review.

Statutory And Regulatory Compliance

The Food Protection Section (FPS) was the Department of Health and Human Services (DHHS) agency responsible for executing statutory and regulatory responsibilities related to food safety and security. The Legislature provided the DHHS authority to promulgate rules to implement, interpret, or make specific food safety-related statutes. Rules prescribe or interpret agency policy, procedure, or practice requirements binding on the public and employees of other State agencies. Rules allow the DHHS to develop procedures, filling in the details between statute and the practices needed to achieve its statutory purpose. Rules also provide greater certainty and regularity in agency action. Rules must be specific. Rules requiring further clarifications or interpretations to be understood are not sufficiently detailed. Rulemaking is a key underpinning of administrative procedure and due process. Properly adopted rules have the force and effect of law. Incomplete or improper promulgation can lead to ad hoc rulemaking, and requirements not properly included in rules may be unenforceable. Compliance with law and rule is a fundamental element of effective management control and aids agencies in achieving their objectives.

Observation No. 19

Improve Compliance With Food Safety Statutes

The DHHS was required to promulgate rules to implement food safety-related statutes, and the FPS was responsible for complying with and enforcing statutes and rules related to food safety. Several FPS practices were noncompliant with statute and rules, and some DHHS rules did not comply with enabling statutes and exceeded statutorily-provided authority.

Restrictions On Past Violators

Rules required the FPS to deny, or refuse to accept, for up to three years, applications from applicants who had previously had their licenses, certificates, or permits revoked for violations. Statute did not provide the DHHS the authority to deny license, certificate, or permit applications

to the FPS based on previous violations and past loss of permissions. The lone exception was for the Beverage and Bottled Water subprogram, which required applicants present a plan of correction and pass a food safety class meeting certain requirements before restoring a license. In two instances, statute specifically *required* the FPS to issue licenses to food establishments which were in compliance with statute, including establishments which had recently revoked licenses. Rules may not impose penalties unless specifically authorized by statute.

Inspection Fees

Statute also required the DHHS charge a fee for each inspection performed, but rule required licensees pay \$100 for each inspection conducted after the second inspection in any licensing period, excluding inspections conducted during any provisional licensing period. The FPS infrequently charged inspection fees under this erroneous rule, with unaudited FPS data demonstrating only three such charges were issued during the audit period, of at least 203 instances where the fee should have been charged. If the rule requirement had been enforced, the FPS would have collected \$20,300 in additional revenue during the audit period. If statutory requirements had been properly enforced and a \$100 per inspection fee charged, the FPS would have collected approximately \$715,800 in additional revenue during the audit period. Requiring fees for inspections and follow-up visits encourages establishments to comply with regulations to avoid additional inspections and help cover the costs of any additional visits.

Inspection Occurrence And Timeliness

The FPS inconsistently complied with the statutory requirement to inspect new food service establishments or retail food stores and beverage manufacturers within 45 days of issuing a provisional license and before a full license could be issued. In the Food subprogram, unaudited FPS data indicated the FPS did not conduct inspections within 45 days of issuing a provisional license 87.8 percent of the time, and 65.3 percent of establishments did not receive an inspection of any type within the 90-day period during which the provisional license was valid. Similarly, FPS files demonstrated 84.6 percent of food establishments did not have an inspection within 45 days of the provisional licensing date, 38.5 percent of inspections occurred more than 90 days after provisional licensing, and 53.6 percent of inspections did not have the second inspection.

Beverage and Bottled Water subprogram files indicated one instance of a new license process occurring during the audit period, and the new establishment was not inspected within 45 days of the provisional license issuance.

Statute required provisional licenses to expire within 90 days. Statute and rule specified an establishment must close if no inspection occurred within the 90-day lifespan of its provisional license.

Dairy Subprogram

Statute required in-State milk plants, distributors, and producer-distributors selling milk or milk products from out-of-State sources to only sell milk or milk products made under substantially equivalent requirements to State statute and regulations, including equal sanitation ratings. New

Hampshire-licensed out-of-State plants were also required to produce under provisions substantially similar to the State's requirements and achieve equivalent sanitation ratings. Rules required the FPS to issue new and renewal out-of-State plant licenses to applicants achieving a score of 90 or higher during a federal rating inspection, but required the FPS deny an initial license for an in-State plant if the applicant did not receive a minimum score of 95 during a pre-licensing inspection, or had a critical violation. Additionally, rules required license renewal applications be denied for out-of-State plants if the previous federal rating inspection scored below 90, while in-State plant renewal applications were to be denied if an inspection in the previous three months had resulted in a score below 90, or identified a critical violation. Revocation circumstances also differed between in- and out-of-State plants, with in-State plants having more opportunities to correct errors prior to license revocations.

These discrepancies were reportedly caused by a DHHS desire to set a higher threshold requirement for in-State plants on their initial inspections. The requirement for out-of-State plants to score 90 or higher matches the federal requirement to ship milk across state lines.

Homestead Inspections

Rules limited FPS statutory authority and responsibilities regarding homestead food operations. During the audit period, homestead food operations, where food was produced in the home kitchen of a primary residence, were exempted by statute from licensure if the operation had less than \$10,000 in gross annual sales; sold only from the homestead, farm stands, or farmers' markets; and did not sell potentially hazardous food. Rule exempted homestead operations from both licensure and inspection. This mismatch may have been caused by the labeling requirements for exempt homestead products identified in statute, which required homestead products be labeled as "exempt from licensure and inspection," but the statute's regulatory language only exempted homestead operations from licensure, and statute required inspections of food on sale or possessed for sale in the State.

Recommendations:

We recommend the Commissioner revise rules:

- **to remove penalties without statutory basis;**
- **related to inspection fees;**
- **related to in- and out-of-State dairy operations; and**
- **to remove language exempting homestead operations from inspection, or seek clarification from the Legislature whether it intended these homestead operations to also be exempted from inspection.**

We recommend FPS management develop policies and procedures to ensure inspections are completed as required in statute.

Agency Response:

The Department concurs in part.

The FPS agrees to modify rules to align with statute regarding penalties without statutory basis as it would be a rare instance that an outright bar would ever be pursued by the Department.

The FPS concurs in part but sees the need to change statute and rules to re-balance charging appropriate inspection fees and making subsequent reductions in licensing fees. We will study the feasibility of including the cost of initial inspections and one additional routine inspection within a two-year period in our licensing fee structure and consider charging for all additional non-routine inspections. All changes are subject to legislative and Joint Legislative Committee on Administrative Rules (JLCAR) review and approval.

The FPS concurs in part. While we agree that this recommendation has validity, it is not feasible in practice. This is an artifact of the FDAs reporting mechanism, which does not delineate beyond 90 percent. New Hampshire's rules promote better public health practice by ensuring new farms and plants are held to higher standards.

The FPS agrees to seek legislative clarification because, the FPS believes it was legislative intent to exempt homesteads from inspection.

The FPS agrees to develop a Standard Operating Procedure (SOP) to assure that inspections are required at a frequency as stated in statute.

Observation No. 20

Improve Compliance With The *Administrative Procedure Act*

The DHHS did not promulgate or timely refile rules required by statute, and some rules exercised non-existent authority. The FPS did not have policies and procedures to ensure the timeliness of responses to applications.

Lack Of Rules

Some rules required to operationalize statutes enforced by the FPS were expired or were never adopted by the DHHS, rendering some statutes or FPS regulatory methods unenforceable or unexplained and the DHHS noncompliant with the *Administrative Procedure Act*.

- Cold storage establishments had expired rules for legal definitions, application requirements, water and wastewater systems, inspections, license requirements and suspension processes, fine procedures and appeals, waivers, product recalls, equipment and handling procedures, and sanitary requirements.
- *Purity and Branding of Foods and Drugs; Immature Veal (Pure Food)*, which provided authority and requirements for embargo and condemnation of adulterated food, food inspections, and sampling, did not have rules promulgated to enforce its provisions.

- *Sanitary Production and Distribution of Food (Sanitary Production)*, which provided authority for inspecting any location, including vehicles, used for the production, storage, sale, or distribution of food, did not have rules implementing the *General Provisions* of the Chapter. Existing rules citing the *General Provisions* were applied solely to licensed, registered, or certified establishments.
- Rules describing the FPS's organization and some of its methods and formal and informal procedures did not exist.

Requirements Not In Rule

To be enforceable, rules must be formally adopted. Improper or incomplete promulgation of rules increases the risk the rules, and the statute they seek to implement, cannot be enforced. The FPS required, through forms and policy declarations, the public take certain actions without rules describing those requirements, including:

- the use of the milk sanitation license application;
- affidavit requirements in the shellfish, beverage license, and beverage registration applications;
- establishment closure requirements when water supplies were contaminated or establishments lack electricity;
- requirements related to food service and display lines, which appeared to be artifacts from previous rules;
- requirements for water system recovery after contamination;
- unsafe food embargo and destruction authority provided in statute;
- the recall procedure for shellfish harvesters;
- requirements for scheduling inspections on the food service establishment, food processor, homestead, and mobile food license applications; and
- a requirement for a compliance meeting on the Corrective Action Plan (CAP) form as a step before a fine would be levied or license revoked.

Application Response Timeliness

The FPS was required to respond to all applications, requests, and petitions from the public and to notify them of errors and omissions, and provide them contact information for questions, within 60 days of receipt. The FPS was also required to approve or deny applications or commence adjudicative proceedings within 120 days. However, the FPS lacked policy or procedure to ensure this notification occurred in the accreditation, variance, and complaint processes.

- The FPS did not notify establishments of application receipt, relying instead on inspectors arriving at the establishments for licensing inspections to make the initial contact. The FPS appeared not to meet the 60-day deadline in at least five instances. Lack of notification may have left at least two establishments unaware of the status of their applications and the legality of their continuing operations.
- Our file review indicated 93.8 percent of food establishment records did not contain an approval date. We found in at least one instance, the FPS did not comply with the

120-day requirement to respond to application requests, but comprehensive compliance measurement was impossible.

- The FPS did not record receipt dates for variance requests. Of the 44 food service establishment variances listed as granted during the audit period, 13 (29.5 percent) did not have a date granted in FPS records.
- There was no documentation indicating the FPS provided complainants with contact information or with feedback once investigations were completed. Notice and information on the results of investigations were only supplied upon request.
- Nineteen complaints had been open an average of 334 days at the end of the audit period, exceeding the 120-day upper limit for FPS action.

Recommendations:

We recommend the Commissioner promulgate rules:

- **addressing the *General Provisions* subdivision of *Sanitary Production*, including vehicle inspections;**
- **for cold storage establishments;**
- **for *Pure Food*, including rules for inspections, sampling, and prosecution;**
- **describing the FPS's organization, processes, the general course and method of its operations, and rules of practice for all formal and informal procedures available; and**
- **incorporating informal requirements contained in application forms and policy declarations, including application, disaster recovery, and closure requirements and recall, embargo, and destruction procedures.**

We recommend FPS management develop policies and procedures to ensure timely response to applications and complaints.

