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**INDEPENDENT STATE AUDITOR'S REPORT ON
CERTAIN ACTIVITIES OF THE
DEPARTMENT OF PUBLIC HEALTH
FOOD PROTECTION PROGRAM
JULY 1, 2003 THROUGH DECEMBER 31, 2005**

**OFFICIAL AUDIT
REPORT
MARCH 26, 2007**

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INTRODUCTION**1**

The United States Center for Disease Control and Prevention (CDC) estimates that approximately 76 million cases of foodborne illness (a.k.a., “food poisoning”) occur across the country each year. In addition to the efforts of federal agencies such as the Food and Drug Administration (FDA) and the CDC, the nation relies on state and local health authorities to carry out food protection activities such as public education initiatives, inspections of retail and wholesale food establishments, and investigation and response activities when foodborne illnesses occur. In Massachusetts, the Department of Public Health’s (DPH) Food Protection Program (FPP) carries out these responsibilities in conjunction with local health authorities across the Commonwealth. Under the provisions of MGL, Chapter 111, Section 127A, DPH is responsible for administering State Sanitary Code provisions applicable to food protection and other public health matters, while local boards of health and their staff are responsible for enforcement of the code at the local level. While the DPH Food Protection Program has direct operational responsibilities for inspection and enforcement activities involving over 2,200 wholesale establishments such as warehouses, seafood firms, and dairy plants, employing an estimated 11,270 food processing workers, day to day responsibility rests with 328 local city, town, and regional health authorities for ensuring the food safety of thousands of restaurants, schools and other institutions, supermarkets, mobile food, vending, catering, and other temporary food events staffed by an estimated 250,490 food preparation and serving-related employees in the Commonwealth. These local authorities operate under the oversight and coordination of the state, but are directly responsible to and are primarily funded by the Commonwealth’s 351 city and town governments. While the total number of food service establishments in the Commonwealth is not known by DPH, data for 2002 from health authority annual reports covering 239 communities accounting for 79.5% of the Commonwealth’s population documented a total of at least 30,264 retail food service establishments in those communities.

Past reviews conducted by our office and the FDA of the Food Protection Program identified significant deficiencies, primarily involving the quality, frequency, and standardization of retail food inspections at the local level and inadequacies in state oversight systems. The initial scope of our audit was to reassess the DPH’s FPP activities and its oversight of food protection activities at local health authorities for the period July 1, 2003 through December 31, 2005. However, program changes and information shortcomings at DPH caused us to expand our review to information available for prior periods and to review certain activities after December 31, 2005. Our audit was conducted in accordance with applicable generally accepted government auditing standards for performance audits issued by the Comptroller General of the United States. The objectives of our audit were to (1) determine whether the deficiencies identified by our prior audit had been appropriately corrected and (2) assess the current performance of the Food Protection Program under currently applicable state and national standards.

As detailed in our Audit Results, we found that previously identified deficiencies at both the state and local level remain uncorrected. At the same time, program challenges have increased as food distribution arrangements become more complex and new threats arise

from evolving disease pathogens and potential bio-terrorism activity. Due to widespread resource, training, information technology, and organizational deficiencies, inspection and other food protection activities in the Commonwealth are not conducted with adequate frequency, quality, standardization, coordination, or oversight. A comprehensive strategic planning initiative is needed to address these problems.

AUDIT RESULTS

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1. RESOURCE CONSTRAINTS IMPAIR DPH OVERSIGHT OF LOCAL HEALTH BOARD FOOD PROTECTION ACTIVITIES AND DPH WHOLESALE FOOD INSPECTION CAPACITY

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Our prior audit report on the Commonwealth's FPP disclosed that DPH devoted significant staffing resources to the oversight of local food protection activities, including five DPH inspectors assigned to conduct quality assurance reviews of local inspections and a full-time foodborne illness response coordinator. Additional oversight was also provided at that time by separate federal reviews of local inspections. However, even with those resources, our audit identified deficiencies in the quality, frequency, standardization, and oversight of local inspections of retail food establishments. In response to that audit, DPH planned to augment program staffing at the state level with 10 additional positions, including seven additional inspectors. However, the Administration put those plans on hold due to a then developing state fiscal crisis. Our follow-up review found that, while limited improvements have been made in some areas such as regulatory language, foodborne illness investigation and response, and industry and community relations, the planned corrective staffing measures were never implemented even during better economic periods. The elimination and reassignment of positions over the years has reduced DPH staffing to less than one full-time position available for current oversight of the thousands of retail food establishment inspections conducted across the Commonwealth's 351 cities and towns. The program's operational capacity for planned inspections of wholesale firms is also inadequate. With the exception of 150 high-priority firms engaged in interstate milk and shellfish commerce, more than 2,000 other wholesale firms in the Commonwealth are inspected on an average of only once every four years. In response to our audit report DPH asserted that it has made many significant food safety improvements with available resources. We acknowledge that while the DPH program can fairly claim an extensive list of accomplishments despite the significant resource constraints and limitations inherent in the Commonwealth's decentralized system of operations, we found that results have been far more limited in the program standard areas of Trained Regulatory Staff, Inspection Program Based on Hazard Analysis Critical Control Point (HACCP) principles, Uniform Inspection Program, Compliance & Enforcement, Program Support and Resources, and Program Assessment. We identified notable weaknesses generally attributable to these resource constraints and the unique decentralized inspection and enforcement approach used by the Commonwealth.

2. LOCAL HEALTH AUTHORITY FOOD INSPECTION ACTIVITIES ARE SIGNIFICANTLY UNDERSTAFFED IN MANY COMMUNITIES

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Both DPH staff and local health officials told us that they believed inspection and other local food protection activities suffered from a lack of resources at the local level, that local health departments were forced to compete with local school and public safety functions for funding, and that local funding of food protection efforts was usually not adequately prioritized, particularly in communities where health agents and inspectors are responsible for multiple public health functions and food inspection activities lack separate budget and reporting mechanisms. Our review confirmed the existence of these problems for the 26 communities represented by the 13 local health authorities we visited. While DPH does not gather revenue and expenditure information through its annual reporting process for local food protection activities, the process does gather limited information on staffing levels, food protection activities, and on the number of food establishments as reported by each community participating in the reporting process. Analysis of available data covering 156 communities for the year 2002 suggests that food inspection positions are probably understaffed for most communities in the Commonwealth and that in many instances staffing levels are at least a third less than the federally recommended levels. In the communities for which data was available, over 70% of the communities had too few inspectors and over half of the communities had less than two-thirds of the recommended numbers of inspectors. These communities with inadequate numbers of inspectors were also responsible for the inspection of a disproportionate number of food establishments. Approximately 90% of the establishments in the dataset were in communities with too few inspectors and over 75% of the establishments were in communities with less than two-thirds of the number of inspector full-time equivalencies recommended for the number of establishments in the community. In addition, approximately two-thirds of the communities in the dataset appeared to be operating entirely with only part-time food inspectors. In response to the audit report, DPH indicated that it provides technical assistance, guidance, and training for local authorities and further stated that the current status of local public health staffing ratios should be re-analyzed due to what they believed were recent revisions to FDA guidance. We discussed the recent guidance change with the FDA. We were told that the new guidance is still very much under discussion and subject to change and that the new guidance language is not inconsistent with the original guidance calling for 1.0 FTE inspectors per 150 establishments. We were also told our analytical approach had been appropriate and that it might in fact be the only way the analysis could reasonably be conducted. During our visits with local health authorities, professionals we met with also generally agreed with our analytical approach. Therefore, we see no reason to re-analyze the available data or to modify our conclusions.

3. LOCAL INSPECTION FREQUENCY IS OFTEN INADEQUATE AND APPROPRIATE RISK-BASED SCHEDULING SYSTEMS ARE RARELY USED

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Both DPH/FPP and the FDA recommend that inspection authorities use a risk-based classification system to schedule the frequency of regular routine inspections for food establishments so that high-risk settings such as hospitals, nursing homes, and large restaurants are routinely inspected three to four times per year; while medium-risk

establishments are inspected two or three times per year; and low-risk establishments, such as convenience stores serving only coffee, soda, and snacks, are inspected at least once per year. DPH/FPP regulations (e.g., 105 CMR 590.013) require that, with the exception of certain low-risk situations, all establishments must be routinely inspected at least every six months unless DPH has approved additional exceptions as part of a written risk-based scheduling plan submitted by the local authority. However, both annual reports submitted to DPH by local boards of health and our visits to the 13 local health authorities indicate that few authorities use formal risk-based assessment plans and that establishments are not inspected with the required frequency despite the fact that the six month/twice a year frequency requirement is minimal compared to higher standards in other states such as Maryland, which mandates a minimum of three inspections per year for full service restaurants. We noted inspection frequency violations at 11 of the 13 local health authorities we visited. In some instances relatively high-risk establishments have gone well over a year without a routine inspection and we even found some establishments that had gone as long as seven years without a routine inspection. At one authority where we reviewed all available records for 13 establishments from fiscal year 2002 through October 31, 2005 we found that not a single establishment had received the minimum required number of inspections over the multi-year period. Discussions with food safety professionals suggest that these inspection frequency violations are primarily attributable to the significant local health authority resource constraints identified in Audit Result No. 2. We also found that DPH/FPP has no system for reliably identifying and addressing inspection frequency violations that occur. The problem also involves cafeteria and other food operations in school systems, where the federal Child Nutrition and WIC (Women, Infants, and Children) Reauthorization Act of 2004 separately mandates that food inspections be conducted at least twice a year. In response to our audit report, DPH reiterated the statutory responsibilities of local authorities and the state's non-mandatory recommendation that risk-based systems be used. The Department also indicated that it is continuing to work with state educational officials and local health authorities regarding compliance with federal requirements applicable to school food services. Our audit work disclosed that risk-based inspection systems are few and far between and do not operate on a consistent basis in the Commonwealth. As stated in our recommendation, we believe that DPH should consider the merits of implementing a uniform statewide risk-based scheduling process and has the authority to do so under existing statutes. While we are pleased that the Department is continuing to address implementation issues for the new federal school food program requirements, our audit work suggested actual compliance rates may be far lower than the 80% DPH suggested in its response. At the time of our visits, we also found that, notwithstanding DPH outreach efforts, several local authorities were unaware of the new requirements. As noted in our recommendation, DPH needs to establish better tracking systems to ensure that local authorities fulfill their responsibilities in this regard.

4. INADEQUATELY TRAINED AND QUALIFIED LOCAL INSPECTORS

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When DPH modified its regulations in 2000 to incorporate provisions of the 1999 Food Code, it also established minimum qualification requirements for food inspectors. 105 CMR 590.010(G) provides several qualification options, the lowest of which is nothing more than the same Certified Food Protection Manager (CFPM) certification approval

required for food establishment operators. This minimalist approach to inspector qualification requirements was taken despite the fact that outside food safety professionals reviewing the proposed qualification provisions had characterized them as “woefully inadequate.” While the regulation also requires completion of “food safety inspection training recognized by the Department,” the Department has never promulgated mandatory training specifications and has never enforced the requirement for supplemental training or continuing education requirements. As a result, local inspectors (who typically conduct food inspections as a secondary part-time activity in addition to other public health responsibilities accounting for most of their work time) are sometimes no more qualified than, and may in some cases be less knowledgeable than, the food establishment managers they regulate. DPH/FPP staff acknowledged that a higher level of qualifications and training for inspectors is desirable due to the importance of using science-based (e.g., food microbiology and epidemiology) Hazard Analysis Critical Control Point (HACCP) principles to conduct inspection and other food protection activities, but stated that, had a higher regulatory minimum standard been adopted, the result would have been to “wipe out” 60% to 70% of the existing local inspectors. Our review of DPH data on inspector qualification levels and training participation data, as well as our interviews with local health authority staff and with trade association representatives for both inspectors and the food industry confirmed that inadequate inspector training and qualification levels remain a serious problem five years after adoption of the qualification standards. In response to our audit report, DPH noted its ongoing voluntary training activities and asserted the existence of statutory limitations on its ability to mandate inspector qualification and training requirements, but did not identify any plan to seek statutory changes that might be needed to address these problems. If the DPH believes that they do not have the statutory authority and responsibility to mandate appropriate inspector training and qualification requirements, they should propose appropriate statutory language to remove that barrier. As demonstrated by our audit work, the existing voluntary approach utilized by the DPH is clearly not sufficient and many authorities and inspectors remain inadequately trained and qualified.

5. INADEQUATE DOCUMENTATION AND STANDARDIZATION AT LOCAL AUTHORITIES

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Our visits to 13 local health authorities across the Commonwealth revealed wide variations in inspection and related practices at different authorities. Inspectors focused on different compliance requirements of the Food Code. Similar violations such as inadequate dishwashing final rinse temperatures, not keeping food containers off the floor, and not protecting food from contamination were treated differently, with some authorities characterizing these violations as critical violations posing imminent risks to consumers and requiring immediate correction, while other authorities treated the same violations as non-critical matters to be addressed over multi-week periods or even as non-violation discussion matters referenced in inspection report notes with no follow-up until the next routine inspection. Documentation practices were also deficient, in part due to the use of “exception only” documentation practices at most authorities. Only a few authorities documented inspection activity with information on the specific inspection procedures and results (e.g., food and dishwasher temperatures) where items were found to be in compliance. As a result, authorities were generally unable to provide

documentation that inspections were conducted in a thorough, standardized manner. For example, 27 (69%) of the routine inspection reports we reviewed at one authority did not identify a single non-critical violation, and 25 of those reports simply bore the notation "satisfactory" with no other inspection details. That pattern was in marked contrast to the remaining 12 authorities, where only between 0% and 20% of routine inspections did not identify violations. It also contrasts with violation frequency results we were able to obtain for other states. Even at authorities with apparently higher violation rates, there were distinct differences in the frequency of use for standard violation codes used on the inspection report promulgated by DPH for local authority use. In the absence of adequate underlying documentation or comprehensive quality assurance systems (see Audit Results No. 8) to satisfactorily account for these variances, the quality and thoroughness of inspections and the extent of standardization across local authorities remains as questionable now as we originally found it to be 18 years ago. These results also suggest that inspections often remain focused on traditional "good retail practice" sanitation compliance, with insufficient attention to federally identified critical risk factors for foodborne illness. In response to the audit report, DPH noted that it issued a standard retail food service inspection form requiring that inspectors evaluate critical risk factors and asserted that the Department is continuing voluntary training efforts to further field standardization and uniform inspection grading. However, as noted by our review, local authorities do not always use the retail food service inspection form developed and distributed by DPH. As indicated by Table 8 of our report, even when the form is used, it is often not used as intended and inspections appear to be not adequately focused on critical risk factors. Although the DPH indicated that FPP is working with the newly established Local Public Health Institute to develop a voluntary comprehensive training program on food safety that will be a prerequisite to field standardization and uniform inspection grading, as of March 1, 2007, the internet site for the Local Public Health Institute did not reflect any training programs specifically focused on food inspection documentation and standardization.

6. FOOD-BORNE ILLNESS AND GENERAL COMPLAINT INVESTIGATION AND RESPONSE ACTIVITIES ARE DEFICIENT IN MANY COMMUNITIES AND AT THE STATE LEVEL

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Food-borne illness reporting, investigation, and response activities at the local level are not always adequate. Statewide oversight, coordination, and information sharing arrangements are also inadequate, contributing to communication deficiencies between state and local officials and incomplete and inadequate investigations of all suspected foodborne illness incidents, particularly those involving only one reported victim. As stated by DPH's own "Guide to Surveillance and Reporting:" *"State public health officials rely on local boards of health, healthcare providers, laboratories and other public health personnel to report the occurrence of notifiable diseases. Without such data, trends cannot be accurately monitored, unusual occurrences of diseases (such as outbreaks) might not be detected or appropriately responded to, and the effectiveness of control and prevention activities cannot be easily evaluated... The importance of timely reporting cannot be overemphasized."* While under-reporting of suspected foodborne illness incidents is a nationwide problem, with federal estimates of national reporting rates ranging from 1% to 10% nationwide, we found evidence suggesting that reporting and documentation rates in Massachusetts are far lower than 1%, and may even be as low as one-tenth of 1%. Even when suspected foodborne illness incidents are reported

to local authorities, they are often not reported to DPH food protection program staff in a timely manner or with sufficient case-specific detail. In some instances it appeared that delays and reporting issues also involved DPH's separate Bureau of Communicable Disease Control, responsible for passing information regarding suspect cases reported from laboratories and other sources on to the Food protection program and the interdepartmental "Working Group on Foodborne Illness Control." We question DPH's ability to adequately conduct foodborne illness surveillance and response activities under these circumstances, as well as DPH's ability to determine that local authorities are properly investigating and following up on locally reported foodborne illness complaints. Audit work identified multiple instances where investigation and response activities had been impaired by resource constraints at the local level and our review suggests that if apparent foodborne illness under-reporting problems were resolved, and the number of suspected illness incidents reported to DPH were to increase significantly; the Department's own capacity to appropriately investigate and respond to reported cases might be quickly overwhelmed due to existing DPH resource constraints. We found similar deficiencies in both state and local systems established to investigate and respond to general complaints received regarding possible food establishment code violations, particularly those involving food store and restaurant chains operating establishments across the jurisdictions of multiple local health authorities. DPH also did not adequately investigate and address complaints regarding alleged inadequacies in local authority inspection and enforcement practices. In response to the audit report, DPH stated that it "strongly objects to the audit report's characterization of the foodborne illness and complaint investigation response activities at the state level as deficient," and noted that it had recently enrolled in the FDA's voluntary national standards program, and further asserted that it recently conducted a self-assessment revealing compliance with 18 out of 20 federal criteria items related to foodborne illness activities. Since the enrollment occurred after the completion of our audit fieldwork and DPH did not provide us with details of its enrollment and compliance self-assessment, we contacted an FDA representative for further information. The official was not aware that a formal self-assessment had been completed or whether results of the assessment had been independently verified by an outside party. The official expressed concern that continuing food protection resource and system structure inadequacies at both the state and local level are likely to impair efforts to adhere to appropriate national standards. He also expressed his belief that the resource situation had actually worsened since the time of our audit work and stated that it was his understanding that staffing for the DPH/FPP Retail and Foodborne Illness Unit, reported by DPH to be 2.65 full-time-equivalent (FTE) positions for fiscal year 2006, has now been reduced even further to approximately 1.5 FTE.

7. INFORMATION TECHNOLOGY SYSTEMS ARE INADEQUATE AT BOTH THE STATE AND LOCAL LEVEL

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In contrast to many food protection regulatory authorities around the country, most food protection program activities at DPH and at local authorities remain unautomated or operate with inadequate and unstandardized information systems. The result is lost efficiency, significant communication problems for both public health officials and others seeking information on food protection activities, and inadequate information for program oversight, evaluation, planning, and other management activities. While a

number of local authorities are attempting to address internal operational issues by moving to electronic inspection systems (EIS) typically operating on hand-held computing devices (PDAs), this effort is uncoordinated. Uniform data standards have not been promulgated by either DPH or the FDA, and our visits to local authorities identified instances where some authorities were attempting to implement commercially marketed systems that had already been evaluated by other authorities and deemed deficient. As recommended to us by regional FDA officials, it would be desirable for DPH to assume responsibility for coordinating information technology upgrade activities in order to ensure that upgrade activities are efficiently conducted, effective, and that the end result is a state-wide information network where standardized data on both state and local inspection and related activities is readily available to all local, state, and federal officials responsible for the operation and oversight of food protection activities in the Commonwealth. In response to the audit report, DPH noted that it has provided local authorities with certain assistance related to the Commonwealth's Emergency Response System and the Health and Homeland Alert Network. While we agree that additional resources have been given to the local boards to further enhance their registering with the Health and Homeland Alert Network and to facilitate participation in the Commonwealth's Emergency Response System, these measures do not necessarily ensure the capacity of local authorities to participate in a uniform inspection process or to share electronic data in the manner recommended by the Council of State and Territorial Epidemiologists. The Department needs to carry through with the planning, development, implementation and monitoring steps to ensure that standardized, timely sharing of electronic data on a statewide basis with all participants is ongoing.

8. QUALITY ASSURANCE SYSTEMS TO PROMOTE SAFE FOOD PRACTICES NEED IMPROVEMENTS**80**

As part of its effort to promote high quality standardized and effective food inspection and protection activities across the nation, the FDA has promulgated Recommended National Food Regulatory Program Standards for use by both state and local health authorities. While not mandatory, those standards establish reasonable expectations for standardization and other quality assurance systems. The recommended standards or comparable arrangements are in use elsewhere in the nation. With the exception of recent commitments by the DPH Food Protection Program and two local health authorities to enroll in the national program to implement the recommended national standards, the Commonwealth's health authorities have not been able to adhere to the standards or commit themselves to their adoption in the near future. We found that existing systems are largely inadequate and that DPH has relatively little reliable concrete information on local health authority food protection operations. As a result, inspection, enforcement, and other activities are not reasonably well-coordinated and standardized across local authorities. The Commonwealth and its local authorities have also generally not implemented public information initiatives such as restaurant inspection grading and internet posting systems that have been implemented elsewhere in the nation and have been asserted to effectively reduce foodborne illness incidence rates. In response to the audit report, DPH indicated that it has now enrolled the state program office in the FDA voluntary standards program and that it is continuing to promote participation at the local level. DPH also stated that it should also be noted that increased training, provision of common inspection forms tied to the specific references in the regulations, and other

factors have improved standardization of food service inspections and reports. In addition, FPP organizes and chairs regular meetings with the Food Establishment Advisory Committee to promote education, standardization, and uniformity in the retail food industry. Although DPH has been working for the past five years to encourage local enrollment in the FDA standards program, only two local authorities had enrolled as of December 2005. Since then we have been told that two additional local authorities have enrolled, for a total of only four of the 328 local authorities responsible for food protection activities in the Commonwealth. Based on our audit work and discussions with FDA officials and other public health professionals, it is our belief that local authority participation in the voluntary standards system will remain minimal and the many problems identified in our report are likely to continue unless significant additional resources are made available at both the state and local level.

9. DECENTRALIZATION OF FOOD PROTECTION ACTIVITIES RESULTS IN INEFFICIENCIES AND ADMINISTRATIVE PROBLEMS

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In most states, relatively large county-based health authorities carry out retail food protection activities, often with significant coordination and oversight by state agencies. The Commonwealth's highly decentralized system, operated by generally small town government health authorities with minimal oversight, coordination, or technical assistance from state government has been characterized by the FDA as "unique" in the nation and has presented concerns to federal food protection officials at least as far back as 1982. The results of both our prior audit and this present audit suggest that while there are certain strengths associated with the Commonwealth's model, it remains inherently inadequate in many respects, and decentralization issues have been a contributing factor to the many deficiencies identified in this report. Multiple public health officials, including representatives of local health authorities, told us that in their view, food protection and other local health authority activities should be restructured using a regionalization approach. DPH needs to identify and implement measures to address these structural issues. In response to the audit report, DPH agreed that a regional approach is optimal and noted ongoing efforts to facilitate inter-municipal and regional collaboration. However, the collaborative arrangements described in the DPH response do not address the need for regional structures to carry out day-to-day local food protection activities across the Commonwealth. We noted that at an October 17, 2006 legislative hearing, multiple participants described serious resource issues and a need for fundamental restructuring of local health activities going far beyond the limited arrangements being implemented by DPH. Our audit analysis suggests that, at a minimum, a regional health authority or district health office model should be considered across the many local jurisdictions with populations of less than 100,000.

10. STRATEGIC LONG TERM PLANNING BY DPH FOR THE COMMONWEALTH'S FOOD PROTECTION EFFORTS NEEDS TO BE STRENGTHENED

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Both systematic program and operational planning and budgeting activities have been inadequate and have been constrained by a top-down state budgeting process without seriously considering the need for changes to existing resource arrangements or modifications to what DPH staff describe as the "home rule" nature of the Commonwealth's decentralized arrangements for local food protection operations. FDA officials have recommended that the Commonwealth conduct a formal self-evaluation of

its food protection systems, starting at the state level, to determine what system and resource changes are needed to meet recommended national standards. We concur and believe that the process should be used to develop appropriate strategies to correct the many statewide issues identified in this report. We have also included a brief description of some of the possible corrective action options that should be evaluated as part of a statewide review and strategic planning process. In response to the report, DPH stated that this section provides a number of recommendations for the FPP and optimal statewide approaches, but does not address the feasibility of implementing any of our suggestions. It was DPH's position that many of these suggestions cannot be implemented without significant changes in state law, with major implications for local control, and that it should not be implied that FPP alone can advance such changes. DPH also asserted that the occupational licensing of food inspectors, as suggested in the audit report, would require authorizing legislation, as is the case with other occupational licenses. However, Food and Drug Administration officials and other stakeholders such as the Massachusetts Health Officers Association have already indicated their willingness to participate in the recommended planning process. In fact, FDA officials indicated that the development of a detailed statewide resource model is essential for compliance with requirements of the national standards program. While DPH may be correct in its assertion that some of the recommended approaches may require changes in state law, we note that it is appropriate for the Department to identify the need for such changes and to develop proposed legislation. In fact, Massachusetts General Laws, Chapter 111, Section 2, Duties of Commissioner of Public Health states: "*He shall submit annually to the council a report containing recommendations in regard to health legislation.*" Finally, as stated in our report, the Department's strategic long term planning and budgeting activities for both state and local food protection activities have been inadequate and appear to have been generally undercut by a prevailing assumption that planning should be limited primarily to decisions involving allocation of existing limited resources.

Based on the results of our review, we have made several recommendations that, if adopted, would improve DPH's oversight of the Food Protection Program. The recommendations are summarized as follows:

- Work cooperatively with its Secretariat, the Executive Office of Health and Human Services, to ensure that sufficient resources are made available for proper oversight of local health board food protection activities and wholesale food inspection capacity.
- Develop detailed resource models as part of a statewide strategic planning process.
- Implement a combination of local health system restructuring measures and full cost recovery systems or expanded alternative funding mechanisms thereby ensuring that local food protection activities are adequately and uniformly conducted in conformance with state and federal guidelines.
- Implement a uniform statewide risk-based scheduling process driven by FDA-recommended risk assessment practices and reasonable inspection frequencies for each risk category.

- Implement significant operational changes such as comprehensive real time data exchange and tracking systems needed to ensure that activity is carried out as scheduled, that special federal provisions applicable to schools are met, and that risk-based classifications for establishments are modified in a timely manner to reflect the results of inspections and foodborne illness investigations.
- Confirm the extent of DPH statutory authority regarding local food inspector qualifications and promptly adopt more appropriate qualifications and training standards for both public and private food inspectors and establish appropriate controls over the use of consultant inspectors. Take additional measures to ensure that all food inspectors operating within the Commonwealth are as well trained in HACCP principles, standardized inspection practices, enforcement procedures, plan review, foodborne illness investigation/response activities, and other food protection related matters as are the Department's own inspectors. Also, consider establishing licensing and tracking systems for food inspectors in order to ensure that qualification standards are met, that inspectors adhere to appropriate professional standards on an ongoing basis with regular continuing education and inspection procedure re-standardization requirements, and that a reliable mechanism exists to deny, suspend, or revoke licenses for inspectors who do not fulfill professional standards. Similar licensing controls should be considered for food establishment managers.
- Implement a mandatory statewide system of standardization measures and program-monitoring procedures similar to those recommended by the FDA Recommended National Food Regulatory Program Standards on currently inadequate quality assurance systems.
- Establish an appropriate “tone at the top” oversight environment stressing the importance of code enforcement and full adherence to detailed foodborne illness and complaint investigation and response standards.
- Establish electronic data exchange systems for both inspection activity and for foodborne illness response activities thereby ensuring more efficient, economical, and effective operations and standardized timely sharing of electronic data on a statewide basis with all participants, including the public.
- Develop appropriate arrangements to ensure that all state and local inspection and food-establishment related foodborne illness investigation results are publicly posted in a prominent, easily accessible manner both at food establishment locations and online over a central state internet site, together with any educational guidance needed to minimize misinterpretation of results.
- Establish a statewide strategic long-term plan for the Commonwealth's FPP.
- Propose specific legislation where appropriate to modify existing statutory provisions in order to implement corrective measures developed through the strategic planning process.

In our opinion, statutory restrictions are not as significant an issue as asserted by DPH. We also believe that the composite language of multiple sections of the General Laws establishes a fiduciary responsibility for the Department to provide oversight and, where necessary, enforcement at the local level. If the Department's ability to carry out its mission and fiduciary responsibilities is impaired by resource deficiencies, statutory issues, or the need for modifications to the structure of local and regional public health delivery systems, the Commissioner has a duty to bring these problems and proposed solutions to the Public Health Council, the Secretary of Health and Human Services, the Governor, the General Court, and finally work collaboratively with local officials to improve this important public health and safety responsibility.

Finally, it should be noted that in January 2007, the U.S. Government Accountability Office (GAO) designated as a "High Risk", federal oversight of food safety because of the risks to the economy and to public health and safety.

