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## Foodborne Illness Risk Factor Study

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# **MPH Capstone Final Report**

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## **Foodborne Illness Risk Factor Study**

# **Data Collection Manual**

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3/17/2015

## Table of Contents

Scope of Project .....	3
Statement of Need.....	3
Background .....	4
Structure .....	5
Results.....	6
Integration of Knowledge .....	9
References.....	11
Table A: Capstone Gantt Chart.....	12
Table B: Capstone Logic Model .....	13
Table C: Inventory Development Summary & Abbreviation Keys.....	14

### Attachment

Data Collection Manual

## Scope of Project

The initial purpose of this capstone was to establish a baseline for the occurrence of the top five foodborne illness risk factors, to write a report on the baseline findings and to develop a plan to repeat this study at least once every 60 months for the Portland Environmental Health & Safety Program. It soon became clear, however, that the scope was too broad.

An extensive effort was required to integrate national methodology and comparability principles with the State and local restaurant inspection structure. Subsequently, the focus of the capstone shifted to the development of a comprehensive data collection manual. The statement of need and background did not change; the revised Gantt Chart (Table A) and Logic Model (Table B) are attached.

## Statement of Need

Each year, contaminated food consumed in the United States (US) results in an estimated 48 million illnesses, more than 128,000 hospitalizations, and 3,000 deaths.<sup>1</sup> These numbers represent laboratory confirmed foodborne illnesses only; it is believed that the incidence of foodborne illness is significantly under-reported and under-diagnosed. Foodborne illness is a public health issue that contributes to preventable morbidity and mortality.

Food comes from all over the world and is at risk of contamination from farm to consumption. However, more than half of all foodborne illness outbreaks in the US are associated with food prepared in restaurants.<sup>1</sup> Given that 80% of Americans eat out at least once per week; a better understanding of how and why transmission of foodborne diseases occurs in restaurants is needed to develop better prevention measures.<sup>2</sup>

### Risk Factors

Epidemiological outbreak data repeatedly identifies five major risk factors related to employee behaviors and preparation practices in retail and food service establishments as contributing to foodborne illness.<sup>3</sup>

- Improper holding temperatures;
- Inadequate cooking;
- Contaminated equipment;
- Food from unsafe sources; and
- Poor personal hygiene.

Appropriate hygiene and food handling processes in retail and food service establishments are critical to prevent the growth of microorganisms in foods which include but are not limited to *Salmonella*, *Vibrio*, *Campylobacter*, *E. coli* 0157, *Listeria*, and *Norovirus*.<sup>3</sup>

While everyone is susceptible to foodborne illness, children, pregnant women, people with disabilities, the elderly and individuals with compromised immune systems are at greater risk of foodborne morbidity and mortality.<sup>4</sup>

## Background

The Food and Drug Administration's (FDA) Center for Food Safety, in collaboration with the CDC and the US Department of Agriculture (USDA), is responsible for the federal Food Code. The Food Code, however, is neither federal law nor regulation. The Food Code is a practical, science-based guidance that serves as a model for state, municipal, county and tribal agencies that regulate operations such as restaurants, retail food stores, food vendors, and food service operations in a variety of settings.<sup>3</sup> Adoption of the FDA Food Code at the state and local level has been necessary to promote greater uniformity; however, a widely recognized continuous improvement process had been a missing piece.<sup>5</sup> As a result, the FDA implemented the Voluntary National Retail Food Regulatory Program Standards (Program Standards) in 2002; Program Standards establish best practices and quality assurance and improvement strategies for regulatory authorities that license and inspect food service and retail food establishments.<sup>5</sup>

Of the six food safety (FS) Healthy People 2020 objectives, three (FS-1, 2 and 3) are related to reducing key pathogens commonly transmitted through food; these objectives have more than 18 action areas.<sup>6</sup> Objective FS-5 is related to increasing the number of consumers who follow food safety practices (clean, separate, cook and chill) at home. There is only one objective specific to food safety practices in restaurants (FS-6); however, no baseline or other data were available for this objective on the Healthy People 2020 webpage.<sup>6</sup>

The Maine Department of Health and Human Services (DHHS) Health Inspection Program and the Maine Department of Agriculture are responsible for the Maine Food Code which appears to be patterned after the 2011 federal Food Code. The Maine Food Code is enforceable by law.<sup>7</sup>

In Maine, restaurants are required to be inspected at least once every two years; the frequency of these routine inspections is determined based on risk factors such as type of food served, preparation steps foods require, volume of food, population served and previous compliance history.<sup>7</sup> Restaurants may be inspected more frequently based on complaints or problems noted on previous health inspections.<sup>7</sup> The Maine DHHS, by delegation of its authority, may contract with municipalities to employ health inspectors directly.<sup>7</sup>