Agency Response:

The Department concurs in part.

*The Department does not agree to promulgate rules addressing the *General Provisions* subdivision of *Sanitary Production*, including vehicle inspections and for purity and branding of foods, including rules for inspections, sampling, and prosecution. The Department suggests an alternative approach of updating the *Food Safety Statutes* as recommended in *Observation No. 3* and then promulgating rules under this statute to address the elements of vehicle inspection and purity and branding of foods, including rules for inspections, sampling, and prosecution.*

As part of an SOP manual, the Department will include organization, processes, the general course and method of its operations, and rules of practice for all formal and informal procedures available.

The Department agrees to promulgate rules and incorporate informal requirements contained in application forms and policy declarations, including application, disaster recovery, and closure requirements and recall, embargo, and destruction procedures.

Where these recommendations have been addressed in prior responses, they will be addressed by the FPS as stated.

Observation No. 21

Formally Delegate Authority

Statute required written delegations of authority from the Commissioner to subordinates, but no formal delegations of authority to the FPS or its employees existed. Statute assigned the Commissioner most of the substantive authorities carried out by the FPS, such as issuing and revoking accreditations, approving variances, conducting inspections, imposing fines, closing establishments, and forbidding ill food service employees from working, and the Commissioner generally held any power assigned to the Department or component thereof as well. Formal delegations enable efficient and effective operations, compliance with law and rule, and help agencies to achieve objectives. Other than Supplemental Job Descriptions assigning 1) provisional licensing and corrective action plan development and approval authority to inspectors and 2) supervision of the development and implementation of training programs for self-inspecting towns, no written delegations to the FPS or FPS employees existed. This led to:

- ad hoc decisions to approve license and permit applications by different staff members, and inspectors and staff issuing or withholding final permits and licenses without management review;
- inspectors altering or extending corrective action plans;
- waiving fines;
- refunding nonrefundable fees;
- transferring nontransferable fees;
- informally granting variances;
- ineffective oversight of self-inspecting towns; and
- selecting inspection priorities contrary to rule and law.

Statute also required out-of-State dairy inspectors of FPS licensees and permit holders in other states to have written approval from the Commissioner to conduct required inspections. No written approvals or delegated authority to issue approval existed, and this requirement was reportedly unenforced.

Recommendation:

We recommend the Commissioner formally delegate food safety-related authority assigned directly to the Commissioner, the Department, or another subordinate, to the FPS administrator, including authority to:

- oversee all aspects of the State’s relationship with self-inspecting towns;
- approve out-of-State dairy inspectors;
- issue and approve variances, waivers, and accreditations;
- schedule or not schedule inspections; and
- initiate major, or levy minor, sanctions.

Agency Response:

The Department concurs.

These recommendations have been addressed in prior responses and will be addressed as stated.

Observation No. 22

Improve Rules

The Commissioner was required to promulgate rules to implement the State’s food safety laws. The FPS was responsible for operationalizing statutory requirements, contained in more than six statutes, and regulatory requirements contained in four chapters of rule, including: licensed food establishments, cold storage establishments, beverage and bottled water establishments, shellfish establishments, dairy establishments, and Milk Sanitation Board rules. Rules were fragmented, did not implement some statutory responsibilities, did not reflect some FPS practices, did not reference certain required forms, referenced the wrong versions of other forms, lacked clarity regarding the issuance of revised licenses and license expiration deadlines, and did not clearly identify and reference incorporated federal requirements.

License Processing Fee Requirements

Processing fees defray costs to taxpayers and cover the administrative burdens of regulating the food service industry. Statute required the DHHS to charge a fee for each license application processed. Rules exempted municipally-run cafeterias from a license processing fee but all other public institutions with a food service component operated by political subdivisions were subject to processing fees. If municipally-run cafeterias were charged the same licensing fee as other public institutions, the FPS would have collected approximately \$21,500 in additional fees each year during the audit period.

Simplification And Clarification

A single organization managing multiple accreditation programs should standardize functions to promote efficiency and consistency. Rules related to application processing, administrative fees, and fines promulgated to address the requirements of specific chapters of statute individually had common elements both within and between chapters which could have been combined and standardized.

Statute authorized the Commissioner to revoke a food establishment license if an establishment repeatedly violated statute or rules, created an imminent health hazard, or failed to pay a fee after a hearing. Rules listed ten conditions under which an application must be denied or a license revoked, including the three provided for by statute. The rule's structure required *all ten* conditions be met before revocation or denial, but statute and the apparent intent of the rule demonstrated *any one* of these infractions would *individually* lead to revocation. As written, the rules appeared to undermine the effectiveness of sanctions, as it limited the instances in which licenses could be denied or revoked relative to statute, and resulted in an interpretation of noncompliance with rule in at least one instance during the audit period.

Outdated And Undated References

Statute required forms to either be incorporated by reference or described fully in rule. However, the FPS did not provide the version of forms provided for by rule, instead using different forms for food service, food processing plant, homestead, and mobile food unit license applications; plan review applications; and out-of-state residential, non-commercial kitchen registration applications. Utilizing forms not adopted properly may constitute ad hoc rulemaking by imposing uncodified requirements on the public.

Statute required materials incorporated in rules by reference to identify and preserve the version of the incorporated materials. Materials incorporated by reference were required to have a fixed date or fixed version established in rule. Several sections of DHHS rules incorporated undated federal materials by reference, establishing requirements for food processing plants and beverage and bottled water operations and products. Further, the rules did not indicate whether the incorporations were for informational purposes or imposed substantive restrictions on *intrastate* commerce. Ambiguity in rule may create confusion for regulated establishments and permit substantive requirements to change without any State action.

Food Code Conflicts

The DHHS adopted the FDA's 2009 *Food Code* into rules for food service establishments. The nearly 700-page *Food Code* intended to help safeguard public health, help ensure consumer food was safe, and set standards for food establishments, plan reviews, and license issuance and suspension. However, the *Food Code* conflicted with several sections of statute. For example:

- Statutes and rules explicitly provided for the sale of raw milk and cheese, and food produced in residential kitchens, but the *Food Code* identified these actions as illegal. These conflicting requirements created confusion among the regulated industry.

- Statute also forbade employing persons with communicable diseases in places where food was stored, prepared for sale, served, or sold, but the *Food Code* permitted food establishment employees with communicable diseases to work in certain capacities and situations.
- Rules excluded several sections from the *Food Code*, including the chapter describing enforcement, plan review, accreditation, and inspection processes. These topics were supplanted by rules, but other, adopted sections of the *Food Code* referenced and relied upon the removed sections and chapter. Misdirected or incomplete references may lead to improper or incomplete rules and may create a lack of clarity in rules.

Recommendations:

We recommend the Commissioner amend rules to:

- **remove inconsistent fee requirements on political subdivisions;**
- **simplify, standardize, and combine rules for functions common among subprograms;**
- **provide for revoking licenses in specific, individual instances established in statute or rule;**
- **update references to forms;**
- **clarify references to federal statutes and rules to identify the intent of the reference and to identify the version when incorporating by reference;**
- **de-conflict federally adopted standards with components of State statute and rules; and**
- **resolve orphaned components of the *Food Code*'s sanctions and administration structure.**

Agency Response:

The Department concurs.

The Department agrees to amend rules to address inconsistent fee schedules for political subdivisions.

This area has already been brought up repeatedly and related comments have been provided. We will work with the DHHS Rules Unit to review and address the issues noted, and upon a thorough review submit proposed changes.

Conflicts with the 2009 Food Code are notable in that sections of the Food Code did not precisely align with NH law. During the legislative process lawmakers have been advised of conflicts with proposed changes to NH law (such as sale of unlicensed and uninspected raw milk) that conflict with the Food Code, but have made the legislative changes anyway. Reconciliation of the Food Code Inspection chapter and sections of it not in rule will be reviewed. The FPS agrees to review this to determine what changes are needed. As part of a strategic planning process, the FPS will consider adopting a more recent version on the Food Code along with this alignment.

Please note the FPS has entered into rulemaking to address forms within He-P 2300, the New Hampshire Rules for the Sanitary Production and Distribution of Food, so that they are properly adopted. These rules were conditionally approved by JLCAR on June 19, 2015.

Fiscal Controls

Three different statutes addressed FPS funding and led to inconsistencies in how FPS operations were funded. The FPS was largely funded by general funds, but recouped some program costs through fees charged to regulated establishments for licensing activities, and had two dedicated funds intended to be at least revenue-neutral. The FPS also imposed and collected fines on noncompliant establishments, depositing proceeds into the General Fund. Unlike some other regulatory agencies within the DHHS, there was no statutory limit on how high the DHHS could set fees, or the amount of revenue which could be collected. Food establishment fees reportedly funded not only the Food subprogram, but also Dairy and Shellfish subprograms. In the State fiscal years (SFY) 2014-2015 biennial budget, food establishment fee revenue was budgeted in both a restricted account and the General Fund. However, statute required food establishment fee revenues be deposited to the General Fund, resulting in a \$907,000 budgeting error.

Observation No. 23

Improve Fiscal Management

The DHHS lacked management controls to ensure statutory requirements applicable to FPS dedicated funds were adhered to, and to ensure rules the FPS was responsible for enforcing reflected statute. The FPS lacked management controls to ensure required fees were collected, subprogram fees reflected subprogram costs, and payments were processed according to rule. There was no methodology or accounting system to accurately track subprogram costs, and detailed subprogram cost analyses were not performed. The lack of a subprogram cost accounting system hindered analysis which could have informed subprogram fee setting to recover subprogram costs. Consequently, licensed food service establishment subprogram fees subsidized other FPS subprograms.

Dedicated Funds

Subprogram fees should be aligned with subprogram costs to avoid enterprises regulated by one subprogram subsidizing enterprises regulated by another subprogram. Statute required:

- all expenses related to the licensing and regulation of milk plants, milk distributors, and milk producer-distributors be paid for using dedicated funds, and Dairy subprogram fees cover subprogram costs; and
- all expenses of the Beverage and Bottled Water subprogram be paid using dedicated funds, and subprogram fees cover subprogram costs.

We found imbalances between subprogram expenditures and fee revenue collected. Table 3 depicts the funding source, fee revenue, estimated expenditures, and estimated audit period balances for the four FPS subprograms as of June 30, 2014. Food subprogram establishments paying licensing fees funded more than Food subprogram operations cost and created the largest funding imbalance, an estimated \$1,196,339 surplus for SFYs 2013 and 2014.

