

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Administration BUREAU OF AUDITS One Capitol Hill Providence, R.I. 02908-5889 TEL #: (401) 222-2768 FAX #: (401) 222-3973

November 8, 2011

Michael Fine, M.D., Director Rhode Island Department of Health Three Capitol Hill Providence, RI 02908

Dear Director Fine:

The Bureau of Audits (Bureau) has completed its review of the Rhode Island Department of Health (DOH), Office of Food Protection (OFP), Food Safety Program, which was initiated at the request of the Executive Office of Health and Human Services (EOHHS). Our review was conducted pursuant to Rhode Island General Laws (RIGL) §35-7-3 entitled "Audits performed by the Bureau of Audits" which states in part that "The bureau of audits is authorized to conduct audits of any state department, state agency, or private entity that is a recipient of state funding or state grants."

Subsection (b) of the aforementioned General Law states that "Within twenty (20) days following the date of the issuance of the final audit report, the head of the department, agency, or private entity audited shall respond in writing to each recommendation made in the final audit report..." The findings and recommendations included herein were discussed with management. Accordingly, management submitted its response to the audit findings and recommendations on November 8, 2011, and such response is included in this report.

In accordance with RIGL §35-7-3(b), the Bureau may follow up on recommendations included in our reports within one year following the date of issuance of the report.

We thank the officials and employees of the OFP for the cooperation extended to the members of our staff during the course of this review.

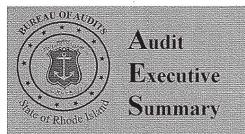
Respectfully yours,

H. Chris Der Vartanian, CPA

Chief, Bureau of Audits

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Why the Bureau Did This Review

The Bureau of Audits (Bureau) performed its review of the Rhode Island Department of Health (DOH), Office of Food Protection, at the request of the Executive Office of Health and Human Services (EOHHS).

Background Information

The Office of Food Protection (OFP) is a program within the State Department of Health. Its mission is to protect and promote public health and prevent disease by assuring the safety and quality of the food supply.

The OFP accomplishes the above through the following:

- Inspecting, reviewing plans, and licensing food establishments.
- Investigation of illness complaints and food-borne disease outbreaks.
- Provision of 24-hour emergency coverage for fires, accidents, and natural disasters involving food products.
- Protection against consumer fraud related to food.
- Development of assisted living food standards.
- Licensing of Certified Food Safety Managers.
- Monitoring water quality at beach and bathing areas.

Programs within the OFP include the Food Safety Manager Certification, Dairy Industry Program, and the Shellfish Inspection Program. The OFP partners in these efforts with the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture.

What the Bureau Found

Our audit resulted in the following findings:

- Rhode Island requirements for Certification of Food Safety Managers are confusing.
- Current statutory requirement does not mandate a food safety manager to be present during the preparation of potentially hazardous foods.
- The OFP does not currently mandate nor promote the certification of food service workers who handle food.
- State Law does not require that municipalities first obtain approval from the OFP before granting a Certificate of Occupancy or Victualing and/or Beverage License.
- Managers in the OFP are not applying standard operating procedures for the conduct of inspections in a consistent and uniform manner.
- Organizing staff by field offices that no longer physically exist has resulted in inefficiencies in the assignment of staff and inconsistencies in the inspection process.
- There is a lack of organization and control over scheduling of inspections and oversight of inspectors' assignments.
- The OFP does not have a Uniform Risk Rating Methodology for determining inspections.
- Current staffing levels cannot accommodate the required number of annual inspections.
- There is no systematic process for generating letters of suspension to licensees.
- The OFP did not prepare a statutorily required quarterly report relative to the hiring of the on-site consultant Data Manager.
- The number of hours allowed by the purchase order for the engagement of a Digital Manager Consultant differs from the actual hours that the consultant has been invoicing the OFP.
- Access to the Garrison System was not terminated with respect to some former employees of the OFP.
- The OFP is exceeding its statutory responsibilities per review of the Food/Water Licensing Coordination Policy and Procedures and RIGL §46-13.
- Data required to be collected is not always obtained during the investigation of a food-borne illness outbreak.
- The OFP does not have uniform policies or procedures for addressing, recording, or following up on complaints.
- The OFP, in calculating the federal reimbursement amount for FDA-required inspections, has been using non-current wage information. As a result, the OFP has been understating payroll costs in its reimbursement calculation; consequently receiving less money in federal reimbursements than it is entitled.

INTRODUCTION

Objectives, Scope, and Methodology

At the request of the Executive Office of Health and Human Services (EOHHS), the Bureau of Audits (Bureau) conducted an audit of the Office of Food Protection (OFP) for the period January 1, 2010, to April 30, 2011. The scope of our audit was limited to OFP's Food Protection Program and consequently did not encompass OFP's Beach Monitoring Program.

Pursuant to the above, we evaluated current business policies and procedures, the organizational structure, efficiency of operations, and compliance with significant laws and regulations of the OFP. The Bureau performed tests of transactions related to routine inspections as well as to those inspections initiated as a result of complaints, reviewed recommendations suggested by the Food and Drug Administration (FDA) regarding mandated inspections and enforcement actions, and reviewed similar programs in other states with the intent of identifying effective best practices that might be considered for implementation in the State of Rhode Island. We also tested the adequacy of the request for reimbursement made by the OFP from the Federal Government regarding FDA inspections pursuant to a Memorandum of Agreement (MOA) between the OFP and FDA.

The Bureau discussed its findings and recommendations with management and considered its comments in the preparation of this report. Rhode Island General Law (RIGL) §35-7-3(b) entitled "Audits performed by the bureau of audits" states in part that "Within twenty (20) days following the date of the issuance of the final audit report, the head of the department, agency; or private entity audited shall respond in writing to each recommendation made in the final audit report..." Accordingly, management submitted its response to the audit findings and recommendations on November 8, 2011. Said response is included in this report.

Background

The Department of Health (DOH) is responsible for a broad range of public health oversight responsibilities, including food safety. OFP is a program within the State DOH. Its mission is to protect and promote public health and prevent disease by assuring the safety and quality of the food supply.

The OFP accomplishes the above through the following:

- Inspecting, reviewing plans, and licensing food establishments.
- Investigating illness complaints and food-borne disease outbreaks.
- Providing 24-hour emergency coverage for fires, accidents, and natural disasters involving food products.
- Protecting against consumer fraud related to food.
- Developing assisted living food standards.
- · Licensing Certified Food Safety Managers.
- Monitoring water quality at beach and bathing areas.

Programs within the OFP include the Dairy Industry Program and the Shellfish Inspection Program. The OFP partners in these efforts with the FDA and the Department of Agriculture.

In 1994 the DOH promulgated the Food Code, a regulation based on the FDA Food Code, which was developed for the purpose of establishing minimum standards for food safety and sanitation in food businesses and food establishments. The OFP amended the Food Code in January 2002 and again in October 2007 to reflect changes in the updated FDA Code.

Food control is defined as:

... a mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all foods during production, handling, storage, processing, and distribution are safe, wholesome, and fit for human consumption; conform to safety and quality requirements; and are honestly and accurately labeled as prescribed by law. ¹

Effective food control systems are essential to protect the health and safety of consumers. As a result of consumers taking unprecedented interest in the way food is produced, processed, and marketed, there is an increased calling for the Government to accept greater responsibility for food safety and consumer protection.

The primary responsibility of food control is to enforce the food law(s) protecting the consumer against unsafe, impure, and fraudulently presented food by prohibiting the sale of food not of the nature, substance, or quality as standards dictate. In addition, FDA guidelines suggest that regulators consider a proactive approach as part of their programs, including outreach and education, to prevent food-borne illnesses.