GAO recommended that Congress consider a fundamental re-examination of the system to help ensure rapid detection of and response to any accidental or deliberate contamination of food before public health and safety is compromised.

David M. Walker, Comptroller General of the United States, in testifying before the House Sub Committee on Agriculture, stated that the "nation enjoys a plentiful and varied food supply that is generally considered to be safe, however, each year about 76 million people contract a food-borne illness in the United States; about 325,000 require hospitalization, and about 5,000 die, according to the Centers for Disease Control and Prevention."

Walker added: "We added the federal oversight of food safety to our list of programs needing urgent attention and transformation in order to ensure that our national government functions in the most economical, efficient and effective manner possible."

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INTRODUCTION

Background

The United States Center for Disease Control and Prevention (CDC) estimates that each year almost 30% of the population experiences an illness transmitted by food. These illnesses are referred to collectively as “food poisoning” or, more accurately, as “foodborne illnesses¹”. The CDC estimates that 76 million foodborne illnesses occur across the country each year, with effects ranging from short-term discomfort and time lost from work and other activities to hospitalization (325,000 people per year) and death (5,000 per year). In its 1997 Foodborne Illness Investigation and Control Reference Manual, the Massachusetts Department of Public Health provides an even higher estimate of 10,000 national deaths per year and an economic impact of between \$7 billion and \$17 billion per year just for diarrhea foodborne illnesses. National efforts to address this problem have been complicated by inadequate information regarding specific disease pathogens such as various strains of bacteria and viruses, under-reporting of illness incidents, and lack of knowledge by both food handlers and the public about food safety issues. The nation’s increased reliance on food transported through interstate and international commerce, increased chemical contamination (e.g., mercury and organophosphate pesticides) associated with environmental degradation, and risks of food-related bio-terrorism incidents present further challenges for prevention and control initiatives. In the face of these challenges and the serious impact of foodborne illness on our society, the federal government has established an ambitious goal of reducing the incidence of foodborne illness by 20% by the year 2010 (compared to 1997 baseline levels). While progress has been reported for some pathogens, illnesses associated with other pathogens, such as certain strains of salmonella, appear to be increasing. Even some of the pathogens that appear to be decreasing in frequency are becoming more resistant to treatment, so adverse health consequences attributable to those pathogens are not declining proportionately. Also, the majority of foodborne illness cases are believed to be caused by viral agents, many of which remain unidentified.

At the federal level, food protection responsibilities are split across multiple agencies such as the CDC, the Food and Drug Administration (FDA), and the US Department of Agriculture (USDA). These agencies work with state and local officials across the country, including an estimated 3,000

¹ Both the Department of Public Health and other public health professionals use the terms “Foodborne Illness” and “Foodborne Illness” interchangeably. This report uses the term “Foodborne Illness” except where quotations and document titles have used the other spelling convention.

state and local health authorities responsible for inspecting food processors, wholesalers, and a variety of retail and institutional food establishments. The scope of food service industry operations in the Commonwealth has been estimated to include 250,490 employees in Food Preparation and Serving Related Occupations and an additional 11,270 Food Processing Workers, accounting for a combined total of approximately 7.4% of the state's workforce in the year 2000.² Retail and institutional establishments (legally defined in Massachusetts by 105 CMR 590.002(B)) include operations such as restaurants, markets, school cafeterias, nursing homes, bed and breakfast operations, food pushcarts, and temporary food service arrangements at events such as fairs and church suppers. As documented in our report, DPH does not adequately track the total number of retail food establishments in Massachusetts; however, incomplete data for 2002 reported a total of at least 30,264 retail food service establishments in 239 communities accounting for 79.5% of the Commonwealth's population. While federal agencies have not mandated use of a standardized approach to food protection and illness prevention measures, the FDA encourages voluntary compliance with standards established in the periodically updated Federal Food Code and, for state and local regulatory and inspection agencies, the Recommended National Retail Food Regulatory Program Standards (<http://www.cfsan.fda.gov/~dms/ret-toc.html>). These standards, developed over the past decade, represent a shift from traditional one-size fits all inspectional approaches to a risk-assessment oriented system of science-based regulations and programs that are based on Hazard Analysis Critical Control Point (HACCP) principles and foodborne illness risk factor data. These principles are firmly based on scientific knowledge from fields such as food microbiology and epidemiology and require enhanced qualification and training levels for food protection regulators, inspectors, and food establishment managers and their employees. HACCP is an internationally recognized systematic scientific approach to ensuring food safety through preventive measures by controlling the production process from beginning to end, rather than detecting and addressing problems at the end of the line. For example, studies indicate that not properly storing potentially hazardous foods at temperatures below 41 degrees Fahrenheit is a significant risk factor, yet 40% or more of establishments inconsistently adhere to this standard. Greater emphasis therefore needs to be placed on improving temperature control systems. This approach emphasizes:

- Self-assessment and HACCP based risk management by food establishments with on-site certified food protection managers responsible for training and oversight of food preparation workers and operations; and

² Massachusetts Division of Unemployment Assistance, "Employment Projections 2000 – 2010".

- State and local regulatory and inspection systems based on nine standards covering Regulatory Foundation, Trained Regulatory Staff, Inspection Program Based on HACCP Principles, Uniform Inspection Program, Foodborne Illness Investigation & Response, Compliance & Enforcement, Industry & Community Relations, Program Support and Resources, and Program Assessment.

In Massachusetts, state and local inspection activities, educational efforts, and foodborne illness reporting and response activities are coordinated through the Massachusetts Department of Public Health (DPH), which promulgates a variety of food-related health and licensing regulations as part of the Commonwealth's "State Sanitary Code" established under the authority of Massachusetts General Law Chapter 111, Section 127A. DPH's Food Protection Program (DPH/FPP), operating under the Department's Environmental Health Division since a 2004 reorganization transferring the program from the Department's Food and Drug Division, has overall responsibility for food protection activities in the Commonwealth.

DPH/FPP directly licenses and inspects over 2,200 non-retail food establishments, with partial funding provided by federal contracts for the inspection of certain milk and shellfish plants involved in interstate commerce, and intergovernmental service agreement funding from the Commonwealth's Department of Education (DOE) for the inspection of approximately 100 DOE funded Summer Food Programs. Staff at the Department's separate Epidemiological Program and at the State Laboratory also participate with DPH/FPP staff in the Working Group for Foodborne Illness Control (WGFIC). That group coordinates state and local investigation and response for reported cases of foodborne illness where suspected cases involve two or more victims (referred to as "Food-Borne Illness Outbreaks") or where confirmed single-victim cases involve certain designated reportable diseases such as hepatitis-A. Other cases, such as those involving only a single victim where diagnosis of a specific reportable disease has not been confirmed, account for the vast majority of foodborne illness incidents and are handled primarily by local health authorities.

Although the DPH/FPP office is responsible for regulation, coordination, and oversight of retail food inspection and foodborne illness-related activities conducted by local health authorities, it does not routinely conduct retail food inspections or respond to unconfirmed single-victim foodborne illness incidents.

In an arrangement characterized by the FDA as "unique" in a nation where most "local" health authorities are units of relatively large county government entities, retail food protection activities in

Massachusetts are highly decentralized. While Massachusetts law establishes a statewide “Sanitary Code” comprised of a combination of statutory provisions and regulations promulgated by DPH, MGL, Chapter 111, Section 127A vests local boards of health in the Commonwealth’s 351 cities and towns with primary responsibility for enforcing the State Sanitary Code, which may be supplemented but generally not waived by local ordinance provisions. This local responsibility includes licensing, inspection, and code enforcement for retail food establishments. DPH regulations comprising the State Sanitary Code also provide for licensing, inspection, and code enforcement by local boards of health for additional firms with certain milk pasteurization, frozen dessert, bottled water, and carbonated non-alcoholic beverage operations. There is a certain amount of overlap between these inspectional arrangements. For example, a restaurant may be subject to inspection as a retail food service establishment and also subject to additional locally administered permit requirements applicable to frozen dessert (e.g., soft serve ice cream) operations on the premises. Or a bakery or other establishment engaged in both retail and wholesale operations may be subject to dual inspections by local authorities for retail operations and DPH inspectors for wholesale operations. In addition to these food-related responsibilities, the Commonwealth’s local board of health system is also responsible for a wide array of other activities including, but not limited to, the operation of public health clinics, bio-terrorism preparedness, mosquito control, and hazardous waste disposal activity in many communities, housing code and septic system inspections, and the inspection of public and semi-public swimming pools, camp programs, and tanning salon, massage therapy, and body art establishments. Oversight jurisdiction for these activities rests with DPH or, for some matters, the Commonwealth’s Department of Environmental Protection. Certain exceptions to the single community – single board of health/health department system have been provided for by statutes such as MGL, Chapter 111, Sections 27A, B, and C, which permit establishment of regional health districts to operate retail food inspection and other health services on behalf of multiple communities on a voluntary participation basis. However, such regional arrangements are not in widespread use in the Commonwealth. As described later in this review, one regional health district, Nashoba Associated Boards of Health, serves 14 towns with a combined total population of approximately 92,000. Four additional regional districts serve 14 additional towns with a combined total population of only 54,000. Individual local health authorities serve all other cities and towns. Approximately 3.1 million people (50% of the Commonwealth’s population) live in 297 communities with populations less than 35,000 which receive food protection services either from 283 decentralized local boards of health or from four small regional health districts. All

but four local health authorities in the Commonwealth serve population bases of fewer than 100,000 people.

DPH/FPP has the authority to coordinate local board of health food protection-related activity and to set minimum standards for the qualification and training of both food establishment managers and food establishment inspectors through provisions included in 105 CMR 590.000. However, unlike other states (e.g., Connecticut, Pennsylvania, and Florida), DPH does not directly license food establishment managers or inspectors. Instead, the Department relies on local authorities to ensure that inspectors are properly qualified and trained. Local authorities are also relied upon to ensure, through the inspectional process, that food establishment managers have been certified by private food safety certification exam administration organizations. DPH has approved three nation-wide organizations to administer these examinations but does not fund the process. Instead, examination fees paid by individual food establishment managers and others (e.g., inspectors) seeking certification fund the system.

In the wake of 9/11, DPH/FPP has taken on additional responsibilities for food related bio-terrorism preparation and response activity. The additional responsibilities are funded in part by federal grant contract arrangements with the Department. Food Protection Program staff also work with a variety of additional groups such as federal and inter-state organizations, food industry representatives, health officer associations, and food safety advocates on food safety issues. The program carries out these operations with a staff of 16 full-time and six part-time positions, equivalent to a total of just under 20 full-time positions and a budget of approximately \$1.5 million per year. Fewer than three full-time equivalent positions are assigned to the Retail Food/Foodborne Illness Unit within the FPP. The remaining positions, including 12.15 FTE inspector positions, are assigned to non-retail inspection and administrative activities.

Prior Audit Results

The Office of the State Auditor conducted a program performance review of DPH/FPP activities for 1983 through 1987 when the program was known as the Food Establishment and Local Health Operations Unit. At that time the unit was administered through the Department's Division of Food and Drugs. In a report issued in August 1988, we identified significant deficiencies in the program, particularly involving inadequacies in the quality, frequency, and standardization of retail food establishment inspections conducted by local boards of health and inadequate oversight

provided by the Department, which had, at that time, assigned five inspectors to provide oversight to local inspection and enforcement activities. In response to our audit, the Department committed to a variety of corrective measures including regulatory reforms, staffing increases, and enhanced reporting arrangements for food protection activities conducted by local boards of health and an initiative to standardize activities at the local level. While many of the issues and recommendations appearing in the prior audit report, such as the need to improve state oversight over the quality, frequency, and standardization of locally-conducted inspections, remain relevant to successful implementation of food protection strategies now recommended by the federal government, others, such as specific data gathering recommendations, have been antiquated by information technology changes. Also, since that audit, significant advances in the understanding of foodborne illness risk factors indicate that food protection efforts should place special emphasis on the use of risk-based HACCP principles by both food establishment managers and regulatory/inspection agencies, as well as on industry and community relations initiatives needed to supplement inspection and illness outbreak response activities.

Audit Scope, Objectives, and Methodology

In accordance with Chapter 11, Section 12 of the Massachusetts General Laws, we conducted an audit of the DPH Food Protection Program for the period July 1, 2003 to December 31, 2005. Our audit was conducted in accordance with applicable generally accepted government auditing standards (GAGAS).

Our audit was initiated to review program performance and to follow up on the issues identified in our prior audit. However, significant operational changes since the prior audit and deficiencies in departmental information regarding local board of health activities conducted during 2004 and 2005 required us to expand elements of our review to develop an understanding of these changes and evaluate the most recent available local board of health retail inspection data.

DPH regulation 105 CMR 590.010(F) mandates submission of annual reports from each local board of health no later than July 31 of each year. DPH asks that this data be provided on a calendar year rather than fiscal year basis. At the start of our field work in July of 2005, we were advised that DPH waived the reporting requirement for calendar year 2003 since local boards of health were instead asked to provide detailed needs assessment information for that year covering their many non-retail inspection-related public health responsibilities. In addition, we found that the 2004

annual reporting process had not been initiated by DPH in a timely manner and local boards had been told that reports would not be due until September 15, 2005. As a result, no data on local board retail inspection activity was available through DPH at that time for the entire original audit scope period. We therefore expanded our review to examine local board of health report data available for prior years and departmental information regarding significant operational and regulatory changes since our prior audit.

Due to the decentralized nature of local food protection operations and the extremely limited information maintained by DPH regarding local activities, we designed our review to achieve our objectives by including limited local health authority site visits for the purpose of verifying information submitted to DPH and identifying possible program issues that might not be apparent from records maintained at DPH. The local visits included interviews with inspectors and managers, review of management information systems, and record reviews covering a small number of retail food establishments (e.g., five to 13 establishments) for each authority. We did not accompany inspectors on food establishment inspections, nor did we conduct formal independent inspections to test the accuracy of local inspections in identifying establishment deficiencies and code violations. We did, however, perform a small number of observations in the course of purchasing meals in these communities in order to see if some of the most obvious violations, such as food preparers not appropriately using gloves where required, were occurring or whether gross sanitation violations visible from customer service areas were apparent. These site visits covered 13 local health authorities, including one regional health district for 14 communities. Local authorities were selected on a judgmental basis for a variety of considerations, including inclusion of authorities from different geographical areas of the Commonwealth, rural and urban, large and small authorities, annual report filers and non-filers, at least some authorities familiar with the use of electronic inspectional systems, an authority with an Internet system for reporting inspection results, authorities reporting varying frequencies of inspections, and at least one of the Commonwealth's five regional health districts. Together, the 13 selected local authorities cover food protection activities for 26 (7.4%) of the 351 cities and towns in the Commonwealth. According to the 2000 Census population statistics, these communities account for approximately 21% of the Commonwealth's 6.2 million residents. (See Appendix B for listing). Since the sample was not selected on a random basis and is known to disproportionately include larger authorities, it is not appropriate to use the results of these local visits for the purpose of developing statistical

extrapolations regarding exact statewide code compliance violation or inspection frequencies. Instead, the results of our visits to local authorities simply reflect issues identified at those authorities. The exact extent to which these issues exist at other local authorities was not determined by our review, although in many instances the results appear to be consistent with annual report data gathered by DPH, with professional opinions expressed by DPH staff and others, and with information gathered during background research on national food protection issues. We also contacted selected stakeholders for the program, including US/FDA Center for Food Safety and Nutrition (CFSAN) regional officials and associations representing Massachusetts food inspection professionals and food establishments. These included the Massachusetts Health Officers Association (MHOA), the Massachusetts Environmental Health Association (MEHA), and the Massachusetts Restaurant Association (MRA).

AUDIT RESULTS

1. RESOURCE CONSTRAINTS IMPAIR DPH OVERSIGHT OF LOCAL HEALTH BOARD FOOD PROTECTION ACTIVITIES AND DPH WHOLESALE FOOD INSPECTION CAPACITY

Our prior audit report on the Commonwealth's Food Protection Program (FPP) disclosed that the Department of Public Health (DPH) devoted significant staffing resources to the oversight of local food protection activities, including five DPH inspectors assigned to conduct quality assurance reviews of local inspections and a full time foodborne illness response coordinator. Additional oversight was also provided at that time by separate federal reviews of local inspections. However, even with those resources, our audit identified deficiencies in the quality, frequency, standardization, and oversight of local inspections of retail food establishments. In response to that audit, DPH planned to augment program staffing at the state level with 10 additional positions, including seven additional inspectors. However, the Commonwealth's Secretary of Administration and Finance put those plans on hold due to a then developing state fiscal crisis. Our follow-up review found that, while limited improvements have been made in some areas such as regulatory language, foodborne illness investigation and response, and industry and community relations, the planned corrective staffing measures were never implemented even during better economic periods. The elimination and reassignment of positions over the years has reduced DPH staffing to less than one full-time position available for current oversight of the thousands of retail food establishment inspections conducted across the Commonwealth's 351 cities and towns. The Program's operational capacity for planned inspections of wholesale firms is also inadequate. With the exception of 150 high-priority firms engaged in interstate milk and shellfish commerce, more than 2,000 other wholesale firms in the Commonwealth are inspected on an average of only once every four years.

We reviewed the recent history of the program's budget and staff changes. In some instances positions were simply eliminated. Other positions were reassigned to duties that have been added to the program's responsibilities over the years. For example, in 2002 the program experienced a \$400,000 cut to the program's primary appropriation account (4510-0600) during the budgeting process for fiscal year 2003. The cut effectively eliminated 3.4 full-time equivalent (FTE) positions. At the same time, the program received additional federal funding to carry out new bio-terrorism-related food security responsibilities. While layoffs were averted by reassigning staff to the new functions, existing program activities such as oversight of local food

inspection activities had to be cut. At the time of our audit work approximately 4.7 of the program's 19.9 FTE positions in fiscal year 2005 were directed to bio-terrorism related activity that was not within the program's scope of operations during the prior audit. Review of staffing arrangements for fiscal year 2006 showed a planned additional reduction to a total of 19.5 program FTE. As our field work was being completed, we noted that the Governor's proposed fiscal year 2007 budget for the above mentioned 4510-0600 appropriation account (which covers the entire DPH Environmental Health Services Division, including the Department's lead poisoning prevention radiation and nuclear hazard, drug control, and other activities, as well as the Food Protection Program) had been cut by an additional 3.9%, based on the assertion that funding was reduced "to meet projected need." This assertion of reduced need was surprising, since when we interviewed FDA regional district officials, we were told that, in their opinion, major resource limitations were adversely affecting the FPP in Massachusetts at both the state and local level, and were specifically impairing progress towards federal standardization goals. When asked about staffing resources needed by DPH/FPP for oversight of local board of health inspectional activities, the FDA would not provide a needs estimate, but stated that it certainly would require "a lot more" than the current three employees in the DPH/FPP Retail Unit. Without providing us with specifics, we were told that several years ago the FDA had been verbally given an internal estimate by DPH of additional resource requirements at that time, but had been told that the state couldn't afford to do it, so DPH believed there was no point in talking about it. In discussing this issue with a group of local public health authority representatives, we were told that DPH/FPP resource levels were grossly inadequate. As presented later in this review, resource allocation decisions are made in a top-down manner with little input from program managers. We saw no evidence that realistic need projections have been completed or that past or pending resource reductions are warranted. In addition, the Department's general administrative appropriation account (4510-0100), which funded 9% of FPP operations at the time of our field work, had been cut by 12.7% in the Administration's Budget Request for Fiscal Year 2007, based on the same assertion of reduced projected need.

Subsequently, the final enacted budget provided only a small 1.6% net increase for the 4510-0600 account over the fiscal year 2006 appropriation level, while the 4510-0100 administration account was reduced by 12.7% as proposed by the administration. As a result, final fiscal year 2007 funding levels may be insufficient to fully cover the routine compensation cost increases

required simply to maintain the fiscal year 2006 staffing levels. Program resource deficiencies cited by FDA officials and local public health authority representatives are likely to be impacted.

As a result of the prior resource reductions and reallocations, the program already operates in what was described by staff as “triage mode” on a daily basis. Most staff are assigned to functions associated with the program’s direct inspection responsibilities for wholesale food establishments or with bio-terrorism related activity. These resource reallocation decisions have largely been driven by the program director’s obligation to fulfill grant and contract obligations (primarily federal) associated with approximately 38% of the program’s funding. Table 1 summarizes program-funding sources for fiscal years 2005 and 2006.

Table 1
Food Protection Program Funding by Source and Account

Funding Source*	Account Number	Fiscal Year 2005		Fiscal Year 2006	
		Amount	Percentage	Amount	Percentage
State Account – Administration**	4510-0100	\$ 136,766	8.9%	\$ 140,869	9.0%
State Account – Operational***	4510-0600	<u>815,064</u>	53.3%	<u>823,823</u>	52.8%
Total Direct State DPH Funding		951,830	62.2%	964,692	61.8%
CDC Bio-terrorism Grant	4516-1021	287,777	18.8%	297,279	19.0%
CDC Foodborne Illness Related Epidemiology and Laboratory Capacity Grant	4512-0180	55,055	3.6%	55,816	3.6%
USFDA Inspection Contract****	4510-0619	191,170	12.5%	200,000	12.8%
DOE Summer Food Contract	7053-2202	<u>43,758</u>	<u>2.9%</u>	<u>43,758</u>	<u>2.8%</u>
Total Contract/Grant Funding		<u>\$ 577,760</u>	<u>37.8%</u>	<u>\$ 596,853</u>	<u>38.2%</u>
Total All Funds		<u>\$1,529,590</u>	<u>100.0%</u>	<u>\$1,561,545</u>	<u>100.0%</u>

*Although the program generates certain permit fee revenues from non-retail firms directly inspected by the program, all revenue is deposited in the state’s General Fund without any reserve for direct program use.

**General departmental administration account from which the program receives an internal departmental allocation.

***Funds Environmental Health Division, including Food Protection Program (FPP). Amounts shown are the internal departmental allocations to FPP.

****FY 2006 USFDA Inspection Contract amount had not yet been finalized at the time of our audit work.

At present,³ the Retail Food/Foodborne Illness Unit within the DPH/FPP has only 2.65 FTEs (13% of program resources) with no full-time inspectors. In addition to bio-terrorism related responsibilities assigned to the unit, 0.5 FTE for a program coordinator is used to carry out intergovernmental service agreement responsibilities for inspecting approximately 100 Department of Education (DOE)-funded Summer Food Program sites, while a 0.8 FTE epidemiologist position is federally funded for the purpose of enhancing foodborne illness investigation and response functions. Remaining unit staff, including the 0.4 FTE unit director, also devote considerable time to foodborne illness investigation and response activities. What little time is left is primarily spent on educational and training activities, coordination with federal and inter-state groups, and complaint response, leaving no significant resources devoted to oversight of local board of health retail inspection activity. Table 2 summarizes program staffing arrangements.

Table 2
Food Protection Program Staffing by Activity Group

Activity Group	Fiscal Year 2005 FTE*	Fiscal Year 2006 FTE*
Retail Food/Foodborne Illness**	2.65	2.65
Water	0.30	0.30
Seafood	3.90	3.50
Dairy	3.75	3.50
Non-Retail Food	4.50	4.75
Administration	<u>4.80</u>	<u>4.80</u>
Bio-terrorism	Included in all above groups	
Total	<u>19.9</u>	<u>19.5</u>

*Staff reported on Full Time Equivalency basis since several staff are either part-time or work across multiple activity groups.

**Includes approximately 0.5 FTE each year working on contracted DOE Summer Food Program inspections and 0.8 FTE each year for federal CDC grant funded foodborne illness related Epidemiology and Laboratory Capacity enhancements.

The prioritization of the unit's extremely limited discretionary resources appears to be a pragmatic and rational response to significant limitations on the Department's authority to oversee activities of local health authorities. DPH staff acknowledge that realistically there is little they can do to address any deficiencies at the local board level, given what they characterize as the "home rule" nature of the system of independent local boards of health and the severely

³ Present tense references are to fiscal year 2006, as of the time of our fieldwork during the first half of the fiscal year.

constrained resources at DPH. By statute (MGL, Chapter 111, Section 127A), the Department can step in and perform the duties of a local board if it does not carry out its responsibilities; however, there is no mechanism to fund the additional costs the Department would incur by stepping in. Staff could point to only a single instance where they had intervened during the late 1990s at the request of the Commonwealth's Department of Environmental Protection to enforce water quality requirements at a local market on Plum Island after the Newbury Board of Health allegedly did not enforce the code. The only other established enforcement alternative is that of referring local officials for prosecution – hardly a reasonable course of action where deficiencies at the local level may be due to resource constraints facing local boards rather than willful non-performance by board staff.

In addition to providing oversight to retail food inspection activities of local health authorities, the DPH/FPP is directly responsible for licensing and inspecting approximately 2,265 non-retail firms falling into approximately 38 separate categories such as wholesale bakeries, custom meat and poultry processors, Interstate Milk Shippers (IMS), and firms on the Interstate Certified Shellfish Shippers List (ICSSL). The program uses 12.15 FTE inspectors and supervisory staff to conduct these inspections and associated food sample collection, food embargo, and enforcement activities, but has had to prioritize 440 planned inspections per year for 150 IMS and ICSSL firms in order to meet the Commonwealth's interstate commerce participation responsibilities. These interstate commerce responsibilities are also contractual obligations associated with substantial federal funding received by DPH for IMS and ICSSL inspections and associated food sampling activities. As a result, DPH has only been able to conduct approximately 533 planned inspections per year for the remaining 2,115 non-retail firms for which it is also responsible. As presented in Table 3, these non-prioritized inspections are conducted on a risk-based schedule with planned inspectional frequencies varying from once every two years to once every four years. However, some firms are actually inspected less frequently and the overall average frequency of these non-prioritized inspections is once every four years (47.6 months).

Table 3**Scheduled Non-Retail Firm Food Protection Program Inspections**

Type of Firm	Assessed Health Risk	Assessed Bio-Security Risk	Number of Firms	Planned Inspections Per Year	Inspection Frequency (Months)
ICSSL Shellfish Plants	Federally Determined	Low	140	320	5.25*
IMS Milk	Federally Determined	High	<u>10</u>	<u>120</u>	1
Total federal Cooperative Program for Certain Interstate Commerce Related Firms			<u>150</u>	<u>440</u>	4.1
36 separate additional Type of Firm categories. Examples include:					
Warehouse (Dry Storage)	Low	Low	520	130	48
Vegetables (Raw)	Medium	High	35	12	35
Prepared Salad Products	High	Low	6	3	24
Snack Foods	Low	Low	10	2	60
Custom Meat and Poultry	High	Low	43	20	25.8
Bakery (Wholesale)	Medium	Low	360	120	36
Total All 36 Non-federal Cooperative Program Categories			<u>2,115</u>	<u>533</u>	<u>47.6</u>
Total All DPH/FPP Non-Retail Planned Inspections			<u>2,265</u>	<u>973</u>	<u>27.9</u>

*ICSSL Shellfish plants are actually inspected on two risk based frequency schedules with 20 firms inspected every 3 months and 120 firms inspected every 6 months.

In contrast, we noted during background research for our audit that the state food protection program in Kentucky has asserted that it conducts approximately 1000 inspections per year for its 1200 food manufacturing and storage firms. Kentucky also asserts that it conducts extensive sampling of fresh fruit and produce offered for sale in the state and of edible fish species for pesticide and other residues posing potential health risks. However, as presented in Table 4, we found that the Massachusetts FPP statistics for fiscal year 2004 (latest statistics available) show extremely limited sampling activity by the program.

Table 4**Fiscal Year 2004 DPH Food Protection Program Sampling Activity**

Sample Type	Samples Collected
Food Processing	12
Seafood	-
Dairy	279
Retail Complaint & Foodborne Illness Related	7
Special Projects	<u>4</u>
Total	<u>302</u>

In addition to these non-retail inspection frequency and sampling concerns, we received comments from local health officials that, in their opinion, resource limitations for DPH non-retail licensing and inspection activities also impaired the Department's ability to adequately carry out its responsibility under the food code to conduct full operational plan reviews for facilities such as bakeries, whose wholesale operations are directly licensed by DPH.