The Dairy subprogram was not at least revenue neutral as required by statute. The Dairy subprogram collected \$60,525 in revenue during SFYs 2013 and 2014, and expended an estimated \$468,902 for two inspectors and one supervisor who dedicated a majority of their time to Dairy subprogram operations, with a net estimated deficit of \$408,377. The Beverage and Bottled Water subprogram collected \$177,208 and expended an estimated \$117,226, leaving an estimated \$59,982 net surplus. However, a \$238,758 dedicated fund balance for these two subprograms was brought forward to the subsequent year. During the audit period, general funds subsidized the combined Dairy and Beverage and Bottled Water subprogram dedicated fund because low fees led to insufficient revenue within the Dairy subprogram and balances in the dedicated funds being brought forward instead of expended.

Table 3

Fee Revenue And Expenditures By Subprogram, SFYs 2013 And 2014

Subprogram	Fund Source	SFY 2013		SFY 2014		Balance As Of June 30, 2014 ²
		Revenue	Estimated Expenditures ¹	Revenue	Estimated Expenditures ¹	
Food	General	\$1,410,713	\$ 794,570	\$1,403,339	\$ 823,143	\$1,196,339
Dairy	Dedicated	30,275	230,310	30,250	238,592	-408,377
Beverage and Bottled Water	Dedicated	90,608	57,578	86,600	59,648	59,982
Shellfish	General	8,975	69,093	10,675	71,578	-121,021
Total		\$1,540,571	\$1,151,551	\$1,530,864	\$1,192,961	\$ 726,923

Notes:

¹ Due to a lack of cost accounting at the subprogram level, the expenditure breakdown by subprogram was estimated using budget data and includes all direct and indirect costs to the extent they were included in DHHS data.

² LBA estimate based on DHHS data; not actual account balances.

Source: LBA analysis of unaudited FPS data.

Inspection Fees

Accreditation fees, primarily from Food subprogram licensing fees, were the FPS's main revenue. Inspectors were the FPS's main expenditure and inspections the main activity, but the FPS rarely charged required inspection fees, and charged improper amounts when fees were imposed. Rule required a \$100 inspection fee be charged on the third and subsequent inspections within a licensing period, but statute required a fee be charged for all inspections. According to unaudited data, the FPS charged \$25 each for only three of 7,158 non-complaint inspections conducted during the audit period. FPS inspection fee practices resulted in deficient and more

risky entities consuming disproportionate amounts of FPS resources through multiple inspections and, in effect, being subsidized by the well-behaved and lower-risk entities receiving fewer or no inspections. During the audit period, 27.5 percent of licensed food establishments included in the FPS inspection database did not receive an inspection, while 1.5 percent of licensed food establishments received six or more inspections. A licensed food establishment receiving a license and no inspections subsidized the cost of a licensed food establishment receiving a license and one or more inspections. For example, during the audit period one licensed food establishment received 11 follow-up inspections, and another received six follow-up inspections for an outstanding violation, with no inspection fee charged in either case. Meanwhile, compliant establishments in the same license class paid the same amount to the State for licensing fees. As we detail in Observation No. 19, as much as \$715,800 in general fund revenue was lost by not requiring a \$100 fee for each inspection.

Fee And Fine Payments And Transfers

According to rules, fees were non-transferrable and non-refundable. However, the FPS refunded portions of annual fees after a change or cancellation of a license and transferred revenue from licensing fees to pay a portion of the fines levied against an establishment. The FPS also used a payment plan, which was not provided for in rules, for the payment of a fine and did not enforce the requirements of that plan. Rule instead required fines be paid within 30 days of imposition without exception, and required an additional fine of \$500 per day for each day the payment was late. We were unable to quantify the fiscal impact of these deviations from rule.

Net Loss To The General Fund

Table 4 depicts the total estimated net loss to the General Fund based on the FPS mis-operationalizing regulatory and statutory financial controls during the audit period. This estimate was based on figures which could be quantified, as we were unable to quantify some additional losses to the General Fund.

Table 4

Estimated Net Loss To The General Fund, SFYs 2013 And 2014

Mis-operationalized Requirement	Net Loss To The General Fund
Uncollected Inspection Fees	\$ 715,800
Net Deficit Within Dairy Subprogram	408,377
Sanctions Not Applied	39,500
Total	\$1,163,677

Source: LBA analysis of unaudited FPS data.

Recommendations:

We recommend the Commissioner:

- **analyze program costs to ensure the Dairy subprogram is at least revenue neutral as required by statute;**

- **amend the subprograms' rules regulating fees;**
- **expend dedicated Dairy and Beverage and Bottled Water subprogram revenues on subprogram expenses;**
- **ensure fund balances brought forward are not general funds;**
- **amend rules to require a fee for each licensed food establishment inspection;**
- **amend Food subprogram rules to reduce emphasis on licensing fees; and**
- **balance licensing revenues with inspection revenues.**

We recommend FPS management:

- **charge licensed food establishments for each inspection;**
- **undertake subprogram revenue and cost accounting; and**
- **comply with rule and cease providing refunds, payment plans, and account transfers for establishments.**

Agency Response:

The Department concurs in part.

Although the fees are separated by revenue source code, operating costs are not tracked at the same level as revenue. Based on the review, the FPS will institute a form of full timekeeping to track staff time for staff not exclusively assigned to the Food Establishment inspections based on what subprogram they are working on. Based on this timekeeping, the FPS will monitor revenue versus expenses monthly. This will be a tool to use in future decision making with regard to fee structure of licensees.

The FPS agrees to consult with the Legislature on the issue of funding the Dairy subprogram. The revenue that is generated by the subprogram does not cover its operating costs. This either needs to be addressed by agreeing that the program should be subsidized with general funds or that license fees should be increased.

The Department agrees to comply with rule and cease providing refunds, payment plans and account transfers.

Other recommendations have been addressed in other observations.

Performance Measurement And Information And Records Management

Effective management control relies on relevant and reliable data. Agencies are required to establish and maintain a continuing, economical, and efficient records management program containing adequate and proper documentation of its organization, functions, policies, decisions, procedures, and transactions. The life cycle of each transaction should be completely, accurately, and promptly recorded to maintain relevance and value, and protect legal and financial rights. Procedures for handling confidential information are essential and records must be properly managed and maintained for a management control system to be effective. Effective information

systems help agencies achieve objectives and respond to risks, evaluate results, and ensure data are complete, accurate, and valid. Sustained monitoring assesses performance over time.

Observation No. 24

Improve Performance Measurement And Information And Records Management

The FPS lacked management controls sufficient to permit quantifying how well it performed, and FPS information management practices inefficiently and ineffectively supported operational needs.

Performance Measurement

The FPS did not measure organizational performance. Performance measures facilitate evaluating an organization's achievement of its objectives, and are key elements of effective management control. Agencies develop plans, and specific and measurable objectives, sub-objectives, and performance levels and the means to achieve them. Evidence-based practice hinged in part on data collection and analysis, and was integral to realizing the State's health improvement strategy and focusing limited resources on the greatest risks to food safety.

The FPS collected some output data, but lacked consistently reliable data, information management systems sufficient to support operational needs, and analytical systems to demonstrate performance and outcomes over time. Although published FPS data varied for SFYs 2011 through 2015, six of the seven output measures listed in budget submissions were expected to remain static over time, and one was expected to decrease significantly, before increasing and leveling-off near historical levels. None of these output measures were directly connected to:

- 1) the FPS mission to protect the safety and security of the State's food supply and reduce foodborne illness statewide;
- 2) decreasing the occurrence of priority violations in licensed food establishments from 33.4 percent to 25.0 percent by 2015, the single FPS goal specified in the *State Health Improvement Plan, 2013-2020 (SHIP)*; or
- 3) ensuring federal compliance to permit dairy and shellfish exports to continue.

Neither did FPS outputs support delivery of evidence-based services or measureable improvements in health and wellbeing, which were Division of Public Health Services (DPHS) objectives. Further, the single FPS goal and supporting actions detailed in the *SHIP* were focused only on licensed food establishments subject to the *Food Code*, rather than focusing on food safety risks generally.

Additionally, staff performance was not measured. Unaudited FPS data indicated widely varying amounts of administrative time claimed by staff and varying rates of inspections among staff. Management had no way to objectively verify staff productivity, and had to trust staff was accomplishing what they reported. Draft goals and priorities of the DPHS included institutionalizing performance management, promoting accountability, and ensuring employee

performance supported organizational objectives. Management control includes management evaluating individual performance and holding individuals accountable for achieving objectives.

Information And Records Management

To ensure necessary operational data were available, the FPS relied upon three primary databases; more than 50 additional, but separate, data files; and multiple categories of hardcopy records. Up to seven of the FPS's 15 employees (46.7 percent) were responsible for entering operational data and records management, and rekeying some data was required.

Each of the three primary databases contained inconsistent data, had missing data, and maintained unused features. The licensing database did not consistently operate as expected, produced aberrant and unreliable results, and did not include required forms or key data elements, such as food establishment status. The complaint database history was not readily accessible. The FPS had to discontinue posting food establishment inspection results online, because the inspection database, intended to provide public disclosure of inspection results and establishment status, was unreliable and labor-intensive to correct. A substitute, largely manual, method for disclosing establishment status and inspection results was developed, but the FPS did not maintain any data on its effectiveness or efficiency.

Other databases separated licensing and inspection data; contained data differing from hardcopy records; inconsistently contained data, such as suspensions; inconsistently used common identifiers for the same establishment; and tracked the same or similar operations in multiple databases.

Additionally, the FPS lacked a formal records management policy and a records retention schedule, and staff were unaware of any formal records management requirements. The FPS lacked a formal confidential information management policy. Records related to applications and accreditations were reportedly routinely destroyed after one year, not retained at all, or retained only in draft form electronically. Hardcopy files were at times inadequate. For example, we found:

- one establishment's entire licensing record, which typically included as a minimum applications and copies of licenses issued, contained a single document, a re-inspection report with the remainder reportedly misfiled;
- eight of 23 complaint cases (34.8 percent) lacked corresponding hardcopy records in either the central complaint file or the implicated establishment's record;
- two of eight (25.0 percent) out-of-State non-commercial producer records were missing, one had a registration certificate on file while others did not, and one record was stored separately from other establishment records;
- one of 16 beverage and bottled water establishments received an inspection without a date recorded, one license was missing, and two inspections conducted under the Dairy subprogram were undocumented; and
- files for Dairy establishments recorded as licensed during the audit period were missing in three of 23 (13.0 percent) of in-State license files we reviewed.

Subprogram reporting was generally ad hoc and the FPS has never had an in-depth review. FPS management reported undertaking an effort to measure performance as part of the DPHS effort to institutionalize performance management, and which may be realized in the future. FPS staff also indicated a new database management system was planned as part of the DPHS's effort to improve information technology systems and support.