The OFP employs inspectors who are responsible for the administration, implementation, and enforcement of the Food Code. These individuals have day-to-day contact with the food industry (establishments) and are responsible for investigating food-borne illness complaints and performing the following types of inspections:

- New establishment/new license,
- · New owner for an existing establishment,
- · Establishment damaged by fire or flood,
- FDA contracted inspection,
- · Routine inspection, and
- Re-inspection due to critical violations found during routine inspection.

In 1978 there were 7,888 licensed establishments, and the OFP employed as many as 45 food inspectors, senior inspectors, and supervisors located at 4 satellite field offices; in 1990 there were 7,224 licensed establishments, and there were as many as 18 food inspectors, senior inspectors, and supervisors located at 3 satellite field offices; in 2002 there were 7,756 licensed establishments, and there were as many as 13.5 food inspectors, senior inspectors, and supervisors located at one field office. As of April 30, 2011, there were 8,369 licensed establishments, and there were 13 inspectors, senior inspectors, and supervisors.

¹ "Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems," a joint report from the Food and Agriculture Organization of the United Nations and the World Health Organization.

FINDINGS, RECOMMENDATIONS, AND MANAGEMENT'S RESPONSE

PROACTIVE MEASURES TO PREVENT FOOD-BORNE ILLNESS

The Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. The Act aims to ensure that the U.S. food supply is safe by shifting the focus of federal regulators from reacting to food contamination at the time that it occurs to focusing on preventing food-borne illness. Under this model, it is important to not only focus on food establishments that traditionally have been problematic, but to emphasize the importance of food safety education for the workers at all food establishments. Food safety education is essential to ensuring that the proper procedures for handling and preparing food are followed in all establishments. Recommendations made herein with respect to proactive practices are intended to ensure awareness at every level of food preparation in those licensed establishments that handle and prepare potentially hazardous foods² and to emphasize an environment of self monitoring.

RIGL §21-27-11.6 entitled "Requirements of food establishments" calls for food establishments that prepare potentially hazardous foods to employ at least one full-time manager certified in food safety; establishments that employ ten (10) or more full-time equivalent employees directly involved in food preparation to employ two (2) managers certified in food safety; and establishments that primarily serve the elderly and individuals with diminished immune systems have a manager certified in food safety present during preparation of all hot potentially hazardous foods. A certified food safety manager is educated about hazards which may make food injurious to the health of the consumer and also about proactive steps to prevent such hazards from occurring. This certification program is offered through the National Restaurant Association (NRA). The food safety manager is a line of defense between potentially hazardous foods and the consumer.

Confusion exists as to licensing requirements of Certified Mangers in Food Safety

The OFP requires individuals who seek certification by the State of Rhode Island in food safety to first meet the requirements of the certificate program known as "ServSafe" administered by the NRA. The NRA certificate is valid for a period of five years. RIGL §21-27-11.5 states that [state] certificates issued shall expire triennially unless sooner suspended or revoked. After the food safety manager is initially certified by the State, he or she, on a go-forward basis, needs only to complete the triennial requirements for State recertification – completing six hours of State-approved education in food safety and paying the current renewal fee of \$50.00. The food safety manager does not need to renew his or her certificate through the NRA after its expiration in five years, nor does the individual need to meet the NRA re-certification requirements.

During our review, we noted that many individuals who are certified in food safety do not understand the State requirements for the certificate program, and it is unclear to them whether they need to complete re-certification requirements of the NRA certificate program.

²Potentially hazardous foods is defined in RIGL §21-27-11.1 as "any food or food ingredient, natural or synthetic, in a form capable of supporting: (i) the rapid and progressive growth of infectious or toxigenic microorganisms, or (ii) the slower growth of Clostridum botulinum" [a bacterium that produces neurotoxins].

³RIGL 21-27-11.8 provides exemptions to this provision, including: (1) special events sponsored by a city or town or nonprofit civic organization; (2) temporary food services having a frequency of less than six events per year; (3) itinerant vendors and other food establishments that serve only commercially pre-packaged foods, beverages, and commercially precooked potentially hazardous foods requiring no manual handling; (4) retail food stores and delicatessens where only cold foods are prepared; (5) private homes, and bed and breakfast establishments; (6) any private or public housing complex designated by the Federal Government as housing for the elderly in connection with limited, not-for-profit sales of food to residents; and (7) private clubs which do not charge the general public for sale of food or beverages which serve less than 20 at any one time or less than 100 meals per month.

⁴Managers of municipal or state food establishments are exempt from payment of the fee set forth in this section.

Finding 1 – The requirements of Rhode Island State Law are confusing as to whether Certified Food Managers need to renew the NRA ServSafe Certification subsequent to the five-year expiration date.

Recommendation:

The Bureau recommends that the OFP clarify its requirements in all written certification and renewal materials and on its website; and if possible, notify all current certified managers in food safety as to the State requirements.

Management's Response:

The Department agrees with the recommendation to clarify food manager recertification requirements in all written certification and renewal materials and on its website. Clarification of current requirements is provided in the Appendix.

Current law does not require a Certified Food Safety Manager to be present when food is prepared in most establishments

As noted earlier in this report, RIGL §21-27-11.6 requires food establishments that prepare potentially hazardous foods to employ at least one full-time manager certified in food safety and establishments that employ ten (10) or more full-time equivalent employees directly involved in food preparation to employ two (2) managers certified in food safety. However, only those establishments that primarily serve the elderly and individuals with diminished immune systems are required to have a manager certified in food safety present during the preparation of all potentially hazardous foods.

A more proactive approach to food safety would require any food establishment that prepares potentially hazardous foods to have a Certified Food Safety Manager present whenever food preparation takes place. This requirement was recently contemplated in the 2011 legislative session via House Bill 5086 introduced by Representative Joseph McNamara. Contained in this Bill was a clause stating that food establishments engaging in activities considered to present a certain food safety risk must have a certified food manager(s) present whenever food preparation is in process.

Finding 2 – Current State requirement that food establishments hire a manager certified in food safety is deficient, in that in most cases it does not mandate a food safety manager to be present during the preparation of all potentially hazardous foods.

Recommendation:

The Bureau recommends that the OFP pursue legislation [possibly similar to House Bill 5086 introduced in the 2011 legislative session] requiring a manager certified in food safety be present during the preparation of all potentially hazardous foods.

Management's Response:

The Department strongly agrees with the recommendation and the Department will request that legislation be introduced similar to House Bill 5086 to require that a manager certified in food safety be present during preparation of potentially hazardous foods.

No current requirement for food handler/worker to be educated in basic food safety

As noted in the previous section, State law requires most food establishments to have a certified food safety manager on staff. It does not, however, require individuals who handle food (e.g., waiters, cooks, etc.) be trained in food safety.

The Bureau learned in its review of best practices utilized by food protection regulators outside of Rhode Island that many jurisdictions have implemented programs requiring all individuals who handle food to be educated in food safety. Such programs require all food handlers to enroll in a food safety self-study course followed by an examination. Once the examination is passed, the food handler receives a food handler certificate/card indicating that they have basic knowledge of food safety. In the states that require this certification, the food handler/worker card is typically valid for a two-to three-year period for a minimal (ten dollar) fee. This measure ensures that all food service workers, who traditionally have little or no formal training regarding proper food handling, are educated in basic food safety thus reducing the potential impact of food-borne illness.

Finding 3 – The OFP does not currently mandate nor promote the certification of food service workers who handle food.

Recommendation:

Propose legislation or create a regulation that would require food handlers/workers to attain a basic knowledge of food safety by taking a self-study course culminated by an examination and the issuance of a food handler/worker card.