Despite the above noted resource, structural, and legal constraints, DPH/FPP has made significant accomplishments in certain areas. Accomplishments generally fall in the areas referred to by FDA standards as Regulatory Foundation, Foodborne Illness Investigation & Response, and Industry & Community Relations. For example, the Department modified the 105 CMR 590 regulations (also known as Chapter X of the Sanitary Code) in 1991 and again in 2000 to address changes on the national scene such as promulgation of the 1999 Food Code, which was incorporated by reference as the fundamental framework for retail food safety requirements in the State Sanitary Code. (Certain details of the 1999 Food Code have since been updated through the 2001 Food Code and the recently released 2005 Food Code issued in September, 2005, which have not yet been incorporated into the State Sanitary Code). Various supplemental guidance documents have been issued, standardized inspection forms consistent with federal Hazard Analysis Critical Control Point (HACCP) principles were developed and recommended for use by local inspectors, and food establishments were mandated to employ managers certified by national independent testing organizations as Certified Food Protection Managers (CFPM). These CFPM certifications are commonly referred to by different certification names used by the private firms issuing the certificates (e.g., ServeSafe). Training has also been developed and offered on a voluntary basis to both local inspectors and food establishments to the limited extent permitted by program resources. We were told that DPH/FPP has also recently committed to enrollment in the FDA's voluntary system promoting adherence to the Recommended National Food Regulatory Program Standards. While the DPH program can fairly claim an extensive list of accomplishments despite the significant resource constraints and limitations inherent in the Commonwealth's decentralized system of operations, we found that results have been far more limited in the program standard areas of Trained Regulatory Staff, Inspection Program Based on HACCP Principles, Uniform Inspection Program, Compliance & Enforcement, Program Support and Resources, and Program Assessment. We identified notable weaknesses, generally attributable to these resource

constraints and the unique decentralized inspection and enforcement approach used by the Commonwealth, which we have set forth in the remaining Audit Results sections of this report.

Recommendation

Substantial additional resources are required for wholesale food protection inspections and sampling for state-level foodborne illness prevention testing, investigation, and response activity as well as for oversight and coordination of retail inspections and other food protection activity conducted at the local level. The Department should work cooperatively with its Secretariat, the Executive Office of Health and Human Services, to ensure that sufficient resources are made available for proper state oversight of local health board food protection activities and DPH wholesale food inspection capacity. Additionally, detailed resource models should be developed as part of a recommended statewide strategic planning process.

Auditee's Response

Since 2000, the adoption of the HACCP-based federal 1999 Food Code, mandatory food protection management certification for industry, establishment of minimum training and certification requirements for food inspectors, development of food-borne illness investigation manual and training for local Boards of Health are all major improvements accomplished with available resources.

Auditor's Reply

We acknowledge that while the DPH program can fairly claim an extensive list of accomplishments despite the significant resource constraints and limitations inherent in the Commonwealth's decentralized system of operations, we found that results have been far more limited in the program standard areas of Trained Regulatory Staff, Inspection Program Based on HACCP Principles, Uniform Inspection Program, Compliance & Enforcement, Program Support and Resources, and Program Assessment. We identified notable weaknesses generally attributable to these resource constraints and the unique decentralized inspection and enforcement approach used by the Commonwealth.

2. LOCAL HEALTH AUTHORITY FOOD INSPECTION ACTIVITIES ARE SIGNIFICANTLY UNDERSTAFFED IN MANY COMMUNITIES

Both DPH staff and local health officials told us that they believed inspection and other local food protection activities suffered from a lack of resources at the local level, that local health departments were forced to compete with local school, fire protection, and police functions for

funding, and that local funding of food protection efforts was usually not adequately prioritized, particularly in communities where health agents and inspectors are responsible for multiple public health functions and food inspection activities lack separate budget and reporting mechanisms. Our review confirmed the existence of these problems for the 26 communities represented by the 13 local health authorities we visited. While DPH does not gather revenue and expenditure information through its annual reporting process for local food protection activities, the process does gather limited information on staffing levels, food protection activities, and on the number of food establishments as reported by each community participating in the reporting process. At the time of our fieldwork during the summer of 2005, the most recently completed DPH survey results covering local board of health food protection activities were for calendar year 2002. Since DPH has not enforced annual reporting requirements and instead treats the reports as a voluntary survey process, local staffing data was only available for 156 communities that year. Analysis of the available 2002 data suggests that food inspection positions are probably understaffed for most communities in the Commonwealth, and that in many instances staffing levels are at least a third less than the federally-recommended level of one full-time inspector for every 150 food establishments. In the communities for which data was available, over 70% of the communities had too few inspectors and over half of the communities had less than two-thirds of the recommended numbers of inspectors. These communities with inadequate numbers of inspectors were also responsible for the inspection of a disproportionate number of food establishments. Approximately 90% of the establishments in the dataset were in communities with too few inspectors, and over 75% of the establishments were in communities with less than two-thirds of the number of FTE inspectors recommended for the number of establishments in the community. In addition, approximately two-thirds of the communities in the dataset appeared to be operating entirely with only part-time food inspectors.

Our local health authority visits produced information generally consistent with this data. 10 (77%) of the 13 local authorities were staffed well below the FDA's recommended level of one full-time inspector for every 150 food establishments. Nine (69%) were staffed at less than 50% of the recommended staffing level. Eight (62%) conducted their food inspection activities entirely with part-time inspectors. Due to the widespread use of part-time inspectors or full-time inspectors with only part-time food protection responsibilities, the 13 authorities used 48

individuals to provide the equivalent of 34 full-time food inspectors. Had they adhered to federally recommend staffing levels, over 60 FTE food inspectors would have been needed to carry out these responsibilities.

While the data for inspectional staff numbers covers only approximately 44% of the communities in the Commonwealth, it disproportionately covers approximately 60% of the population, which suggests that the data may understate the extent of these problems in the large number of small communities excluded from the dataset. The DPH data also appears to be subject to reporting accuracy issues, since it is not clear that all communities properly reported the proportion of work time devoted to inspections. In some instances it appeared that activity had been reported entirely as full-time for a board's health agent, when the community had only a handful of food establishments, and it was obvious that the individual could only have been devoting a few hours per year on inspections, with most of his or her time spent on other non-food related health department activities. The sample of 13 local authorities we visited was somewhat more distorted than the DPH annual report filer dataset, including three communities with populations under 35,000, plus the Nashoba Associated Boards of Health regional health district which covers an additional 14 towns and the small community at the former Fort Devens site spanning three towns in the district. Our audit visit sample covered only 7.4% of the Commonwealth's cities and towns but 21% of the state population, primarily due to the inclusion of the City of Boston in the sample. In total, these 13 authorities are responsible for the inspection and related food protection activities covering over 9,000 food establishments plus additional miscellaneous permit holders (e.g., temporary food events). When we visited these authorities, we found that, even in larger authorities, the authorities often used staff for both food and non-food related inspections, systems for tracking staff time-utilization for food inspections were inadequate, and FTE inspector information had in some cases been inaccurately reported (usually over-reported) to DPH. It would not be surprising if most non-reporting small to mid-sized communities in the Commonwealth are operating with staff who must devote most of their time to septic system, housing, and other non-food related public health functions, with inadequate resources available for their food establishment inspection responsibilities. An example of these pressures was provided in one community we visited where two out of four health inspector positions were left vacant from September 2004 through the date of our site visit in late November 2005. In that community each of the four inspectors

had performed a combination of food inspections and non-food health inspections such as housing, septic system, and swimming pool inspections. Analysis of inspection data indicated that, while the number of inspectors had been reduced by half and the total number of inspections performed was reduced by 50.5%, the reductions were disproportionately made to food inspections. The number of food inspections conducted for January through September of 2005 was 74.8% lower than the number performed over the same nine months during the prior year, while the number of non-food inspections had only been reduced by 17%. In the case of Title V septic system inspections, where health departments have little practical discretion to reduce inspections, the reduction was only 5.6%. While DPH provided only anecdotal information regarding known staffing situations in non-reporting communities, we were told that the DPH/FPP regularly encounters even more extreme situations where small communities have vacant health agent positions and elected board of health members are attempting to carry out all public health functions, including food inspection responsibilities, without any trained professional staff or contractors.

During our background research on food protection systems elsewhere in the nation, we noted that numerous jurisdictions operate under so-called “full cost recovery” models activity and costs are carefully tracked and permit and inspection fees are required to be set at high enough levels to cover the full costs of operating the programs. That is not a requirement in Massachusetts. When we asked DPH/FPP managers if they had ever gathered data on local authority fee levels or special funding arrangements such as dedicated revolving accounts, we were told that they had no information. However, we did find that the Massachusetts Health Officers Association (MHOA) had posted limited data on their internet site from a fee survey distributed to their members. That information only covered 27 communities, none of which were covered in the local health authority sample picked for our site visits. The 27 fee arrangements varied significantly with some communities establishing simple systems (e.g., one fee price for all restaurants regardless of seating capacity) and others using more complex systems with separate charges for plan reviews, supplemental inspections, and tiered rates based on seating capacity. However, all charged fees substantially below those charged under full cost recovery systems such as those used in California or the state of Washington. For example, none of the 27 communities covered by the MHOA survey charged more than \$300 per year for a large restaurant (e.g., 200 seats), while the charge in southern California (e.g., Los Angeles or

San Diego) for a large restaurant would be approximately \$1,200 per year. In King County, Washington, “full cost recovery” based permit fees are somewhat lower, but still exceed \$700 per year for large restaurants. The 13 local authorities we visited had fee arrangements similar to those included in the MHOA survey, but were sometimes somewhat higher for certain establishments. For example, several charged a \$100 minimum restaurant fee with a \$1 per seat add-on for every seat over 100 seats, resulting in an annual fee of \$200 for a 200-seat restaurant but higher fees for larger restaurants. The highest annual fee for a 200-seat restaurant was only \$600 – well below what might be expected under a full cost recovery system. One municipality uses a \$100 minimum plus a \$1 per seat system, with a maximum fee of \$1,000 applicable to restaurants with 1,000 or more seats. However, a 200-seat restaurant in that municipality pays an annual permit fee of only \$200 under that system. That municipality also derives a substantial portion of fee revenues from special gross-revenue based sliding fees for fast-food take-out establishments. Even there, we were told that fee revenues only cover direct payroll costs for their current number of inspectors, a number approximately 50% below FDA recommended staffing levels, and that additional operating costs are borne by the municipality’s General Fund. No authority reported that its food protection activities were fully funded by fees, none reported the use of revolving or other special accounts, and all relied on local community General Fund appropriation support to supplement fee revenues. With the exception of the single regional health authority, where the authority retained most fee revenues and appropriations from member communities were correspondingly reduced, all fees were paid into local community General Funds. Operational costs absorbed by community General Funds were only partially offset by the fees and (indirectly) by state general local aid “Cherry Sheet” payments to the communities. Staff at local health authorities told us that their ability to establish full cost recovery fee schedules was constrained both by local impediments and the pattern of fee schedules in neighboring communities. Each authority’s ability to fulfill its food protection responsibilities under the State Sanitary Code has been constrained by its ability to secure local operational subsidies, and few authorities receive sufficient funding to fully staff food protection activities.

In researching this issue, we found that similar issues were identified by the State Auditor for Colorado, where program responsibilities are carried out under a hybrid system of state, regional, and local authorities funded by a combination of inadequately low permit fees (split between

state and local authorities under a 50/50 revenue sharing arrangement) and state and local general fund support, with approximately 70% of overall costs paid from the state general fund. The Colorado State Auditor recommended in her 2003 report that Colorado move to a Full Cost Recovery system in order to better address its program resource deficiencies.⁴ During our review, we received input that current fee arrangements at some local health authorities involve add-on charges for follow-up inspections conducted to verify correction of previously identified violations. A food industry representative told us that this approach could motivate inspectors to over-inspect and identify extra violations as a means of generating more revenue for often resource-strapped local authorities. This concern may have limited validity under current funding arrangements where revolving funds are not in use and local health budgets are fixed by town appropriations. However, this issue could take on significance in any restructuring of funding systems and should be examined as part of any initiative to adopt full-cost recovery or alternative funding arrangements for local food protection activities.

Recommendation

While we do not necessarily recommend the adoption of full cost recovery systems in Massachusetts without additional study relating to economic issues such as potential adverse impacts on non-profit organizations (entities such as a small lodge or social club that often run meal events to raise funds for scholarships or other charitable donations), we recommend a combination of local health system restructuring measures and full cost recovery fee systems or expanded alternative funding mechanisms. In this manner, local food protection activities can be adequately and uniformly conducted in conformance with state and federal guidelines.

Auditee's Response

FDA is no longer using the 1.0 FTE/150 food establishment ratio for calculating the number of inspectors needed; they are now using a ratio of FTEs per number of inspections and re-inspections, not per restaurant. For the purpose of this audit report the current status of local public health staffing ratios should be re-analyzed based on the current guidance.

⁴ Consumer Protection Division, Department of Public Health and Environment, Performance Audit, May 2003 – Report Control Number 1502, State of Colorado, Office of the State Auditor.

Auditor's Reply

We discussed the recent guidance change with the FDA and were told that the new guidance is still very much under discussion and subject to change, and that the new guidance language is not inconsistent with the original guidance calling for 1.0 FTE inspectors per 150 establishments. We were also told that our analytical approach had been appropriate, and that it might in fact be the only way the analysis could reasonably be conducted. During our visits with local health authorities, professionals we met with also generally agreed with our analytical approach. Therefore, we see no reason to re-analyze the available data or to modify our conclusions.

3. LOCAL INSPECTION FREQUENCY IS OFTEN INADEQUATE AND APPROPRIATE RISK-BASED SCHEDULING SYSTEMS ARE RARELY USED

Both DPH/FPP and the FDA recommend that inspectional authorities use a risk-based classification system to schedule the frequency of regular routine inspections for food establishments so that high-risk settings such as hospitals, nursing homes, and large restaurants are routinely inspected three to four times per year; while medium-risk establishments are inspected two or three times per year; and low-risk establishments such as convenience stores serving only coffee, soda, and snacks are inspected at least once per year. DPH/FPP regulations (e.g., 105 CMR 590.013) require that, with the exception of certain low-risk situations, all establishments must be routinely inspected at least every six months unless DPH has approved additional exceptions as part of a written risk-based scheduling plan submitted by the local authority. However, both annual reports submitted to DPH by local boards of health and our visits to the 13 local health authorities indicate that few authorities use formal risk-based assessment plans and that establishments are not inspected with the required frequency despite the fact that the six month/twice a year frequency requirement is minimal compared to higher standards in other states such as Maryland, which mandates a minimum of three inspections per year for full service restaurants. We noted inspection frequency violations at 11 of the 13 authorities we visited. In some instances relatively high-risk establishments have gone well over a year without a routine inspection and we even found some establishments that had gone as long as seven years without a routine inspection. At one authority where we reviewed all available records from fiscal year 2002 through October 13, 2005 for 13 establishments, we found that not a single establishment had received the minimum required number of inspections

over the multi-year period. Discussions with food safety professionals suggest that these inspection frequency violations are primarily attributable to the significant local health authority resource constraints identified in Audit Results No. 2. We also found that DPH/FPP has no system for reliably identifying and addressing inspection frequency violations that occur. The problem also involves cafeterias and other food operations in school systems, where the federal Child Nutrition and WIC [*Women, Infants and Children*] Reauthorization Act of 2004 separately mandates that food inspections be conducted at least twice a year.

The 105 CMR 590.013 DPH/FPP regulations require that, except for certain low-risk establishments such as bed and breakfast homes and convenience stores serving only coffee, soda, and pre-packaged non-hazardous snacks, all establishments must be routinely inspected at least every six months unless *“the food establishment is assigned a less frequent inspection frequency based on a written risk-based inspection schedule approved by the department that is being uniformly applied throughout the jurisdiction and at least once every six months the establishment is contacted by telephone or other means by the FC [Food Code] – regulatory authority to ensure that the establishment manager and the nature of food operation are not changed.”* Both DPH/FPP and the FDA recommend that inspectional authorities use a risk-based classification system to schedule the frequency of regular routine inspections for food establishments. An example of such a risk-based system is provided in an “Annex” to the Federal Food Code. That example has been included in this report as Appendix A. Using the FDA’s recommended example approach, the highest risk establishments such as hospitals, nursing homes, and large restaurants serving complex menus of potentially hazardous food items such as sushi (raw fish) might be routinely inspected four times per year, while most full service restaurants and other medium-risk establishments would be inspected three times per year. Establishments with menus limited to one or two main items and no high-risk items (i.e., no seafood, deli, eggs, etc.) would be inspected two times per year and only minimal-risk establishments such as convenience stores would be inspected once per year.

a) Recommended Risk-Based Scheduling Approaches are Generally Not Used

Data submitted by 240 annual report filers to DPH/FPP for calendar year 2002 indicates that only 71 (29.6%) claimed to be using risk-based scheduling approaches, and only 12 (5%) claimed to be using the formal written risk assessment plans that DPH regulations provide for.

Only two of the 13 authorities we visited used formal written risk-based scheduling plans:

- In one case a four level system essentially identical to the federally recommended plan was used. Under the plan provisions, 3.6% of the establishments for that authority should receive routine inspections four times per year, 49.6% three times per year, 18.6% twice a year, and 28.2% should need only one inspection per year. However, that authority did not track compliance with the plan and authority managers acknowledged to us that resource constraints had resulted in some establishments not being inspected with the planned frequency. When we reviewed records for six of that authority's establishments we discovered that none of the six had been inspected as frequently as required by the plan and that a high-risk nursing home was only being inspected once a year, while a school cafeteria had gone four years (from December 2000 to December 2004) without an inspection.
- The second authority had a written plan with three risk levels calling for inspection frequencies of once a year for low-risk establishments, twice a year for medium-risk establishments, and three times per year for high-risk establishments. That authority classified only a small number of establishments as high risk, with three planned inspections per year each. In some instances we noted that establishments such as elder meal sites, with consumer populations generally regarded by the federal government and other food safety professionals as being high-risk, had been classified as medium-risk by the authority and only scheduled for two inspections per year. Only 7% of establishments were classified as high-risk, with 19% classified as low-risk and 74% classified as medium-risk. That authority did track the number of inspections by risk category and their records indicated that approximately the planned numbers of inspections were being conducted for both high and low-risk categories. However, while the anticipated number of initial annual inspections was performed for medium-risk establishments, only 32% of the planned number of second inspections was being conducted for that category. As a result, most medium-risk establishments were only being inspected once a year. As a result, approximately 70% of establishments covered by that authority were being routinely inspected only once a year rather than the 19% called for by their risk-based scheduling plan. Since the inspectional staffing level for that authority was only approximately one half of the federally recommended level, the number of inspections not done as called for by the risk-based plan can reasonably be attributed to the resource problem identified in our review.

While some of the remaining nine authorities we visited stated that they informally used unwritten risk-based approaches for making scheduling decisions, the descriptions they gave were essentially "triage-based" approaches where they devoted their limited resources to the inspection of what they believed to be likely problem establishments, making these decisions on the basis of past inspection results and the receipt of complaints. While these approaches are understandable given the resource constraints faced by the local authorities, they are not in compliance with the above quoted regulation mandating that each plan be put in writing, be approved by DPH, be uniformly applied, and that each establishment inspected less frequently than every six months be contacted at six month intervals to ensure that the establishment

manager and nature of food operation have not changed. None of the authorities we visited had implemented the required status change contact arrangements, and status change information for un-inspected establishments was being gathered only once a year through permit renewal applications.

These triage-based approaches are also highly problematic from a food safety perspective, since they can result in large numbers of establishments being inspected even less frequently than the marginally adequate six-month standard set by DPH. In discussing the impact of inadequate inspection frequency even for low-risk establishments, the food protection program director of a neighboring state facing resource constraints similar to those in Massachusetts stated to us:

A serious concern is that many of these facilities are no longer low risk. Many facilities that were previously only selling prepackaged refrigerated food years ago are now cooking and leaving foods at unsafe temperature for long periods of time. In essence, low risk [establishments] have become high risk due to the lack of inspections. Based on existing staff, a very high percentage of our time is reactive (responding to complaints, openings, reinspections, outbreaks, responding to fires in food establishments, etc.)...Facilities should be inspected much more often to properly protect public health but this is the best we can do with existing resources.

Food protection professionals we interviewed in Massachusetts agreed that the same increased risks associated with inadequate inspection frequency exist in our own state.

For the two authorities with written risk-based plans, we also noted that the disparities between the two plans were significant. One authority determined that 52% of its establishments warranted three or more routine inspections per year each, while the second authority determined that only 7% of its establishments warranted that inspection frequency. However, we saw no reason to believe that a corresponding difference really exists in the underlying nature of operations for establishments in the two communities. Even disregarding the impact of local resource constraints on actual inspection frequency, we question whether such extreme disparities in risk-based scheduling plans is consistent with the principle that local authority inspection systems should operate in a reasonably standardized manner across the Commonwealth. During our background research for the audit we noted that some states require use of uniform risk-based scheduling approaches by all local food inspection authorities. Louisiana, for example, has adopted the federally provided model (see Appendix A) for required statewide use by all parishes (the equivalent of counties in that state), while Maryland mandates use of a similar three-tier prioritization system that effectively requires most full service

restaurants and establishments serving at risk populations to be inspected at least three times per year. We believe that the existing 105 CMR 590.013 provision referenced above does not adequately ensure that full service restaurants, assisted living facilities, nursing homes and other moderate and high-risk establishments will be routinely inspected at least three to four times per year as called for by best-practice risk-based scheduling systems used elsewhere in the nation.

b) Inspections are Often not being Performed with the Required Frequency

Before visiting the 13 selected local health authorities, we contacted each authority and asked that a list of all food establishments be prepared reporting the number of inspections conducted for each establishment during the reporting period covered by their annual report to DPH. While each authority provided establishment lists, only three of the 13 were able to generate lists showing the number of inspections for each individual establishment. As described further below, only two of those three authorities were substantially in compliance with inspection frequency requirements. We found that most of the other 10 authorities only tracked information such as the total number of inspections conducted each month by type of establishment and/or risk category. In many instances only the most recent inspection date for an establishment was tracked for the purpose of scheduling the next inspection; however, these lists were often not retained. As a result, the authorities were generally not able to verify either the accuracy of inspection numbers reported to DPH or the full extent of compliance or noncompliance by each authority with the inspection frequency requirements established by the State Sanitary Code. At each authority we also reviewed a limited number of records for individual food establishments, primarily for the purpose of testing the accuracy of each authority's summary tracking systems and to assess the extent to which inspection practices were standardized across authorities (as discussed separately in Audit Result No. 5). Conclusions regarding inspection frequencies were based on these record reviews, interviews with authority staff and, where available, data from tracking systems and summary reports for each authority. Our review of individual establishment records was limited to only 113 food establishment files (five to 13 files for each authority). A relatively small sample size such as this might be expected to miss inspection frequency violations for a community if only a small percentage of the community's establishments were being inspected with inadequate frequency. However, these limited reviews revealed that most authorities had multiple establishments with inspection frequency issues. At one authority, we identified inspection frequency problems for all 13

establishments reviewed during our visit. At two authorities, our limited review identified only a few inspection frequency delays of less than 30 days each or not completing the required inspections for temporary food events such as local fairs and church suppers. We have not characterized those two authorities as materially deficient for the purpose of the presentation in this Audit Results section, although we are aware that even temporary food events can present high risks of foodborne illness. We also had separate significant concerns regarding inadequate documentation of the quality and thoroughness of inspections performed by one of the two authorities with apparently adequate inspection frequencies (See Audit Result No. 5). For the remaining 11 authorities we visited, there were at least some establishments subject to the six-month inspectional frequency requirement that had gone at least seven months between routine inspections. We have characterized the practices of those authorities as out-of-compliance. At nine of the 13 authorities we visited, our limited review identified medium to high-risk establishments where routine inspections had occurred less frequently than once a year. For five authorities, we found at least some establishments in each community that had not been inspected for periods exceeding two years. In some instances it had been as long as seven years since the last inspection of the establishment. These inspection frequency compliance issues are summarized in Table 5.

Table 5**Inspection Frequency Compliance Issues for 13 Visited Local Health Authorities**

In Compliance with 6-Month Inspection Frequency Requirement		
<u>2</u>	<u>(15.4%)</u>	Authorities in Substantial Compliance (except for temporary food event inspections)
Out of Compliance		
2	(15.4%)	Authorities with some medium/high risk establishments inspected less frequently at 7 to 12 month intervals
4	(30.7%)	Authorities with some inspected at 12 to 24 month intervals
<u>5</u>	<u>(38.5%)</u>	Authorities with some inspected less frequently than every 24 months
<u>11</u>	<u>(84.6%)</u>	Total Authorities with compliance issues for at least some medium/high risk establishments

Additional evidence of this problem is presented in the section below on the inadequacies of DPH systems for identifying and addressing inspection frequency deficiencies.

c) DPH/FPP has no System for Reliably Identifying and Addressing Inspection Frequency Issues

The only mechanism DPH has for tracking the relative frequency of inspections conducted by local authorities is the annual reporting system, for which no enforcement action is taken against approximately 115 communities that do not report in any given year. Even where communities do file reports, the system does not gather information for individual establishments and instead tracks only the total number of establishments and inspections for seven establishment categories:

- Food Service (e.g., restaurant, school, charitable food facility, caterer, nursing home) and Retail Food Store (e.g., supermarket, convenience store)
- Residential Kitchen (e.g., bed and breakfast, retail sale)
- Mobile Food Unit and/or Pushcart
- Temporary Food Establishment
- Frozen Dessert Manufacturer
- Bottle Water and Carbonated, Non-alcoholic Beverage Manufacturer
- Milk Pasteurization Plan

This reporting approach is out-of-date and inconsistent with the need to monitor the success of each local authority in ensuring that all establishments receive inspections with the appropriate frequency. For example, the single “Food Service and Retail Food Store” category on the form inherently covers the span of risk levels from high-risk nursing homes warranting three or four routine inspections per year to the lowest risk convenience stores selling only coffee and unpackaged or prepackaged non-potentially hazardous food items such as bottled soda and snacks such as chips, nuts, popcorn, and pretzels. Those lowest-risk establishments may only need a single annual inspection and are expressly exempted by the Food Code (FC 8-401.10(B)(3)) from the six-month inspection frequency requirement even where the local authority has not established a risk-based inspection scheduling system. As a result, gathering consolidated total establishment and inspection numbers for this consolidated annual reporting category provides information of limited usefulness and users cannot determine from the report whether or not the local authority conducted the appropriate number of inspections with the

required frequency for all of the establishments under its jurisdiction. More specifically, this monitoring deficiency presents the following problems:

- **The reporting system does not identify situations where significant numbers of establishments receive too few inspections or even go un-inspected for the year.** Since only total establishment and inspection numbers are provided for each category, only average inspection frequencies can be computed. Those average frequencies can be deceptive. For example, in a community with 100 establishments, five might be inspected four times per year (20 inspections), 30 might be inspected three times per year (90 inspections), 40 inspected two times per year (80 inspections), 10 inspected once per year (10 inspections), and 20 might go un-inspected. The result would be a total of 200 inspections reported for 100 establishments, effectively obscuring the fact that 10% of the community's establishments had only been inspected once and that 20% had not been inspected at all that year. The system also does not identify whether inspection frequency problems occur across-the-board at a local authority or whether only lower risk establishments have been inadequately inspected (although inspecting even so-called low risk establishments with inadequate frequency carries significant food safety risks as noted in the above comment by the food protection program director from a neighboring state).
- **While approximately 21% of authorities acknowledge on annual reports that they are out of compliance with inspection frequency requirements, the compliance assurances provided by other authorities also appear to be questionable.** The most recent version of the report promulgated for the reporting of calendar year 2004 activity has added a single "yes" or "no" question: "Is the Board able to conduct the minimum number of food inspections required in accordance with 105 CMR 590.000"? Of 118 authorities that had reported to DPH by the time our analysis was conducted in November 2005, over 21% acknowledged being out of compliance with minimum inspection frequency requirements. Even that figure appeared to be significantly understated in light of the number of blank responses (6%) and the number of authorities claiming to be compliant but reporting implausibly low numbers of inspections. Three authorities even claimed to be in compliance when the number of reported inspections was actually lower than the number of reported establishments for the community. We calculated the ratio of reported inspections to reported establishment numbers for each reporter and compared the results to the self-reported compliance status for each health authority. The results are presented in Table 6.

Table 6

**Self Reported Inspection Frequency Compliance
and the Ratio of Reported Inspections Per Year to
the Reported Number of Food Service
Establishments in 2004 ***

	Number of Inspections Left Blank	Computed Inspection to Establishment Ratio Range**								Total	Percentage
		<1.0	1.0 – 1.49	1.5 – 1.99	2.0 – 2.49	2.5 – 2.99	3.0 – 3.49	3.5 – 3.99	4.0 – 4.5		
Claimed Compliance	4	3	14	16	23	17	3	3	3	86	73%
Admitted Non-Compliance	1	4	11	7	-	1	1	-	-	25	21%
Compliance Left Blank	-	-	<u>2</u>	<u>3</u>	<u>1</u>	<u>1</u>	-	-	-	<u>7</u>	6%
Total	<u>5</u>	<u>7</u>	<u>27</u>	<u>26</u>	<u>24</u>	<u>19</u>	<u>4</u>	<u>3</u>	<u>3</u>	<u>118</u>	
Percentage***	4.2%	5.9%	22.9%	22%	20.3%	16.1%	3.4%	2.5%	2.5%		

*Includes Retail Food Stores

**E.g., computed ratio of between 1.0 and 1.49 inspections per year per establishment

***The percentage of establishments by ratio range totals 98.8% due to rounding effects.

As shown in the table, in addition to the three authorities claiming compliance but reporting an average of less than one inspection per establishment, 30 of the 86 claiming to be in compliance averaged between one and two inspections per establishment and four did not provide the required inspection data. As a result, the compliance assurances of as many as 37 of the 86 authorities appear to be questionable and the actual number of authorities in compliance may be significantly less than the self-reported 86 (73%) of 118 report filers. The “yes or no” compliance status self-reporting process used by DPH is clearly an inadequate monitoring system, particularly when the Department does not enforce reporting requirements and only approximately two-thirds of local authorities file reports in any given year.