Recommendations:

We recommend FPS management:

- **develop organizational goals, objectives, and sub-objectives representing the full scope of the FPS's responsibilities;**
- **establish specific and measurable performance levels for each organizational goal, objective, and sub-objective;**
- **establish specific and measurable individual performance levels supporting organizational goals, objectives, and sub-objectives;**
- **collect and routinely analyze relevant data and assess whether measurable improvements in food safety are being achieved over time;**
- **develop, implement, and enforce a formal records management policy establishing retention and confidentiality requirements;**
- **centralize, integrate, and simplify information management systems by focusing on data supporting measurement of goals, objectives, and sub-objectives; and**
- **improve the completeness, accuracy, and validity of records and data.**

Agency Response:

The Department concurs.

The FPS agrees to utilize the LBA audit as a baseline for a strategic planning initiative, then prioritize feasible goals and objectives, develop a work plan, and track performance and improvement. Strategic planning would occur using contracted facilitation in late Fall 2015 and the FPS would engage the services of the DHHS Project Management Office in developing and tracking progress on prioritized goals and objectives. The record for this would be made available to our oversight administrators and other interested parties. This will be consistent with the Division wide Performance Management initiative and system DPHS is moving towards. While the FPS cannot complete all of the recommended improvements and changes (the ones we concur with or concur in part), the FPS can establish reasonable plan with identified smart objectives and assigned staff. Much of this burden will fall to the managers within the FPS, and the challenge is often choosing between performance improvement and planning and daily operations. That said, the strategic planning process will help to set realistic priorities and time frames. The FPS may request additional FTEs or other supports to move ahead with the multiple tasks and structures being recommended.

The FPS will provide an annual report with reference to the priority metrics identified and progress towards these selected objectives. The FPS will also use the new database to track selected metrics (such as inspections of higher risk establishments and decreasing the

occurrence of priority violations, and where feasible tracking staff performance). The new system will offer recent inspection history and other essential establishment compliance information to field staff on demand. Records management will be addressed in SOPs. The DPHS Performance Management Application will be used to track overall program performance with selected metrics. Staff performance evaluations will require review and sign-off at the next level up to assure alignment with program objectives has been considered.

Observation No. 25

Improve Communication With The Public

Agencies should publically communicate program results to demonstrate value and to permit external parties to help an agency achieve its objectives and address related risk. However, the FPS did not complete a statutorily-required annual or biennial report. Further, the FPS initiated posting inspection results at each licensed food establishment, but after industry input, settled upon posting results online instead. However, the information technology system to permit such reporting was ineffective and the FPS discontinued online posting. The public subsequently had to rely on either calling or emailing the FPS during normal business hours to obtain establishment status, a process for which the FPS did not track activity. Public disclosure of food-related health risks permits informed consumer decision-making.

The FPS also lacked a formal and consistent manner for the regulated industry to submit complaints regarding inspectors or other FPS operations, or to obtain general input from industry and the public. The FPS estimated receiving three to four complaints about FPS operations annually. A complaint mechanism can help ensure objective handling of complaints and minimize fear of retaliation. Without formal mechanisms, the FPS may have discouraged complaints or public input and limited information FPS management might have used to improve program operations.

Recommendations:

We recommend FPS management:

- **clearly communicate public health risks by posting inspection results online,**
- **regularly report program outcomes,**
- **regularly obtain industry and customer feedback, and**
- **develop formal processes to obtain complaints about FPS operations and generalized input from the public.**

Agency Response:

The Department concurs.

The FPS agrees that communication is particularly important to inform the legislative process. The FPS also plans to use the new integrated Food Protection Licensing and Inspection Information System to establish an automated customer feedback loop.

As noted previously, the FPS will complete an annual report which will include metrics and tracked progress based on a strategic planning process that utilizes the recommendations in the audit with which the FPS concurs.

An automated feedback loop will be made available to licensees and reviewed by administrative staff in the FPS for follow up and quality improvement purposes.

The general public will continue to have the complaint option currently available, but this process will be reviewed to assess for any disincentives and revised if needed. The FPS will address this as an SOP.

Observation No. 26

Improve Risk Management

Risk assessments help agencies identify, analyze, and respond to risk. The FPS lacked sufficient risk management practice, policy, procedure, and a strategic approach. Risks identified by FPS management were limited and a strategic plan draft did not address risks. The FPS formally identified only one risk, priority violations within licensed food establishments, but lacked the data and analysis to completely assess the risk or progress in addressing this risk. The FPS addressed economic risks during the audit period by ensuring dairy, shellfish, and beverage and bottled water establishments received inspections required to permit the export of their product across State lines, but other risks were inconsistently identified, analyzed, and addressed leading to noncompliance with State law, rules, and the *Food Code*. Further, the FPS identified staffing needs as a potential risk to achieving their mission, but did not analyze required staffing levels or base activities on risk to focus available staff.

Recommendations:

We recommend FPS management conduct an entity-wide risk assessment and develop a strategic plan that identifies, analyzes, and helps respond to agency risk, including staffing-related risks.

Agency Response:

The Department concurs.

The FPS agrees to study the process of conducting a risk assessment and after the FPS has an understanding of the actual task, the FPS will assess feasibility during the strategic planning process.

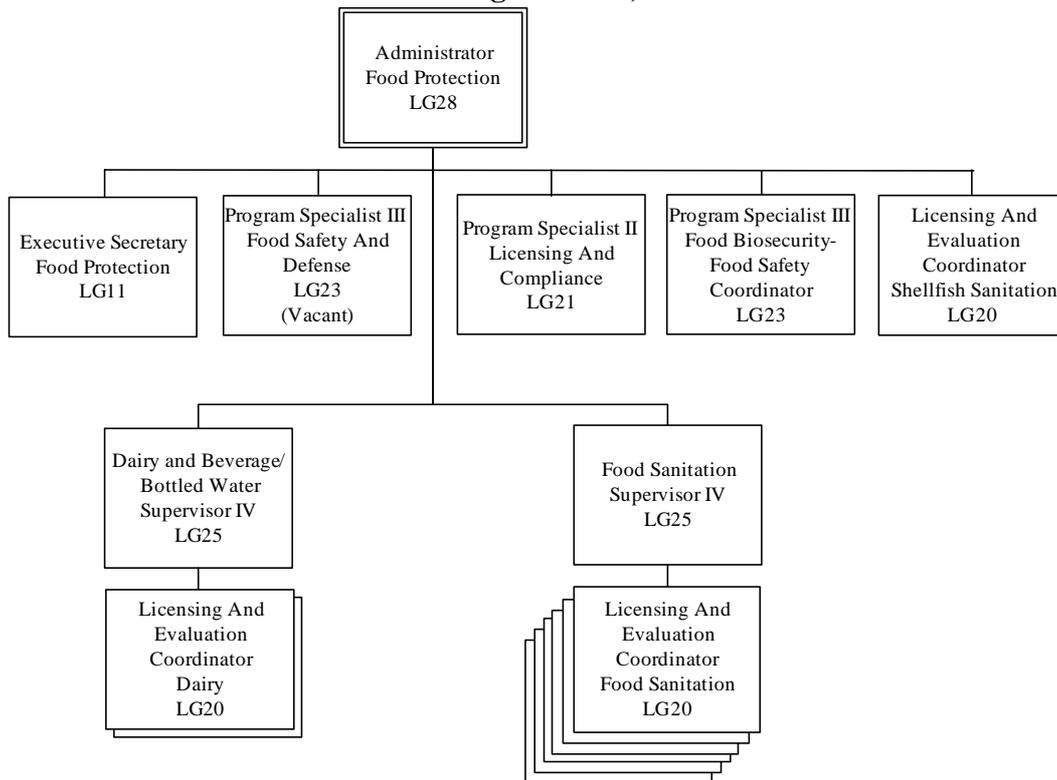
The recommendations outlined in the audit will require a great deal of time. The FPS is concerned that the current budget will not allow for the increase in staff to accomplish this work. As the strategic plan is written, the FPS will make a concerted effort to outline the staffing hours required to complete the responsibilities added by policy, operating procedures, rule or statute. A timeline will be established during strategic planning in 2016.

Organizational Structure

Management establishes the organizational structure necessary to enable an agency to plan, execute, control, and assess the organization in achieving its objectives. Management of human capital is essential to effectively and efficiently achieving organizational objectives. Human capital management ensures personnel are given appropriate responsibilities, training, tools, and supporting structure. Agencies perform human capital management by routinely assessing how to maintain workforce continuity, develop workforce skills, link individual performance to objectives, and identify the workforce needs of the agency. As detailed in Figure 6, the FPS consisted of 16 positions with 15 filled.

Figure 6

Food Protection Section Organization, As Of November 2014¹



Note:
¹Labor grade = LG.

Source: The FPS.

Observation No. 27

Improve Organizational Efficiency And Effectiveness

FPS administrative activities, inspection practices, and personnel management demonstrated several inefficiencies. In SFY 2014, inefficient practices cost the State between \$40,744 and \$48,484 and hours approximately equal to 1.07 full-time equivalent (FTE) inspectors, or as many as 558 food establishment inspections and 42 dairy establishment inspections. Agencies should minimize wasteful practices, but the FPS burdened inspection staff with administrative activities and did not perform an in-depth review of inefficiencies. Given the reported challenges in accomplishing inspection goals, using inspectors for administration was inefficient. Additionally, during the audit period, we estimated 288 consulting inspections were completed free-of-charge, further detracting from the time available for routine inspections.

Accreditations

Accreditation activities and telephone inquiries were the bulk of the FPS's administrative work. As we discuss in Observation No. 4, except for certification under the Shellfish subprogram, accreditations under the other three subprograms were not federally mandated to be annual. A change to biennial accreditation in statute would reduce the administrative burden on the FPS and decrease the need to keep inspectors out of the field.

Additionally, due to centralized plan reviews, the FPS inefficiently used approximately 0.2 of a FTE inspector which equated to the loss of as many as 236 inspections during the audit period.

Data Entry

Due to assigning data entry responsibilities to an inspector and supervisor, an estimated \$17,545 in base salary and overtime wages was used inefficiently during SFY 2014. During the audit period, approximately a 0.1 FTE inspector was allocated to data entry which resulted in the loss of as many as 118 inspections.

Consulting Inspections

During the audit period, some food establishments requested consultation inspections before a provisional licensing inspection, totaling an estimated 288 consulting inspections. The FPS viewed consulting inspections as useful, but lacked controls to ensure efficient resources utilization. Had the FPS applied the required \$100 inspection fee established in rule to consulting inspections, the FPS could have collected an estimated \$28,800 in additional general fund revenue. Charging fees might also have reduced the frequency of requests for this service, increasing the hours available to inspectors to conduct inspections of higher-risk, in-service establishments.