Management's Response:

The Department agrees with the recommendation and legislation will be requested to require that food handlers/workers be trained and tested and that they be provided a card demonstrating that they have obtained basic knowledge in food safety.

Law does not require municipalities to first ensure that the OFP has approved the license of food establishments prior to issuing Certificates of Occupancy or Victualing Licenses

Municipalities issue certificate of occupancy and victualing⁵ licenses to businesses that wish to operate in their jurisdictions. State law requires that establishments be in compliance with all laws before the aforementioned municipal licenses are issued. There is a State requirement that a license be obtained from the OFP prior to opening a food establishment.

Per the OFP, most communities have implemented a protocol for first obtaining approval from the OFP prior to granting an initial Victualing and/or Liquor License. There is, however, no specific statutory requirement that municipalities ensure that a food establishment be licensed by the OFP before issuing a Certificate of Occupancy or a Victualing License. Additionally, not all municipalities license food markets or food processors, and, as such, the municipalities may not contact the OFP for approval prior to granting a Certificate of Occupancy. Such a requirement would ensure that food establishments and other establishments that prepare food on the premises have been approved to operate by the OFP before a municipal license is granted.

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⁵ A Victualing License is required by any business where food is prepared and/or consumed on the premises.

Finding 4 – State Law does not require that municipalities first obtain approval from the OFP before granting a Certificate of Occupancy or Victualing and/or Beverage License to a food establishment that prepares food on its premises.

Recommendation:

Propose legislation that would require municipalities to obtain approval or proof of licensing from the OFP prior to granting a Certificate of Occupancy and a Victualing and/or Beverage License to an establishment that prepares food on its premises.

Management's Response:

The Department agrees and such legislation will be proposed.

OPERATIONS OF ORGANIZATION NOT CONSISTENT AND EFFICIENT

OFP management is not applying standard operating policies and procedures consistently

The OFP has a standard operating policy and procedure manual for the conduct of inspections of food establishments. This manual provides a uniform process for conducting the inspections.

During our review, which consisted of interviewing OFP staff, reviewing policies and procedures, and verifying the application and implementation of the policy and procedure manual, we learned that the policy and procedures were not being applied consistently by staff as a result of different management directives.

The fact that management oversight has been applied inconsistently seems to have resulted in varying quality levels of inspections and misunderstandings regarding standard operating procedures.

Finding 5 – Managers in the OFP are not applying standard operating procedures for the conduct of inspections in a consistent and uniform manner.

Recommendation:

All managers should ensure that OFP staff is conducting inspections in a consistent and uniform manner in conformity with standard operating procedures. The director of the agency must ensure that managers are applying office standards consistently and properly.

Management's Response:

The Department will initiate a quality assurance process with additional performance measures posted on the Department's dashboard and assessed by management of the Office of Food Protection.

Organizational structure is not consistent with effective practices

Dating back to 1990, the OFP had three field office locations in the East Bay, the Southern Region, and the Metro/Northern Region of Rhode Island. The physical locations for these "field offices" no longer exist, and all of the OFP staff is located in the DOH Building in Providence.

Although there are no longer physical field office locations, the inspection staff, to-this-date, are assigned to these locations as if they exist. Additionally, employees bid for the opportunity to work in these non-existent offices. Due to the fact that there are no longer physical field offices, the process for assigning

employees should be reviewed and revised to allow management to deploy its staff resources in a more efficient manner and ensure that standard operating policies and procedures are applied consistently.

Finding 6 – Organization by field offices that no longer exist has resulted in inefficiencies in the assignment of staff and inconsistencies in the inspection process.

Recommendation:

The Bureau recommends the OFP eliminate assignments by "field offices" and instead assign inspections based on factors such as expertise, need, and staff availability.

Management's Response:

The Office of Food Protection will be restructured based on expertise needed to comply with federal mandates for milk and shellfish products, conduct FDA contract inspections for interstate commerce, investigate foodborne outbreaks and high hazard complaints, conduct opening inspections, and assure food safety from farm to table throughout the state. A new Office of Food Protection food safety plan (based on Healthy People 2020 Objectives) will also be used to structure the Office to have the greatest impact in reducing illnesses, assure uniformity, focus on the most critical hazards to health in the highest risk facilities, and assure rapid and effective follow-up to make certain the greatest hazards to health are quickly eliminated.

Lack of organization and control over scheduling of inspections

We reviewed the methodology utilized by OFP management in assigning staff and senior staff to inspections to determine whether the process is efficient.

During the course of our field work, we learned that there is no consistent method of assigning work schedules to inspectors or senior inspectors. The current process is to produce a list of food establishments requiring inspection on a quarterly basis, sort this information by city or town, organize the information by the no longer existent "field offices" (discussed above in Finding 6), and distribute to the staff assigned to these "field offices." There is little or no direction provided to the inspection staff to prioritize this list. They subjectively select the establishments they wish to inspect on any given day. This subjective method results in confusion, inconsistent periods of time between routine inspections, inability to easily track the inspection status of establishments never inspected, and inefficient use of the inspectors' time.

In addition to receiving the aforementioned list, the inspectors are called upon during the course of their day to respond to complaints and opening ("new or initial") inspections. These last-minute tasks are often considered "emergencies" and may result in inspectors having to backtrack to locations from where they just left and possibly leaving inspections incomplete. The complaints and opening inspection information is organized in an ad hoc manner and is not tracked in a database nor included on any list provided to inspectors.

This lack of proper planning and scheduling has resulted in a disorganized approach to the day-to-day operations of this unit. Additionally, the lack of proper control over the schedule often times results in an inefficient use of inspectors' time and an increase in mileage reimbursement costs.

Finding 7 – There is a lack of organization and control over scheduling of inspections and oversight of the inspectors' assignments.

Recommendation:

Develop a uniform methodology for selecting and assigning routine inspections, new establishment inspections, and follow-up inspections to ensure that all food establishments are inspected within the time period required by statute, regulation, and/or policy. Additionally, this methodology should consider a more efficient approach in addressing daily complaints.

Management's Response:

The Department agrees that greater control over scheduling inspections is needed. (The current methodology used in assigning inspections is described in the Appendix). With the FY2011 level of staffing, the lowest risk food establishments would be inspected once every 6 years. With the 12 additional inspectors recommended in the audit, the target would be to inspect the highest risk food establishments twice per year and the lowest risk establishments once every two years.

To greatly improve supervisory control over scheduling, the Department will provide inspectors with smart phones. Staff will also use the GroupWise shared Calendar and the scheduling module in the inspection data management system. The Office will also be restructured and a quality assurance system will be implemented to make certain that the highest priority inspections are conducted.

DETERMINATION OF REQUIRED INSPECTIONS AND ESTIMATE OF INSPECTORS NEEDED

The OFP does not have a uniform risk rating methodology for determining inspections

During our review we noted that the OFP did not have a process in place for determining the risk presented by the various types of licensed food establishments. Additionally, the OFP does not have a systematic method of determining how frequently these establishments should be inspected.

We met with Dr. Ernest Julian, Chief of the Office of Food Protection, to discuss this matter. Dr. Julian suggested that the risk model published by the FDA provides an appropriate approach for the OFP to assign risk to licensed food establishments.

Accordingly, the OFP modeled its risk assessment after the example provided by the FDA using four risk categories as follows: Category 4 – High Risk (e.g., preschools, hospitals, nursing homes, retail food processors, etc.); Category 3 – Advance Preparatory (e.g., full-service restaurants, extensive menu of raw ingredients and complex preparation of cooking, cooling, and reheating); Category 2 – Cook/Serve (e.g., retail food store operations, schools not serving highly susceptible population, and quick-serve operations); and Category 1 – Low Risk (e.g., most convenience stores, hot dog carts, and coffee shops).