The City of Portland contracts with the Maine DHHS to maintain its own inspection program and employs three municipal health inspectors (2.0 full-time equivalent) to monitor the more than 500 permanent food service establishments where food is sold or served in Portland.<sup>8</sup> The City also inspects approximately 1,000 temporary food service licensed events annually.<sup>8</sup> However, the Portland Health Inspectors do not inspect food service facilities located in gas stations or convenience stores; that type of facility is licensed and inspected by the Maine Department of Agriculture.<sup>8</sup> The Portland Code of Ordinances, Chapter 11: Food and Food Handlers is modeled after the Maine Food Code and is enforceable by law.<sup>9</sup>

The City of Portland has made a significant commitment to public health and food safety by adopting its own food code and health inspection program. To further this commitment, the Portland Environmental Health & Safety Program enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards (Program Standard) in 2014.

## Structure

Program Standard 9, Program Assessment, applies to the process used to measure the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors.<sup>5</sup> The Food and Drug Administration (FDA), in collaboration with subject matter experts from the Center for Food Safety and Applied Nutrition's (CFSAN) Division of Mathematics, developed a data collection manual to ensure statistical validity of conclusions derived from the analysis of data collected to meet Program Standard 9.<sup>10</sup>

### Key Research Questions

Based on Standard 9 and the revised scope of this project, the research questions were revised.

1. What portions of the FDA data manual are applicable to the Portland Program?
2. What is the inventory of food service establishments (FSE) for 2013 (baseline year)?
3. What FSE meet the criteria for inclusion in the baseline study?
4. Are State/Local data elements comparable to FDA requirements?
5. What, if any, additional data elements should be added to enhance local program assessment?

### Anticipated Outcomes

- A comprehensive data collection manual that contains methodology for determining sample size, selection of establishments, data collection and analysis, and comparability principles.
- An inventory of all food service establishments (FSE) with active licenses in calendar year 2013 (master inventory).
- Inventories for each FSE type that are considered medium and high risk (baseline inventory).
- Randomized primary and substitute lists of FSE to be included in the baseline risk factor study (study inventory).
- A standardized data collection spreadsheet to overcome any differences between the State and FDA data points and includes additional data elements defined by the Portland Program. The spreadsheet will contain formulas to automatically calculate items for analysis.
- Documentation to support FDA Voluntary National Retail Food Regulatory Program Standard 9 and applicable Public Health Accreditation Board (PHAB) requirements.

## Results

A meaningful baseline upon which to measure the occurrence of foodborne illness risk factors relies upon a consistent approach to data collection.<sup>10</sup> The Portland Environmental Health & Safety Program is the primary audience and stakeholder for the data collection manual. The student and the Portland Program Manager worked closely throughout this project to ensure that the final product would meet the specific needs of the Portland Program and remain comparable at the national level.

### **1. What portions of the FDA data manual are applicable to the Portland Program?**

The Portland Program chose to integrate the FDA's four basic comparability principles into its program assessment to ensure statistically valid compilations and comparability at the national level. The manual contains methodology for defining food service establishment (FSE) inventories, determining sample size, and random selection of FSE. It also defines data analysis measures and continuous quality improvement (CQI) strategies. The FDA manual is approximately 100 pages; the Portland manual is 21 pages (9 pages of text, 10 of tables).

#### Outcome

A comprehensive data collection manual specific to the Portland Program was developed. The data collection manual is designed to meet the FDA Program Standard 9 and the PHAB Standards 2.1.1A (timely investigations) and 9 (CQI).

### **2. What food service establishments (FSE) are included in the 2013 inventory?**

A master inventory for 2013 did not exist. The Portland Program had a tracking document that included information about 2012-2014 inspections. The tracking spreadsheet was not developed to meet the requirements of a baseline study and did not include: a complete list of restaurants, a breakdown by risk type, or a breakdown by facility type.

#### Outcome

A master inventory of all FSE with regular inspections in calendar year 2013 (baseline year) and other required data elements was developed. An inventory development summary and the associated abbreviation keys are available in Table C.

### **3. What FSE meet the criteria for inclusion in the baseline study?**

Retrospective reviews of routine health inspection reports, which are publically available, are the data source for the Portland risk factor studies. This eliminates the need to distinguish between data collection and regulatory compliance oversight.