Monthly Meetings

Monthly, the FPS conducted day-long staff meetings to discuss and interpret the *Food Code* and conduct staff training. The *Food Code* had been enforced by the FPS since 2011 and the FPS developed three documented policies to further assist inspectors interpret the *Food Code*. As staff became more familiar with the *Food Code*, a decrease in the number of meetings on interpreting the *Food Code* should have occurred. Also, standardization, an ongoing process used to demonstrate inspector knowledge and ability, as a training tool may be more efficient than monthly meetings, since it required one inspector to be taken away from conducting inspections, instead of the entirety of the FPS staff. Approximately 0.25 FTE of a food inspector and a 0.08 FTE of a dairy inspector could have been allocated to field inspection activities had the frequency of staff meetings been reduced to quarterly. During the audit period, this may have resulted in the loss of as many as 294 food inspections and 84 dairy inspections.

Travel-related

While the FPS correctly allocated State vehicles to employees driving the most miles during SFY 2014, it also relied on private vehicle mileage reimbursement for others. Two inspectors traveled a total 23,435 miles in private vehicles, exceeding the break-even threshold established by the Department of Administrative Services, and resulting in an estimated \$4,453 of additional avoidable travel expenses.

Inspectors worked from home offices and generally worked in adjacent regions or areas. However, one inspector was assigned an inspection area almost two hours away from home, commuting there 15 times during SFY 2014. Another inspector resided less than an hour away from this area. We estimate this arrangement cost an additional \$871 in wages and travel expenses.

The inspector assigned data entry responsibilities had to travel from home to Concord biweekly, instead of using a local DHHS District Office. During SFY 2014, we estimate this inefficient practice cost \$3,362 in wages and travel expenses.

Additionally, inspectors statewide traveled to Concord regularly to handle paperwork and assist administrative staff in answering phones. The DHHS has eleven district offices and other State agencies, over 100 in total. We did not estimate potential inefficient avoidable wage and travel expenses, and lost inspection time resulting from this practice.

Human Resource Administration

The FPS lacked a regular review and correct implementation of employee Supplemental Job Descriptions (SJD). All 16 SJDs had some form of inaccurate or outdated information: 50.0 percent had an inaccurate supervisor and 93.8 percent were reviewed by an employee no longer with the FPS. Two of the three SJDs assigned to employees who were shared by subprograms failed to include both subprograms in the SJD. The third SJD included two subprograms, but the inspector was assigned responsibilities in one subprogram. Additionally, sample collection

activities included in the Food subprogram inspector's SJD was not consistently implemented in practice.

In SFY 2013, the FPS planned to adopt performance measurement and quality improvement measures into inspectors' SJDs, but this plan remained unimplemented during the audit period. Instead, personnel were supervised without performance goals or metrics to measure inspector productivity. Unaudited FPS data demonstrate a wide range of individual inspector outputs was achieved, but there were no goals to compare performance to, nor were there methods to verify efficient resource use.

Additionally, three SJDs were based on job classifications predicated upon providing direct supervision to other staff, but no direct supervision was assigned to any of the three positions. Since pay scales account for supervisory duties, we estimate between \$16,341 and \$24,081 in wages during SFY 2014 were expended for supervision not rendered.

The FPS lacked a formal succession plan for key roles within the organization and there was limited cross-training on key duties. Two employees in key roles retired during the audit period without a succession plan in place, creating challenges for the FPS. Reportedly, five additional FPS employees were or will soon be eligible for retirement. Succession plans ensure key roles within the organization are replaced with trained individuals and provide continuity in performance. Succession plans identify key roles, candidates, and enable knowledge sharing with candidates.

Integration And Simplification

The FPS managed ten different license, certification, registration, and permit types established by statute. Agencies managing multiple accreditation programs should standardize functions to promote efficiency and treat consistently establishments and applicants. FPS accreditations applied to establishments across four subprograms operating under four different chapters of rule. Neither statute nor rule required separate food safety subprograms. Operations were convoluted due to this structure, and other impediments, such as:

- subdividing licensing and plan review processes among two subprograms, and not fully integrating inspection information resulting in inconsistent identification of noncompliance;
- separate accreditation, inspection, and subprogram databases;
- different processes between subprograms for accrediting establishments, including licensing inspection and construction review and approval requirements; and
- regulatory and accrediting responsibilities divided between the DHHS, the Milk Sanitation Board, and the Department of Agriculture, Markets, and Food.

Recommendations:

We recommend the Commissioner facilitate improved efficiency by coordinating for routine FPS field staff use of DHHS District Offices.

We recommend FPS management increase inspector output by:

- **standardizing and simplifying common practices and features among subprograms, to the extent permitted by law, including accreditation and construction review processes;**
- **assigning plan reviews to field inspectors within their district;**
- **reassigning data entry responsibilities to administrative staff;**
- **ceasing to offer and provide consulting inspections to establishments free of charge; and**
- **reducing the frequency of staff meetings.**

We further recommend FPS management:

- **seek to increase the FPS fleet size by two vehicles;**
- **ensure employees comply with their SJDs;**
- **review and amend SJDs;**
- **add performance measures and quality improvement mechanisms to SJDs;**
- **ensure SJDs have responsibilities compatible with the corresponding job classifications; and**
- **create succession plans for key roles within the FPS.**

Agency Response:

The Department concurs in part.

The Department does not see the use of District Offices for Field Staff as a necessity or as a way to improve efficiency due to implementation of the new licensing and inspection database.

Previous data entry required a high level of review which is why an inspector and dairy supervisor were assigned this duty. This practice was ceased in March 2015 in anticipation of this function being accommodated without data entry with the new database. As mentioned previously, the Department is currently undergoing implementation of a new licensing and inspection database. As a result of implementation, many current business practices that the FPS engages in will stop or change. Post implementation, the Department agrees to annually evaluate the processes of licensing, plan review, data entry and holding staff meetings for quality improvement.

Standardization of common practices has been addressed in previous observations and will be studied with regard to feasibility and included in an SOP.

The FPS agrees to address the addition of two vehicles if still needed in the 2018-2019 budget and to explore a leasing option if feasible in SFY 2016-2017.

The FPS does not agree to cease consulting which would be an available as a technical assistance (TA) service to licensed entities as TA can be a means to improve future compliance and customer service. However, we agree to define and distinguish between TA and actual

inspections and to treat each accordingly. The FPS agrees to study quantifying the cost-benefit of these consulting inspections and to include this distinction between TA and inspections in a modification of the rules if deemed appropriate.

The FPS agrees to review SJDs and amend as applicable and to also include performance measures related to inspector output and quality improvement within SJDs. The FPS will review SJD compliance as part of the performance review process.

The FPS will seek guidance on how succession planning can be operationalized in the current hiring freeze. It is also not compatible with state personnel rules as applying for jobs is a competitive process and the FPS cannot identify specific individuals to fill positions in advance of positions being posted. The FPS does agree to develop SOPs for key roles.

FPS staff meetings have been reduced to bimonthly since February 2015. FPS will consider future reductions after training and implementation has been completed for the new database.

Information Technology

Information technology (IT) systems can improve efficiency, but must be well-designed and adequately controlled to ensure they effectively and efficiently achieve business objectives. Information system general controls are the policies and procedures regulating an agency's operation of information systems. Effective general controls create the environment for proper operation of application controls. General controls include security management, logical and physical access, configuration management, segregation of duties, and contingency planning. Access controls should be designed to allow system use only in accordance with management's authorization and limited to authorized individuals. Database controls are designed to ensure that activities related to the security, integrity, accountability and recoverability of the database are controlled.

Observation No. 28

Improve Information Technology Controls

Control of FPS IT assets and systems was insufficient. The FPS maintained a mobile device user agreement, computer use policy, and continuity of operations planning tables but lacked documentation detailing controls over essential systems. The FPS lacked sufficient documentation related to risks facing its systems and data assets, physical security, logical access, change control, disaster recovery and continuity of operations, telecommunication and network controls, and documentation related to the structure of databases.

FPS field staff relied on various devices, remote access, three primary databases, over 50 supplemental databases for specific subprograms and establishment types, and associated systems and hardcopy records to ensure necessary operational data were available. Some data were also essential in demonstrating compliance with federal requirements, which allowed the

State's dairy and shellfish producers to export their products across State lines. Each of the three primary databases contained incomplete, inaccurate, and invalid data.

Controls

Management should design information systems and related controls to achieve operational objectives and respond to risks. However, the three main databases' designs poorly supported FPS business requirements. For example:

- Some databases were generally accessible by all staff, creating potential control problems and raising data reliability concerns.
- The licensing database contained 58 tables, 1,072 fields, and over a quarter-million records, but only 16 (27.6 percent) of the tables were actively used for storage during the audit period. Eight (13.8 percent) tables had not been used since the 1990s.
- The FPS had to discontinue posting food establishment inspection results online, because the inspection database, intended to provide public disclosure of inspection results and establishment status, was too unreliable and labor-intensive to correct. A substitute, largely manual, method for disclosing establishment status and inspection results was developed.
- The more than 50 supplemental databases for specific subprograms and establishment types resulted in nearly half of the FPS's employees, including field inspectors, having data entry responsibilities, taking them away from their primary responsibilities.

Quality Data

Quality information made available timely underpins adequate management control. Application controls are system controls designed to achieve data validity, completeness, accuracy, and confidentiality during processing. Transaction data should be complete, accurate, and valid. We found errors within unaudited databases, among databases, and between databases and hardcopy records.

- Complaint data were inaccurate, such as intake dates including the year 2020, and incomplete, such as 54.5 percent of complaints received in the audit period lacking a complaint description.
- Licensing data were invalid, such as containing non-date data in date fields; incomplete, such as missing data; and inaccurate, such as dates including the years 460 and 9795.
- Inspection data were incomplete, missing data; inaccurate, such as dates including the years 111 and 2032; and invalid, such as numbers in lieu of text describing an inspection type.

Our comparison of select electronic and hardcopy record data indicated:

- 7.0 percent of routine inspection dates, 15.1 percent of follow-up inspection dates, and 21.4 percent of provisional licensing inspection dates for food establishments were inaccurately recorded;
- 4.1 percent of dairy farm permit inspection dates, 5.1 percent of licensed plant inspection dates, 10.0 percent of bulk milk hauler and sampler inspection dates, and 5.6 percent of bulk milk tanker inspection dates were inaccurately recorded; and
- 3.4 percent of shellfish inspection dates or types did not match, 1.1 percent of inspections found during file review were not present in the database, 1.1 percent of inspections were categorized as “attempted” but no record of these attempts existed in hardcopy files, and 0.5 percent of inspections marked as “attempted” in the database were documented as occurring in hardcopy files.