- Our visits to local authorities revealed that even the consolidated total inspection numbers on the annual reports were reported in an inconsistent manner, with some communities over-reporting the number of true full inspections.** Some authorities reported only the total number of full routine inspections while other authorities had reported the total number of all visits to an establishment for routine full inspections, complaint investigations, educational visits and other visits that did not involve full food code compliance inspections (e.g., visits to verify correction of previously identified violations). As a result, the ratio of the reported number of inspections to the number of food establishments for an authority is deceptive for many filers and likely to lead an uninformed reviewer to believe that an authority is in compliance with inspection frequency requirements when it is not. For example, the annual report for one authority we visited had included complaint response partial inspections, compliance follow-up visits, and other activity in the report total. This resulted in a misleading ratio of reported annual inspections to establishments of 3.49 to 1, which was among the highest ratios in the Commonwealth even though the authority had marked the “No” box on the report question regarding inspection frequency compliance. This was the same authority noted above where approximately 70% of

establishments were only being routinely inspected once a year. Based on unaudited internal data maintained by that authority, we computed a corrected average ratio of only 1.39 full routine inspections per establishment per year. We calculated that if that authority had actually conducted the minimum number of inspections for each establishment called for by its written risk-based scheduling plan, the average ratio should have been at least 1.88 to 1. As a result of these reporting inconsistencies, we concluded that the overall data gathered by DPH on the number of inspections conducted is of limited usefulness for compliance monitoring purposes.

- **The statewide percentage of authorities with questionable inspection frequencies appears to be far higher than the self reported 21% regulatory noncompliance rate shown by the DPH survey.** As presented in Table 6 above, even without correction for misreported partial inspections, over half of the 118 authorities covered by the table reported fewer than two average inspections per establishment per year. Technical compliance with the DPH regulation is possible where accurately reported statistics result in ratios of less than 2.0 to 1 if the number of truly low-risk establishments warranting only a single inspection per year offsets the number of high-risk establishments warranting more than two inspections per year. However, our analysis suggests that such situations are atypical. In order to compare the reported results with those that might be expected if appropriate risk-based scheduling systems had been in use, we computed the expected ratio that would result from use of the federally endorsed risk-based scheduling plan described in section a) above for one local authority we visited. We determined that adherence to the plan would have resulted in a ratio of approximately 2.3 to 1 for that community. We also compared the Massachusetts data to detailed establishment specific data available for 67 counties in the state of Florida, where over 112,000 full inspections were performed for over 42,000 food establishments during fiscal year 2005. The Florida data showed that only 7% of Florida establishments were inspected once a year, while approximately 49% received two full inspections and 44% received three or more full inspections, resulting in an inspection to establishment ratio of 2.6 to 1. The Florida ratio may be somewhat elevated due to the fact that the data for their state excludes separately licensed retail food stores, many of which typically warrant classification as lower-risk establishments. However, the Florida data is consistent with the 2.3 to 1 risk-based system ratio computation in suggesting that the use of appropriate inspection frequencies should result in significantly higher ratios than those computed for the majority of authorities covered by Table 6. The inspection frequency problems reported above for 11 (85%) of our 13 audit sample authorities may have been somewhat atypical or they may actually have been representative of the true proportion of local authorities with such problems. In any case, both the DPH survey results and our own site visits indicate that a significant number of establishments in communities across the state are not being inspected with reasonable frequency and that DPH has not been adequately monitoring or addressing the problem. A food industry representative also identified inadequate frequency of inspections as a widespread issue, stating that the industry needs frequent contact and follow-up from inspectors and that not inspecting with appropriate frequency doesn't help anyone. We were told that restaurants would rather have food safety problems pointed out sooner rather than later.

- **The Department does not separately track inspection frequencies for school system food facilities, making it difficult to assess the degree to which the Commonwealth will experience compliance problems with recently established federal requirements.** Section 111 of the Child Nutrition and WIC Reauthorization Act of 2004 (Public Law 108–265; June 30, 2004) amended section 9(h) of the Richard B. Russell National School Lunch Act (NSLA) (42 USC 1758(h)) by increasing the number of mandatory food safety inspections for schools participating in national school lunch and breakfast programs from one to two per year beginning July 1, 2005. Section 111 also requires state agencies to annually monitor the number of food safety inspections obtained by schools and to report the results to the federal funding oversight agency. These requirements are implemented through federal Department of Agriculture, Food, and Nutrition Service regulations (7 CFR Parts 210 and 220). Prior to Public Law 108–265, no monitoring or reporting requirements existed. Section 111 further adds a requirement that school food programs comply with Hazard Analysis and Critical Control Point (HACCP) food safety requirements established by the Secretary of Agriculture. These requirements are separate from and in addition to the State Sanitary Code requirements administered through DPH/FPP, and responsibility for monitoring and reporting rests with the Commonwealth’s Department of Education rather than DPH. However, the required food safety inspections are the same inspections conducted by local health authorities under the oversight of DPH/FPP. It is therefore essential that this activity be coordinated. While DPH/FPP managers were familiar with the school food inspection requirements and have consulted with state DOE officials regarding implementation issues, our visits to local health authorities revealed that only a few of the authorities were familiar with the new requirements and that those authorities had generally heard about the issue only indirectly through local school officials rather than through DPH officials. If local authorities had actually been adhering to State Sanitary Code inspection frequency requirements, compliance issues would likely be minimal other than possible HACCP plan implementation and compliance verification issues. However, our review of local health authority activity indicates that school food inspection frequency problems exist and that some school food facilities have not even been inspected on a once a year basis. We believe that, as the oversight agency for local health authorities, DPH/FPP should actively monitor compliance with school food inspection frequency and HACCP plan requirements and take further action to ensure that all local health authorities fulfill the requirements of their role in ensuring school system food safety.

As already described, DPH/FPP has not been provided with adequate resources to effectively monitor and enforce requirements that local authorities inspect establishments at appropriately frequent intervals and local authorities typically lack the resources necessary to carry out their obligations.

Recommendation

DPH should consider the merits of implementing a uniform statewide risk-based scheduling process driven by FDA-recommended risk assessment practices and reasonable inspection

frequencies for each risk category instead of existing de-facto local triage-based considerations. As discussed in our Audit Results regarding information technology, quality assurance, foodborne illness and complaint response, and strategic planning deficiencies, the Department also needs to implement significant operational changes such as centralized food establishment licensing and comprehensive real time data exchange and tracking systems needed to ensure that activity is carried out as scheduled, that special federal provisions applicable to schools are met, and that risk-based classifications for establishments are modified in a timely manner to reflect the results of inspections and foodborne illness investigations.

Auditee's Response

Local boards of health, which have the statutory authority and responsibility for retail food establishments, have the option of adopting a risk-based inspection program or conducting inspections twice each year as mandated by the federal 1999 Food Code. FPP provides guidance on and recommends a risk-based system for local Boards of Health.

Schools in Massachusetts, unlike in many other states, are not exempt from local board of health inspections under 105 CMR 590.000. Since the Massachusetts Department of Education (DOE) is the primary state agency responsible for promoting school compliance with the new law, FPP has been working very closely with DOE by coordinating presentations on school compliance for local boards of health at Massachusetts Health Officers Association seminars on the federally-mandated School Hazard Analysis, Critical Control Point (HACCP) process for ensuring food safety. FPP has updated local Boards of Health on school HACCP, and at a recent training program for school food service directors (which FPP helped develop and present), approximately 80% of the participants indicated that they were inspected not once, but at least twice a year by their local board of health. FPP also met with DOE in September of this year to initiate plans to send out a joint letter to local boards of health reminding them of their school inspection responsibilities under 105 CMR 590.000.

Auditor's Reply

As our audit work documented, risk-based inspection systems are few and far between and do not operate on a consistent basis in the Commonwealth. As stated in our recommendation, we believe that DPH should consider the merits of implementing a uniform statewide risk-based scheduling process and has the authority to do so under existing statutes.

While we are pleased that the Department is continuing to address implementation issues for the new federal school food program requirements, our audit work suggested that actual compliance rates may be far lower than the 80% DPH suggested in its response. At the time of our visits, we also found that despite DPH outreach efforts, several local authorities were unaware of the

new requirements. As noted in our recommendation, DPH needs to establish better tracking systems to ensure that local authorities fulfill their responsibilities in this regard.

4. INADEQUATELY TRAINED AND QUALIFIED LOCAL INSPECTORS

When DPH modified its regulations in 2000 to incorporate provisions of the 1999 Food Code, it also established minimum qualification requirements for food inspectors. 105 CMR 590.010(G) provides several qualification options, the lowest of which is nothing more than the same Certified Food Protection Manager (CFPM) certification approval required for food establishment operators. This minimalist approach to inspector qualification requirements was taken despite the fact that outside food safety professionals reviewing the proposed qualification provisions had characterized them as “woefully inadequate.” While the regulation also requires completion of “food safety inspection training recognized by the Department,” the Department has never promulgated mandatory training specifications and has never enforced the requirement for supplemental training or continuing education requirements. As a result, local inspectors (who typically conduct food inspections as a secondary part-time activity in addition to other public health responsibilities accounting for most of their work time) are sometimes no more qualified than, and may in some cases be less knowledgeable than, the food establishment managers they regulate. DPH/FPP staff acknowledged that a higher level of qualifications and training for inspectors is desirable due to the importance of using science based (e.g., food microbiology, and epidemiology) HACCP principles to conduct inspection and other food protection activities but stated that, had a higher regulatory minimum standard been adopted, the result would have been to “wipe out” 60% to 70% of the existing local inspectors. Our review of DPH data on inspector qualification levels and training participation data, as well as our interviews with local health authority staff and with trade association representatives for both inspectors and the food industry confirmed that inadequate inspector training and qualification levels remain a serious problem five years after adoption of the qualification standards.

105 CMR 590.010(G), the regulation governing inspector training and qualification states:

(1) Any person conducting food inspections for the board of health shall be knowledgeable in foodborne disease prevention, application of the hazard analysis critical control point principles, and the requirements of 105 CMR 590.000 as they relate to food establishments in their city or town.

(2) *Effective one year from the date of promulgation of 105 CMR 590.000, any individual conducting food inspections shall demonstrate the knowledge referenced in 105 CMR 590.010(G)(1) by:*

(a) Passing a certified food protection manager or certified food safety professional test that is part of an accredited program recognized by the Department and completing food safety inspection training recognized by the Department, or;

(b) Being a registered sanitarian or certified health officer who has completed food safety inspection training recognized by the Department.

DPH does not license food inspectors and does not even maintain a registry of all individuals conducting local food inspections in the Commonwealth. Instead, it simply gathers limited data regarding claimed qualifications for local food inspectors through its annual board of health survey process. As previously discussed, this process is conducted as a voluntary exercise despite mandatory annual reporting language appearing in the Department's regulations at 105 CMR 950.010(F). At the time our field work was started in July 2005, the most recent data available from these surveys was for the year 2002. DPH provided us with its database covering 240 filers that year. The raw data on inspector qualifications covered 407 inspector positions. However, upon reviewing the data, we found that duplicate entries existed for a number of individuals due to the fact that some regional health district member communities had filed separate reports specific to the food establishments in their individual communities and these multiple reports listed the same inspectors working for the regional districts. In addition, we found that several communities not participating in organized regional health districts had either employed or contracted with individual inspectors providing part-time services to each community. After adjusting for these entries, we identified a total of approximately 346 individual food inspectors covered by the database. These inspectors are responsible for inspections in the 68% of the Commonwealth's communities covered by the dataset. Since the data disproportionately covers larger communities and accounts for approximately 80% of the Massachusetts population, it is difficult to reliably project the total number of food inspectors active in the Commonwealth. Depending on whether an assumption is used that the number of inspectors is proportionate to either population or the number of communities, it appears that the DPH data does not cover perhaps 20% to 32% of the local inspectors in the Commonwealth. Since the data is also significantly out of date due to not having a reporting process for 2003 and not initiating the 2004 process in a timely manner, we believe that this approach to monitoring inspector qualifications is inadequate. We also found that in the case of

12 inspectors for whom multiple communities had submitted qualification information for the inspector, there was conflicting information from different communities regarding the inspector's qualifications. For the purpose of analysis we resolved these discrepancies by assuming that each individual was qualified at the highest level reported by any authority for that individual. We then reviewed the data with the following results suggesting that inspectional staff appear to be under qualified in most communities:

- Only 8% of inspectors were reported to have Certified Food Safety Professional (CFSP) status, the preferred qualification identified by both DPH/FPP staff and several of the local food inspection professionals we interviewed. These CFSP qualified inspectors worked at a total of only 28 (12%) of the 240 annual report filers for that year.
- 52% of inspectors met only the minimum Certified Food Protection Manager (CFPM) requirement, and for 88 (37%) of reporting communities, no inspectional staff were qualified above the minimum CFPM level.
- For 30 individuals (9% of the total), qualification information had been left blank. These inspectors were used by 22 reporting communities (9%). 20 of those communities did not report qualification levels for any of their inspectors.
- Less than 40% of inspectors were reported to possess qualifications better than the CFPM minimum. The reported qualifications for these inspectors included the above reported 8% qualified as CFSPs and others licensed as Community Health Officers and Registered Sanitarians.
- Less than 30% of inspectors were Registered Sanitarians (with or without supplemental training or certifications).

DPH initiated the annual reporting process for the year 2004 during our audit work. Reporting forms were not distributed until mid-summer 2005 and DPH requested that the local boards of health respond by September 15, 2005 – rather than the July 31 deadline established by regulation. At the time we ended on-site audit work at the DPH/FPP office, updated data for 2004 was available for only 95 of the 240 report filers covered by the 2002 dataset. We reviewed the updated data and also cross-referenced it to separate attendance data maintained by DPH/FPP for foodborne illness and HACCP training sessions conducted through the spring of 2005 (see Table 7). That analysis indicated that inspector qualification problems appear to be continuing. While approximately 30% of inspectors previously covered by 2002 data submissions were reported to have improved their qualification levels or to have at least attended some DPH training sessions, qualification levels appeared to remain unchanged for

over two thirds of the inspectors. In addition, over half of newly hired food inspectors for the 95 local authorities were reported to be qualified only at the minimum CFPM level. As a result, five years after the regulations were modified to establish what were described by outside professionals as “woefully inadequate” minimum qualification standards for inspectors, it appears that over 50% of inspectors may still have questionably low qualifications and 38% or more of reporting local boards of health may lack at least one well qualified inspector to either conduct inspections or oversee inspectors with lower levels of qualification. As a restaurant association representative told us, inspectors need to be qualified at a level higher than CFPM certification and need regular annual continuing education updates. We were told that many food establishment operators find food microbiology issues to be difficult to understand and that establishment managers want inspectors to be able to answer questions on issues such as time and temperature controls, with explanations of the underlying reasons for food code requirements.

The DPH practice of relying on unverified assertions made by local authorities about the qualifications of their inspectors is also questionable, particularly since in many communities the annual reports are prepared by the inspectors themselves rather than by independent administrators. We attempted to independently verify inspector qualification levels by seeking listings of all individuals who had passed various qualification examinations. However, unlike some other states that directly license inspectors or administer qualification examinations, Massachusetts DPH/FPP staff stated that they did not have this information and had not independently verified inspector qualifications. We used State Board of Registration data to verify the qualifications of 63 inspectors reported by 33 communities to be either registered sanitarians (RS) or certified health officials (CHO). Eight individuals (12.7%) appeared not to have possessed the qualifications reported to DPH. These misreported qualifications involved seven (21%) of the 33 communities. Unfortunately, DPH, by not securing certification information from independent entities used to certify both Certified Food Protection Managers (CFPM) and Certified Food Safety Professionals (CFSP), made verification of those qualification categories impossible except for the small number of inspectors covered by our on-site visits to local authorities. During our on-site visits, which did not cover any of the seven communities with apparent RS or CHO qualification issues, we found that, with the exception of one authority, certification and licensure copies were maintained and generally documented the

accuracy of reported qualification information. However, at one of the 13 authorities we noted that both the Director and the Food Inspector, who had been only minimally qualified through the CFPM process for five year periods, had allowed their certifications to expire within the past year and were rescheduling themselves to take the certification examination after the completion of our audit visit. In addition, while reported correctly on the 2002 annual report as CFPMs, they had been misreported on their local authority's 2004 annual report as Certified Food Safety Professionals even though they had never been certified at the higher CFSP level. During our visits, managers at local authorities expressed concern regarding the potential for forgery of paper based credential documentation issued by private companies authorized to conduct the CFPM certification process for food establishment managers. They complained that it is not possible for them to readily verify the authenticity of these certifications (e.g., by internet or other database lookups) and stated that in some instances they had found that apparently certified food establishment managers clearly lacked the food safety knowledge that the certification process is supposed to verify. This potential problem also extends to CFPM-based food inspector qualifications. Together with the above described inspector qualification under-reporting and misreporting issues, this verification deficiency indicates that DPH/FPP did not establish effective control systems needed to monitor and enforce minimal qualification standards for local food inspectors and suggests that the true level of qualifications for local authority inspectors may be even worse than indicated by the 2002 and 2004 annual report statistics.

Inspector qualification issues involve inadequate training arrangements as well as the above-described licensure and certification problems. DPH/FPP staff maintained a database with attendance records for multiple foodborne illness and HACCP training events from May 2002 through April 2005. We reviewed that attendance data to determine the extent of participation by local health authority representatives across the Commonwealth and found that only 143 local health authorities, representing 158 (45%) of the Commonwealth's 351 communities, had sent inspectors or other representatives to the training sessions and that only 59 communities (17%) had been represented at both the foodborne illness and the HACCP training events. These results are presented in Table 7.

Table 7

**Local Board of Health Participation at DPH,
HACCP, and Food-borne Illness Trainings
May 2002 – April 2005**

	HACCP Only	FBI Only	Both HACCP and FBI	Total
BOH Trainees	19	194	56	269*
Communities Represented	8	91**	59	158**
				(45% of 351 Commonwealth Communities)

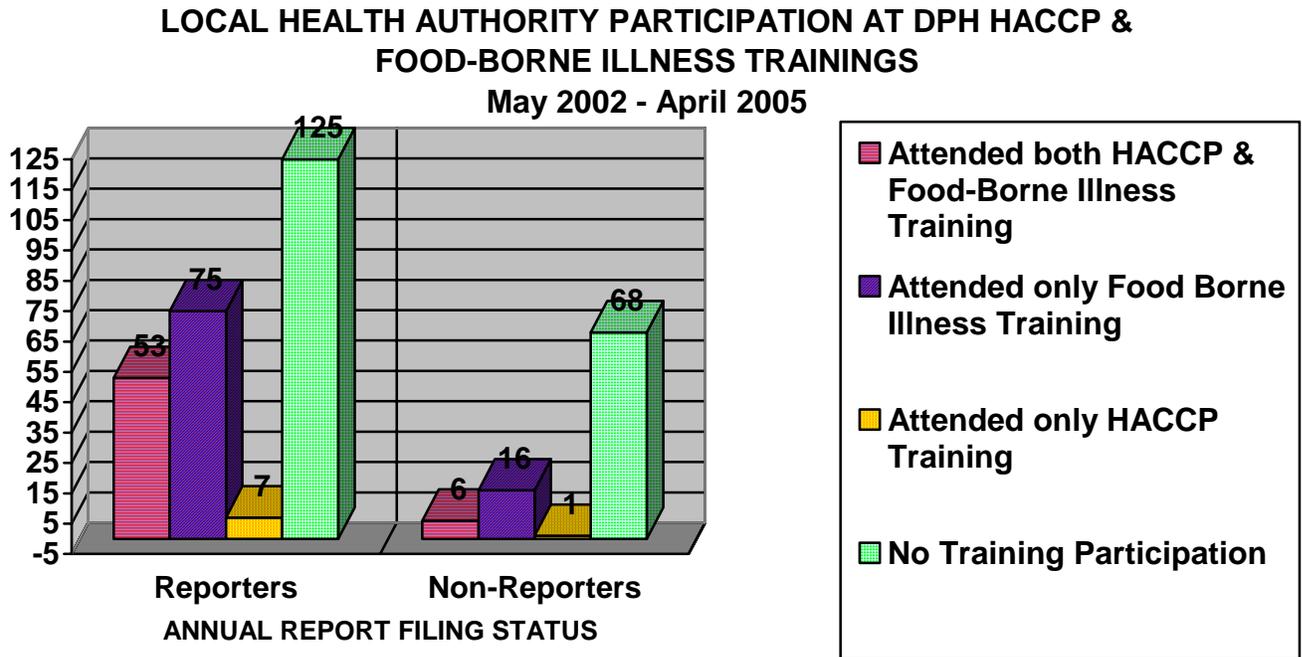
*Data indicated that an additional 14 BOH trainees attended unspecified events but, in most cases, left early and did not complete the full training event. No statewide total percentage has been calculated since DPH does not have a registry of all local food inspectors and the total number of inspectors in the Commonwealth is not known.

**Includes 17 communities represented by two regional health districts, so the total number of health authorities represented at one or more training events = 143.

The Department's approach of offering only limited, partially funded, voluntary training has clearly not been sufficient to ensure that all local health authorities and their inspectors receive adequate training. The program's Director and Assistant Director acknowledged this, telling us that while participation was good for a few communities who actively sought out training opportunities, the majority of communities could not or would not participate to the extent desired by the Department.

In an attempt to assess the extent to which inspectors for communities who did not file reports with DPH might be inadequately trained and qualified, we also analyzed the training participation data to see whether there were any differences between communities actively participating in the DPH annual reporting process and communities that did not report on their activities and on the qualifications of their inspectors. As illustrated in Chart 1 below, 135 (51.9%) of 260 communities that had reported staffing information to DPH for either 2002 or 2004 were represented at one or more of the trainings. Only 23 (25.3%) of 91 communities that were non-reporters for both 2002 and 2004 were represented at the trainings. Almost three quarters of the communities that were out of compliance with DPH reporting requirements also did not send representatives to the DPH training events. This suggests that overall qualification and training issues for those communities may be at least as serious as those known to exist for reporting communities.

CHART 1



What should have been: All 351 of the Commonwealth's cities and towns should have filed the required annual reports with DPH and all should have been represented at both the HACCP and Foodborne Illness Training events conducted during this three-year period.

DPH staff acknowledged that training activities have been limited due to resource constraints and have been focused primarily on voluntary training of industry representatives and of public health officials willing and able to participate. Training has typically been provided directly by FPP staff under arrangements with industry and local public health professional associations, where only costs such as facility rental and printing expenses incurred by the partnering sponsors have been recovered rather than the full costs of public employee trainer staff time. The capacity of DPH/FPP to offer training has been limited and, while costs have been held down for participants, many local inspectors have still been unable to fully participate due to time and budget constraints. DPH managers stated that public funding for training activities has been extremely limited at the federal level, as well as state and local levels. For example, at a three day joint state and federal training event held in Springfield in July 2004 on how to properly review food establishment plans (which are required to be filed and approved before a license to operate is granted), only 33 representatives of Massachusetts local boards of health attended. All other participants were state, federal, or out-of-state inspection and regulatory

staff and funding constraints limited the total number of slots available to participants from Massachusetts.

We asked staff at the local authorities we visited to comment on qualification and training issues as they saw them. A variety of opinions were expressed. One community asserted that since its inspectors were already Registered Sanitarians, it was inappropriate for DPH to impose any additional food protection certification or training requirements. However, in several other communities staff agreed with the characterization of the DPH minimum standards as “woefully inadequate” and noted that even qualification as a Registered Sanitarian or Certified Health Officer was inadequate without significant additional training specific to food inspections and enforcement procedures, food microbiology, foodborne illness, and use of the HACCP process. One community, the City of Boston, stated that it was in the process of having all 18 of its inspectors qualified as Certified Food Safety Professionals, the preferred qualification level identified by most of the food inspection professionals we interviewed. Some interviewees also suggested that ongoing continuing education requirements should be established. Staff at one local authority noted that even if DPH was concerned about the potential complications of establishing suitable qualification standards when the regulations were updated in 2000, it could have used a “grandfathering” approach by establishing appropriately high qualification requirements for new inspectors and providing a short transition period for existing inspectors to obtain supplemental certifications and training where needed. Almost uniformly, local authorities also reported that local budgetary constraints, coupled with training availability issues, impaired their ability to hire and retain optimally qualified inspectors. In addition, they expressed the opinion to us that DPH resource constraints had limited the Food Protection Program’s ability to provide adequate training to local authorities in inspection procedures and documentation practices. Opinions expressed regarding the best way to address perceived shortcomings in the Commonwealth’s training arrangements were diverse and not entirely consistent. Examples include:

- DPH needs to provide more training without charge to local authorities.
- Limited training opportunities available at present have generally been offered indirectly through one professional group that, we were told, does not really represent even the majority of local health officials across the state, and a perception exists that local authorities who are not members of that association are not always notified of trainings (which are not always separately announced by the Department) and association

- members appear to receive preferential access to the limited number of available training slots.
- The challenge of adequately training all inspectors is complicated by both turnover involving movement of trained inspectors to the private consulting sector and by the large number of individuals involved in food inspections on a part-time basis due to the decentralized, small-scale nature of local food protection activities in the Commonwealth.
 - While considerable program activity has recently been devoted to training and coordination activities related to bio-terrorism food security issues (e.g., addressing the risks of intentional food contamination), a good portion of that training is perceived as having relatively little bearing on or benefit to existing day-to-day retail food inspection matters.
 - DPH should establish a mock food establishment inspector training facility for the Commonwealth.
 - DPH should (assuming inspections continue to be conducted at the local level) have local health authority staff temporarily assigned to DPH for extensive on-the-job training by the Department in order to ensure that inspectors are fully trained and carry out inspections in a uniform, standardized manner across the Commonwealth.
 - DPH should restrict the existing practice by some local authorities of relying on inspections conducted by private inspectors receiving significant income from the food industry. These inspectors are not always adequately trained and qualified and in some instances these individuals work as part-time inspectors for one or more authorities and conduct all inspections on behalf of a community. In other instances they are brought in as consultants, paid for by individual food establishments to correct problems that have repeatedly been cited as violations. However, authorities should not be allowed to rely on the work of these consultants in lieu of conducting independent verification inspections by authority staff. (One DPH manager also expressed concern to us about this problem, but stated that reliance on consultant work might be less of an issue if establishments were required to pay consultant costs directly to the authority so that the authority then selected and paid the consultants, making them more independent of the food establishments.)
 - DPH should further promote a “train the trainer” approach where properly trained and certified local inspectors are used as instructors to train less qualified inspectors both within their own local authorities and in neighboring authorities.
 - DPH should revitalize the Department’s system of district health offices authorized by MGL, Chapter 111, Section 4, with training officers assigned to each district office. This district office approach is distinct from the separate regional health district system authorized by MGL, Chapter 111, Section 27B and referenced elsewhere in our report. While the statute refers to these internal departmental offices as “district offices,” they are now commonly referred to as “DPH regional offices.” We were told that while the

district office system was largely dismantled in prior departmental reorganizations, there has been recent discussion by public health officials across the Commonwealth of the potential benefits of revitalizing regional district approaches for both food protection and other public health activities.

We also noted that the DPH Retail Food/Foodborne Illness Unit Director is currently participating in an initiative by the national Conference for Food Protection, a voting body of state delegates that provides recommendations to FDA officials on the model federal regulations, to develop national qualification and training standards for inspectors. Those standards are expected to significantly exceed the Massachusetts requirements. At the time of our audit fieldwork, draft standards were being distributed to Conference participants on a Discussion Draft/Not for Release basis and were then expected to undergo an extensive review and modification process at both the national and state level before adoption. However, many jurisdictions around the country already employ far higher standards than Massachusetts. For example, in Maricopa County, AZ, all inspectors are required to hold at least undergraduate science degrees, pass the state's Registered Sanitarian examination within one year of appointment, and undergo additional training related to their responsibilities as food inspectors. In the state of Maryland, which uses inspectors at approximately two-dozen county health departments to conduct local retail food inspections, all inspectors are required to receive "basic training in retail food, state laws and regulations pertaining to food, plan review, and HACCP." After completing this basic training, each candidate for an inspector position must undergo a standardization process conducted by the local authority's "Standardization Officer." That process involves multiple practice and test inspections and must be repeated every three years under the direction of a "State Food Rating Officer" at the state Office of Food Protection and Consumer Health Services, who is responsible for "standardizing" each local authority's standardization officer. Further assurance is provided by program reviews of each local authority, which are conducted by the state office every four years.