In anticipation that one or more FSE may be randomly selected that should be excluded, substitute FSE should also be randomly selected. The substitute FSE is selected at the same time as the primary sample and shall equal 10% of the minimum sample to ensure an adequate pool of

substitute establishments. If the sample size is less than 9 FSE, 100% of the facilities are selected and there would be no substitutes. As few as one facility type can be used to make a baseline measurement that has value and can be compared with the FDA's baseline.<sup>10</sup>

To assure baseline comparability, industry segments and facility types must not be merged (Principle 2).<sup>10</sup> Risk category definitions are not part of the FDA's four comparability principles; the Portland Program has developed its own risk category definitions. The Portland Program risk categories are:

- **High Risk:** A FSE with a history of one or more failed inspections, confirmed complaints, suspected or confirmed foodborne illness or imminent health hazards within two years of the most recent inspection. High Risk FSE are inspected every six months.
- **Medium Risk:** A FSE that serves potentially hazardous food (i.e. time and temperature controlled) with no history of one or more failed inspections, confirmed complaints, suspected or confirmed foodborne illness or imminent health hazards within two years of the most recent inspection. Medium Risk FSE are inspected once per year.
- **Low Risk:** A FSE that serves non-potentially hazardous food (e.g. donuts) and/or has a history of active managerial control (e.g. McDonald's) and no history of one or more failed inspections, confirmed complaints, suspected or confirmed foodborne illness or imminent health hazards within two years of the most recent inspection. Low Risk FSE are inspected once every two years.

#### Inclusion Criteria

- Routine inspection in the year to be studied; the baseline year is 2013.
- High or medium risk category
- Hospital, K-5, Fast Food or Full Service facility

#### Exclusion Criteria

- An inspection report completed due to a complaint or follow-up to a routine health inspection; inspection reports for any year other than the year to be studied
- Low risk category

#### Outcome

Minimum sample size per facility type was determined using the FDA methodology to ensure a statistically valid minimum sample size. Only FSE determined to be high or medium risk, as defined by the Portland Program, are included in the baseline inventory; all low risk and "other" FSE were removed. A summary of this breakdown is available on the next page.



Facility Type	2013 FSE All Risk Levels	2013 FSE High & Medium Risk Only	Minimum Sample Size	Substitutes = 10% of Sample Size
Hospital	5	4	4	0
Elementary Schools (K-5)	3	3	3	0
Fast Food Restaurants	172	84	48	5
Full Service Restaurants	140	137	59	6
<b>Total</b>	<b>320</b>	<b>228</b>	<b>114</b>	<b>11</b>
Source: Portland Health Inspection Inventory, FSE inspected in calendar year 2013.				

While there are more than 500 permanent food service establishments inspected by the Portland Program, the sample size represents a subset that meets the inclusion criteria.

#### **4. Are State/Local data elements comparable to FDA requirements?**

The Portland Program uses the health inspection form required by the State of Maine<sup>7</sup>. This form uses the naming conventions of IN (in compliance), OUT (out of compliance), NA (not applicable) and NO (not observed) which match the FDA's naming convention<sup>10</sup> (Principle 3). The "not applicable" notation is used when an item is not part of the food service operation; the "not observed" notation is used when an item is a usual practice of the food service operation but the practice was not observed during the time of inspection.<sup>10</sup> Using NA or NO are necessary for statistical validity even if a jurisdiction chooses to design its own data collection form.<sup>10</sup>

The FDA Baseline Data Collection Form contains 42 individual data<sup>10</sup> items; the State inspection form contains 54 data<sup>7</sup> elements. The two forms have been compared and the elements have been cross-referenced to ensure national comparability (Principle 1<sup>10</sup>).

#### Outcome

Standardized data collection spreadsheets were developed to overcome any differences between the State and FDA data points. These spreadsheets also contain formulas to automatically calculate items for analysis. The column titles and the associated abbreviation keys are available in Table C.

#### **5. What, if any, additional data elements should be added to enhance local program assessment?**

The State inspection form includes a place to capture the number of risk factor/intervention violations and the number of repeat risk factor/intervention violations. These items are not part of the FDA data elements; however, the Portland Program would like to monitor the numbers.

The inspection form also indicates if the inspection is follow-up or not. Follow-up inspection reports should not be included in the baseline study. Addition of this item to the data collection spreadsheet serves as verification step.

## Outcome

Capturing initial and repeat risk factor/intervention violations and follow-up status data elements were added to the risk factor study data collection spreadsheet.

## **Integration of Knowledge**

The topic of this capstone was generated from a literature review and synthesis assignment for the Environmental Health class (MPH555). In searching for a topic, I became fascinated with food safety and the many layers of activities that ensure access to “unadulterated” food. As my interest in the topic grew, I talked with Mike Russell, City of Portland Health Inspector and colleague at the Public Health Division. Through these casual conversations, a capstone project was born. This capstone project has truly been an integration of prior experience and knowledge learned through the Masters in Public Health program.