With regard to scheduling inspections, the OFP established a protocol for the frequency of inspecting the various risk categories of food establishments as follows: Category 4 – two times per year; Category 3 – one inspection every eight months; Category 2 – one inspection per year; and Category 1 – one inspection every two years. Going forward, the number of inspections required annually total 9,760.

Finding 8 - The OFP does not have a uniform risk rating methodology for determining inspections.

Recommendation:

Management should maintain a risk rating for all establishments; such rating should be updated each time an establishment is inspected. Management should implement standard operating procedures to define the risk ratings and frequency for which they should be updated and use this as a platform for

scheduling inspections. The Bureau noted that the OFP implemented this recommendation during the course of this audit.

Management's Response:

While the audit found there were over 2,700 establishments with no risk assigned, this was due to the fact that these facilities had not been inspected since 2007, not due to the lack of a risk rating system (The risk categories assigned by staff during inspections are described in the Appendix). The Office of Food Protection will contact Garrison Enterprises to determine if a means can be developed to assign a risk rating to a facility in the inspection data management system that has not been inspected. Facilities that have not been inspected will be a priority for inspection as new staff are added and a risk rating will be assigned at the time of inspection.

Current staffing levels can not accommodate the required number of annual inspections

FDA guidelines suggest there be one inspector for every 280 to 320 inspections. The number of inspections required annually, (based on licensed establishments on the date of this audit, a number which fluctuates directly with the economic climate), is approximately 9,760. Thus, based on the higher end – 320 inspections per inspector – of the FDA guidelines, approximately 30 inspectors would be needed in the State of Rhode Island to perform the required number of inspections. This figure takes into consideration additional inspections that must be performed annually, including follow-up inspections, new establishment opening inspections, FDA mandated inspections, and complaint inspections which were determined by considering historical data.

According to data provided by the OFP, the actual average of inspections per inspector in the last year was 487. This figure is 50% - 75% greater than the guidelines provided by the FDA and will probably decrease as a result of more complicated and time-consuming inspections that must be performed under the new risk policy. However, assuming the actual average of 487 inspections per inspector were factored into the equation to determine the number of inspectors needed in the State of Rhode Island, approximately 20 inspectors would be needed to perform the required number of inspections.

The figures above reflect the estimated number of inspectors needed to perform the 9,760 required inspections, assuming that all new inspectors will be able to immediately perform 487 inspections per year. However, the Bureau was informed that it takes between six months to one year to train a new inspector where he or she is able to perform all types of inspections on his or her own. Consequently, time needed to train new inspectors must be factored into the hiring equation.

The OFP has eight FTE's currently available to perform inspections determined as follows:

The OFP has seven inspectors available to perform routine, follow-up, new establishment openings, FDA-mandated, and complaint inspections. Also, there are three senior inspectors available to perform the duties set forth in their job description; and when special circumstances arise, they shall also inspect other food establishments at the request of his/her supervisors, as well as problematic establishments. As such, the Bureau has included senior inspectors in its calculation of current staff available to perform inspections. The Bureau estimated that each senior inspector could perform approximately one third of the inspections a staff inspector performs on a yearly basis. The Bureau noted that of the three senior inspectors, one is not dedicated full-time to OFP job responsibilities, but still approximates that the three combined could perform the work of one staff inspector.

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⁶ This estimate assumes that the total number of establishments subject to inspection will remain the same from year to year.

⁷ Based upon the inspection system data, the current staff performs annually an average 487 inspections each.

Therefore, it is evident that the OFP must hire at least 12 additional inspectors and potentially more considering that significant time is needed to train new inspectors, which, as noted above, must be factored into the hiring equation; and future inspections will be more extensive than they have been in past years.

Finding 9 - Current staffing levels cannot accommodate the required number of annual inspections.

Recommendation:

The Bureau recommends management increase the total number of inspectors assigned to this unit by at least 12 inspectors, a number that must be re-evaluated periodically in consideration of the number of licenses issued and the average number of annual inspections being performed by inspectors.

Management's Response:

The Department agrees that the number of food inspectors needs to be increased by at least 12 inspectors to inspect food establishments at half the frequency recommended by FDA. The number of inspectors needed is likely to rise as staff transition from partial to complete inspections. The Department will report back to the Governor and legislature as to staffing needs one year after new staff have been added. The Appendix provides a description of what levels of inspection can be performed at different levels of staffing.

DATABASE RELIABILITY AND USE OF SYSTEMS

Lack of automated correspondence for license suspension and pending suspension notifications resulting from non-payment of license renewal fee

Licensees are required to pay an annual licensing renewal fee. RIGL §23-1-20 entitled "Compliance order" states that whenever a violation of a law occurs, the director may give notice in writing of the alleged violation to the person responsible. This notice shall set forth the alleged violation and shall provide for a time within the violation for remedy, and shall inform the person or entity that a written request for a hearing may be requested within ten days after service of the notice. The notice is considered properly served if a copy of the notice is served upon the person or entity personally, or sent by registered or certified mail to the last known address of that person. Licensees who do not pay the renewal fee in a timely manner are in violation of this statutory requirement.

With respect to cases where license renewal payments are not received timely, the Bureau noted that the system is capable of generating a letter to the licensee notifying the entity of a pending suspension of license for non-payment. However, this letter is not automatically generated by the licensing system and mailed in a timely manner. Instead the OFP has established a practice of reviewing the pending suspensions and later directing the system to produce the suspension letters which are then manually mailed by the OFP. Furthermore, the OFP has not established a procedure that requires that this review take place within a specific period of time. As a result, this practice has resulted in significant delays in sending pending suspension letters; and establishments whose licenses should be suspended, and potentially revoked for non-payment, have continued to operate. This is not in the best interest of fair competition, nor in the best interest of timely collection of licensing revenue for the State.

Finding 10 – There is no systematic process for generating letters of suspension to licensees or follow-up procedures for ensuring timely collection of licensing revenues

Recommendation:

The licensing system should automatically generate and deliver the letters for mailing to the operations center. The OFP should not be involved with the process of mailing out the lack-of-payment, pending suspension, and suspension notifications. The licensing section must ensure that all notices comply with the requirements of Rhode Island General Laws, specifically RIGL § 23-1-20 entitled "Compliance order."

Management's Response:

The Office of Food Protection is working with License 2000 staff to generate automatic suspension letters. With current staffing, a target completion date is November 1, 2012.

Statutorily required quarterly reports relating to subcontracted labor were not prepared and submitted and the purchase order is not accurate relative to the hiring of consultant

The OFP has a contract with Garrison Enterprises, Inc., (Garrison) for the maintenance and on-site support of its Digital Health Department software. This inspection system software application is web-based and retrieves data from the current licensing system to provide real-time access to electronically filed reports; enter food-related complaints; receive laboratory results on food and beach water samples; generate reports for management and inspectors; store emergency contact information and educational flyers; and transmit blast fax/email to industry during an emergency boilwater advisory, food recall, or beach closure.

With respect to the maintenance of the aforementioned system, Garrison is obligated to provide a full-time, on-site consultant (Data Manager) to manage all facets of the OFP Digital Health software and to provide information technology support to the OFP staff and management. Accordingly, Garrison submitted a cost proposal which outlined the terms for the hiring of the Data Manager. The terms of the proposal [which became part of the purchase order] stated that the Data Manager is to be physically situated in the OFP office, and work a full-time, (35-hour) workweek. The Bureau noted however that the purchase order (No. 3120288) created for this position allows for the hiring of a Data Manager for only 10 hours per week. Consequently, there is a conflict between the cost proposal attached to the purchase order and the actual purchase order.