Recommendation

DPH should confirm the extent of its statutory authority regarding local food inspector qualifications and should promptly adopt more appropriate qualification and training standards for both public and private food inspectors and should establish appropriate controls over the use of consultant inspectors. The track record of past DPH training activities indicates that

voluntary training approaches have been inadequate. Regardless of the specific training approaches adopted, DPH should take additional measures to ensure that all food inspectors operating within the Commonwealth are as well trained in HACCP principles, standardized inspection practices, enforcement procedures, plan review, foodborne illness investigation/response activities, and other food protection related matters as are the Department's own inspectors. The Department should also consider directly licensing food inspectors in order to ensure that qualification standards are met, that inspectors adhere to appropriate professional standards on an ongoing basis with regular continuing education and inspection procedure re-standardization requirements, and that a reliable mechanism exists to deny, suspend, or revoke licenses for inspectors who did not fulfill professional standards.

Auditee's Response

In response to concerns regarding training of the workforce and minimum qualification standards, we strongly urge you to recognize the statutory limitations of DPH authority with regard to mandating inspector qualifications and training. However, despite these limitations, FPP has been the primary training resource for local Boards of Health, relative to food safety regulations, inspections, and foodborne illness. Since 2001, many hundreds of trainings and presentations have been provided for the boards of health in all 351 municipalities.

FPP supports local Board of Health training and related initiatives, including the promotion of FDA's food inspector certification courses. It conducts educational presentations at professional conferences and meetings, and has also initiated a food inspector field training program pilot that is part of a well-respected national initiative.

In addition local health leadership organizations are currently working with the National Association of County and City Health Officials (NACCHO) and others to design proposed minimum qualifications for local health departments statewide that will be disseminated statewide to all local health officials.

Auditor's Reply

If the DPH believes that they do not have the statutory authority and responsibility to mandate appropriate inspector training and qualification requirements, they should propose appropriate statutory language to remove that barrier. As demonstrated by our audit work, the existing voluntary approach utilized by the DPH is clearly not sufficient and many authorities and inspectors remain inadequately trained and qualified.

5. INADEQUATE DOCUMENTATION AND STANDARDIZATION AT LOCAL AUTHORITIES

Our visits to 13 local health authorities across the Commonwealth revealed wide variations in inspection and related practices at different authorities. Inspectors focused on different compliance requirements of the Food Code. Similar violations such as inadequate dishwashing final rinse temperatures or not keeping food containers off the floor and protect food from contamination were treated differently, with some authorities characterizing these violations as critical violations posing imminent risks to consumers and requiring that the violations be immediately corrected, while other authorities treated the same violations as non-critical matters to be addressed over multi-week periods or even as non-violation discussion matters referenced in inspection report notes with no follow-up review until the next routine inspection. Documentation practices were also deficient, in part due to the use of “exception only” documentation practices at most authorities. Only a few authorities documented inspection activity with information on the specific inspection procedures and results (e.g., food and dishwasher temperatures) where items were found to be in compliance. As a result, we were unable to determine whether inspections were really conducted in a thorough, standardized manner at some authorities. For example, 27 (69%) of the routine inspection reports we reviewed at one authority did not identify even a single non-critical violation, and 25 of those reports simply bore the notation “satisfactory” with no other inspection details. That pattern was in marked contrast to the remaining 12 authorities where only between 0% and 20% of routine inspections did not identify violations. It also contrasts with violation frequency results we were able to obtain for other states. Even at authorities with apparently higher violation rates, there were distinct differences in the frequency of use for standard violation codes used on the inspection report promulgated by DPH for local authority use. In the absence of adequate underlying documentation or comprehensive quality assurance systems (see Audit Result No. 8) to satisfactorily account for these variances, the quality and thoroughness of inspections and the extent of standardization across local authorities remains as questionable now as we found it to be in our last audit of the program. These results also suggest that inspections often remain focused on traditional “good retail practice” sanitation compliance, with insufficient attention to federally identified critical risk factors for foodborne illness.

As part of our prior audit, we were able to work in conjunction with DPH and FDA quality assurance inspectors and compare reports prepared by local inspectors to inspection reports

prepared for the same food establishments by state and federal quality assurance staff. That review process documented significant problems with inadequate inspections and a lack of standardization of the inspection process across local health authorities in the Commonwealth. It also documented a pattern of inspection deficiencies where local authorities often did not identify violations that were identified by state and local quality assurance inspectors who visited the same food establishments. We were not able to replicate that review process as part of this audit due to the fact that both DPH and the FDA have discontinued those quality assurance-monitoring inspections. However, FDA officials expressed their belief that these standardization issues probably continue to exist. Our interviews with local health officials and with other interested parties such as the Massachusetts Health Officers Association (MHOA), the Massachusetts Environmental Health Association (MEHA), and the Massachusetts Restaurant Association (MRA) also identified this as a continuing issue. When we reviewed inspection process documentation and inspection records for a total of 113 different food establishments at the 13 local health authorities we visited, we confirmed that the problem continued even after our prior audit. Only one authority has a comprehensive policy and procedures document covering the inspection process and internal quality control mechanisms. Authorities use different approaches for carrying out inspections, for documenting the results of inspections, and for resolving individual establishment compliance issues identified by inspections. Not all Food Code requirements are being enforced across all authorities and most authorities document their inspection activity on an “exception reporting” basis, documenting only problems they have identified and decided to cite the establishment for, rather than documenting the completion of each inspection step and the results for each step such as measurements of the holding temperatures for hot and cold foods being served by the establishment. Based on the record sample we reviewed, it appeared that only two of the 13 authorities consistently documented the review process for each inspection. One other authority did so in an inconsistent manner, while the remaining 10 authorities appeared to be documenting activity only on an exception-reporting basis. In the absence of adequate documentation, we were unable to verify that extreme variations in inspection results from one authority to the next were the result of actual differences in food establishment conditions rather than the result of non-standardized inspection practices. For some local authorities it was not unusual for inspectors to identify at least some “critical violations” at most establishments and frequently as many as a dozen or more such violations at a single establishment during a single

routine inspection visit. Other local authorities rarely identified a significant number of violations even at establishments where multiple individuals had reported foodborne illness incidents. As referenced above, one authority identified no violations whatsoever for 69% of the inspections we reviewed. In contrast, records sampled at three authorities showed that they had identified violations at every routine inspection we reviewed. For the remaining nine authorities, the percentage of routine inspections reporting that establishments were free of violations ranged from 7% to only 20%. Our review of 113 establishment files at the 13 authorities also revealed questionable inconsistencies across authorities in the focus of their inspections, as evidenced by the frequency at which different code violations were identified by inspectors at the different authorities. Managers at multiple authorities told us that different inspectors often tend to focus on different issues and identify different violations when conducting inspections. For example, one inspector may regularly cite establishments for not taking adequate measures to protect ice from contamination, while others pay little attention to that risk. Similar focus issues can involve hand-washing facilities and compliance restrictions for bare-hand contact with food, attention to cross-contamination and food storage issues, sanitization of meat slicing equipment, and dishwasher final rinse temperature or alternative sanitization arrangements. Unless effective standardization and quality assurance systems are in place, the result can be a situation where areas of risk are overlooked for an establishment or even for all establishments inspected by a local authority. The result can also be confusion for food establishment operators and the public, as well as a lack of equitable enforcement activity across local authorities. We evaluated the possible extent of such standardization inadequacies by examining the types of violations identified by inspectors at different authorities. Most local authorities use the standard inspection report form and violation coding system promulgated by DPH, although we found that some authorities use their own separate systems or document their findings inadequately by not classifying violations as critical or non-critical in nature as called for by DPH regulation and the federal Food Code. At some authorities, inspectors noted the existence of violations within a given category without fully quantifying the number of multiple violations for that category, while at other authorities inspectors count multiple individual violations within each category (e.g., a counted violation for each separate freezer or cooling unit with temperature compliance problems). These classification and reporting issues caused us to limit our analysis to a total of 561 violations identified for sampled establishments at nine of the 13 authorities. The summary data in Table 8 was derived from that analysis.

TABLE 8

Use of Standard DPH Food Establishment Violation Codes by Nine Local Authorities

DPH Code Number	Violation Description	Total Number	Percentage of Total	Number of Authorities Using Code	Minimum Percentage for Any Authority	Maximum Percentage for Any Authority	Code Never Used	Code Rarely Used	Code Inconsistently Used	Code Regularly Used
Critical Foodborne Illness Risk Factor Violations										
1.	Person In Charge	17	3.0%	5	0.0%	10.0%			X	
2.	Employee Disease Reporting	2	0.4%	1	0.0%	3.6%		X		
3.	Exclusion of Infectious Personnel	0	0.0%	0	0.0%	0.0%	X			
4.	Approved Food & Water Source	0	0.0%	0	0.0%	0.0%	X			
5.	Receiving/Condition	1	0.2%	1	0.0%	1.9%		X		
6.	Records/Ingredient Statements	1	0.2%	1	0.0%	1.0%		X		
7.	HACCP/Procedure Conformance	0	0.0%	0	0.0%	0.0%	X			
8.	Separation/Protection from Contamination	29	5.2%	6	0.0%	12.0%			X	
9.	Sanitized Food Contact Surfaces	43	7.7%	6	0.0%	13.0%			X	
10.	Proper Hand washing	7	1.2%	4	0.0%	6.2%	X			
11.	Good Hygienic Practices	10	1.8%	5	0.0%	11.5%			X	
12.	Glove Use/Prevention of Contamination from Hands	17	3.0%	8	0.0%	9.3%			X	
13.	Hand washing Facilities	49	8.7%	7	0.0%	16.0%			X	
14.	Approved Additives	0	0.0%	0	0.0%	0.0%	X			
15.	Toxic Chemicals	7	1.2%	3	0.0%	4.0%		X		
16.	Cooking Temperatures	0	0.0%	0	0.0%	0.0%	X			
17.	Reheating	0	0.0%	0	0.0%	0.0%	X			
18.	Cooling	3	0.5%	3	0.0%	2.0%		X		
19.	Hot & Cold Holding	22	3.9%	5	0.0%	7.5%			X	
20.	Time as Public Health Control	2	0.4%	1	0.0%	3.1%		X		
21.	Food & Preparation for Highly Susceptible Populations	0	0.0%	0	0.0%	0.0%	X			
22.	Consumer Advisories	<u>6</u>	<u>1.1%</u>	4	0.0%	4.0%		X		
		216	38.5%							
Good Retail Practice Violations (May be Critical or Non-Critical)										
23.	Management and Personnel	9	1.6%	5	0.0%	4.6%		X		
24.	Food & Food Protection	63	11.2%	9	3.7%	34.6%				X
25.	Equipment & Utensils	99	17.6%	9	5.6%	27.3%				X
26.	Water Plumbing & Waste	21	3.7%	7	0.0%	12.7%	X			
27.	Physical Facility	120	21.4%	9	3.8%	45.5%				X
28.	Poisonous/Toxic Materials	6	1.1%	3	0.0%	3.6%		X		
29.	Special Requirements	9	1.6%	5	0.0%	4.6%		X		
30.	Other	<u>18</u>	<u>3.2%</u>	8	0.0%	15.4%			X	
		<u>345</u>	61.5%							
		<u>561</u>								

For one local authority no critical risk factor related violations were used for the sampled establishments and all 22 identified violations were related to Good Retail Practices only. For two other authorities the critical risk factor violation rate was under 24%. For the remaining six local authorities for which violation data was quantified, critical risk factor rates varied between 34.3% and 64%. Data for 4 additional visited authorities was not gathered due to issues such as authority use of non-standard coding systems.

We did not independently inspect the sample group of establishments and we therefore cannot rule out the possibility that substantial differences in establishment operations might have existed for sampled establishments from one community to the next; however, both the degree of variation between authorities and additional detail gathered from individual inspection reports indicate that the variances are at least in part attributable to a lack of standardization in inspection practices. For example, one authority did not identify any critical foodborne illness risk factor violations at all. Two other authorities had percentages of 12% and 24% respectively, and the remaining six had percentages of 34%, 39%, 45%, 50%, 55%, and 64% for the establishments we sampled. In reviewing underlying detail of documentation regarding code violations, we noted that in some instances documentation maintained by the authorities made it clear that low incidence rates for problems in some communities may have been attributable to the fact that their authorities consistently reviewed and documented compliance in areas such as dishwashing and refrigeration unit temperatures and enforced requirements that establishments maintain regular logs documenting compliance between inspection visits. However, as noted above, only two of the 13 authorities we visited consistently maintained such thorough documentation. In other instances we repeatedly saw evidence that critical violations such as storing open food containers on the floor, not providing adequate hand-washing facilities, or inadequate dishwashing or refrigeration temperatures had been inappropriately characterized as non-critical good retail practice violations or even as discussion-note-only items without even being cited as non-critical violations. When an authority did not adequately document inspection practices, it was often impossible to determine whether low violation rates for an item were attributable to high compliance rates on the part of establishments or to inspectors not inspecting for compliance with those code items.

The above cited critical risk factor violation rates, together with the inspector qualification and training deficiencies identified in the other Audit Results sections of this report, also suggest that some authorities may not yet be focusing inspection activity on high priority critical risk factors for foodborne illness as recommended by both DPH and the FDA. For example, at one authority where we noted that hand washing and glove or bare-hand food contact violations were generally not identified, the authority received numerous complaints of violations in these areas. We were told that since establishments generally complied while inspectors were on the premises, it was difficult to catch violations so inspectors did not focus on this risk factor. In

contrast, we were told by two other authorities that their inspectors evaluated compliance through a combination of measures such as using visual examination of employee hands and lower arms and sometimes ultraviolet lamp tests immediately upon the unannounced arrival of the inspector at the establishment. Hand-washing facilities were also examined upon arrival for evidence of disuse such as bone-dry sink basins, missing paper towels or soap dispensers, or even situations where access to sinks is totally blocked by boxes, mop buckets, etc. Even poor practices such as not regularly changing gloves can be evaluated by looking at the rate at which gloves had been discarded in trash receptacles. Also, since properly conducted full inspections should generally take hours rather than minutes to complete, careful observation by an inspector is likely to identify situations where ingrained unacceptable working habits make it difficult for food handlers to maintain compliance, especially during busy periods, throughout the entire course of an inspection visit. It was obvious to us that inspection practices for these risk factors had not been reasonably standardized across the authorities we visited.

Other common documentation and standardization issues we encountered included:

- **Inconsistent documentation of follow-up action on complaints and previously identified code violations** – We identified inadequate documentation, tracking, and/or follow-up action on at least some complaints at six authorities and inadequately documented, delayed, or non-existent follow-up by seven authorities to verify correction of previously identified violations at some of their licensees. At one authority, we encountered a situation where a March 25, 2005 inspection of one restaurant had identified 17 violations, five of which involved critical risk factor items, but a follow-up re-inspection visit to verify corrective action was not conducted until two weeks later on April 11, 2005. Depending on the nature of the violations identified, sound inspection practice requires that, if the establishment is not closed on the spot, critical risk violations be corrected either before the inspector leaves the premises or by the next day. Generally, only non-critical violations should be allowed to continue for up to two weeks pending implementation of corrective measures. In the interim, on April 2, 2005, one week after the initial inspection, a customer reported becoming ill after consuming chicken at the restaurant. This was the second foodborne illness complaint involving the restaurant in less than a year.
- **Inadequate documentation of establishment site plan and HACCP reviews** – Only two authorities appeared to be conducting thorough well-documented site-plan and HACCP reviews for their establishments. Required review activity appeared to be absent or undocumented at two authorities and inadequately documented at the remaining nine authorities.

- **Inconsistent documentation and enforcement of CFPM certification and other requirements applicable to so-called Persons-In-Charge (PIC) at food establishments** – At six authorities we found that required documentation was missing for some establishments or applicable food code certification requirements had sometimes remained un-enforced for extended periods.

At least some required documents such as inspection reports, site plans, or even entire establishment folders were missing at 11 of 13 authorities.

We also identified significant record retention period issues at three authorities. DPH regulation 105CMR 590.013(H) states:

All inspection report forms and other related enforcement documents shall be maintained by the board of health for a minimum of five years or longer if otherwise required by law.

One authority retained these records for only two years due to storage space limitations. Two additional authorities retained their inspection records for even shorter periods. When questioned about this practice, they indicated that they were unaware of the regulatory requirement and had instead been operating under separate conflicting guidance provided by the Municipal Government Board of Health Records Disposal Schedule 07-82 (revised September, 1991) issued by the Secretary of the Commonwealth. The language regarding inspection reports in that document simply states “*Retain until superseded by subsequent report.*” We brought this issue to the attention of the DPH/FPP Retail Food and Foodborne Illness Unit Director, who told us that she was unaware that the records disposal guidance document had not been updated for DPH regulatory changes made after 1991 and stated that the Department would work with the Secretary of the Commonwealth to resolve the discrepancy and alert local health authorities to the problem.

Recommendation

The extensive documentation and standardization issues identified by our review are largely attributable to the serious resource, qualification and training, oversight, quality assurance, and decentralization issues identified in this report. We recommend that DPH take action to address these issues through the strategic planning process discussed at the end of this report. In particular, we believe that DPH should implement a mandatory statewide system of standardization measures and program-monitoring procedures similar to those recommended by

the FDA Recommended National Food Regulatory Program Standards on currently inadequate quality assurance systems.

Auditee's Response

A risk-based retail food service inspection form was developed and distributed for use by local health departments in 2000. This inspection form requires the evaluation critical risk factors for food-borne illness control (e.g., potentially hazardous food storage and temperature maintenance) and federal standards for food safety, and has served as the basis for the national model now being disseminated. Additionally, DPH indicated that the FPP is working with the newly established Local Public Health Institute to develop a comprehensive training program on food safety that will be a prerequisite to field standardization and uniform inspection grading....

Auditor's Reply

As noted by our review, the retail food service inspection form developed and distributed by DPH is not always used by the local authorities. As indicated by Table 8, even when the form is used, it is often not used as intended and inspections appear to be not adequately focused on critical risk factors. Although the DPH indicated that FPP is working with the newly established Local Public Health Institute to develop a voluntary comprehensive training program on food safety that will be a prerequisite to field standardization and uniform inspection grading, as of November 1, 2006, the internet site for the Local Public Health Institute did not reflect any training programs specifically focused on food inspection documentation and standardization.

6. FOODBORNE ILLNESS AND GENERAL COMPLAINT INVESTIGATION AND RESPONSE ACTIVITIES ARE DEFICIENT IN MANY COMMUNITIES AND AT THE STATE LEVEL

Foodborne illness reporting, investigation, and response activities at the local level are not always adequate. Statewide oversight, coordination, and information sharing arrangements are also inadequate, contributing to communication deficiencies between state and local officials and not fully and adequately investigating all suspected foodborne illness incidents, particularly those involving only one reported victim. We found similar deficiencies in both state and local systems established to investigate and respond to general complaints received regarding possible food establishment code violations, particularly those involving food store and restaurant chains operating establishments across the jurisdictions of multiple local health authorities. DPH is not adequately investigating and addressing complaints regarding alleged inadequacies in local authority inspection and enforcement practices.

a) Foodborne Illness Investigation and Response Issues

Responsibility for responding to and addressing the surveillance and control of communicable disease, including foodborne illness, is fragmented, with some responsibilities assumed directly by DPH and other responsibilities resting with local health authorities, medical practitioners, and public and private testing laboratories operating under regulations and guidance promulgated by the Department. DPH responsibilities rest primarily with the Bureau of Communicable Disease Control, whose overall activities were not within the scope of our review. However, the Department has established a special Working Group on Foodborne Illness Control (WGFIC) to further coordinate reporting, investigation, and response activities involving foodborne illness. The working group is operated jointly by staff of the FPP within the DPH Center for Environmental Health and representatives of other departmental units such as the Epidemiology Program within the separate Bureau of Communicable Disease Control (CDC). We conducted a limited review of the working group's activities and data, and reviewed related reporting, investigation, and response activity within the Food Protection Program and at the local health authorities within our sample. While senior management at the Department's Bureau of Communicable Disease Control asserted to us that the Commonwealth's communicable disease surveillance systems are among the best in the nation, we noted that, at least in the area of foodborne illness reporting, investigation and response, statewide information sharing arrangements are not yet adequate, resulting in communication deficiencies between state and local officials and not fully investigating all suspected foodborne illness cases. Incidents involving only one reported victim often receive scant attention and even some multi-victim cases are inadequately investigated due to local resource constraints. Information regarding foodborne illness rates in the Commonwealth and each of its communities appears to be incomplete and information regarding suspected foodborne illness events, particularly those involving single victims, is not always reported as required or shared with all parties with a need for the information.

As noted in the introduction to this report, the CDC has estimated that each year approximately 76 million foodborne illnesses occur across the country. On a per capita basis this translates to over 1.8 million estimated foodborne illness cases per year in Massachusetts. (This estimate could actually be low if Massachusetts follows national patterns of somewhat higher foodborne illness rates for northern states compared to the rest of the nation). The development of such

estimates and the efforts of public health agencies to address foodborne illness problems and evaluate the success of inspection systems, public education activities, and other prevention and control measures are complicated by the fact that the vast majority of foodborne illness cases go unreported in the United States. The CDC estimates that perhaps only between 1% and 10% of these illnesses are ever reported to state or local health authorities.⁵ In order to improve the accuracy of information regarding foodborne illness rates, the CDC established an “active surveillance” system called FoodNet, which has been gathering data since 1996 for use in evaluating the success of national foodborne illness control efforts. That system gathers information from sites in 10 states with data covering 15% of the nation’s population. Massachusetts is not included in the FoodNet system; however, the Commonwealth gathers its own data through the Bureau of Communicable Disease Control, the FPP local authority annual reporting process, and the WGFIC, one of whose main purposes is to track cases and complaints of foodborne illness. According to the “Foodborne Illness Investigation and Control Reference Manual” issued by the Department in 1997:

The earlier problems are recognized, the quicker control measures may be implemented and additional cases of illness prevented. For this reason, it is important to track consumer complaints and review the data periodically for clusters of illness or changes in trends of illness. Changes in the occurrence of disease compared to previous time periods may necessitate further investigation.

The Working Group’s main functions, in addition to its role in complaint and case tracking, are:

- To respond to consumer complaints regarding foodborne illness,
- To assist and/or train local boards of health in investigations of foodborne illness or outbreaks,
- To identify causes of outbreaks (through environmental inspections, lab analysis, and epidemiologic analysis), and

⁵ For example the CDC has estimated that only one in every 38 cases of salmonellosis (2.6%) is actually diagnosed and reported to health authorities. Studies by public health professionals suggest that the reporting problem is aggravated by the public not recognizing the foodborne nature of the many illnesses with incubation period longer than a few hours after meal consumption, not identifying symptoms other than diarrhea with foodborne illness, not reporting illness to either the establishment or to health authorities in approximately 92% of the cases even where the victim recognizes the likely foodborne nature of the illness, and a tendency to file complaints only with the food establishment rather than with the local health authority (i.e., 5 complaints made only to the establishment for every 2 complaints made to a health authority). Even where a person is aware that other individuals eating at the same establishment became ill at the same time, reports may not be made to either the establishment or to the health authority in over 80% of such suspected cases. See Journal of Food Protection, Vol. 68, No. 10, 2005, Pages 2184–2189, “Beliefs about Meals Eaten Outside the Home as Sources of Gastrointestinal Illness”; Laura R. Green, Carol Selman, Elaine Scallan, Timothy F. Jones, Ruthanne Marcus, and the EHS-Net Population Survey Working Group.

- To make recommendations and take necessary steps for the prevention and control of foodborne illness.

The importance of this reporting, tracking, analysis, and response process is also stressed in the Department's separate "Guide to Surveillance and Reporting" (2001 edition), which states:

State public health officials rely on local boards of health, healthcare providers, laboratories and other public health personnel to report the occurrence of notifiable diseases. Without such data, trends cannot be accurately monitored, unusual occurrences of diseases (such as outbreaks) might not be detected or appropriately responded to, and the effectiveness of control and prevention activities cannot be easily evaluated....

The importance of timely reporting cannot be overemphasized. For example, if a local health authority saves up all its reports of salmonella and only submits them once a year, a potential outbreak occurring across city/town limits may go unnoticed and uncontrolled.

DPH regulation 105 CMR 300.131: Illness Believed to be Due to Food Consumption mandates the reporting of suspect foodborne illness to health authorities by a wide variety of individuals, stating:

Every person who is a health care provider or who is in a supervisory position at a school, day care, hospital, institution, clinic, medical practice, laboratory, labor or other camp who has knowledge of the occurrence or suspected occurrence of a case or cases of illness believed to have been due to the consumption of food, shall report the same immediately by telephone, by facsimile or other electronic means to the local board of health in the community in which the facility is located. If the local board of health is unavailable, contact the Department directly.

Additional reporting requirements apply to food establishment operators and other individuals and reports are also received on a voluntary basis from members of the public. Local health authorities are then obligated to advise DPH of all notifiable cases known to them and to initiate local investigative activity "immediately" for suspected foodborne illness "outbreaks" involving multiple victims and for some of the highest risk single victim notifiable diseases such as botulism. Other notifiable cases are to be reported and investigated "as soon as possible."

While local health authorities are not mandated to conduct full investigations and submit full case reports to DPH for certain lower-risk single victim cases, the Foodborne Illness Investigation and Control Reference Manual calls for the gathering of at least preliminary data for all complaints, including information on all foods and beverages consumed for 72 hours prior to illness onset, using a standardized "Foodborne Illness Complaint Worksheet" developed

by the Department. Departmental regulations only mandate that local authorities file worksheets and case reports for complaints involving multiple victims or “cluster” cases of single victims and certain suspect and confirmed diagnosis single cases involving “notifiable” serious illnesses such as hepatitis-A, botulism, and salmonellosis. However, DPH strongly encourages local authorities to also report timely case specific information on all complaints of suspect foodborne illness to the WGFIC, even where formal reporting is not mandated by the regulation. In addition, the existing annual reporting system mandates year-end summary reporting of the total number of foodborne illness complaints and the total number of general complaints received by the local authority.

Despite these reporting arrangements, it appears that far fewer than 1% of suspected foodborne illnesses are reported to DPH and/or the Commonwealth’s local health authorities. If actual foodborne illness rates in Massachusetts are approximately those estimated by the CDC for the nation as a whole, the reporting rate in the Commonwealth may be closer to one tenth of 1% than to the CDC’s minimum national reporting estimate of one percent. We found it impossible to determine the exact number of reported suspect foodborne illness cases for the Commonwealth due to approximately one-third of the Commonwealth’s local authorities not filing annual reports each year. The Department’s regulations do not fully mandate that local authorities file timely detailed reports on all suspected or confirmed foodborne illness cases known to them. If DPH believes that gathering information on these additional cases is important, then the reporting requirement should be incorporated into departmental regulations.

DPH’s practice of gathering only summary complaint totals through the annual reporting system also made it impossible to fully reconcile separate annual report and WGFIC data maintained by the Department in order to verify the accuracy of annual reports and to determine unduplicated case count combined totals for the two reporting systems. We did, however, analyze case totals by community for each dataset and determined that the two datasets together appear to cover little more than 1,000 cases per year and that DPH is receiving timely detailed information for no more than approximately 600 suspected foodborne illness cases per year. That case specific information only involves approximately 142 communities (40% of the 351 cities and towns in the Commonwealth). While additional summary case total numbers are reported by other communities, the Department receives no data whatsoever through either of the two reporting systems for as many as 150 communities. In reviewing annual reports for the year 2002 (the

most recent final annual report data available at the time of our audit work), we found that only 103 of the 240 filers reported receiving any foodborne illness complaints. The 103 reported receiving a total of 887 complaints for the year, while the remaining 137 communities did not report receipt of any foodborne illness complaints. Those 137 communities account for approximately 1.6 million of the Commonwealth's population and include at least 11 communities with populations in excess of 30,000 people. It is implausible that the reported numbers accurately reflect foodborne illness incidence patterns in the Commonwealth. Based on an estimated 1.8 million foodborne illness cases per year for the Commonwealth and a reporting rate of only 1%, DPH would be expected to have at least year end summary documentation of approximately 18,000 cases, over 10 times the numbers currently being recorded by the Department. DPH is also concerned that, even where data is being reported, some of the reporting communities are submitting less than complete information to the Department. For example, the total of nine WGFIC reported cases over a two year period for one city with a population well in excess of 100,000 appears to be implausibly low in the professional judgment of DPH staff when compared to the over 250 cases reported over the same period for the City of Boston with its population of less than 600,000. Approximately two-thirds of the cases reported to the WGFIC are reported through local health authorities and only one-third are reported directly to the Department by testing laboratories, medical practitioners, consumers and others. Since DPH relies heavily on the reporting and investigation activities of local authorities, food protection program activities are significantly impaired when local authorities do not carry out their responsibility. We question the Department's ability to adequately conduct foodborne illness surveillance and response activities under these circumstances, as well as the Department's ability to determine that local authorities are properly investigating and following up on locally reported foodborne illness complaints. Our review also suggests that if apparent foodborne illness underreporting problems were resolved and the percentage of suspected illness incidents reported to DPH were to increase significantly, the Department's capacity to appropriately investigate and respond to all reported cases might be quickly overwhelmed due to existing resource constraints.