Because FPS management lacked data quality control measures and processes did not understand the quality of its databases. Effective management controls include oversight and periodic review, but the FPS has never had an in-depth review. Ineffective IT controls limited management reporting and performance measurement. FPS staff also indicated a new database management system was planned as part of the DPHS’s effort to improve IT systems and support.

The control issues we found compel our qualification of each aspect of this audit relying on agency data.

Recommendations:

We recommend FPS management improve IT controls, and:

- **develop and implement controls that address security management, logical and physical access, configuration management, segregation of duties, and contingency planning;**
- **ensure system designs eliminate the need for and use of supplemental databases to maintain operational data;**
- **reduce data entry requirements on field staff to permit them to maximize their productivity in their main responsibility; and**
- **develop and implement controls to assure data accuracy, validity, and completeness, and establish goals for and monitor routinely data accuracy, validity, and completeness.**

Agency Response:

The Department concurs.

The FPS is implementing a new database that will address the recommendation. The completion date is November 2015.

There is also a recommendation for greater control which seems to apply to DHHS/DPHS agency wide policy rather than for one individual section. The exception would be if the FPS has specific business practices that distinguish the IT security needs for that section.

Observation No. 29

Improve Policies And Procedures

Documented policies are a necessary part of an effective management control system and help guide inspectors and other staff in their duties. The FPS lacked several written policies and procedures, such as those:

- detailing standard inspection practices;
- guiding inspection scheduling and frequency;
- establishing standardization requirements, performance objectives, and inspector productivity measurement;
- on inspector discretion and judgment, including triggers for sanctions for certain repeated violations and decisions to follow-up or not follow-up on inspections;
- specifying when supervisor involvement in sanctions, corrective action plans, and noncompliant establishments was required;
- on handling certain disaster events, including the frequency and necessity of inspector visits;
- defining the frequency, duration, and necessity of construction or other consulting inspections;
- to ensure complaints and accreditation applications received timely responses;
- on sharing information with management and supervisory or management review of inspector and licensing staff work;
- defining document retention and right-to-know request processes;
- defining variance process management; and
- requiring sampling and handling information received from self-inspecting jurisdiction sampling processes.

Additionally, the FPS lacked a commonly-understood ethics policy, but staff were exposed to opportunities for unethical conduct regularly. This included the role of the FPS regulators on the Dairy Practices Committee. Conflicts of interest were addressed on an ad hoc basis. Management defines an organization's ethics and standards of conduct, in part, through policies or guidelines. These policies should include periodic disclosure of any conflicts of interest, define the tolerance level of deviations in conduct, require training, and establish reporting lines.

Lack of policies and procedures may have contributed to inconsistent inspection practices and inspection frequency; inefficient use of field inspectors and resources; inconsistent application of sanctions; repeated construction- or disaster-related inspections, including one establishment which, according to unaudited FPS data, received seven disaster-related visits in one month; confusion among some licensed establishments about the status of their licenses; and documents

being destroyed before statute permitted. Lack of guidance in scheduling inspections also created dilemmas for inspectors between scheduling a high-risk establishment, a low-risk establishment without a recent inspection, and an inspection based on convenience. Management was unable to ensure inspections occurred or assess productivity, since inspection time was inconsistently documented.

Recommendations:

We recommend FPS management develop written policies and procedures detailing FPS practices and ensure staff have a common understanding of the ethics policy, include a consistent method for reporting deviations from policy or statute, and periodically review and disclose conflicts of interest.

Agency Response:

The Department concurs.

The FPS agrees to develop written policies and procedures for FPS practices as previously discussed within responses to other observations. The SOP manual will include awareness of state and DHHS ethics and conflict of interest policies.

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**STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD PROTECTION SECTION**

**APPENDIX A
OBJECTIVES, SCOPE, AND METHODOLOGY**

Objectives And Scope

In April 2014, the Fiscal Committee of the General Court adopted a joint Legislative Performance Audit and Oversight Committee recommendation to conduct a performance audit of the Department of Health and Human Services (DHHS), Food Protection Section (FPS). We held an entrance conference with DHHS management in November 2014.

This audit was designed to answer the following question:

How efficient and effective was the Department of Health and Human Services in preventing foodborne illness in New Hampshire during State fiscal years 2013 and 2014?

This audit had two primary foci:

- 1) the effectiveness of the FPS in preventing foodborne illness, and
- 2) the efficiency with which the FPS operated its subprograms to prevent foodborne illness.

Methodologies

To gain an understanding of the FPS's management control environment, we:

- reviewed State laws, rules, executive orders, organizational charts, policy documents, public notices, data, supplemental job descriptions, class specifications, and forms;
- reviewed similar audits from the federal government and other states;
- reviewed industry standards, academic literature, and relevant materials from the federal government and other states;
- interviewed DHHS personnel familiar with the Department's food safety efforts;
- interviewed leaders of industry associations;
- observed 57 food, dairy, shellfish, and beverage and bottled water establishment inspections conducted by each of the FPS's active inspectors;
- completed Food and Drug Administration training courses which covered Hazard Analysis and Critical Control Point plans, inspection issues and observations, food law for state regulators, and auditing for regulators; and
- reviewed policy goals, plans, and measures of effectiveness.

To evaluate the effectiveness of FPS in reducing foodborne illness, we:

- reviewed State laws, rules, executive orders, organizational charts, plans, policies, and procedure documents;
- reviewed academic literature and industry practice;

- reviewed public health policy, goals, and plans;
- interviewed government and advocacy group officials;
- observed food establishment, dairy, shellfish, and beverage and bottled water establishment inspections conducted by each of the FPS's inspectors;
- reviewed data describing incidents of foodborne illness, inspections, sanctions, licensing, fees, complaints, and productivity-related data; and
- reviewed external audits and reviews.

To gain an understanding of the FPS's interactions with other government agencies with roles in protecting the State's public food supply, and to assess the effect those relationships had on FPS's effectiveness, we:

- reviewed State laws, rules, and policies;
- interviewed officials familiar with the State-local relationship;
- reviewed each memoranda of agreement the FPS has with several self-inspecting towns;
- surveyed each of the self-inspecting jurisdictions active during 2015 using online survey software;
- interviewed officials from six State agencies with a role in the State's food protection system; and
- reviewed external audits and reviews.

To evaluate the effectiveness of the FPS's accreditation and re-accreditation processes, we:

- reviewed State laws, rules, executive orders, policies, procedure documents, and forms;
- reviewed industry practice;
- observed an initial licensing inspection;
- observed the plan review process;
- reviewed federal ordinances and requirements;
- interviewed FPS staff responsible for plan reviews; and
- reviewed accreditation and inspection files and databases to produce descriptive statistics on the timeliness and completeness of accreditation, reaccreditation, and inspection processes.

We also tested for timeliness and completeness of the re-accreditation process by selecting, using judgmental and stratified random sampling, 182 files for detailed review of re-accreditation processes, important dates in these processes, notifications and documents sent between the establishments and the FPS, fee payments, waiver submissions and responses, organizational changes at the establishments, FPS mechanisms for determining application completeness, establishment deficiencies or issues, the frequency and timeliness of plans of correction, and incidents of fines. Based on analysis of the sampled files, we calculated descriptive statistics for key measures of completeness and timeliness in the re-accreditation processes, measured the timing of inspections relative to accreditation expiration dates and regulatory deadlines, the

timeliness of organizational change responses, and accreditation suspension and nonrenewal processes. Because we used a nonstatistical sample, results cannot be projected to the entire population of re-accreditation and inspection files.

We also tested for timeliness and completeness of the initial accreditation processes using the same 182-file sample. We reviewed application completeness and FPS determinations of completeness, timeliness and nature of FPS responses to applications, inspection evaluations of establishment readiness, accreditation issuance process completeness, and the timeliness of required inspections. Based on analysis of the sampled files, we calculated descriptive statistics for key measures of completeness and timeliness in the initial accreditation processes. Because we used a nonstatistical sample, results cannot be projected to the entire population of re-accreditation and inspection files.

To evaluate the effectiveness of the FPS's complaint management and resolution processes, we:

- reviewed State laws, rules, plans, and FPS complaint policies and procedural documents;
- reviewed industry practice;
- reviewed relationships with self-inspecting jurisdictions;
- interviewed FPS staff familiar with complaint processes;
- analyzed the complaint database, which included 558 complaints received during State fiscal years (SFYs) 2013 and 2014 and produced statistics describing timeliness, completion, and follow-up complaint processes;
- conducted a file review of a sample of the complaint files; and
- analyzed a stratified random sample of 23 complaint files, testing for timeliness, apparent completeness of processes and documentation, management control effectiveness, the source of the complaint, the resolution of the complaint, and timeliness using important dates in the complaint. Because we used a nonstatistical sample, results cannot be projected to the entire population of complaint files.

To evaluate the effectiveness of the FPS's utilization of sanctions, we:

- reviewed State laws, rules, policy and procedure documents, public notices, and forms;
- interviewed FPS staff;
- observed food establishment, dairy, shellfish, and beverage and bottled water establishment inspections conducted by each of the FPS's inspectors;
- reviewed 182 establishment files and analyzed use of sanctions to test compliance with rule and law;
- reviewed 23 complaint files and analyzed use of sanctions to test compliance with rule and law;
- analyzed inspections data to determine compliance with rule and the frequencies of violation types and severities; and
- analyzed fine data.

To determine the efficiency of FPS's operation, we:

- reviewed State laws and rules;
- policies and procedures;
- reviewed and analyzed budget documentation and estimated subprogram costs;
- reviewed federal grants and grant program requirements;
- accompanied State inspectors on 57 inspections of 54 establishments over 24 unique days, including:
 - 27 Food subprogram establishment routine and licensing inspections of 27 establishments on 13 different days,
 - 11 Food subprogram establishment follow-up inspections of nine establishments on eight different days,
 - four Food subprogram establishment construction inspections of three establishments on four different days,
 - ten routine Dairy subprogram inspections or sampling visits to ten establishments on three different days,
 - four routine and certification Shellfish subprogram inspections of four establishments on four different days, and
 - one routine Beverage and Bottled Water subprogram inspection on one day;
- reviewed industry practice;
- assessed consistency between FPS practices and industry practice;
- interviewed personnel familiar with budgeting and cash handling, and related control processes;
- reviewed Supplemental Job Descriptions and compared to duties in practice; and
- reviewed staffing levels and staff travel.

To determine the reliability of FPS licensing, inspection, and complaint databases, we:

- compared key fields from a sample of hard-copy records with the corresponding fields in the relevant electronic records;
- analyzed select databases for internal consistency and completeness;
- reviewed FPS management controls over information assets and systems;
- reviewed select Department of Information Technology management controls over information technology assets and systems; and
- interviewed personnel familiar with related control processes.

**STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD PROTECTION SECTION**

**APPENDIX B
DEPARTMENT OF HEALTH AND HUMAN SERVICES RESPONSE TO AUDIT**



NICHOLAS A. TOUMPAS
COMMISSIONER

State of New Hampshire

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July 1, 2015

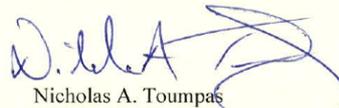
Steven M. Grady, MPA, MSS
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RE: Audit of Food Protection Section

Thank you and your team for completing the comprehensive performance audit for the Food Protection Section (FPS) within the Department of Health and Human Services, Division of Public Health Services.

While the number of recommendations is over 150, there are some themes that emerge which we will plan to address in several ways. The FPS will utilize the audit as a component of strategic planning, prioritize objectives and set time frames and measure follow-up. Areas that will need further feasibility study include expanded sampling and testing of food products, as well as expanding inspections to include high-risk unlicensed food venues. As a component of feasibility, FPS will consult with legislators regarding legislative intent related to inspection of unlicensed food venues, fee and fine structures, and options for increasing licensure as a component of inspection expectations. Further, the review and recommendations for alignment, simplification, integration and consistency of rules and law across all FPS program sectors will be studied and revisions will be pursued. Data management is expected to be improved with the launch of the new data system in October of 2015, and utilization of data for assessment of program and staff performance will be a priority.

While the audit has revealed several inconsistencies within the FPS related to law, rule and practice, it will serve as a baseline for performance improvement. The program has begun the development of a corrective implementation plan and will start working on these improvements as soon as possible.


Nicholas A. Toumpas
Commissioner

*The Department of Health and Human Services' Mission is to join communities and families in providing
opportunities for citizens to achieve health and independence.*

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**STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD PROTECTION SECTION**

**APPENDIX C
SELF-INSPECTING JURISDICTION SURVEY RESULTS**

We surveyed the 15 self-inspecting jurisdictions active at the end of State fiscal year 2014 and 12 completed the survey, for a response rate of 80 percent. Survey questions sought standardized responses and prompted the respondents to provide more information when warranted. We combined and simplified similar answers to the open-ended questions and present them in topic categories. Some totals in the following tables may not add up to 100 percent due to rounding or where respondents could respond multiple times to the same question.

Q1. What is your title/position?		
Answers Provided	Response Count	Response Percent
Health Officer, Inspector, Chief, or Director	10	83
Director or Manager of Building, Zoning, Licensing, Inspections, or Code Enforcement	2	17
<i>answered question</i>	12	
<i>skipped question</i>	0	

Q2. How many employees, excluding contractors, in your jurisdiction:		
Answer Options	Response Count	Response Percent
Have food protection responsibilities of any type?	12	100
Conduct food establishment inspections?	12	100
Conduct food establishment licensing?	12	100
Provide administrative or support functions?	12	100
Have another food protection responsibility?	12	100
<i>answered question</i>	12	
<i>skipped question</i>	0	

Q2. (Continued) How many employees, excluding contractors, in your jurisdiction:					
	Have Food protection responsibilities of any type?	Conduct food establishment inspections?	Conduct food establishment licensing?	Provide administrative or support functions?	Have another food protection responsibility?
Minimum	1	1	1	0.5	0
Maximum	8	6	6	3	6
Average	2.4	1.8	1.8	1.5	1.6
Median	2	1	1.3	1	1
Totals	29	22	21.5	17.5	19
<i>answered question</i>					12
<i>skipped question</i>					0

Q3. Does your jurisdiction use contractors?		
Answer Options	Response Count	Response Percent
Yes	1	8
No	11	92

answered question **12**
skipped question **0**

Q4. How many full-time equivalent contractors in your jurisdiction:				
Have food protection responsibilities of any type?	Conduct food establishment inspections?	Conduct food establishment licensing?	Provide administrative or support functions?	Have another food protection responsibility?
0	0	0	0	0

answered question **1**
skipped question **11**

Q5. Do food protection employees receive food sanitation-related education, training, or certification?		
Answer Options	Response Count	Response Percent
Yes	12	100
No	0	0

answered question **12**
skipped question **0**

Q6. Is the education, training, and certification employees received adequate?		
Answer Options	Response Count	Response Percent
Yes	10	83
No (Please explain why not.)	2	17

answered question **12**
skipped question **0**

Q6. Text Comments. Please explain why not.	
Inadequate funding at the local level	1
Due to limited staffing, not enough training from the Food Protection Section	1

provided comment **2**

Q7. Who was responsible to ensure adequate employee education, training, and certification?		
Answer Options	Response Count	Response Percent
The local jurisdiction	7	58
The State Department of Health and Human Services (DHHS)	3	25
Another State agency	0	0
Other	2	17
	<i>answered question</i>	12
	<i>skipped question</i>	0

Q7. Text Comments. Other.	
All of the above.	1
The inspector's responsibility.	1
	<i>provided comment</i>
	2

Q8. How many food establishments are in your jurisdiction?	
Minimum	62
Maximum	850
Average	249.8
Median	182
Total	2,997
	<i>answered question</i>
	12
	<i>skipped question</i>
	0

Q9. Are all types of food establishments offering food for public consumption subject to local "regulation?" "Regulation" is defined as the licensing or inspection of establishments to help ensure compliance with existing local food safety standards.		
Answer Options	Response Count	Response Percent
Yes	10	83
No	2	17
	<i>answered question</i>	12
	<i>skipped question</i>	0

Q10. What types of food establishments or types of food are not “regulated” by your jurisdiction? “Regulated” is defined as the licensing or inspections of establishments to help ensure compliance with existing food safety standards.		
Answer Options	Response Count	Response Percent
The following type(s) of establishments or food are not locally regulated, but the State Food Protection Section regulates them:		
Homestead businesses	2	100
The following type(s) of establishments or food are not locally regulated, and the State Food Protection Section does NOT regulate them:		
Bed and Breakfast, Vending Machines	1	50
Recreation Camps	1	50
	<i>answered question</i>	2
	<i>skipped question</i>	10

Q11. How many “routine” food establishment inspections are completed by your jurisdiction each year? “Routine” can be defined as being a periodic inspection conducted as part of an on-going regulatory scheme.	
Minimum	62
Maximum	1,697
Average	519.3
Median	360
Total	6,231
	<i>answered question</i>
	12
	<i>skipped question</i>
	0

Q12. Has your jurisdiction established a minimum frequency standard for routine food establishment inspections?		
Answer Options	Response Count	Response Percent
Yes	11	92
No	1	8
	<i>answered question</i>	12
	<i>skipped question</i>	0

Q13. What is the established routine inspection frequency?		
Answer Options	Response Count	Response Percent
At least one inspection every three years for all establishments	0	0
At least one inspection every two years for all establishments	0	0
At least one inspection every year for all establishments	2	18
At least two inspections every year for all establishments	7	64
At least four inspections every year for all establishments	0	0
More than four inspections every year for all establishments	0	0
We have different inspection frequencies for different establishment types (please explain)	2	18
	<i>answered question</i>	11
	<i>skipped question</i>	1

Q13. Text Comments. We have different inspection frequencies for different establishment types (please explain).	
At least two inspections a year with higher risk establishments receiving more frequent inspection.	2
	<i>provided comment</i>
	2

Q14. How many “non-routine” inspections of food establishments occurred during 2014? “Non-routine” would include follow-up inspections resulting from a deficiency discovered during a routine inspection, pre-opening inspections of establishments, and any inspection not defined as “routine.”	
Minimum	4
Maximum	1,352
Average	221.3
Median	100
Total	2,656
	<i>answered question</i>
	12
	<i>skipped question</i>
	0

Q15. Does your jurisdiction undertake other types of inspections?		
Answer Options	Response Count	Response Percent
No	2	17
Yes (Please specify type and quantity per year.)	10	83
	<i>answered question</i>	12
	<i>skipped question</i>	0

Q15. Text Comments. Please specify type and quantity per year.	
Inspections: 343 septic and well, 17 school/daycare, 66 body art/massage, 63 housing, 63 beach, 128 nuisances, and 28 groundwater protection.	1
Inspections: food, housing, electrical, plumbing, life safety, and building.	1
Inspections: sanitation for housing.	1
Inspections: 30-70 complaint inspections per year, plus 10-20 educational trainings per year.	1
Inspections: 18 temporary and occasional establishments per year.	1
Inspections: school, day care, foster care, public swimming pools, mobile food vendors, communicable disease, beach inspections, and septic systems.	1
Inspections estimated during FY 2014: 125 pool and spa, 24 institutional, 14 housing, and 53 land-use.	1
Inspections: approximately 20 housing, three school, five child or foster care, and 18 septic.	1
Inspections: septic.	1
Inspections: child care, tenant complaints, and nuisance inspections.	1
<i>provided comment</i>	10

Q16. Does your jurisdiction publically post the results of an inspection?		
Answer Options	Response Count	Response Percent
Yes	2	17
No (Why are results not publicized?)	10	83
<i>answered question</i>	12	
<i>skipped question</i>	0	

Q16. Text Comments. Why are results not publicized?	Response Count
Inspections are available to those who request.	5
Resource constraints in technology or staffing.	3
A desire exists to publicize results.	2
<i>provided comment</i>	10

Q17. Where does your jurisdiction post inspection results? (Check all that apply.)		
Answer Options	Response Count	Response Percent
On the city/town website	2	100
At the health department or municipal offices	0	0
The establishment must post them	0	0
Other (Please specify where results are posted.)	0	0
<i>answered question</i>	2	
<i>skipped question</i>	10	

Q18. How many “sanitation complaints” did your jurisdiction receive in 2014? “Sanitation” is defined as the cleanliness and safety of food and food preparation environments. This excludes foodborne illness complaints.	
Minimum	1
Maximum	100
Average	20.6
Median	9
Total	247
	<i>answered question</i> 12
	<i>skipped question</i> 0

Q19. Does your jurisdiction conduct investigations into sanitation complaints?		
Answer Options	Response Count	Response Percent
Yes	12	100
No (Why not? Do others conduct these investigations?)	0	0
	<i>answered question</i> 12	
	<i>skipped question</i> 0	

Q20. Are sanitation complaints always reported to the State Food Protection Section?		
Answer Options	Response Count	Response Percent
Yes	3	25
No (Please explain when they are and are not.)	9	75
	<i>answered question</i> 12	
	<i>skipped question</i> 0	

Q20. Text Comments. Please explain when they are and are not:	Response Count
No requirement to report complaint exists.	3
Only foodborne illness outbreaks or major events.	2
Only if required or requested.	2
Only for chain establishments.	1
Only complaints relative to the State’s jurisdiction.	1
	<i>provided comment</i> 9