Also, with respect to the hiring of the Data Manager/Consultant, RIGL §42-149-3 requires all agencies that contract for individuals to provide services in lieu of full-time equivalents (FTEs) to submit quarterly reports of all non-state employee expenditures for legal services, financial services, temporary workers, and other non-state employee personnel costs. The reports must be submitted to the State Budget Office and the chairpersons of the House and Senate Finance Committees, and such reports shall contain the following information:

- (1) Efforts made to identify qualified individuals or services within state government;
- (2) Factors used in choosing a non-state employee or firm;
- (3) Results of Requests for proposals for services or bids for services; and
- (4) The actual cost and the budgeted cost for the expenditure.

The OFP was unable to provide evidence that such documentation was prepared and submitted to the General Assembly regarding this position.

Finding 11 – The OFP did not prepare and submit a statutorily required quarterly report relative to the hiring of the on-site consultant Data Manager.

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Recommendation:

We recommend that the OFP comply with RIGL §42-149-3 and submit the quarterly reports to the chairpersons of the House and Senate Finance Committees and the State Budget Office relative to the hiring of the on-site consultant Data Manager.

Management's Response:

These reports are automatically generated through the RIFANS system via Accounts and Controls in order to comply with the provisions of the RIGL, 42-149-3.

Finding 12 – The number of hours allowed under the purchase order for the engagement of a Data Manager differs from the actual hours outlined in the cost proposal submitted by the vendor.

Recommendation:

We recommend that the OFP ensure that the hours worked and invoiced by the Data Manager Consultant do not exceed the number of hours allowed by the purchase order. If additional hours are required, we recommend that this matter be rectified with the Division of Purchases, and the purchase order be amended.

Management's Response:

Upon notification of audit finding, going forward the office has corrected the purchasing matter to meet recommendations.

Access to the Garrison System was not terminated with respect to some former OFP employees of the OFP.

In our audit we learned that the Garrison System contains active users who are no longer employees of the OFP. This is a security issue, in that individuals who are no longer employees of the OFP are able to access the web-based inspection software application system and alter data.

The Bureau also noticed that the OFP does not have a comprehensive policy for the administration of user access to the Garrison System.

Finding 13 – Access to the Garrison System was not terminated with respect to some former employees of the OFP, and there is not a comprehensive policy over administration of user access to the system.

Recommendation:

Management must implement a procedure whereby access to state systems, including the Garrison System, is immediately terminated upon the departure/termination of OFP employees. Management should also immediately terminate access for those former employees currently active in the system. Additionally, the OFP should develop a comprehensive process for the administration of user access to the Garrison System, including procedures for written access requests, documented review of required privileges, and management review of permissions granted.

Management's Response:

The Department agrees that when employees leave the Office of Food Protection employee access to the Garrison data processing system must be immediately terminated. Access has been removed for

former employees. The exception is that approved third parties enter school inspection reports into Garrison. Procedures for access and removal from the Garrison data processing system will be documented.

OFP has overlapping functions with Drinking Water Quality (DWQ) Program

During our audit we were made aware of an overlap in responsibilities between OFP and the (DWQ) Program in the DOH. The OFP's policies and procedures state that it is the responsibility of the DWQ Program to first administer the drinking water supply/well license requirements before the OFP issues food licenses to establishments. After notifying applicants of the DWQ Program process, OFP should take no further action with regard to licensing establishments until they receive confirmation that DWQ Program has issued its license.

Per discussion with OFP management, the OFP often performs work that should be performed by DWQ Program in order to expedite the licensing process. As a result, the OFP is expending valuable staffing resources to perform a function of another unit; resources that should be used in completing OFP functions.

Finding 14 – The Bureau found that OFP is exceeding its statutory responsibilities per review of the Food/Water Licensing Coordination Policy and Procedures by performing duties that are the responsibility of the Drinking Water Quality Program.

Recommendation

The Bureau recommends that OFP refer owners of food establishments to DWQ for proper handling of drinking water supply/well licenses and immediately cease performing drinking water supply/well reviews. Due to the limited staff within OFP, all resources need to be directed toward the inspection and regulation of food establishments for the benefit of the public.

Management's Response:

The bulk of Office of Food Protection time is devoted to food safety concerns and food establishments with wells are referred to the Office of Drinking Water Quality (DWQ). Office of Food Protection staff do collaborate with DWQ staff when appropriate.

Procedures for gathering evidence in matters related to food-borne illness outbreaks are not always followed and such procedures should be reviewed to ensure that they are necessary in addressing the actual risk of a disease

According to the regulatory definition (2005 FDA Model Food Code), a food-borne disease outbreak is defined as: the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. The OFP has food-borne illness outbreak complaint and investigation guidelines. These guidelines include step-by-step procedures for handling potential food-borne outbreak concerns, required forms and checklists to be completed by OFP, and instructions for inspectors responding to the matters. Per discussion with the OFP epidemiologist, the guidelines are often not followed (such as: incomplete forms or checklists, not collecting required samples, not obtaining a menu, etc.) resulting in collection of incomplete data during the investigation and the need for additional resources to obtain the required information after the initial investigation.

It is essential for these guidelines to be followed to ensure that adequate evidence is gathered so that the DOH can make accurate, real-time assessments regarding a potential food-borne disease outbreak and notify the public accordingly. Additionally, the OFP should review its policies and procedures to ensure that measures taken are evidenced-based, and employ processes that have been demonstrated

to reduce actual risk of disease. Evidenced-based inspection might eliminate some practices that are inefficient or unnecessary; and add some practices that might improve outcomes.

Finding 15 – Procedures for gathering evidence in matters related to food-borne illness outbreaks are not always followed and such procedures should be reviewed to ensure that they are necessary in addressing the actual risk of a disease.

Recommendation:

The Bureau recommends that procedures be implemented to prevent this from occurring. These procedures may include but are not limited to the following:

- o Provide staff training on the process and related forms that are to be used.
- o Make the required forms and checklists part of the Garrison System to ensure that the information is readily available.
- o Ensure that a copy of the electronic forms/checklist is kept on all desktops in case Internet access to Garrison is not available.
- o Require that the sampling kit be kept with the inspectors/seniors at all times, so they are ready to respond when needed.
- o Require that sampling kit is restocked after an investigation.
- o Ensure that management consistently applies the guidelines for these types of inspections.
- Review policies and procedures to ensure that measures taken are evidenced-based, and employ
 processes that have been demonstrated to reduce actual risk of disease.

Management's Response:

The Department's Foodborne Outbreak Response Manual is being updated based on national Guidelines from the Council to Improve Foodborne Outbreak Response (CIFOR) and FDA standards. An updated food safety plan is being used to further target inspections on the greatest hazards to health. Staff will be trained in implementation of the updated plans, procedures, and forms. An outbreak response team will be used whenever possible due to the specialized skills needed during investigations. The Epidemiologist will help coordinate investigations. The data processing system and needs will also be re-evaluated within the next year. Hardcopies of new forms will be distributed to all staff. Additional sampling kits will be developed and distributed and steps will be instituted to assure the kits are restocked as necessary.

The OFP does not have uniform policies or procedures for addressing, recording complaints in a central database, or following-up on complaints received

The vast majority of complaints received by the OFP are via telephone calls which are forwarded to one of the supervisors. However, we noted that there is no policy or procedure for addressing, recording, or following up on complaints received. This appears to be related to the fact that supervisors do not effectively communicate with one another. As a result, complaints are not addressed in a consistent manner and follow-up reviews stemming from complaints may not be performed timely and uniformly. Finally, complaints are not recorded in a central database and thus are not accessible by other staff.