DPH staff told us that they believe foodborne illness rates have significantly declined in the Commonwealth as a result of their adoption of the federally recommended Model Food Code and, in particular, the requirement that each food establishment employ a properly trained and

CFPM certified manager. However, the Model Food Code and certification requirements for food establishment managers have been implemented by most states in the nation and estimated reductions in national foodborne illness rates, while promising, have not been high enough to suggest that Massachusetts no longer has a significant underreporting problem. In fact, national goals anticipate no more than a 20% reduction in foodborne illness rates by the year 2010. In discussing this issue with local health authority representatives, those representatives instead emphasized to us their concern that the low numbers of reported illness incidents in the Commonwealth involved the fact that the Commonwealth's existing health system creates disincentives for doctors to order tests such as stool samples needed to confirm the diagnosis for many types of foodborne illness and that, as a result, doctors all too often leave the diagnosis unconfirmed, simply treat the victim's symptoms, and do not report the illnesses to public health authorities. While there may be merit to the assertion by DPH staff that the Commonwealth's foodborne illness incidence rates have declined in recent years, at least for certain types of foodborne illness, the Department did not gather complete data from local authorities on all foodborne illness complaints. This made it impossible to verify the total number of complaints reported across the state, to determine whether statewide reported foodborne illness rates were truly increasing or decreasing, or to evaluate whether any changes were really attributable to actual changes in the incidence of foodborne illness or to other factors such as changes in underlying reporting practices by doctors and other reporters or changes in the completeness or accuracy of reporting by local authorities to DPH.

What is clear is that both the mandatory reporting requirements established by DPH for local authorities, medical providers, and other mandated reporters such as food establishment managers appear to be widely disregarded and DPH has not yet adequately addressed the problem. The supplemental voluntary reporting arrangements established by the Department appear to be similarly deficient.

These problems are, however, not unique to Massachusetts. Challenges for foodborne illness surveillance, investigation, and response activities exist across the nation as documented by studies conducted by the Council of State and Territorial Epidemiologists (CSTE) with active participation by Massachusetts DPH representatives.⁶ Common problems include staff

⁶ Available on the Internet at www.cste.org including: National Assessment of Epidemiologic Capacity in Food Safety: Findings and Recommendations, September 2002 whose recommendations were subsequently adopted as a Council of

qualification issues, information technology and other infrastructure limitations, and delays in the reporting of information required to identify and respond to outbreaks in a timely manner. Recommendations include the need to make significant state and local infrastructure improvements; the need for centralized surveillance and response approaches coupled with the use of local health authorities to provide faster response times for case interviews; the need to keep records on all foodborne illness complaints, as well as databases and electronic communication systems for sharing electronic versions of inspection, investigation, testing, and other records; the need for adequately trained and qualified epidemiological staff with cross training for both inspectors and epidemiological staff; provision of adequate reserve “surge capacity” to address large scale outbreaks; the need to develop specific performance criteria and standards and systematic program performance evaluation systems; and the need for national standardization of state and local surveillance, investigation, and response activities, particularly in view of both food-related bio-terrorism risks and the increasing role of nationally distributed food items in illness outbreaks. Additional findings and recommendations are too numerous to summarize here but can be obtained from the CSTE source publications.

Although DPH is currently making improvements such as database system enhancements and testing capacity increases at the State Laboratory, it is not clear that these measures will adequately address existing problems. DPH program managers also expressed concern that, despite their efforts to educate local authorities about foodborne illness issues and appropriate standards for foodborne illness investigation, reporting, and response, some local authorities appear to not be carrying out their roles as required under the existing structure of state and local food protection activities in the Commonwealth.

DPH staff note that many local officials are inadequately qualified in areas such as knowledge of food microbiology, and that statewide information technology arrangements needed to carry out foodborne illness reporting and investigation activities are inadequate. While DPH staff try to provide technical assistance regarding illness investigations to local health authorities upon request, DPH staff expressed concern to us about the Department’s own resource limitations and stated that if significant multi-town illness outbreaks were to occur at the same time due to

State and Territorial Epidemiologists Position Statement on State Food Safety Minimum Performance/Capacity Standards for Epidemiology and Surveillance; Position Statement on National Guidelines for Foodborne Enteric Disease Surveillance and Response June 2005; and Enteric Disease Timeline Study, August 2005.

either natural causes or bio-terrorism, the Department would not have adequate resources to respond and communities might be left on their own to deal with the outbreaks.

Our review of WGFIC meeting minutes noted that response capacity problems already exist for more routine outbreaks. For example, review of group minutes for seven meetings conducted over a three-month period during mid-2005 revealed that the group processed 38 separate cases involving either single victim serious illness cases (e.g., shellfish poisoning) or multi-victim cases, including 28 residents of an assisted living facility who became ill at a catered event. In two of the 38 cases, investigation and response activities were impaired when two separate local health authorities did not carry out their responsibilities to conduct interviews, inspections, and investigations in a timely manner. In one case involving eight victims, the local authority reported that it had been unable to obtain necessary assistance from staff at the local visiting nursing association. In the other case, DPH staff indicated that the local authority had cited resource constraints and declined to investigate a case at a local hotel where 11 students from a neighboring community had become ill at a school prom event conducted at the hotel. Response activities were delayed until DPH staff eventually prevailed in securing participation by the local health authority for the community in which the hotel was located. DPH staff told us that given the Department's own resource constraints, they could not always step in to carry out investigation and response activities that were the responsibilities of local authorities and sometimes had no alternative but to simply record the problem in working group minutes, leaving a case less than adequately resolved.

Our visits to local authorities confirmed the existence of distinct variations in foodborne illness investigation, response, and tracking practices at the local level:

- At some local authorities, food inspection staff worked directly with local public health nurses and even had access to local laboratory services for diagnostic testing, while in other authorities these local resources are unavailable. We noted that these resource deficiencies are not just concerns of DPH staff, but that the above-referenced CSTE recommended standards specifically state:

Every jurisdiction should have a dedicated enteric/foodborne disease epidemiologist. Smaller jurisdictions where an entire full time equivalent is not justified should identify a staff member as the point of contact. At least a Master's level education with specific training and education and/or practical experience in foodborne disease epidemiology is recommended.

As discussed in the above Audit Results sections regarding resource constraints and inspector training and qualification inadequacies, it appears that many, if not most, local authorities have staff qualification and training deficiencies regarding foodborne illness investigation and response issues (e.g., see Chart 1 regarding participation in DPH foodborne illness trainings). The extremely decentralized structure of the Commonwealth's food protection activities in comparison to the rest of the nation may further aggravate these problems.

- Some local authorities indicated that, as requested by DPH/FPP, they reported all complaints of suspected foodborne illness to DPH regardless of the number of victims involved or the confirmed or unconfirmed status of diagnoses, while other authorities stated that they only reported incidents where reporting was mandated by DPH regulation or by state communicable disease reporting laws.
- Certain local authorities classified all suspected but unconfirmed individual foodborne illness incidents as foodborne illness complaints on annual reports to DPH, while others classified only a handful of confirmed cases as foodborne illness complaints on the annual reports and improperly reported all suspected but unconfirmed foodborne illness complaints as "general complaints" even where the complaints may have involved so-called multiple victim suspected "foodborne illness outbreaks." DPH staff told us that local authorities had been given clear reporting instructions and that the reporting practices we identified were improper. All complaints of suspected or confirmed foodborne illness incidents received by local authorities should have been reported on annual reports from local authorities regardless of the number of victims involved or the confirmed or unconfirmed status of the suspected illness.
- While systems for taking complaints even during evening, weekend, and holiday hours were well developed in some jurisdictions and the nature and status of complaints was carefully tracked, we found that in other jurisdictions these arrangements were deficient and that information had not been recorded or had been misplaced. Complaint logging and tracking systems were often so rudimentary that foodborne illness, general food establishment sanitation or food code compliance complaints, and non-food related complaints such as those involving housing code violations were all consolidated into a single complaint process with no means to classify or quantify complaints by type with the detail required for DPH reporting purposes.⁷ In some localities the logging system consisted of little more than a pile of phone message slips, which did not always even result in entries to records maintained for individual food establishments.
- There also appeared to be significant variance in the attitudes of local staff, with apparent problems in some jurisdictions where staff voiced the opinion that most complaints were false and motivated by a desire to extort free meals or other settlements from local food establishments. In contrast, staff in other jurisdictions regarded their complaint systems as a critical element in their foodborne illness prevention and response activities and as a valuable resource for prioritizing inspection and educational efforts.

⁷ One commonly used commercial software package was designed to classify different health department inspectional services complaints simply by category such as "food," "housing," "septic," etc.

- While some local communities reported that they had no issues at all with foodborne illness investigation and response arrangements with DPH, others expressed concern that they were not always provided with information in a timely manner by DPH in situations where the initial complaint had been reported directly to DPH (e.g., by a testing laboratory) rather than through the local authority. Our review of documentation at local authorities confirmed at least two such situations where there had been a delay of at least 10 days in notifying the local authority after the report had been initially logged in at DPH.

We also identified at least one instance in which it appeared that standard procedures had not been followed by DPH in the documentation of activities involving investigation of an incident in which a Springfield, MA college student died in December 2004 of hepatitis-A, and three other students at the same college contracted the disease. Documentation indicated that investigation by FPP staff suggested that the outbreak may have been contracted through food prepared at the college's dining facility, but did not rule out the possibility of non-food related transmission. While explaining working group operations to us, DPH staff stated that they enter full information for all multi-case outbreaks into the WGFIC database when foodborne transmission is the "suspected" cause, regardless of confirmation of diagnosis or transmission mechanism. This serves to document the investigative activity taken during the process of confirmation, and consistent with the working group's mandate, ensures that program records completely reflect all received complaints and reports. However, senior managers elsewhere in the Department had instructed that this particular incident be excluded from the database on the grounds that other possible exposure sources had not yet been ruled out. When asked to explain the situation, FPP staff referred us to DPH's separate epidemiological unit managers and their superiors. Our inquiry received a response from the Department's Assistant Commissioner for the Bureau of Communicable Disease Control, who acknowledged responsibility for the decision, attributing the exclusion simply to the fact that the possibility of non-food related transmission could not be ruled out. No further explanation was provided that shed light on why the case should not have been included along with other suspected and investigated but never confirmed foodborne illness incidents reported in the database. Similarly, our review of WGFIC minutes and data did not find reference to a highly publicized incident in late spring of 2004 in which approximately 1,600 restaurant patrons at an Arlington, MA restaurant were offered immunization shots after exposure to hepatitis-A through an infected restaurant employee. Although no consumers were reported to have contracted the disease in that case, the event involved an ill food worker and was subject to foodborne illness investigation by

DPH. We believe that all such incidents, investigations, and response activity should be properly documented and identified in the WGFIC database so that it comprises a complete record of all suspect or confirmed foodborne illness-related complaints and incidents reported to DPH. Program managers acknowledged that there had been a series of communication issues between the program and the Department's separate communicable disease and epidemiological units. FPP managers had not always been advised of investigation and response activities conducted outside their program. We were told that the program has formally requested that they be notified whenever such potentially foodborne illness-related episodes occur.

The situation we encountered at both local authorities and at DPH contrasts with provisions contained in the FDA's Recommended National Food Regulatory Program Standards. In addition to staff qualification and training provisions requiring training in food microbiology and epidemiology, (which both our review and comments received from DPH managers identified as an issue for many local authorities), the standards include detailed expectations regarding Foodborne Illness Investigation and Response activities, including:

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

And:

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

- 1. Multiple complaints on the same establishment;*
- 2. Multiple complaints on the same establishment type;*
- 3. Multiple complaints implicating the same food;*
- 4. Multiple complaints associated with similar food preparation processes;*
- 5. Number of laboratory-confirmed food-related outbreaks;*

6. *Number of non-laboratory-confirmed, but epidemiologically linked, food-related outbreaks;*
7. *Contributing factors most often identified.*

While arrangements at DPH and at some of the local authorities we visited are consistent with at least some of the federally recommended standards, neither DPH nor the local authorities fulfilled all recommended standards regarding essentials such as documentation, response-time, and analysis of details for all complaints, not just those complaints involving outbreaks and certain reportable illnesses.

b) General Complaint Investigation and Response Issues

We also found deficiencies in both state and local systems established to investigate and respond to general complaints received regarding possible food establishment code violations and perceived inadequacies in local authority inspection and enforcement practices. These deficiencies were similar to those identified for foodborne illness complaints. Where complaints are made to DPH regarding problems at the local level, FPP resource constraints limit the Department's ability to investigate the complaints. Even complaints alleging possibly significant problems, such as local officials not initiating enforcement action, favoritism, or other situations where the ability of local inspectors to conduct activities in an impartial manner has been impaired, are typically not investigated but are instead addressed simply by referring the complaint to the local authority and sometimes, but not always, asking for a report back from the local authority.

In addition to the WGFIC database covering foodborne illness complaints, DPH/FPP maintains a separate "general complaint" database covering complaints received directly at DPH from a variety of sources including members of the public, local health authorities, out-of-state authorities, and other DPH employees. While some of these complaints involve foodborne illness, most cover a wide range of concerns where consumers did not become ill. Complaints have involved retail food products sold after expired sell-by dates and products that have been adulterated with foreign objects such as pieces of metal, rodent feces, or, in one case, sausage meat found to contain a human tooth. Other complaints have involved unlicensed wholesale operations under the direct jurisdiction of DPH, alleged food code violations at retail establishments under the inspectional jurisdiction of local authorities, deficient practices at local authorities, and occasional issues involving mattresses and other bedding products, which have

been assigned to the Food Protection Unit as an incidental State Sanitary Code enforcement responsibility.

DPH records identified a total of 724 general complaints from late May 2001 through July of 2005. Our review of these records indicates that DPH has usually taken appropriate action with federal authorities on items involving interstate commerce and has used DPH inspectors to follow up on problems involving wholesale operations directly licensed and inspected by the FPP. Direct DPH action has generally been minimal on complaints alleging matters under the jurisdiction of local health authorities. Typically, these complaints have simply been referred to the responsible authority, sometimes accompanied by a request that the local authority state what action is being taken. While this approach is understandable given the resource constraints facing the program, we noted two distinct deficiencies:

- Complaints are not used to inform the quality assurance process that should be conducted by DPH as part of its oversight and coordination responsibilities, and the Department rarely follows up with its own independent review, even where irregularities are alleged at the local level.
- General complaints are not systematically gathered and analyzed for issues that may warrant follow up by multiple local authorities. DPH lacks any system to consistently obtain complaint and inspection information from local authorities when information goes directly to the authority rather than to DPH. Nor is there an adequate system in place to share information across authorities regarding possible chain-related or other cross-authority complaint or compliance issues. We noted that certain complaints involving similar issues for food establishments operated in multiple communities by store or restaurant chains were handled on an isolated basis through referral to individual health authorities where local health agents were unaware of the overall picture. For example, nine of 81 complaints made directly to DPH regarding outlets of one supermarket chain involved allegations of expiration date violations or the sale of spoiled food. During our review of records at local health authorities, we found that some authorities had themselves received complaints of a similar nature regarding the chain's stores in their communities, but were unaware of the complaints made directly to DPH or to other local authorities. In at least one instance, we were told that local inspectors had identified repeated problems involving the spoilage of meat prior to sell-by dates. After receiving what local inspectors characterized as "improbable" explanations involving the alleged return of meat by consumers, the authority had contacted the chain's regional representative, who assured them that the issue had never been encountered elsewhere in the chain. The local authority was unaware that separately, DPH had received three separate meat and seafood spoilage or sell-by date complaints involving the chain's stores in three separate communities, as well as four similar complaints regarding products other than meat or seafood. The health agent for the authority told us that he wished he'd known about the other complaints since they could

indicate the existence of chain-wide problems such as wholesale supplier or regional distribution problems. In the absence of that information, the local authority's examination of the problem had been limited to store-specific factors, such as cold case holding temperatures. We also noted that the local authority had contacted DPH regarding its concerns and had even mentioned the potential for out-of-store problems such as warehouse to store transportation temperature problems to DPH staff. However, the authority had apparently not been told by DPH of the existence of similar complaints regarding other stores operated by the chain. Instead, DPH simply passed the complaint on to the store chain's director of quality assurance with no further documented investigation. DPH records indicate that in these cases the Department had disposed of each complaint by referring it to the local authority and/or to the chain. This approach for addressing complaints is obviously deficient, particularly when DPH's own records regarding the complaints document a questionable pattern of repeat problems across multiple communities including one complaint regarding sale of a pre-packaged ham where the manufacturer's expiration date of August 8th had been covered over by a store label with a new expiration date of September 8th. According to DPH records: "The complainant notified the Store's customer service department and they took the ham off the shelf but put them back out the next day with the same stickers dated September 8th." We also noted that multiple authorities had cited different stores in the chain for repeatedly not correcting various inspection violations, including one instance in which a local authority had ordered one of the chain's stores to pay a substantial "surcharge" and shut down its bakery operation after the store repeatedly did not address rodent problems.

DPH staff attributed these complaint investigation and communication inadequacies to a combination of limited staff resources and inadequate technology systems at both DPH and local authorities. Complaints such as these should be addressed in a far more comprehensive and coordinated manner at the state level rather than relying on local authorities to investigate on their own and to address problems solely at the local level when underlying operational problems may better be addressed on a statewide basis.

c) Complaints Involving Local Health Authority Inadequacies

Approximately 74 of the 724 general complaints received by DPH raised concerns regarding the adequacy of food protection activities at approximately 54 local health authorities. Alleged deficiencies included establishments not being inspected, food code requirements not being enforced, local response problems for weekends and other after-hour periods, refusal to accept or record complaints, complaints not being followed up on, misinterpretation of regulations, and impairment of inspectional activity due to inadequate independence on the part of inspectors or favoritism situations, including alleged interference by local officials with board of health enforcement efforts. Approximately 55 of the complaints, involving 40 local health authorities,

were filed in the 25 months from July 2003 through July 2005. These 55 complaints represented approximately 15% of the 374 total general complaints logged by DPH/FPP over that 25-month period. Our audit work at DPH and visits to local authorities confirmed the existence of problems in these and other areas. Examples included situations where:

- The same individuals inspected the same establishments for numerous years due to the small scale of inspectional operations and an inability to rotate inspectors as recommended by federal guidelines. Not rotating inspectional assignments and comparing inspection outcomes by different inspectors for the same establishments presents both a quality assurance risk and a potential risk for favoritism or bribery given the potential high-stakes nature of potential enforcement action for repeated code violations or substantiation of establishment responsibility for major foodborne illness incidents.
- Establishments in some jurisdictions had been permitted to operate without imposition of meaningful penalties despite histories of repeated critical violations of code provisions directly related to foodborne illness risks (e.g., storing foods at improper temperatures, not properly sanitizing equipment, etc.). While some jurisdictions routinely issued fines or surcharge penalties, mandated supplemental training for food managers and food handlers, or required establishments to bring in outside food safety consultants at their own expense to bring them into compliance, other jurisdictions expressed frustration regarding financial, political, or legal constraints impairing their ability to hold establishments accountable. As described further below, we also encountered a few situations where staff at local authorities appeared to be less than appropriately concerned about ongoing repeat violation situations.
- Despite provisions in the food code expressly authorizing inspectors to order immediate closures where imminent health hazards are found, inspectors at several authorities had been prohibited from ordering emergency restaurant closures prior to review and approval by senior managers, local board members, or other elected officials. While it is understandable that prior telephone consultation may be desirable to ensure uniform enforcement practices, such prior approval arrangements need to be managed in a manner that will not preclude on-the-spot emergency closures before the inspector leaves the premises.
- It was asserted that in some communities elected board of health members or other senior municipal officials had insisted that food establishment permits be issued over the objection of local inspectors. In one instance, a board of health had reissued the annual permit for a restaurant over the local health agent's objections following the identification of various critical code violations, the food establishment manager not passing the required certification examination, and receipt of a complaint regarding a foodborne illness case allegedly involving the establishment. Additional deficiencies were identified when the health agent inspected the establishment in March 2002 after the permit re-issuance. Less than five months later, a citizen complaint was received regarding alleged continuing critical violations. A demand by the health agent that the

- violations be corrected resulted in threatened litigation by an attorney for the establishment. While additional inspections were conducted, no further enforcement action was initiated until September 2003, after two more foodborne illness complaints were filed within 10 days of each other regarding the establishment, one involving salmonella poisoning. At that point DPH/FPP was asked to mediate the situation. DPH/FPP staff inspected the establishment, confirmed the existence of continuing violations, and recommended that the establishment be required to hire an independent food consultant for six months to bring them into compliance. While the consultant reported that conditions were somewhat improved during the probationary period, documentation indicated that some critical violations were continuing to occur. At the expiration of the six-month period the local health agent attempted to resume inspections of the establishment but was denied access in violation of the code. Several days later the health agent succeeded in obtaining advice from DPH/FPP that the board could initiate enforcement action to close the establishment if it continued to deny access to the inspector. However, before action could be taken, two additional foodborne illness cases were reported to have occurred five days after the enforcement discussion with DPH. At that point the establishment acquiesced to inspections. It remained in operation 21 months later at the time of our audit visit.
- Inspectors in one local health department were placed in the position of inspecting a food establishment managed by the spouse of the department's Director. While this situation was disclosed to both staff and local board of health members at the time of the September 2002 hiring of the spouse by the restaurant and the Director's disclosure stated that he was not to be involved in any matters involving the establishment, we noted that the local authority lacked adequate arrangements such as agreements with DPH/FPP or other local authorities to have inspection or other enforcement responsibilities carried out by independent parties not under the Director's supervision. Only a week after the disclosure, a complaint was received claiming that a customer had caught a cold from an obviously ill food server at the establishment. Since the food code requires establishments to temporarily exclude ill employees from work, the establishment may have been in violation of the code. Despite this situation, the foodborne illness investigation worksheet submitted to DPH/FPP by the health department was signed by the Director, asserted that the complaint was unsubstantiated, and did not disclose his relationship to the establishment. Later, in July 2003, a complaint alleging that an inspector did not fully enforce food code requirements at the establishment was filed directly with DPH/FPP. However, the complaint did not identify the department Director by name or position title, instead incorrectly asserting that the family relationship involved an unnamed inspector assigned to the establishment. DPH simply referred the complaint to the Director for review and did not further investigate the complaint. Subsequently, DPH was notified of three separate foodborne illness incidents involving the establishment in February 2004, May 2004, and May 2005, the last involving a post funeral brunch at the establishment where a large number of attendees became ill. Records of routine inspections conducted by local inspectors during this period revealed that the establishment was repeatedly cited for as many as 19 critical violations during a single inspection, and that the establishment had at one point been issued a written warning regarding repeated violations that were not corrected. Our review of records for 12 other establishments under the jurisdiction of

that health department revealed that two other establishments had similar patterns of large numbers of repeat violations but that, unlike the first establishment, those two establishments had both been required by the local board of health to hire outside food safety consultants to correct their problems. The records provided no explanation for not taking similar enforcement action against the establishment employing the spouse of the health department director. When we discussed this situation with a DPH/FPP manager, we were told that the Department had no knowledge of either the apparent differential treatment afforded the food establishment or of the relationship between the health department director and the establishment manager.

- In another community, an anonymous restaurant employee complained to DPH in November 2003 that multiple employees had become ill after consuming seafood chowder provided by their employer. The complainant refused to identify herself, stating that her boss was a good friend of a senior manager at the local inspectional authority for that community. DPH did not treat the complaint as a formal foodborne illness incident, but rather as a general complaint. Their records characterized the complaint as from a “disgruntled employee” and indicated that the complaint information was simply referred to the local authority. The DPH complaint database contained no information regarding any further follow-up action on the complaint. However, we noted that DPH/FPP foodborne illness database records document four separate additional foodborne illness reports involving the establishment in February 2004, July 2004, March 2005, and July 2005. When we visited that health authority, we reviewed the records for that establishment and found that there was no record of the initial employee complaint referred to the authority by DPH or of the follow-up investigation and inspection activity that would be expected after receipt of such a complaint. The authority’s records on the establishment did, however, cover all four subsequent suspect illness incidents on record at DPH, all of which involved either clam chowder or oyster meals. The file contained information on only two routine inspections (conducted in January 2004 and May of 2005) despite the fact that the local authority’s own risk-based scheduling system called for at least five routine inspections to be conducted during this period.⁸ The records also included five additional general complaints regarding the establishment received on June 14, 2004, June 24, 2004, July 6, 2004, August 10, 2004, and September 13, 2005. Three of the general complaints were regarding mice in the establishment (including the public dining area), one involving flies, and one asserted that the complainant had observed raw oysters in dishes stacked on top of each other in a dirty dumbwaiter used to transport meals from the kitchen to the upstairs dining room. Despite the local authority’s policy that complaints such as these be investigated by on-site inspections within 24 to 48 hours, no inspection reports were present for any of the general complaints. The report for one routine inspection conducted during the period in which these complaints were being received identified no critical violations and six non-critical violations, while the other routine inspection identified three non-critical violations. When we reviewed the available inspection reports covering the suspect illness incidents, only one, a July 2005 report, identified a single critical risk factor violation involving evidence of pests. All nine additional violations identified on that report had been characterized as non-critical in nature.

⁸ An additional inspection conducted as part of a suspect illness investigation less than six weeks after the May 2005 routine inspection had been mislabeled as a routine inspection.

Since the presence of pests, particularly mice and other rodents, is a high-risk factor for foodborne illness and the presence of rodents is readily detectable by the presence of droppings and urine traces visible under ultraviolet lamps carried by inspectors, the absence of on-site inspection reports in response to the pest complaints appeared to be irregular. Had follow-up inspection visits been conducted on the complaints as provided by the local authority's policy and had an inspector actually seen a live rodent on the premises, standard code enforcement procedures would have called for closing the establishment temporarily until the rodent problem could be resolved. We also found that the February 2004 suspect illness inspection report identified only a single non-critical violation related to the condition of interior wall/ceiling surfaces despite the fact that the complaint description read:

We have gone twice late night to [the establishment] and each time asked for oysters (at around 11:30). Each time we were presented with oysters that had been shucked a significant period previously – they were dry, rubbery, and even the lemon was dried up. The sauces were in plastic containers and the sauce was congealed.

Unfortunately this second time two different colleagues of mine at different tables had already eaten several oysters and both became violently sick the next day (with severe diarrhea and one with vomiting).

It should be noted:

- 1. My family business is seafood. I am absolutely certain this was extremely old product.*
- 2. I am a licensed physician. I am almost certain my colleague had Vibro Cholerae or something markedly similar.*
- 3. This egregious disregard for public safety appears to be chronic at this establishment.*

Since the handling of general complaints regarding the establishment did not conform to the inspection policy requirements as they had been stated to us, routine inspection frequency was inadequate, and the absence of critical violations in inspection reports appeared to be unusual, we sought an explanation from the health authority. When we asked the senior manager assigned to represent the local authority during our audit visit (who happened to be the individual named in the Fall 2003 anonymous complaint from the establishment employee) about these issues, he stated that he would have to review the file but that the establishment in question was in an extremely old structure subject to a variety of compliance problems, that its track record was nothing out of the ordinary for a high volume establishment catering to tourists, that had we examined files for other similar establishments they would have been similar, and that most foodborne illness complaints in that community were false, coming from tourists who hoped to secure large settlements from such establishments by threatening litigation. He then noted that it was his job to stick up for the community's food establishments. We judged this explanation to be unsatisfactory and the absence of any significant DPH/FPP quality assurance mechanism to identify the need for and to provide an independent assessment

of the food inspection and suspect illness investigation and response activity in such cases to be disturbing.

- Several local authorities expressed concern regarding communication problems, inadequate standardization of inspections, and variations in the interpretation of code requirements across jurisdictions, particularly regarding food establishment types such as caterers, chain establishments, and vending machine and mobile food businesses. Our review confirmed the existence of such issues. In addition to the previously described supermarket chain issue, we noted a restaurant chain issue where one health department had identified a fundamental flaw in the HACCP-based operational procedures of a large restaurant chain, which had resulted in nation-wide changes to operations in that chain's establishments. However, the chain also operated in other local health authority jurisdictions we visited but those authorities appeared to be unaware of the procedural problems. This example indicates the presence of coordination and inter-authority communication deficiencies in the Commonwealth and also suggests the existence of inspection standardization deficiencies if it is in fact true that deficient standard operational procedures were in use across the chain but remained undetected by some local authorities.