Q21. How many “foodborne illness” complaints did your jurisdiction receive in 2014? “Foodborne illness” is defined as a sickness caused by the consumption of adulterated food.	
Minimum	0
Maximum	39
Average	7.1
Median	2
Total	85
	<i>answered question</i> 12
	<i>skipped question</i> 0

Q22. Does your jurisdiction conduct investigations into foodborne illness complaints?		
Answer Options	Response Count	Response Percent
Yes	11	92
No (Why not? Do others conduct these investigations?)	1	8
	<i>answered question</i> 12	
	<i>skipped question</i> 0	

Q22. Text Comments. Why not? Do others conduct these investigations?	
NH Disease Control conducts the illness investigation and local jurisdiction conducts the food inspection.	1
	<i>provided comment</i> 1

Q23. Are foodborne illness complaints always reported to the State Food Protection Section?		
Answer Options	Response Count	Response Percent
Yes	7	58
No	5	42
	<i>answered question</i> 12	
	<i>skipped question</i> 0	

Q23. Text Comments. Please explain when they are and are not:		Response Count
Only foodborne illness outbreak or a major event.		2
Only when confirmed case of foodborne illness.		2
No requirement to report complaint exists.		1
	<i>provided comment</i>	5

Q24. Does your jurisdiction publically post the results of an investigation?		
Answer Options	Response Count	Response Percent
Yes	0	0
No (Why are results not publicized?)	12	100
	<i>answered question</i> 12	
	<i>skipped question</i> 0	

Q24. Text Comments. Why are results not publicized?	Response Count
Investigations are available to those who request	6
A desire exists to publicize results	3
Resource constraints (technology or staffing)	1
Investigations are not conducted by self-inspecting jurisdiction	1
Investigations are rarely confirmed	1
<i>provided comment</i>	12

Q25. Where does your jurisdiction publically post the results of all investigations? (Check all which apply.)		
Answer Options	Response Count	Response Percent
On the city/town website	0	0
At the health department or municipal offices	0	0
The establishment must post them	0	0
Other (Please specify.)	0	0
<i>answered question</i>	0	
<i>skipped question</i>	12	

Q26. Indicate which set of food protection regulations your jurisdiction has adopted: (Check all which apply.)		
Answer Options	Response Count	Response Percent
The complete State Code of Administrative Rules Chapter He-P 2300, <i>Sanitary Production and Distribution of Food</i>	7	58
A full version of the U.S. Food And Drug Administration <i>Food Code</i>	5	42
Parts of the State Code of Administrative Rules Chapter He-P 2300, <i>Sanitary Production and Distribution of Food</i>	4	33
A modified version of the U.S. Food And Drug Administration <i>Food Code</i>	2	17
Another regulatory standard (please specify below)	2	17
We developed our own standards (please describe below)	0	0
<i>answered question</i>	12	
<i>skipped question</i>	0	

Q26. Text Comments. Please describe.	Response Count
An older version of the He-P 2300 <i>Sanitary Production and Distribution of Food</i>	3
A modified version of the He-P 2300 <i>Sanitary Production and Distribution of Food</i> , with some exclusions	1
<i>provided comment</i>	4

Q27. How often does your jurisdiction perform co-inspections with State Food Protection Section inspectors?		
Answer Options	Response Count	Response Count
Frequently	0	0
Infrequently	7	58
Never	5	42
<i>answered question</i>	12	
<i>skipped question</i>	0	

Q27. Text Comments. If it occurs, under what circumstances do you usually perform co-inspections with the State Food Protection Section?	Response Count
Training and assistance	2
For training, but co-inspections rarely occur	1
<i>provided comment</i>	3

Q28. How often does your jurisdiction perform co-investigations with the State Food Protection Section inspectors?		
Answer Options	Response Count	Response Percent
Frequently	0	0
Infrequently	7	58
Never	5	42
<i>answered question</i>	12	
<i>skipped question</i>	0	

Q28. Text Comments. If it occurs, under what circumstances do you usually perform co-investigations with the State Food Protection Section?	Response Count
Foodborne illness confirmed or outbreak	2
U.S. Food and Drug Administration involvement	1
If an investigation requires involvement of multiple jurisdictions	2
<i>provided comment</i>	5

Q29. Does your jurisdiction have an agreement of any type (e.g., memorandum of understanding [MOU], memorandum of agreement [MOA]) with the State DHHS or the State Food Protection Section?		
Answer Options	Response Count	Response Percent
No	5	42
Yes, we have one agreement	7	58
Yes, we have several agreements (How many?)	0	0
<i>answered question</i>		12
<i>skipped question</i>		0

Q30. [For jurisdictions with an MOA] Does the agreement with the State Food Protection Section need to be updated?		
Answer Options	Response Count	Response Percent
No	3	43
Yes (Please explain why.)	4	57
<i>answered question</i>		7
<i>skipped question</i>		5

Q30. [For jurisdictions with an MOA] Text Comments. Please explain why.	Response Count	
Updates are made when scheduled	2	
Need to reference new <i>Food Code</i>	1	
Governing body has not signed a new MOA	1	
<i>provided comment</i>		4

Q31. [For jurisdictions with an MOA] Does the DHHS or the State Food Protection Section annually evaluate your jurisdiction's compliance with the agreement?		
Answer Options	Response Count	Response Percent
Yes	1	14
No, they never evaluate compliance	4	57
No, less frequent than annually (Please describe the frequency.)	2	29
<i>answered question</i>		7
<i>skipped question</i>		5

Q31. [For jurisdictions with an MOA] Text Comments. Please describe the frequency.	Response Count	
Unknown	1	
Reviewed and signed every three years	1	
<i>provided comment</i>		2

Q32. [For jurisdictions with an MOA] Have food service inspectors received inspection training from the DHHS? (Check all which apply.)		
Answer Options	Response Count	Response Percent
No	0	0
Yes, at quarterly meetings	6	86
Yes, at other events (Please describe those other events.)	4	57
<i>answered question</i>		7
<i>skipped question</i>		5

Q32. [For jurisdictions with an MOA] Text Comments. Please describe those other events.	Response Count
<i>Food Code training or special training</i>	3
<i>Training only done for initial hire of inspector</i>	1
<i>provided comment</i>	4

Q33. [For jurisdictions with an MOA] Are all food service inspectors certified in at least one food manager program approved by the American National Standards Institute (ANSI) Conference for Food Protection (CFP)?		
Answer Options	Response Count	Response Percent
Yes	7	100
No	0	0
<i>answered question</i>		7
<i>skipped question</i>		5

Q34. [For jurisdictions with an MOA] Did your jurisdiction provide an annual statistical report of its activities to the State Food Protection Section in 2014?		
Answer Options	Response Count	Response Percent
Yes	1	14
No	6	86
<i>answered question</i>		7
<i>skipped question</i>		5

Q35. [For jurisdictions with an MOA] Did your jurisdiction provide copies of local regulations to the State Food Protection Section in 2014?		
Answer Options	Response Count	Response Percent
Yes	2	29
No	5	71
<i>answered question</i>		7
<i>skipped question</i>		5

Q36. [For jurisdictions with an MOA] Are other requirements imposed on your jurisdiction by the State Food Protection Section?		
Answer Options	Response Percent	Response Percent
No	6	86
Yes (Please describe those requirements.)	1	14
	<i>answered question</i>	7
	<i>skipped question</i>	5

Q36. [For jurisdictions with an MOA] Text Comment. Please describe those requirements.	Response Count
Follow-up on compliance with a recall	1
	<i>provided comment</i>
	1

Q37. [For jurisdictions without an MOA] Are any requirements imposed on your jurisdiction by the State Food Protection Section?		
Answer Options	Response Count	Response Percent
No	4	80
Yes (Please describe those requirements.)	1	20
	<i>answered question</i>	5
	<i>skipped question</i>	7

Q37. [For jurisdictions without an MOA] Text Comment. Please describe those requirements.	Response Count
A request to share data.	1
	<i>provided comment</i>
	1

Q38. How many meetings with the State Food Protection Section did you attend in 2014?	
Minimum	0
Maximum	6
Average	3.8
Median	4
	<i>answered question</i>
	12
	<i>skipped question</i>
	0

Q39. Are quarterly meetings adequate to provide your jurisdiction with needed training?		
Answer Options	Response Count	Response Percent
Yes	7	58
No (Why inadequate?)	5	42
	<i>answered question</i>	12
	<i>skipped question</i>	0

Q39. Text Comment. Why inadequate?	Response Count
Quarterly meetings are just informational	3
All day trainings (preferably with the U.S. Food And Drug Administration) are necessary	1
Does not attend	1
<i>provided comment</i>	5

Q40. Has your jurisdiction requested technical assistance from the State Food Protection Section?		
Answer Options	Response Count	Response Percent
Never	3	25
Yes (How many requests in 2014?)	9	75
<i>answered question</i>	12	
<i>skipped question</i>	0	

Q40. Text Comment. How many requests in 2014?	
Minimum	1
Maximum	8
Average	3.3
Median	2
Total	30
<i>answered question</i>	9
<i>skipped question</i>	3

Q41. Did you receive the requested assistance?		
Answer Options	Response Count	Response Percent
Yes	9	100
No	0	0
<i>answered question</i>	9	
<i>skipped question</i>	3	

Q42. How effectively do you believe the relationship between the State Food Protection Section and your jurisdiction is at preventing foodborne illness in your jurisdiction?		
Answer Options	Response Percent	Response Count
Very effective	6	50
Somewhat effective	4	33
Neither effective nor ineffective	2	17
Somewhat ineffective	0	0
Very ineffective	0	0
<i>answered question</i>	12	
<i>skipped question</i>	0	

Q43. Please explain the ineffectiveness you have observed.	Response Count	Response Percent
Comment	0	0

answered question **0**
skipped question **12**

Q44. What changes could improve the effectiveness of the relationship? Comments:	Response Count
Unknown, none, or relationship does not need improvement	6
Additional training and resources	2
Training and better coordination between State and local laws	1
Stricter enforcement of current regulations to ensure consistency between jurisdictions	1
More U.S. Food And Drug Administration trainings and better quality technical assistance	1
Trainings are needed to ensure a minimum standard of competency and consistency amongst inspectors. The State Food Protection Section does not conduct inspections of temporary events, occasional food events, fairs, summer camps, and long term care facilities	1

answered question **12**
skipped question **0**

Q45. Please describe any concerns you have with State food protection efforts. Comments:	Response Count
Inadequate resources	2
Inadequate resources as it relates to assistance and training of self-inspecting jurisdiction	2
Inability to inspect all of their facilities within one year due to limited staffing; also, poor enforcement actions	1
Lack of risk assessment as it relates to inspections and lack of oversight over temporary and home-based food establishments	1
Low inspection frequency per establishment due to limited staffing	1
Lack of professionalism presented to the public by a few inspectors	1
None	4

answered question **12**
skipped question **0**