Finding 16 – The OFP does not have uniform policies or procedures for addressing, recording, or following up on complaints received.

Recommendation:

The Bureau recommends that policies be developed and procedures implemented for addressing, recording, and following up on complaints received.

Management's Response:

While policies for follow-up on complaints have been repeatedly discussed with staff, these policies will be committed to writing to assure uniformity in follow-up.

BUDGETARY/FINANCIAL ISSUES

The OFP has been understating the amount that it is contractually entitled to regarding FDA reimbursement

The OFP is reimbursed by the FDA for federally required audits performed by the State. This reimbursement arrangement is documented in a formal agreement between OFP and FDA. The agreement provides an overview of the calculation of the reimbursement which is contingent upon the completion of the inspections by the State.

During our review, we noted that the OFP, in calculating the Federal reimbursement, has been using non-current wage information. As a result, the OFP has been understating payroll costs in its reimbursement calculation, consequently receiving less money in federal reimbursements than it is entitled.

Finding 17 – The OFP, in calculating the Federal reimbursement amount for FDA-required inspections, has been using non-current wage information. As a result, the OFP has been understating payroll costs in its reimbursement calculation, consequently receiving less money in Federal reimbursements than it is entitled.

Recommendation:

For all future FDA reimbursement calculations, the OFP should be using the Salary and Wage Projection File produced by the State Budget Office. It should also be used for the upcoming fiscal year when calculating the projected cost of performing the FDA contract inspections.

Management's Response:

The Department used the wage information it was provided to calculate its costs for the FDA contract. The Department agrees that the most recent payroll costs must be used in identifying these costs. The Office of Food Protection will work with the Key Administrator for the Division of Environmental and Health Services Regulation and the Chief Financial Officer to obtain updated salary projections from the State Budget Office.

BUREAU OF AUDITS

ADDENDUM: MANAGEMENT'S RESPONSES

November 8, 2011

H. Chris Der Vartanian, CPA Chief, Bureau of Audits 1 Capitol Hill Providence, RI 02908

Dear Mr. Der Vartanian:

We wish to thank you and your staff from the Bureau of Audits for all of your efforts in working with Office of Food Protection personnel in evaluating how to improve food safety in Rhode Island.

We have reviewed and discussed the recommendations provided and we have attached our responses following each recommendation.

Thank you again for all of your assistance in this matter.

Sincerely,

Michael Fine, M.D., Director Rhode Island Department of Health

Office of Food Protection Response to Bureau of Audits Recommendations

Finding 1 – The requirements of Rhode Island State Law are confusing as to whether Certified Food Managers need to renew the NRA ServSafe Certification subsequent to the five-year expiration date.

Recommendation:

The Bureau recommends that the OFP clarify its requirements in all written certification and renewal materials and on its website; and if possible, notify all current certified managers in food safety as to the State requirements.

Management's Response:

The Department agrees with the recommendation to clarify food manager recertification requirements in all written certification and renewal materials and on its website. Clarification of current requirements is provided in the Appendix.

Finding 2 – Current State requirement that food establishments hire a manager certified in food safety is deficient, in that in most cases it does not mandate a food safety manager to be present during the preparation of all potentially hazardous foods.

Recommendation:

The Bureau recommends that the OFP pursue legislation [possibly similar to House Bill 5086 introduced in the 2011 legislative session] requiring a manager certified in food safety be present during the preparation of all potentially hazardous foods.

Management's Response:

The Department strongly agrees with the recommendation and the Department will request that legislation be introduced similar to House Bill 5086 to require that a manager certified in food safety be present during preparation of potentially hazardous foods.

Finding 3 – The OFP does not currently mandate nor promote the certification of food service workers who handle food.

Recommendation:

Propose legislation or create a regulation that would require food handlers/workers to attain a basic knowledge of food safety by taking a self-study course culminated by an examination and the issuance of a food handler/worker card.

Management's Response:

The Department agrees with the recommendation and legislation will be requested to require that food handlers/workers be trained and tested and that they be provided a card demonstrating that they have obtained basic knowledge in food safety.

Finding 4 – State Law does not require that municipalities first obtain approval from the OFP before granting a Certificate of Occupancy or Victualing and/or Beverage License to a food establishment that prepares food on its premises.

Recommendation:

Propose legislation that would require municipalities to obtain approval or proof of licensing from the OFP prior to granting a Certificate of Occupancy and a Victualing and/or Beverage License to an establishment that prepares food on its premises.

Management Response:

The Department agrees and such legislation will be proposed.

Finding 5 – Managers in the OFP are not applying standard operating procedures for the conduct of inspections in a consistent and uniform manner.

Recommendation:

All managers should ensure that OFP staff is conducting inspections in a consistent and uniform manner in conformity with standard operating procedures. The director of the agency must ensure that managers are applying office standards consistently and properly.

Management's Response:

The Department will initiate a quality assurance process with additional performance measures posted on the Department's dashboard and assessed by management of the Office of Food Protection.

Finding 6 – Organization by field offices that no longer exist has resulted in inefficiencies in the assignment of staff and inconsistencies in the inspection process.

Recommendation:

The Bureau recommends the OFP eliminate assignments by "field offices" and instead assign inspections based on factors such as expertise, need, and staff availability.

Management's Response:

The Office of Food Protection will be restructured based on expertise needed to comply with federal mandates for milk and shellfish products, conduct FDA contract inspections for interstate commerce, investigate foodborne outbreaks and high hazard complaints, conduct opening inspections, and assure food safety from farm to table throughout the state. A new Office of Food Protection food safety plan (based on Healthy People 2020 Objectives) will also be used to structure the Office to have the greatest impact in reducing illnesses, assure uniformity, focus on the most critical hazards to health in the highest risk facilities, and assure rapid and effective follow-up to make certain the greatest hazards to health are quickly eliminated.

Finding 7 - There is a lack of organization and control over scheduling of inspections and oversight of the inspectors' assignments.

Recommendation:

Develop a uniform methodology for selecting and assigning routine inspections, new establishment inspections, and follow-up inspections to ensure that all food establishments are inspected within the time period required by statute, regulation, and/or policy. Additionally, this methodology should consider a more efficient approach in addressing daily complaints.

Management's Response:

The Department agrees that greater control over scheduling inspections is needed. (The current methodology used in assigning inspections is described in the Appendix). With the FY2011 level of staffing, the lowest risk food establishments would be inspected once every 6 years. With the 12 additional inspectors recommended in the audit, the target would be to inspect the highest risk food establishments twice per year and the lowest risk establishments once every two years.

To greatly improve supervisory control over scheduling, the Department will provide inspectors with smart phones. Staff will also use the Groupwise shared Calendar and the scheduling module in the inspection data management system. The Office will also be restructured and a quality assurance system will be implemented to make certain that the highest priority inspections are conducted

Finding 8 - The OFP does not have a uniform risk rating methodology for determining inspections.

Recommendation:

Management should maintain a risk rating for all establishments; such rating should be updated each time an establishment is inspected. Management should implement standard operating procedures to define the risk ratings and frequency for which they should be updated and use this as a platform for scheduling inspections. The Bureau noted that the OFP implemented this recommendation during the course of this audit.

Management's Response:

While the audit found there were over 2,700 establishments with no risk assigned, this was due to the fact that these facilities had not been inspected since 2007, not due to the lack of a risk rating system (The risk categories assigned by staff during inspections are described in the Appendix). The Office of Food Protection will contact Garrison Enterprises to determine if a means can be developed to assign a risk rating to a facility in the inspection data management system that has not been inspected. Facilities that have not been inspected will be a priority for inspection as new staff are added and a risk rating will be assigned at the time of inspection.