An additional example of inadequate standardization and enforcement was provided by one authority that identified a food code violation involving a local country fair temporary food permit. That authority had denied a permit request from a vendor whose practice was to pre-prepare potentially hazardous seafood items in an unlicensed private home kitchen prior to sale at the fair. When the authority refused to issue a permit due to the code violation, the vendor threatened litigation, complaining that it had been permitted to operate in this manner at similar events all over the state, that no other local authority had enforced the code prohibition regarding its preparation practices, and that in many instances there had not even been any food inspections at events elsewhere in the state. The local authority stated that it had brought the situation to the attention of DPH/FPP and told us that a DPH employee had initially advised them to “look the other way” given the non-enforcement precedents set by other authorities. The local authority stated that it had decided to enforce the code despite that advice and that DPH eventually issued a statewide memorandum to local authorities in August 2005 instructing them to tighten up on inspection and enforcement procedures at temporary events.

Recommendation

DPH should immediately establish an appropriate “tone at the top” oversight environment stressing the importance of code enforcement and full adherence to detailed foodborne illness and complaint investigation and response standards. The Department should ensure that

resources needed to correct identified deficiencies are provided at both state and local levels and that appropriate systems are established to ensure that all state and local inspections and other food protection activities are conducted with fairness and impartiality. Food protection activities must be insulated from impairment by politically connected food establishment operators and from conflict of interest situations. Unfortunately, public awareness of significant foodborne illness incidents such as hepatitis-A incidents can potentially jeopardize a food establishment's revenue stream even in cases where an exposure incident may not have been reasonably preventable by management and may be unlikely to reoccur. Even in these circumstances it may be necessary to immediately initiate public notification and immunization systems to protect the health of exposed individuals. However, these response measures can be rendered ineffective when incidents are not promptly reported and investigated. The financial consequences associated with such situations provide significant disincentives for food establishment compliance with regulatory illness reporting requirements and can also unduly influence response and enforcement activity by health officials, particularly where required response measures such as immunization clinics may carry significant costs. Detailed guidelines for response to high-risk situations such as hepatitis-A incidents should be promulgated to ensure that public health considerations and protective measures such as public immunization clinics are not made subservient to other interests. DPH should consider implementation of additional measures such as formal state licensure of food establishment managers, including provisions for license suspension, revocation, or other sanctions where managers have not complied with reporting and other compliance requirements. As recommended in a previous section of this report, similar licensure provisions should also be considered for all food inspectors in the Commonwealth. Regulatory requirements, education, training and reporting, data exchange, testing, and response systems should all be significantly enhanced consistent with the detailed nationwide recommendations of the Council of State and Territorial Epidemiologists referenced above.

Auditee's Response

DPH strongly objects to the audit report's characterization of the food-borne illness and complaint investigation response activities at the state level as deficient. DPH has a highly successful food-borne illness response system, and the audit report does not accurately reflect the cooperation, coordination with local and federal partners and the high level of epidemiologic, laboratory, clinical, and environmental expertise available to local boards of health in Massachusetts. The report should take the following into consideration:

- *Massachusetts maintains a highly aggressive surveillance system for early identification of food-borne illness and other infectious diseases based on mandating reporting by all clinical laboratories, hospitals and physician's offices. These reports are provided directly to DPH and local Boards of Health. Food-borne illness surveillance is conducted mainly at the state level.*
- *105 CMR 590.000 mandates reporting of all food-borne illness outbreaks (both suspected and confirmed) by local boards of health. Clinical laboratories and health care providers are required by law to report single confirmed cases to the DPH Division of Epidemiology and the State Laboratory Institute at DPH who identify potential outbreaks.*

DPH's food-borne illness policy requires that all single-case complaints, whether suspect or confirmed, be investigated by the local board of health within 24 hours when there is a possibility that the confirmed diagnosis or clinical symptoms are consistent with foods consumed and the onset of illness. All complaints received by the FPP are sent to the local board of health within 24 hours unless preliminary investigation is initiated by FPP.

- *Timely and highly successful preventive measures are taken routinely as a result of our system. For example, rapid interventions (including vaccination, preventive public clinics, food safety and board of health training and emergency changes in Department policy) by DPH in cooperation with local boards of health prevented food-related hepatitis A outbreaks statewide. As a result, there have been no confirmed food-related hepatitis A outbreaks since March 2004, despite a major, concurrent person-to-person outbreak of the disease in the at-risk population.*
- *Underreporting of food-borne illness is a challenge nation-wide, not just in Massachusetts. It is attributed to many factors beyond local and state control, including the lack of reporting by consumers and health care providers. FPP has developed a brochure for consumers and providers on food-borne illnesses and how to report such illness which is distributed to all local boards of health at statewide, regional, and local training programs and conferences.*
- *The draft audit's assertion that neither DPH nor the public health agencies fulfilled the food-borne illness standards in FDA's voluntary program standards is incorrect. A self-assessment conducted this year by the FPP revealed that the program met 18 out of 20 criteria listed in seven areas of FDA Standard #5 – Food-borne Illness. Again, these standards are designed for continuous improvement, not as a minimum standard as referenced in this audit. Significant enhancements since the last audit show continuous improvement.*

In conclusion, the FPP responds to over 2000 inquiries annually from local Boards of Health, the food industry, and consumers. Food-borne illness investigations and surveillance in Massachusetts require multi-agency collaboration and expertise in many different clinical areas to prevent and control food-borne illness. We respond efficiently and effectively to food-borne illness incidents by activating the Working Group on Food-borne Illness Control which is composed of representatives from the Food Protection Program, the Division of Epidemiology and the State Laboratory who provide surveillance, laboratory and investigation support as necessary to local boards of health to ensure that preventive measures are implemented. In fact, the national food-borne illnesses response models are based on the Massachusetts model which was first implemented in the late 1980's.

Auditor's Reply

As our report noted, there have been some significant improvements in the Department's foodborne illness investigation and response activities in recent years. However, the DPH response does not adequately address the significant problems that continue to exist both at the state level and, in particular, at the local level. We found that statewide information-sharing arrangements (described by one DPH official to us as "antiquated") are not yet adequate and impair investigation and response activities. Incidents involving only one reported victim often receive scant attention and even some multi-victim cases are inadequately investigated due to local resource constraints. Information regarding foodborne illness rates in the Commonwealth and its communities appears to be incomplete and information regarding suspected foodborne illness events is not always reported as required or shared with all parties with a need for the information.

- DPH correctly notes that foodborne illness surveillance is conducted mainly at the state level. That system uses what is known as a "passive surveillance" approach, primarily relying on after-the-fact reporting from clinical laboratory services used by medical providers for diagnostic purposes. However, investigation and response activities are heavily reliant on local health authorities facing significant resource and expertise deficiencies and the Department's response appears to skirt those concerns.
- The response reiterates existing reporting mandates, but does not address either the recommendations of national professionals that all suspected cases be reported and analyzed (not just outbreaks and confirmed cases for certain illnesses such as Salmonellosis), or our findings that mandated reporters are not always reporting as required, and that even where local authorities do report cases, they are often not reported in a uniform, consistent, and timely manner.
- DPH asserts that all complaints received by the FPP are sent to the local board of health within 24 hours unless preliminary investigation is initiated by FPP. Even so, we found that in many instances information is not reported directly to FPP staff, but is instead reported solely to Division of Epidemiology and/or State Laboratory Institute staff and is not always processed through the Working Group process. As described in our report, local authorities documented multiple instances where several days elapsed before local authorities were advised of the existence of a potential problem at an establishment and the need to carry out investigation and response activities. Even if the Department was conducting "preliminary investigation" activity during this period, the local authorities should have been informed in a timelier manner. In reviewing the processing of such delayed notification cases, we also noted instances where cases appeared not to have been data-entered in a timely manner. In at least one case, the illness was not data-entered until a year later, and when entered it was miscoded as a current year case.

- We found that information provided to us was insufficient to substantiate the Department's assertion that intervention and other activities have prevented food-related hepatitis A outbreaks statewide since March 2004. We were also not able to rule out the possibility that the improperly documented December 2004 hepatitis A outbreak referenced in our report may have in fact been food-related as suspected by FPP staff, and that statewide inadequacies involving both inspection and enforcement activities and investigation and response activities at both state and local levels may have contributed either to the outbreak itself or to the Department's inability to confirm or refute the suspected food-related nature of the outbreak.
- While the Department correctly notes that it has developed a brochure and has conducted various foodborne illness educational and training activities around the Commonwealth, its response suggests that under-reporting in Massachusetts is attributable to factors beyond local and state control. Although such uncontrollable factors do play a role in reporting rates, the Department's response does not address the disproportionately low reporting rates we found to exist compared to federal estimates for the nation as a whole. In fact, during our audit work, DPH staff told us that federal officials had questioned the unusually low outbreak incidence levels reported by the Department. The response also does not adequately address issues we identified in our report regarding the sufficiency of existing reporting and reporting enforcement mechanisms. We believe that the Department has the responsibility to more assertively address these issues. As just one example, the Department could implement internet-based systems to facilitate reporting by the public, reporting by local health authorities and other mandated reporters, and efficient information sharing. If information technology improvements were made, routine automated monitoring systems could be used to regularly identify questionable reporting patterns and prompt timely investigation and follow-up action by departmental staff where reporting activity appears to be incomplete or otherwise abnormal.
- DPH states that our report incorrectly asserts that neither DPH nor the local public health agencies fulfilled the foodborne illness standards in the FDA's voluntary program standards. The unaltered language in our report actually states:

While arrangements at DPH and at some of the local authorities we visited are consistent with at least some of the federally recommended standards, neither DPH nor the local authorities fulfilled all recommended standards regarding essentials such as documentation, response-time, and analysis of details for all complaints, not just those complaints involving outbreaks and certain reportable illnesses.

We believe that our assessment of arrangements existing as of the December 2005 end-date for the period covered by our review was fair and accurate. The Department's assertion that it has since enrolled in the FDA's national standards program and conducted a self-assessment revealing that the program met 18 out of 20 criteria listed in standards covering foodborne illness prompted us to seek confirmation from the district FDA official responsible for the program. We were told that an FDA representative had met with DPH managers approximately a year ago and had received a commitment to move towards enrollment of at least the DPH/FPP office in the national standards

program. It was only on October 12, 2006 that the Department formally enrolled in the program. The official we spoke with stated that he was unaware that a formal self-assessment of compliance with foodborne illness standards had been completed by the Department and that he did not know whether or not results of the assessment had been independently verified by an outside party. The official also expressed concern regarding continuing resource and system structure inadequacies at both the state and local level, which are likely to constrain enrollment and impair efforts to comply with appropriate national standards. He indicated that the resource situation at DPH/FPP has actually worsened since the time of our work, stating that his understanding is that current staffing for the program's Retail and Foodborne Illness Unit, reported in Table 2 of our report at 2.65 FTE for fiscal year 2006, has now been reduced even further to approximately 1.5 FTE. However, as we note in Audit Result No. 10, the Department's commitment to enroll in the standards program represents a step forward and we hope that the Department will now move forward with appropriate action to address the issues identified in our report, including the serious resource inadequacies that received scant reference in the Department's response to our draft report.

7. INFORMATION TECHNOLOGY SYSTEMS ARE INADEQUATE AT BOTH THE STATE AND LOCAL LEVEL

In contrast to many food protection regulatory authorities around the country, most food protection program activities at DPH and at local authorities remain unautomated or operate with inadequate and unstandardized information systems. The result is lost efficiency, significant communication problems for both public health officials and others seeking information on food protection activities, and inadequate information for program oversight, evaluation, planning, and other management activities. While a number of local authorities are attempting to address internal operational issues by moving to electronic inspection systems (EIS) typically operating on hand-held computing devices (PDAs), this effort is uncoordinated. Uniform data standards have not been promulgated by either DPH or the FDA, and our visits to local authorities identified instances where some authorities were attempting to implement commercially marketed systems that had already been evaluated by other authorities and been deemed deficient. As recommended to us by regional FDA officials, it would be desirable for DPH to assume responsibility for coordinating information technology upgrade activities in order to ensure that upgrade activities are efficiently conducted, effective, and that the end result is a state-wide information network where standardized data on both state and local inspection and related activities is readily available to all local, state, and federal officials responsible for the operation and oversight of food protection activities in the Commonwealth.

Our audit background research noted references to the use of electronic inspection systems around the country, including the inspection authority for Maricopa County in Arizona, where a PDA-based electronic inspection system was implemented approximately 10 years ago. That authority asserted that it had realized 33% productivity improvements as a result of the initiative. We also noted that similar systems are in use at numerous authorities across the nation. For example, the data cited in Audit Result No. 3 for 67 Florida counties was largely generated by PDA-based electronic inspection systems. All 67 counties included in the Florida dataset reported using the devices for at least a third of their inspections, and overall 73% of almost 115,000 fiscal year 2004 full and partial inspections were conducted using the devices. Even where the devices were not used, summary data for each inspection, including specific violation codes, was entered and rolled up for state use. In contrast, during our review of year 2002 annual report data for local authorities in Massachusetts, we noted that only five of 240 filers claimed to be using electronic inspection systems that year, and that preliminary data from the 2004 annual reporting cycle did not indicate any overall increase in use. The five Massachusetts authorities reporting EIS use had only been responsible for the inspection of 656 food service establishments in 2002. We conducted additional internet research and discussed this issue further with federal, state, and local food protection officials, as well as with an official in King County, Washington, where extensive detailed inspection results are readily available to the public on that authority's internet site. Our review disclosed the following:

- The merit of maintaining electronic data systems with standardized data on all inspections appears to be almost universally acknowledged. For example, the September 2002 Council of State and Territorial Epidemiologists (CSTE) findings and recommendations from the National Assessment of Epidemiologic Capacity in Food Safety states:

Food safety programs should have the capability to electronically access environmental health inspection reports. In order to access the reports electronically, the reports must exist electronically. It is recommended that responsible programs within state health departments take steps towards developing an electronically accessible format available to all state enteric/foodborne disease epidemiology programs.

A more recent 2005 CSTE report states that the need for electronic document sharing also extends to documents other than inspection reports, saying; "...states with many independent local health agencies will need to develop systems to standardize interviews and electronically transmit the epidemiologic data to a central surveillance site where it can be linked with the laboratory data." These concerns were also expressed by a regional FDA official who told us that a single uniform EIS platform should be adopted

for the entire Commonwealth to facilitate reporting and information sharing arrangements, saying that all local and state authorities should be able to see what the other is doing. That official also acknowledged the desirability of a uniform nationwide EIS approach, but stated that an FDA initiative to develop EIS software for nationwide use had to be abandoned at the beta testing stage in the late 1990s due to FDA funding cuts. Since then, state and local authorities have been left to develop or purchase EIS systems on their own initiative. DPH/FPP managers acknowledged the advantages of such systems, but stated that they lacked the resources for such an initiative and do not even have an internal EIS system for their own non-retail inspection activity. They characterized the overall state of Information Technology arrangements for state and local FPP activities in the Commonwealth as “antiquated.”

- We designed our audit sample for local authority visits to include one of the communities reporting EIS use in 2002; however, upon contacting the community we learned that it had only initiated the process of moving to EIS technology in 2002, and had not yet completed the process. Our other visits revealed that several authorities in our sample were in various stages of EIS implementation or had evaluated commercially available EIS software and decided not to proceed at this time. This activity was being conducted in a totally uncoordinated manner and many authorities were unfamiliar with the efforts underway at other authorities around the state. This raised significant issues for us since we were told that some of the software on the market is relatively expensive. We found that some authorities had already purchased systems from one Massachusetts software vendor and were experiencing various problems either with that system or with the PDA equipment associated with the system, and that the authorities were unaware that other local authorities had already rejected the system as unsatisfactory. One large authority had recently completed a major procurement process, selecting a different company to automate its inspection and management information systems, but that implementation process had not yet started. Yet another authority was exploring options involving an out-of-state software vendor successfully used by food inspection authorities elsewhere in the country, while one authority was using town employee Information Technology Department staff to custom design software to be used on small, larger than PDA size, mini-laptop computers expressly designed for industrial use applications where equipment is frequently dropped onto concrete floors or exposed to moisture. That authority is planning to use its computers with portable printing devices so that inspection report copies can be printed on-site and signed by the inspector and establishment manager as required by DPH regulation. The situation we encountered can fairly be characterized as chaotic, potentially wasteful, and likely to result in the implementation of systems with conflicting documentation systems, which may present barriers to any future efforts to roll up uniform data from local authorities for statewide use.
- Review of information available for other state and local authorities around the nation revealed that even where uniform software systems have not been purchased on a statewide basis, states such as California have adopted standardization requirements such as uniform data format specifications so that information can be rolled up for common use. We also found that, as an alternative to PDA or mini-laptop systems, King County, Washington has implemented what it believes to be a satisfactory system of continuing

to use handwritten paper inspection forms in the field but then loading all data, including specific inspection details, into a special database application. In addition to meeting the authority's internal management information requirements, the system allows the authority to upload a printed version of each inspection report to the authority's public information internet site.

- FPP information needs go well beyond requirements for electronic data on inspection and foodborne illness investigations. As noted in the other Audit Results of this report, there are major informational deficiencies regarding inspector qualifications and training, and Commonwealth officials are unable even to fully quantify the number of food establishments, food establishment managers, and inspectors in the state, let alone individually identify them. In addition, in the absence of specific information regarding the types of operations engaged in by individual establishments, the Department is unable to quickly contact establishments that may need to be alerted to special issues such as the issuance of state or federal Food Alerts regarding adulterated or infected food products or newly identified issues such as pathogens resistant to existing holding temperature or other protection measures. Instead, the Department has to resort to the use of broad press release approaches or the distribution of information to local authorities and industry groups in the hope that those intermediaries will be able to get the information to all affected food establishments. However, our review of systems at the local authorities we visited revealed only one authority that maintained more than cursory electronic data regarding food establishment operational details such as the existence of sushi or other high-risk operations or provision of meals to immune compromised or other special populations. In most instances the knowledge details needed to implement such alert functions on behalf of DPH seemed to reside in file cabinets containing hundreds of individual food establishment records or in the heads of individual employees of the authorities. Similarly, local authorities generally lacked adequate information systems to track inspection activity and violation history or to readily provide inspectors with information on applicable permit restrictions such as approved seating capacity for an establishment and authorization to conduct certain activities such as sushi, salad bar, buffet, or reduced oxygen packaging (a.k.a., "sous vide cooking") operations requiring special site and/or HACCP plan pre-approvals.

Recommendation

Since the federal authorities acknowledge that they do not adequately address information technology issues, the DPH should step forward and assume responsibility for addressing these issues in an organized comprehensive manner for the Commonwealth as part of a strategic planning process. The Department and local authorities need to secure the resources necessary to implement appropriate information systems required for efficient, economical, effective operations, and standardized timely sharing of electronic data on a statewide basis with all participants, including the public. Electronic data exchange systems need to be established for both inspection activity and for foodborne illness response activities as recommended by the above-cited professional authorities. Wherever possible, development, software, and hardware

procurements should be coordinated and conducted on a statewide contracting basis by a procurement entity, such as the Commonwealth's Operational Services Division.

Auditee's Response

DPH has provided all 351 local boards of health with the resources to register on the Health and Homeland Alert Network (HHAN) that provides electronic capacity for communicating with DPH and local boards of health, timely emergency alerts, and rapid notification of outbreaks of food-borne illness. In addition, as essential components of the Commonwealth's Emergency Response System, all local boards of health were provided the resources (\$1.8M) for computer hardware and software. These resources will ultimately ensure their capacity to participate in a uniform inspection process as proposed in the draft audit report.

Auditor's Reply

While we agree that additional resources have been given to the local boards to further enhance their registering with the Health and Homeland Alert Network and to facilitate participation in the Commonwealth's Emergency Response System, these measures do not necessarily ensure the capacity of local authorities to participate in a uniform inspection process or to share electronic data in the manner recommended by the Council of State and Territorial Epidemiologists. The Department needs to carry through with the planning, development, implementation, and monitoring steps to ensure that standardized, timely sharing of electronic data on a statewide basis with all participants is ongoing.

8. QUALITY ASSURANCE SYSTEMS TO PROMOTE SAFE FOOD PRACTICES NEED IMPROVEMENTS

As part of its effort to promote high quality standardized and effective food inspection and protection activities across the nation, the FDA has promulgated Recommended National Food Regulatory Program Standards for use by both state and local health authorities. While not mandatory, those standards establish reasonable expectations for standardization and other quality assurance systems. The recommended standards or comparable arrangements are in use elsewhere in the nation. With the exception of recent commitments by the DPH/FPP and two local health authorities to enroll in the national program to implement the recommended national standards, the Commonwealth's health authorities have not been able to adhere to the standards or commit themselves to their adoption in the near future. We found that existing systems are largely inadequate and that DPH has relatively little reliable concrete information on local health authority food protection operations. As a result, inspection, enforcement, and

other activities are not reasonably well-coordinated and standardized across local authorities. The Commonwealth and its local authorities have also generally not implemented public information initiatives such as restaurant inspection grading and internet posting systems that have been implemented elsewhere in the nation and have been asserted to effectively reduce foodborne illness incidence rates.

Current DPH systems for monitoring and assuring the quality of inspection and other food protection activities at local authorities are essentially limited to the previously discussed annual reporting process, meeting with representatives of local authorities, professional associations, trade groups, and other food safety professionals, and the general complaint and foodborne illness complaint systems. Annual reporting is mandated by 105 CMR 590.010(F), which requires:

The board of health shall submit to the department by July 31 each year the following information:

- 1. Total number of licensed food establishments by category;*
- 2. Number of yearly inspections by category;*
- 3. Number of reinspections by category;*
- 4. Number of hearings;*
- 5. Number of license suspensions;*
- 6. Number of license revocations;*
- 7. Number of foodborne illness complaints investigated (including the number of cases involving more than two persons and the total number of persons involved);*
- 8. Number of general complaints investigated;*
- 9. A copy of any local ordinances relative to food establishment operations;*
- 10. Number and types of variances issued;*
- 11. Total number of food sanitarians; and,*
- 12. Other information as requested.*

The department shall provide a form on which to submit the required information.

As provided in item 12 of the regulation, the Department does request some additional information such as whether or not an authority uses electronic inspection systems or whether

an authority has approved use of high-risk reduced oxygen packaging food preparation systems. However, as noted in our other Audit Results sections, on average only two-thirds of local authorities file reports in any given year, information is often unstandardized and inaccurate, and the information gathered is inadequate, untimely for many oversight purposes, and antiquated in light of modern information technologies permitting implementation of far more efficient electronic information systems.

Aside from these extremely limited information-gathering measures, the Department lacks any system for ensuring that local authorities are carrying out their food protection responsibilities as required by the state sanitary code, or for ensuring that activities operate in a reasonably standardized and uniform manner across local authorities.

After the issuance of our prior audit report, the FDA established a nationwide program promoting adherence to recommended national standards with broad goals involving two basic principles to build a new foundation for the retail food protection program:

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

The purpose of that program was to provide a foundation for the proper design and management of retail food protection programs across the country and a system for identifying and recognizing programs that meet established standards. With input from federal, state and local regulators, industry, academia, and consumers, the FDA formulated a set of nine standards encompassing training, foodborne illness investigation and response systems and other areas covered in this report. FDA recommended standards, such as those referenced in Audit Result No. 4 regarding the state of Maryland's administration of a statewide system for the standardization of locally based inspectors, have been adopted to some degree across the nation. These standards emphasize the importance of implementing uniform inspection programs through adherence to all standards set forth in nine separate categories, including meeting minimum requirements for program support and resources, careful standardization of individual inspector practices, formal quality assurance programs, and periodic program assessment activities, including both self assessment systems and verification by independent outside parties.

We found that the systems called for by the federally-recommended standards are largely absent in the Commonwealth, and that in the absence of strong centralized control and coordination by DPH, the decentralized nature of local food protection activity here is not conducive to the successful implementation of uniform standardized, high quality active managerial control of foodborne illness risk factors. We found quality assurance systems at the local level to be minimal, largely due to local resource constraints and the small scale of food protection operations in most communities. The use of independent periodic program assessments and performance verification systems appears to be totally absent, and DPH has not implemented statewide systems needed to adequately address these shortcomings. In fact, given the numerous deficiencies in the annual reporting system, DPH has almost no reliable detailed information of any kind regarding operations at local authorities and the extent to which they are meeting state and federal food protection goals.

Coupled with the lack of any meaningful system of enforcement measures available to the Department in cases where deficiencies at local authorities are identified, the result has been the non-uniform and unstandardized pattern of local activity that our local audit visits documented and that both state and federal officials told us they expected we would find. Food establishments, particularly those operating across multiple local jurisdictions, may not be treated in an equitable and consistent manner. For example, one small restaurant proprietor we interviewed reported that he had previously operated his establishment in a community where the local authority had never raised an issue regarding the lack of a grease trap for his low-volume, largely grease-free operations. When he moved his business to another community, operating the business on essentially the same basis, the local plumbing inspector in the new community had not identified any problem with the lack of a grease trap and the issue only surfaced after his plumbing work was completed and local food inspectors conducted a pre-opening plan review and inspection. As a result, the proprietor had to spend an additional \$3,000 tearing out and replacing the newly installed plumbing in order to incorporate a food-code mandated grease trap into his system. Similarly, the public has no way of knowing whether the restaurants, markets, schools, institutions, and other food establishments serving them in the communities where they live, work, and shop are being held to uniformly high food safety standards.

The FDA-recommended standards call for public posting of inspection results through the internet or the media and our background research revealed that such systems are in use across the country. In addition, we found that many jurisdictions have also implemented so-called “food safety grading systems,” where restaurants and sometimes other establishments are given a letter or number grade, a star rating, or similar grade that is required to be publicly and prominently posted in the establishment entrance. Los Angeles County, for example, implemented a grading system in 1998, and claims to have documented a 13.1% reduction of foodborne illness hospitalizations attributable to use of their system.⁹ A separate economic study of that grading system, published in the *Quarterly Journal of Economics*,¹⁰ also asserts that the grading program in Los Angeles has had the desirable economic effect of targeting consumer spending at establishments that received higher food safety grades. DPH officials have not included questions in the Annual Report form regarding use of such systems and were unable to provide us with information in this area other than a statement by the DPH/FPP Director that he was unfamiliar with the studies on the Los Angeles system, that the use of grading systems was controversial among local health authorities, and that DPH took no position on their use.

However, we found that two of the 13 local authorities we visited were in the process of adopting Los Angeles-style grading systems, and that another large authority operates an internet site with limited information confined to restaurant inspection results. The latter system does not cover results for other food establishments such as supermarkets, schools, and senior meal sites, nor does the information cover complaints or foodborne illness incidents. The system also does not display full inspectional detail, and instead simply identifies the general category covering identified deficiencies. We found that the information posted on that site typically covered only the most recent routine inspection and any follow-up visit needed to confirm the correction of violations. The data also appeared to be posted in a less than timely manner for some inspections. A representative of that authority explained the posting delay by stating that the inspection results are posted only after deficiencies have been resolved, rather than immediately upon identification of violations during the routine inspection. As a result, the posting of inspection results on that system may be delayed until several weeks after the

⁹ County of Los Angeles, Department of Health Services press release, March 10, 2005 citing 7 year study published at: Impact of Restaurant Hygiene Grade Cards on Foodborne-Disease Hospitalizations in Los Angeles County, Simon, Paul A., M.D., M.P.H., et al., *Journal of Environmental Health* March 2005, 67.7:32-36.

¹⁰ *The Effect of information on Product Quality: Evidence from Restaurant Hygiene Grade Cards*. G. Jin and Phillip Leslie, *Quarterly Journal of Economics*, 2003, v. 118(2).

inspection date. While none of the authorities we visited stated that they regularly publicized inspection results, a few received periodic inquiries from local news media regarding inspection results. Representatives of local authorities offered a variety of opinions regarding the merits of various public information systems and barriers to their implementation arising from information technology or other resource limitations and the influence of local politics on the process. Of particular note were comments that, although internet posting systems may be useful for journalists and a small segment of the population, they may not be as effective an outreach tool as either direct publication in the press or grading systems requiring posting at the entrance to each establishment. Despite the apparent success of grading systems in reducing foodborne illness rates, one authority manager noted that the implementation of grading systems presents a variety of issues such as the need to base grades on frequent uniformly conducted inspections in order to ensure that they are equitable, accurate, and up-to-date. He believes that the decentralized local authority system in the Commonwealth presents a barrier to the use of such grading systems since, in the absence of statewide standardization of local inspection and grading activities, there is likely to be no assurance that an establishment receiving a “Grade A” from one authority is really adhering to higher standards than an establishment receiving a “Grade B” from a neighboring health authority.

Recommendation

DPH control and coordination of local food protection activities should be strengthened so that DPH can assure that activities are standardized and subject to quality assurance arrangements consistent with recommended national standards. In addition, as part of a strategic planning initiative, DPH should develop appropriate arrangements to ensure that all state and local inspection and food establishment-related foodborne illness investigation results are publicly posted in a prominent, easily accessible manner both at food establishment locations and online over a central state internet site, together with any educational guidance needed to minimize misinterpretation of results.