Finding 9 - Current staffing levels cannot accommodate the required number of annual inspections.

Recommendation:

The Bureau recommends management increase the total number of inspectors assigned to this unit by at least 12 inspectors, a number that must be re-evaluated periodically in consideration of the number of licenses issued and the average number of annual inspections being performed by inspectors.

Management's Response:

The Department agrees that the number of food inspectors needs to be increased by at least 12 inspectors to inspect food establishments at half the frequency recommended by FDA. The number of inspectors needed is likely to rise as staff transition from partial to complete inspections. The Department will report back to the Governor and legislature as to staffing needs one year after new staff have been added. The Appendix provides a description of what levels of inspection can be performed at different levels of staffing.

Finding 10 – There is no systematic process for generating letters of suspension to licensees or follow-up procedures for ensuring timely collection of licensing revenues

Recommendation:

The licensing system should automatically generate and deliver the letters for mailing to the operations center. The OFP should not be involved with the process of mailing out the lack-of-payment, pending suspension, and suspension notifications. The licensing section must ensure that all notices comply with the requirements of Rhode Island General Laws, specifically RIGL § 23-1-20 entitled "Compliance order."

Management's Response:

The Office of Food Protection is working with License 2000 staff to generate automatic suspension letters. With current staffing, a target completion date is November 1, 2012.

Finding 11 – The OFP did not prepare and submit a statutorily required quarterly report relative to the hiring of the on-site consultant Data Manager.

Recommendation:

We recommend that the OFP comply with RIGL §42-149-3 and submit the quarterly reports to the chairpersons of the House and Senate Finance Committees and the State Budget Office relative to the hiring of the on-site consultant Data Manager.

Management's Response:

These reports are automatically generated through the RIFANS system via Accounts and Controls in order to comply with the provisions of the RIGL, 42-149-3.

Finding 12 - The number of hours allowed under the purchase order for the engagement of a Data Manager differs from the actual hours outlined in the cost proposal submitted by the vendor.

Recommendation:

We recommend that the OFP ensure that the hours worked and invoiced by the Data Manager Consultant do not exceed the number of hours allowed by the purchase order. If additional hours are required, we recommend that this matter be rectified with the Division of Purchases, and the purchase order be amended.

Management's Response:

Upon notification of audit finding, going forward the office has corrected the purchasing matter to meet recommendations.

Finding 13 – Access to the Garrison System was not terminated with respect to some former employees of the OFP, and there is not a comprehensive policy over administration of user access to the system.

Recommendation:

Management must implement a procedure whereby access to state systems, including the Garrison System, is immediately terminated upon the departure/termination of OFP employees. Management should also immediately terminate access for those former employees currently active in the system. Additionally, the OFP should develop a comprehensive process for the administration of user access to the Garrison System, including procedures for written access requests, documented review of required privileges, and management review of permissions granted.

Management's Response:

The Department agrees that when employees leave the Office of Food Protection employee access to the Garrison data processing system must be immediately terminated. Access has been removed for former employees. The exception is that approved third parties enter school inspection reports into Garrison. Procedures for access and removal from the Garrison data processing system will be documented.

Finding 14 – The Bureau found that OFP is exceeding its statutory responsibilities per review of the Food/Water Licensing Coordination Policy and Procedures by performing duties that are the responsibility of the Drinking Water Quality Program.

Recommendation

The Bureau recommends that OFP refer owners of food establishments to DWQ for proper handling of drinking water supply/well licenses and immediately cease performing drinking water supply/well

reviews. Due to the limited staff within OFP, all resources need to be directed toward the inspection and regulation of food establishments for the benefit of the public.

Management's Response:

The bulk of Office of Food Protection time is devoted to food safety concerns and food establishments with wells are referred to the Office of Drinking Water Quality (DWQ). Office of Food Protection staff do collaborate with DWQ staff when appropriate.

Finding 15 – Procedures for gathering evidence in matters related to food-borne illness outbreak are not always followed and such procedures should be reviewed to ensure that they are necessary in addressing the actual risk of a disease.

Recommendation:

The Bureau recommends that procedures be implemented to prevent this from occurring. These procedures may include but are not limited to the following:

- o Provide staff training on the process and related forms that are to be used.
- o Make the required forms and checklists part of the Garrison System to ensure that the information is readily available.
- o Ensure that a copy of the electronic forms/checklist is kept on all desktops in case Internet access to Garrison is not available.
- o Require that the sampling kit be kept with the inspectors/seniors at all times, so they are ready to respond when needed.
- o Require that sampling kit is restocked after an investigation.
- o Ensure that management consistently applies the guidelines for these types of inspections.
- o Review policies and procedures to ensure that measures taken are evidenced-based, and employ processes that have been demonstrated to reduce actual risk of disease.

Management's Response:

The Department's Foodborne Outbreak Response Manual is being updated based on national Guidelines from the Council to Improve Foodborne Outbreak Response (CIFOR) and FDA standards. An updated food safety plan is being used to further target inspections on the greatest hazards to health. Staff will be trained in implementation of the updated plans, procedures, and forms. An outbreak response team will be used whenever possible due to the specialized skills needed during investigations. The Epidemiologist will help coordinate investigations. The data processing system and needs will also be re-evaluated within the next year. Hardcopies of new forms will be distributed to all staff. Additional sampling kits will be developed and distributed and steps will be instituted to assure the kits are restocked as necessary.

Finding 16 - The OFP does not have uniform policies or procedures for addressing, recording, or following up on complaints received.

Recommendation:

The Bureau recommends that policies be developed and procedures implemented for addressing, recording, and following up on complaints received.

Management Response:

While policies for follow-up on complaints have been repeatedly discussed with staff, these policies will be committed to writing to assure uniformity in follow-up.

Finding 17 – The OFP, in calculating the Federal reimbursement amount for FDA-required inspections, has been using non-current wage information. As a result, the OFP has been understating payroll costs in its reimbursement calculation, consequently receiving less money in Federal reimbursements than it is entitled.

Recommendation:

For all future FDA reimbursement calculations, the OFP should be using the Salary and Wage Projection File produced by the State Budget Office. It should also be used for the upcoming fiscal year when calculating the projected cost of performing the FDA contract inspections.

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Management's Response:

The Department used the wage information it was provided to calculate its costs for the FDA contract. The Department agrees that the most recent payroll costs must be used in identifying these costs. The Office of Food Protection will work with the Key Administrator for the Division of Environmental and Health Services Regulation and the Chief Financial Officer to obtain updated salary projections from the State Budget Office.

Appendix

Response to Recommendation 1

For clarification, while the National Restaurant Association (NRA) is the main provider of food manager certification courses and tests in Rhode Island, it is not the only approved provider of such services. The Department accepts for certification anyone who has passed one of the certification programs approved by the Conference for Food Protection. There are currently three approved certification programs. In written materials and on the website, it will be emphasized that while recertification through NRA or other training provider is recommended, certified food managers only need to meet state requirements for recertification.

Response to Recommendation 7

Inspections are always conducted on a relative risk basis, with the greatest hazards to health and mandates always being the priority. In developing a uniform methodology for scheduling inspections, there are numerous factors that must be included. With extremely limited resources, staff are constantly shifted to address the greatest hazards to health. In FY 2011, staff conducted approximately 4,600 inspections. Of these, about 2,654 were routine inspections. The remaining 43% were in response to reported hazards or opening inspections.

As stated in the audit, inspectors also conducted an average of 487 inspections per inspector versus the FDA recommended 280 to 320 inspections per inspector. This is accomplished through having staff focus on the greatest hazards to health and not spending a lot of time on lower risk hazards. The problem with this approach is that critical issues may be missed in conducting faster inspections. This is found necessary, however, since thousands of food establishments have not been inspected in years.

In determining the greatest hazards to health in scheduling staff, staff have been repeatedly instructed to inspect the highest risk food establishments, focus on the foodborne illness risk factors most likely to cause illness, and follow-up to make certain that these hazards have been eliminated. They have also been instructed that if they would not feel safe in eating at a food establishment, then someone else should not be eating there. Steps must be taken to eliminate serious hazards.

Another guiding principle is that the greatest predictor of future behavior is past behavior and that establishments with known serious hazards are a higher priority for inspection than establishments that have not been inspected in a long period of time, that may or may not have food safety hazards. For this reason, monthly reports are provided to staff and supervisors that indicate establishments where reinspections and supervisory action were requested, to make certain that reinspections to assure permanent elimination of serious hazards have occurred. Likewise, lists of food establishments with multiple food disposals, and serious repeated foodborne illness risk factors have occurred are now also generated to make certain systems have been put into place to assure food safety.

Once the critical follow-ups are scheduled, then mandated inspections of high risk food establishments are scheduled. This includes milk and shellfish operations shipping food into interstate commerce. Not only are these products high risk, but if national inspection standards are not met, these products would not be allowed to be sold in interstate commerce. Health care facilities are scheduled to be inspected once per year since the sick and elderly are at much greater risk of serious foodborne illness and death due to weakened immune systems. The list of establishments with high risk processes such as advanced food preparation and smoking or curing foods is also used for scheduling.

The FDA contracts with the Office of Food Protection to inspect food establishments shipping food into interstate commerce and these inspections are also a priority. This year, the Office of Food Protection will receive \$311,000 to inspect 150 food establishments plus take steps to meet the FDA National Manufactured Foods Regulatory Program Standards.

The quarterly report identifying the facilities not inspected in the longest period of time, discussed in the audit, is then used. This is just one of the reports provided to staff and supervisors. With current staffing, there were over 2,700 establishments not inspected since 2007. Factors considered in determining which facilities to inspect include: history of the facility, high risk practices, high risk foods, equipment used, high risk populations served, whether the facility/chain has their own well managed food safety system, and the length of time since the last inspection.

Seasonal factors are also considered. Large festivals, where tens of thousands of people will be served, are also a priority since foods at unsafe temperatures are often found at these events. Certain food establishments are only open during the summer. The risk may be high when a seasonal facility first opens due to new seasonal staff. Similarly, during hot weather, food establishments without air conditioning often have refrigeration fail and foods may be kept at unsafe temperatures for days. During heat waves, staff may be shifted to inspect convenience stores, which would otherwise be considered low risk, due to these refrigeration hazards.

While the above factors are used to schedule inspections, 43% of inspections in FY2011 were due to needed reinspections, illness and other complaints, opening inspections, recalls and other issues which confound scheduling with limited staff. Response to outbreaks, recalls, boil water advisories, power outages, fires in food establishments, illness and other complaints where the potential for illness is high are obviously given a high priority, and inefficiencies occur in travel and time when staff need to be pulled from one location to respond to a reported serious hazard in another location. The Office of Food Protection receives approximately 700 complaints per year and considered in scheduling a response are the degree of hazard, history of the establishment, and the time since the last inspection.

Opening inspections are often requested with little notice since the owner is often at the mercy of contractors. Opening inspections are also given a high priority in order to allow businesses to open and to put people to work as quickly as possible.

Also considered in scheduling are how quickly a response is needed, expertise needed, who is available and can get there in the time needed, and disruption to other priority activities.

After a weekly staff meeting to establish the schedule, a supervisor should be able to change an employee's schedule as needed and the employee and supervisors see this change real time. This would greatly improve daily response to illness and other high risk complaints/outbreaks, recalls, etc. This will allow for quicker and better assessment of who can be shifted with the least impact and the best efficiency for time and mileage. For this to occur, each employee needs to be provided with a smart phone. The scheduling feature in the Garrison data processing system also needs to be evaluated using this technology to improve the effectiveness and efficiency of scheduling.

Smart phones provide numerous added advantages such as the ability for new staff to stream video to supervisors for assistance during an assessment of hazards for needed enforcement. Certain phones also have the ability to scan bar codes which can be used to determine if a food product is subject to a recall and where else the recalled product may be sold. These phones can also be used to increase revenue by using them to scan bottled beverages and frozen desserts to see if they have active Rhode Island licenses. The Office of Food Protection will evaluate the latest technology with Information Technology staff and request the appropriate equipment and software to improve scheduling. The scheduling methodology will also be documented.

Response to Recommendation 8

The current Garrison data processing system does not allow Office of Food Protection staff to assign risk to an establishment without an inspection. During each inspection since 2007, each inspector has been required to indicate that the establishment falls within one of the following risk categories:

High Risk Population
Smoking/Curing/Reduced Oxygen Packaging
Advanced Prep
Cook/Serve
Other (Temp. Vendors, Mobile Vendors, Vending Machines)
Pre-Packaged NPHF (Not Potentially Hazardous Food)

The Office of Food Protection also had a method for determining how often establishments should be inspected according to FDA standards. The problem has been that there were insufficient inspectors to meet these standards. The inspection frequencies discussed in the audit report (low risk establishments inspected once every two years, cook/serve operations inspected once per year, establishments with advance

preparation of foods inspected once every eight months, and high risk establishments inspected twice per year) are to meet half the FDA standard.

With 43% of the inspections in FY 2011, responding to identified hazards and opening inspections versus conducting routine inspections, many establishments (believed to be lower risk) were not inspected in years in order to respond to reported serious hazards and open new facilities. This often resulted in lower risk facilities becoming high risk, however, due to changes in practices, and high turnover of food operation managers and workers. The Office of Food Protection will continue to constantly assess risks to assure that the greatest hazards to health are the priority for inspections.

Response to Recommendation 9

There was the equivalent of 8 food inspectors in FY 2011.

The audit recommendation for 20 food inspectors would provide 1/3 the number of inspectors recommended by FDA in the Voluntary National Retail Regulatory Program Standards. This was calculated based on RI inspectors conducting 487 inspections per inspector per year versus the FDA recommended 280 to 320 inspections per year. The number of inspections is significantly higher in Rhode Island since 43% are opening inspections, response to complaints, reinspections and partial inspections. The number of inspections performed per inspector will decrease as more complete inspections are performed. At this staffing level, staff would attempt to inspect the highest risk establishments twice per year and the lowest risk establishments once every two years.

To conduct complete inspections at half the frequency recommended by FDA would require 30 inspectors. This is also half the FDA recommended staffing level.

Background

The 9,760 inspections listed in the audit as being needed annually was calculated based on inspecting food establishments at half the frequency recommended by the Food and Drug Administration. This would entail inspecting lower risk establishments such as most convenience stores, hot dog carts and coffee shops once every two years. Cook/serve operations such as most retail operations, most schools (federal law requires schools receiving federal school lunch funds be inspected twice per year), and most fast food operations would be inspected once per year. Food establishments preparing food a day or more in advance, where the potential for illness is much higher, would be inspected once every eight months. The highest risk establishments such as hospitals, preschools, nursing homes, and food establishments with complex procedures would be inspected twice per year.

It should be noted that there are risks associated with inspecting establishments at half the FDA standard and only once every two years. While a food establishment is placed into a risk category based on the last inspection, business practices often evolve into higher risk areas. Even the lowest risks establishments can pose a high risk for illness (e.g. foods

found at unsafe temperatures for long periods of time in convenience stores without air conditioning during hot weather due to refrigeration failures).