Auditee's Response

FPP is now enrolled in FDA's voluntary National Retail Food Program Standards program, and is also promoting training and adoption of these standards with local Boards of Health. It should also be noted that increased training, provision of common inspection forms tied to the specific references in the regulations, and other factors have improved standardization of food service inspections and reports. In addition, FPP organizes and

chairs regular meetings with the Food Establishment Advisory Committee to promote education, standardization, and uniformity in the retail food industry.

Auditor's Reply

Although we acknowledge the steps taken to date by DPH, unless significant resources are made available at both the state and local levels, participation by local authorities in the voluntary system will remain minimal and the many problems identified in our report will continue. During our review, we noted that for the past five years, DPH has been working with local authorities to encourage formal enrollment in the voluntary program; yet, as of the end of our fieldwork, only four local boards had enrolled in the FDA's National Retail Food Program Standards program.

9. DECENTRALIZATION OF FOOD PROTECTION ACTIVITIES RESULTS IN INEFFICIENCIES AND ADMINISTRATIVE PROBLEMS

In most states, relatively large county-based health authorities carry out retail food protection activities, often with significant coordination and oversight by state agencies. The Commonwealth's highly decentralized system, operated by generally small town government health authorities with minimal oversight, coordination, or technical assistance from state government has been characterized by the FDA as "unique" in the nation and has presented concerns to federal food protection officials at least as far back as 1982. The results of both our prior audit and this audit suggest that while there are certain strengths associated with the Commonwealth's model, it remains inherently weak in many respects and decentralization issues have been a contributing factor to the many deficiencies identified in this report. Multiple public health officials, including representatives of local health authorities, told us that in their view, food protection and other local health authority activities should be restructured using a regionalization approach. DPH needs to identify and implement measures to address these structural issues.

Our prior audit report quoted an earlier 1982 FDA report characterizing the decentralized town board of health-based food inspection system in Massachusetts as "unique" and requiring the state to prioritize implementation of standardized approaches and quality assurance systems. As described to us by FDA officials and confirmed by internet research and communication with officials in other states, the decentralized system of state and local retail food protection program operations in Massachusetts remains unique and inherently weak in certain respects,

such as the extensive reliance on part-time staff, the need for state staff to train and monitor disproportionately large numbers of inspection agencies and individuals relative to the number of food establishments being overseen by the system, and the potential for delays, coordination, and communication problems due to the large number of parties involved in foodborne illness investigations, educational efforts, and other program activities. With few exceptions (such as in Alaska, where inspections outside of urban areas are conducted by the state), most of the nation uses a county-based inspectional system where standardization coordination and economies of scale are fostered by centralized operations in large counties. As a result, retail food establishment inspections elsewhere in the United States can usually be conducted with full-time, properly trained, and supervised food establishment inspectors operating under appropriate quality assurance systems with specialized staff devoted to specific issues such as the coordination of inspection and enforcement activity for chain restaurants and supermarkets, as occurs in Maricopa County, Arizona. We noted that King County, Washington, for example, does all inspections for a county covering the city of Seattle – which is alone approximately the same size as Boston - plus several additional cities within King County. The area covered includes a population of about 1.2 million people, accounting for over one fifth of Washington’s population. Washington and Massachusetts have roughly the same size populations. Due to the limited use of regional health districts in the Commonwealth, approximately 328 different local and regional health authorities are responsible for conducting food inspections in Massachusetts, while, in the state of Washington, only 35 county health offices (including three consolidated offices covering seven counties with a combined total population of 350,099) are involved in operating that state’s inspectional system. Arrangements similar to those in the state of Washington are prevalent across the nation. For example, the state of Utah, with 29 counties and a population in excess of 2.2 million, uses a regional system of only 12 health departments to carry out local food protection activities. A hybrid approach is used in Colorado, where the Denver Environmental Health Department is responsible for inspecting 2,000 food establishments in the City and County of Denver, 14 regional health departments oversee 12,400 establishments in 26 counties, 18 state-contracted local governmental agencies cover 2,700 establishments, and the state Consumer Protection Division directly inspects the remaining 1,000 food establishments scattered across 13 counties.

Reliance on town boards of health to conduct inspections is primarily limited to New England. Even in New England, Massachusetts occupies a position at the extreme end of the spectrum.

Rhode Island uses state inspectors to conduct all inspections for the state on a centralized basis, and Maine, New Hampshire, and Vermont use hybrid systems similar to Colorado's, where inspectional responsibility is delegated to only certain larger communities while state inspectors handle rural areas. Only Connecticut employs a more decentralized town-based approach somewhat similar to Massachusetts. However, in Connecticut the system is less complex and more centrally managed, since there are fewer than half as many towns there (169) than in Massachusetts, Connecticut places more reliance on multi-town health districts to perform inspections, and the Connecticut Department of Public Health exercises far more control over local activities by mandating use of a statewide risk-based inspectional system and directly licensing all inspectors participating in the process. FDA descriptions of the nationwide food protection system roughly estimate that the total number of participating state and local health authorities in the United States is only somewhat higher than 3,000. Massachusetts accounts for roughly 10% or more of this total, despite the fact that the Commonwealth accounts for only approximately 2.3% of the nation's population.

We compared the Massachusetts local population statistics to the number of food service establishments reported by each inspectional authority, to reported staffing levels, and to FDA recommendations that a full time food inspector be assigned for every 150 establishments. We found some variation in the number of food service establishments per 1,000 residents, with typical ratios of approximately four to eight establishments per 1,000 residents.¹¹ Based on this information, it appears that inspectional authorities are likely to need a population base of roughly 25,000 residents to warrant a single full-time food inspector. Approximately 75% of the nation's population, and perhaps roughly the same proportion of food establishments, are in counties with populations of at least 100,000. Authorities in these counties are far more likely to possess the resources needed to economically and efficiently operate inspection and foodborne illness response systems with appropriate training, supervision, specialization (e.g., in food microbiology and epidemiology), and quality assurance systems consistent with FDA's recommended national standards. In contrast, only four of the 328 local inspectional authorities in Massachusetts are this large. Those authorities cover a combined total of less than 16% of the Commonwealth's population.

¹¹ Wider ratio ranges exist for a few smaller communities in the Commonwealth, varying from zero in a community claiming not even school food establishments to the extreme of Provincetown, which reported the existence of 137 food service establishments for a town with a population of only 3,247 but a large tourist based economy.

As noted in the Introduction to this report, MGL, Chapter 111, Sections 27A, 27B, and 27C provide for the establishment of regional health districts in the Commonwealth. Despite the obvious advantages of using larger regional health authorities, these district systems are voluntary, little used, and one local health official described the statutory provisions as somewhat cumbersome. Our review identified only five such districts in the Commonwealth that are used to perform retail food inspections and related food protection activities. (An additional “regional” organization, the Barnstable County Health Department, has been established under separate enabling legislation to provide certain health services to Cape Cod area communities, but those communities continue to independently conduct their own retail food inspections). Only one of the existing regional health districts, Nashoba Associated Boards of Health, with a 14-town catchment area population of approximately 92,000 people, approaches the 100,000 plus population operating scale existing for 75% of the nation’s county authorities. The remaining four regional health districts each serve three to four communities, with catchment area populations ranging from under 7,000 to approximately 24,000 people, well below the operating scale required for efficient operation in full compliance with the recommended national standards described in our other Audit Results sections.

Table 9 documents the existing highly decentralized structure of local health authority food protection activities in the Commonwealth.

Table 9
Decentralization of Massachusetts Local Health Authority Inspection and Related Food Protection Activities*

Nationally, 74.7% of the population resides in counties with populations in excess of 100,000. Services in rural counties are typically consolidated on a regional basis (e.g., 12 authorities in Utah for 29 counties with total population of over 2.2 million)

Number of Authorities	Percentage of Total	Authority Population	Number of Cities and Towns	Percentage of Total	2000 Population	Percentage of Total
4	1.2%	Greater than 100,000	4	1.1%	979,482	15.7%
9	2.7%	75,000 to 100,000	22	6.3%	798,132	12.8%
11	3.4%	50,000 to 75,000	11	3.1%	628,796	10.1%
17	5.1%	35,000 to 50,000	17	4.9%	703,460	11.3%
32	9.8%	25,000 to 35,000	32	9.1%	925,183	14.9%
101	30.8%***	10,000 to 25,000	108	30.8%	1,568,295	25.2%
<u>154</u>	47.0%	Under 10,000	<u>157</u>	44.7%	<u>624,274</u>	10.0%
<u>328</u>			<u>351</u>		<u>6,227,622</u>	

*Excludes Barnstable County Health Department, which provides certain regional health services to 15 county communities but does not perform their retail food establishment inspections.

**Includes Nashoba Associated Boards of Health (14 towns).

***Includes Quabbin (4 towns), Tri-Town (3 towns) & East Franklin County (4 towns) Regional Health Districts.

****Includes Foothills Health District (3 towns).

However, our review did identify certain strengths in our local authority system. Interviews and record reviews repeatedly identified situations where close-working relationships with local public employees such as firefighters and police officers resulted in the prompt identification of food establishment code compliance issues to local health agents. Similarly, during our visit to one local authority we noted that an individual inquiring about permit requirements for a convenience store he hoped to open was directly served by the chief inspector who offered to evaluate the proposed site for any significant operational barriers before the proprietor signed the lease. That level of service is sometimes difficult to provide in larger authorities. The Council of State and Territorial Epidemiologists has also identified the availability of local authority staff to quickly conduct interviews with individuals involved in foodborne illness incidents as an advantage. Our local authority system has also contributed to the development of new public health approaches in the Commonwealth and the nation as a whole, such as restrictions on smoking in food establishments (which were first implemented by a small number of local authorities prior to adoption for statewide use) and requirements for the posting of food safety advisory notices in establishments serving certain types of fish prone to excessive mercury levels, which poses serious health risks to major segments of the population such as young children, pregnant women, and nursing mothers.¹² However, this advantage may become moot if pending national legislation is enacted that would restrict local requirements in excess of those mandated by the FDA. A decentralized system can also present barriers to implementation of other initiatives such as the previously referenced restaurant food safety grading systems. We discussed these decentralization issues with local health authority and other food professionals and received a variety of comments, ranging from support for the status quo to a desire to have all retail food establishment inspections conducted by state DPH employees. While agreement was not universal, we were told by multiple local health authority representatives that the problems identified by our audit, such as use of inadequately qualified inspectors and not performing appropriate inspections with adequate frequency, are even worse at the small local authorities that are disproportionately underrepresented in both our audit sample and in DPH annual report and foodborne illness reporting datasets. In the opinion of those local health professionals, these problems should be addressed by restructuring public health activities using a regionalization approach involving either additional regional health

¹² The Swampscott, MA Board of Health appears to be one of the first local authorities in the nation to implement these advisory notice requirements, which are now being implemented on a statewide basis in California.

authorities authorized by MGL, Chapter 111, Section 27A or alternatives such as revitalized DPH district offices (a.k.a., “regional offices”). At the time our report was being drafted we were told by one leader in the public health community that these decentralization issues apply to a variety of local health authority operations other than food protection activities and that a University of Massachusetts study recommending various regionalization options for local public health functions was expected to be released later in 2006. No further details regarding the potential recommendations of that study were available for our review at the time our audit work was being completed.

Recommendation

A strategic planning initiative should be used, in conjunction with other planning activity for local health operations in general, to reassess the Commonwealth’s existing decentralized operational structure and develop more appropriate, efficient, and effective alternatives such as the larger regional authorities used in many other states. At a minimum, a regional health authority or district health office model should be used across the many existing jurisdictions with population bases fewer than 100,000. Regional models should also be considered even for the Commonwealth’s larger municipalities in light of the successful use of such models in many metropolitan areas across the nation.

Auditee’s Response

We agree that a regional approach is optimal, and, in fact, through the efforts of DPH and local health departments, a regional structure has been put in place to facilitate local health department planning for emergencies. At this time 90% of Massachusetts towns and cities are developing or have in place agreements that facilitate inter-municipal and regional collaboration. This structural change initiated in 2003, includes the assignment of regional coordinators to each of the regional coalitions, and is designed specifically to support regional resources sharing and enhance implementation of uniform retail food service standards.

Auditor’s Reply

The regional collaboration described in the DPH response is insufficient to address the need for regional structures to carry out the day-to-day local food protection activities across the Commonwealth.

At a legislative hearing on October 17, 2006, held by the Joint Committee on Public Health, it was reported that only 35% of communities had actually signed the Memorandums of

Understanding referenced in the DPH response. Additionally, multiple participants in the hearing described serious resource issues at the local level and a need for fundamental restructuring of local health activities going far beyond the limited arrangements being implemented by DPH.

As stated in our recommendation, we reiterate that, at a minimum, a regional health authority or district health office model should be used across the many jurisdictions with population bases fewer than 100,000.

10. STRATEGIC LONG TERM PLANNING BY DPH FOR THE COMMONWEALTH'S FOOD PROTECTION EFFORTS NEEDS TO BE STRENGTHENED

Both systematic program and operational planning and budgeting activities have been inadequate and have been constrained by a top-down state budgeting process, and consideration has not been given to the need for changes to existing resource arrangements or modifications to what DPH staff describe as the "home rule" nature of the Commonwealth's decentralized local food protection operations. FDA officials have recommended that the Commonwealth conduct a formal self-evaluation of its food protection systems, starting at the state level, to determine what system and resource changes are needed to meet recommended national standards. The process should also be used to develop appropriate strategies to correct the many statewide issues identified in this report. We have also included a brief description of some of the possible corrective action options that should be evaluated as part of a statewide review and strategic planning process.

The Department's strategic long term planning and budgeting activities for both state and local food protection activities have been inadequate and appear to have been generally undercut by a prevailing assumption that planning should be limited primarily to decisions involving allocation of existing limited resources. The DPH/FPP Director's response to our information request regarding long term planning and budgeting activities included the following characterization of the process:

The Food Protection Program, due to the nature of the work, the quantity of work, and the resources available, is much more directed towards "tactical" planning, if that's a proper use of the term, than long-range planning.

We specifically asked for all strategic planning, budgeting, and related planning documents and were provided little indicating that a needs-based budgeting process was in use. In fact it was acknowledged that budgeting was a top-down process determined by higher management levels with minimal input from program managers. Each year FPP is simply told what its share of the overall Environmental Health Division budget will be to carry out activities not directly funded by grants or contracts with other federal or state agencies.

One telling document was a fiscal year 2002 two-page Risk Management Summary referencing only three risk issues for the program:

- Not maintaining staffing qualifications and inspection standards for inspections directly conducted by DPH/FPP inspectors;
- Not fulfilling contract obligations with FDA if adequate numbers of properly trained inspectors were not retained and mandated inspections for interstate milk and shellfish firms were not prioritized; and
- Not adequately training local health agents, industry, and other affected state agencies in the requirements of the “Model Food Code.” The document stated that DPH/FPP was addressing this risk by obtaining a federal Center for Disease Control grant to hire an epidemiologist to provide training in the proper identification and investigation of potential foodborne illness outbreaks, revising the 590 regulations to incorporate the new Food Code, conducting 15 training sessions around the state on the new regulations, issuing brochures and other educational materials, and developing a website to improve information access.

That risk analysis provided no specifics regarding details of state and local staffing requirements, the adequacy and frequency of inspection arrangements for inspections conducted by DPH’s own staff for facilities other than IMS and ICSSL Shellfish plants, or information technology requirements. Issues associated with Electronic Inspection Systems and statewide information management needs, such as systems for tracking inspector training and qualification activity and CFPM certification compliance for food establishment managers were not presented, and no details and strategies other than voluntary educational activity were discussed for promoting and monitoring standardization of inspection, enforcement, and regulatory compliance at the local level.

When we interviewed FDA regional district officials we were told that, in their opinion, while it was a pleasure to work with the highly qualified professional staff in Massachusetts, major

resource limitations were adversely affecting the FPP in Massachusetts at both the state and local level, and were impairing progress towards federal standardization goals. When asked about staffing resources needed by DPH/FPP for oversight of local board of health inspectional activities, the FDA would not provide even a rough estimate, but stated that it certainly would require “a lot more” than the current three employees in the DPH/FPP Retail Unit. On the local level, we were told that the decentralized and small part-time nature of local food protection operations makes it difficult to meet the federal uniform program standards for excellence. One FDA representative expressed his opinion that issues involving the numbers of available inspectors and their qualification levels prevented local authorities from enrolling in the voluntary program to implement the Recommended National Retail Food Regulatory Program Standards. FDA would like to see all of the Massachusetts local authorities enroll in the program, not just Boston and Danvers, but according to FDA officials, this is impossible without substantial additional resources at both the state and local level.

FDA believes that a formal self-evaluation process needs to occur, starting at the state level, to determine what system and resource changes are needed to meet the national standards. This would require considerable information gathering, since the state needs to have the facts in order to develop a proper resource model assessment. FDA would be willing to help with this process. Without providing specifics, FDA officials told us that several years ago DPH had verbally given them an estimate of additional resource requirements needed at that time, but DPH had stated that the state couldn’t afford to provide the additional resources, so DPH believed there was no point in talking further about it. Later in our audit DPH staff told us that regional FDA officials had followed up on their discussions with our auditors by conducting a meeting with senior state managers regarding these concerns. We were told that, in response, DPH officials had assured the FDA that the Department would move towards enrollment of at least the DPH/FPP office in the national standards program. While this commitment represents a step forward, we believe a firm public commitment to initiate a full system-wide review of all aspects of food protection activity in the Commonwealth is needed, and we are concerned that proposed appropriations covering program activities for fiscal year 2007 had nevertheless been reduced, despite the National Standards Program enrollment commitment.

The results of our past and present audit work suggest that despite the best efforts of DPH/FPP staff and others involved at the local and federal levels, the food protection system in the

Commonwealth is unlikely to improve significantly and will remain out of conformity with accepted national standards unless major resource and structural changes are implemented.

Recommendation

There are multiple reasonable alternative strategies that might be used to address the numerous problems identified by our review. It would be inappropriate for our recommendations to in every case specify which option should be selected. Those decisions can more appropriately be made through the statewide program assessment and strategic planning process recommended by FDA officials, with participation by independent outside experts and FDA officials as well as the Department and state and local stakeholders. The process of developing an overall strategy should include implementation of specific recommendations made in prior sections of this report, as well as consideration of the advantages and disadvantages of the following:

- Establishing licensing and tracking systems for food inspectors and food establishment managers coupled with DPH authority to suspend, restrict, and if necessary revoke those licenses, and the authority to delegate or restrict inspection responsibilities to selected local or regional entities adhering to acceptably high operating standards.
- Requiring that inspectors meet the qualification requirements emerging from the Conference for Food Protection working group process. If meaningful qualification requirements do not emerge from CFP, then the existing regulatory minimum requirements need to be significantly raised and be truly enforced by DPH.
- Requiring adherence to the FDA-promulgated National Standards by all local or regional authorities or other entities used to perform food establishment inspections.
- Assumption by DPH/FPP of the “Verification Audit” responsibility specified in the National Standards and of responsibility for “training the trainers” to be used by local authorities for training and quality assurance purposes under the National Standards system. The National Standards document is non-specific regarding these responsibilities other than specifying that the “auditor” have no responsibilities for the day-to-day operations of the jurisdiction under review. It may be desirable to impose some sort of further control to ensure that these verification reviews are really meaningful and conducted by truly independent professionals. Maryland’s system for regular state-conducted reviews of local authority activities may provide one possible model to examine.
- Establishing a uniform standardized statewide risk-based inspection scheduling system such as that used in Louisiana, Maryland, and other states. Under these approaches, all establishments are required to be categorized into a uniform categorical system of from three to five steps (Louisiana and others use four), each with a corresponding mandatory frequency for routine inspections (e.g., one, two, three, or four times per year), with

- additional inspections for educational and complaint/illness investigation purposes, verifying that required corrective measures have been completed, etc.
- Implementation of a uniform food establishment grading system with both on-site posting of grades and internet posting of full inspection results.
 - State-funded implementation of a uniform Electronic Inspectional System and complaint and foodborne illness tracking, investigation, and reporting system, with full data roll-up to the state level from all entities authorized to perform inspections. Even if hand-written forms remain in use, data should be converted to electronic format as done in King County, WA, Maricopa County, AZ, the state of Florida, and other jurisdictions around the nation.
 - Implementation of similar improvements to the Foodborne Illness reporting system so that information can be shared electronically as recommended by the Council of State and Territorial Epidemiologists and a central DPH unit can track and provide quality assurance measures for all complaint investigation and Foodborne Illness-related activity.
 - Enhancements to and strict enforcement of reporting requirements for any additional information-gathering requirements needed beyond those built into automated EIS and Food-borne Illness reporting systems. If automated current-time information sharing systems must still be supplemented by annual reporting systems, they should be implemented in a way that will promote complete and accurate reporting by all local or regional authorities with food protection responsibilities. This may require financial consequences such as fines, withholding of a portion of “Cherry Sheet” distributions, or use of other enforcement powers associated with the more centralized funding and system restructuring measures mentioned here. (The current regulatory provision allowing DPH to step in and assume the responsibilities of local authorities where they do not act is clearly insufficient, particularly given DPH’s lack of resources to cover the costs of such intervention).
 - Implementation of regionalization approaches or alternative measures to address the significant decentralization issues identified in this report.
 - Development of a full resource model covering all food protection activities in the Commonwealth, including staff and other resource requirements for implementation of various alternative system reform measures. The current system is so short on resources that any meaningful plan of correction will carry significant costs, particularly if the Commonwealth’s existing inefficient decentralized system is retained. (For example, costs of training, testing, overseeing, and providing continuing education to hundreds of part-time inspectors are obviously higher than they would be for a smaller number of full-time inspectors).
 - Evaluation of advantages and disadvantages of a self-funding “Full Cost Recovery” system for retail inspections as used in California and other states, and identification of any required enabling legislation provisions needed to implement such a system should it be deemed desirable for use here. In such systems food establishment plan-review,

license, and inspection fees are required to be set at high enough levels to cover full costs for operating the system. During our audit we noted that the Colorado State Auditor's Office issued a report in May 2003 identifying numerous Colorado Food Protection Program deficiencies similar to those identified in this report, including significant funding inadequacies, and has recommended implementation of similar self-funding systems in order to address the problems in that state.

Auditee's Response

This section provides a number of recommendations for the FPP and optimal statewide approaches, but does not address the feasibility of implementing any of these suggestions. Since many of these suggestions cannot be implemented without significant changes in state law, and major implications for local control, it should not be implied that FPP alone can advance such changes.

The occupational licensing of food inspectors, as suggested in this audit report, would require authorizing legislation, as is the case with other occupational licenses.

Auditor's Reply

FDA officials and other stakeholders such as the Massachusetts Health Officers Association have already indicated their willingness to participate in the recommended planning process. In fact, FDA officials indicated that the development of a detailed statewide resource model is essential for compliance with requirements of the national standards program.

While DPH may be correct in its assertion that some of the recommended approaches may require changes in state law, we note that it is appropriate for the Department to identify the need for such changes and to develop proposed legislation. In fact, Massachusetts General Laws, Chapter III, Section 2, Duties of Commissioner of Public Health, states:

He shall submit annually to the council a report containing recommendations in regard to health legislation.

Finally, as stated in our report, the Department's strategic long-term planning and budgeting activities for both state and local food protection activities have been inadequate and appear to have been generally undercut by a prevailing assumption that planning should be limited primarily to decisions involving allocation of existing limited resources.

Additional Auditee Comments

In its response to the audit report, the Department stipulated that clarification of statutory and regulatory authority of DPH and local health departments with regard to Retail Food

Establishments and Foodborne Illness was necessary. More specifically, the Department cited MGL, Chapter 111, Section 127A, which authorizes DPH to adopt:

...public health regulations...The code shall deal with matters affecting the health and well-being of the public in the commonwealth in subjects over which the department takes cognizance and responsibility, including, but not limited to...sanitation standards for food service establishments.

The regulations adopted pursuant to MGL, Chapter 111, Section 127A are known as the “State Sanitary Code.” DPH has promulgated regulations with respect to food safety in retail food establishments in Chapter X of this Code (“Minimum Sanitation Standards for Food Establishments”), and updated these regulations in 2000 in order to adopt the standards of the federal 1999 Food Code developed by the US Food and Drug Administration.

MGL, Chapter 111, Section 127A also provides that:

Local boards of health shall enforce said code in the same manner in which local health rules and regulations are enforced, but, if any such local boards fail after the lapse of a reasonable length of time to enforce the same, the department may in like manner enforce said code against any violator. (Emphasis added)

Thus, since 1971, state law has specifically provided that the local health departments in the 351 cities and towns of the Commonwealth have the authority and responsibility to enforce the regulations promulgated pursuant to MGL Chapter 111, Section 127A.

Any changes to this regulatory scheme (leaving aside issues of resources required) that would place DPH in a primary enforcement role would, therefore, require amendment of MGL Chapter 111, Section 127A and would significantly alter the long-standing authority and responsibility of local boards of health to inspect and license local retail food establishments.

Auditor’s Reply

Although we recognize the language within the General Laws, it must be emphasized that the law provides that if a local board does not enforce the state sanitary code, DPH then has the authority to step in and enforce the code.

Additionally, DPH’s mission statement suggests to the public that the Department is responsible for the Commonwealth’s public health system, using language such as:

- We ensure that the people of the Commonwealth receive quality health care and live in a safe and healthy environment, and
- We protect, preserve, and improve the health of all the Commonwealth's residents.

Chapter 111, Section 5 of the MGL, entitled Powers and Duties of the Department, provides, in part:

The department shall take cognizance of the interests of life, health, comfort and convenience among the citizens of the commonwealth; shall conduct sanitary investigations and investigations as to the causes of disease, and especially of epidemics, and the sale of food and drugs and adulterations thereof; and shall disseminate such information relating thereto as it considers proper.

Finally, Chapter 111, Section 4, Health districts; district health officers; enforcement of laws in districts, states, in part:

Each district health officer shall act as the representative of the commissioner, and under his direction shall secure the enforcement within his district of the laws and regulations relating to public health.

We believe that the composite language of these sections of the General Law establishes a fiduciary responsibility for the Department to provide oversight and, where necessary, enforcement at the local level. If the Department's ability to carry out its mission and fiduciary responsibilities is impaired by resource deficiencies, statutory issues, or the need for modifications to the structure of local and regional public health delivery systems, we believe the commissioner has a duty to bring these problems and proposed solutions to the Public Health Council, the Secretary of Health and Human Services, the Governor, and the General Court for resolution.

APPENDIX A

Risk Based Inspection Scheduling Example

(Source: Annex to 2005 Food Code)

Risk Type	Risk Type Category Description	Inspections Per Year
1	Pre-packaged nonpotentially hazardous foods only. Limited preparation of nonpotentially hazardous foods only.	1
2	Limited menu (1 or 2 main items). Pre-packaged raw ingredients are cooked or prepared to order. Retail food operations exclude deli or seafood departments. Raw ingredients require minimal assembly. Most products are cooked/prepared and served immediately. Hot and cold holding of potentially hazardous foods is restricted to single meal service. Preparation processes requiring cooking, cooling, and reheating are limited to 1 or 2 potentially hazardous foods.	2
3	Extensive handling of raw ingredients. Preparation process includes the cooking, cooling, and reheating of potentially hazardous foods. A variety of processes require hot and cold holding of potentially hazardous food. Advance preparation for next day-service is limited to 2 or 3 items. Retail food operations include deli and seafood departments. Establishments doing food processing at retail.	3
4	Extensive handling of raw ingredients. Preparation processes include the cooking, cooling, and reheating of potentially hazardous foods. A variety of processes require hot and cold holding of potentially hazardous foods. Food processes include advanced preparation for next-day service. Category would also include those facilities whose primary service population is immunocompromised.	4
5	Extensive handling of raw ingredients. Food processing at the retail level, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.	4

APPENDIX B

Local Health Authorities Selected for Audit Interviews and Record Reviews

Local Health Authority	Estimated 2000 Population
Boston (Boston Inspectional Services Division)	559,379
Brookline	58,906
Framingham	65,733
Hanson	9,525
Lynn	83,295
Nashoba Associated Boards of Health (Towns of Ashburnham, Ashby, Ayer, Berlin, Bolton, Boxborough, Dunstable, Groton, Harvard, Lancaster, Littleton, Lunenburg, Shirley, Townsend, and the Mass Development Community of Devens located within the towns of Ayer, Harvard, and Shirley)	91,901
Pittsfield	47,050
Revere	41,905
Seekonk	14,176
Somerville	77,302
Waltham	58,011
Watertown	31,572
Worcester	<u>167,507</u>
Total	<u>1,306,262</u>

*21% of total estimated 2000 Commonwealth population of 6,227,622.