<b>MPH Competencies</b>	<b>Capstone Learning Objectives</b>
<ul style="list-style-type: none"><li>• Communication</li><li>• Health Policy &amp; Management</li><li>• Informed Decision Making</li></ul>	1. Demonstrate clear and effective writing skills as measured by a written capstone report which incorporates: <ul style="list-style-type: none"><li>• Appropriate and accurate citation methods.</li><li>• A professional tone and formatting.</li><li>• A logical sequence of information.</li></ul>
	2. Demonstrate health policy and management and informed decision-making skills as measured by the development of a comprehensive data collection manual that: <ul style="list-style-type: none"><li>• Applies systems thinking and performance improvement concepts.</li><li>• Incorporates data collection and analytic methods appropriate to the defined goals.</li><li>• Provides critical review and synthesis of literature and other background information.</li><li>• Meets the FDA Program Standard 9 and the PHAB Standards 2.1.1A (timely investigations) and 9 (CQI) requirements.</li></ul>
<b>Most Influential Classes</b>	
MPH 555 Environmental Health	MPH 630 Health Planning & Marketing
MPH 565 Social & Behavioral Health	MPH 650 Applied Research & Evaluation
MPH 575 Health Systems	MPH 655 Public Health Practice
MPH 698 Field Experience	
(Developed Family Health Performance Management Plan, Portland Public Health)	
<b>Discussion</b>	
<p>As the core focus of my field experience, I developed a performance management plan which provided an opportunity to explore public health quality and performance management literature. This work strengthened the data collection manual. The plan, do, study, act (PDSA) cycle was applied to each step of inventory development. Elements of the above classes are</p>	

integrated throughout the capstone report and data collection manual.

I regularly return to concepts and work products from the MPH program to inform my work at Portland Public Health, examples include:

- Literature review/use of search tools
- Management, social and behavioral health theories
- Judicious use of PowerPoint and audience engagement
- System assessment mapping that integrates business and public health theory
- Strong need statements and writing styles

The MPH program has provided a review of core principles learned through undergraduate studies and life experience; it has also added the next layer of knowledge and “polish” to my skill-set.

### **Life-long Learning**

The MPH program strengthened my professional competencies, especially within a public health framework. I am thrilled to place a checkmark next to my goal of earning a MPH degree on my personal development plan. Goal Met!

## References

1. Centers for Disease Control and Prevention (CDC). Fact Sheet: Environmental public health practice and CDC's food safety winnable battle, November 2013. Retrieved on 2/20/14 from <http://www.cdc.gov/WinnableBattles/FoodSafety/index.html>
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6. US Department of Health and Human Services, Office of Disease Prevention & Health Promotion. Healthy People 2020. Retrieved on 10/24/14 from <http://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives>
7. Maine Department of Health & Human Services, Health Inspection Program. Maine Food Code 2013, 22 MRSA §2496. Retrieved on 3/10/14 from <http://www.maine.gov/dhhs/mecdc/environmental-health/el/index.htm>.
8. City of Portland Maine. Food Safety 2014. Retrieved from <http://www.ci.portland.me.us/594/Food-Safety-Food-Service-Inspections>
9. City of Portland Maine, Portland Code of Ordinances, Chapter 11: Food and Food Handlers (2012). Retrieved from <http://me-portland.civicplus.com/DocumentCenter/Home/View/1075>
10. US Department of Health and Human Services, Food and Drug Administration (2003). Developing a baseline on the occurrence of foodborne illness risk factors: data collection instruction manual Retrieved on 7/15/2014, FDA Technical assistance CD.

**Table A: Capstone Gantt Chart**

Tasks	2014												2015				
	Mar	April	May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May		
Select Topic	Complete																
Conduct Initial Research	Complete																
Conduct Literature Review		Complete															
Choose Analytic Framework		Complete															
Determine Methodology		Complete															
Develop Initial Proposal				Complete													
Register for MPH699						Done											
Select Faculty Advisor							Done										
Determine 2nd Advisor							Done										
Attend Capstone Prep							Complete										
Proposal Presentation-10/29/14								Done									
Advisors Approve Project								✓									
<b>Implement Project</b>																	
Develop data collection manual											Ongoing						
<b>Test methodologies</b>											Complete						
Develop initial FSA inventory											Complete						
Sort inventory by facility/risk type								✓									
Determine sample size & randomize										✓							
<b>Revise Capstone Focus</b>																	
Draft Reviewed/Revised-Advisors												Done	✓				
<b>Final Approved-Advisors</b>														✓			
Prepare Oral Presentation														✓			
<b>Oral Presentation</b>																	
<b>Graduation</b>																	YAY

**Table B: To Develop a Risk Factor Study Data Collection Manual in Accordance with FDA Program Standard 9.**

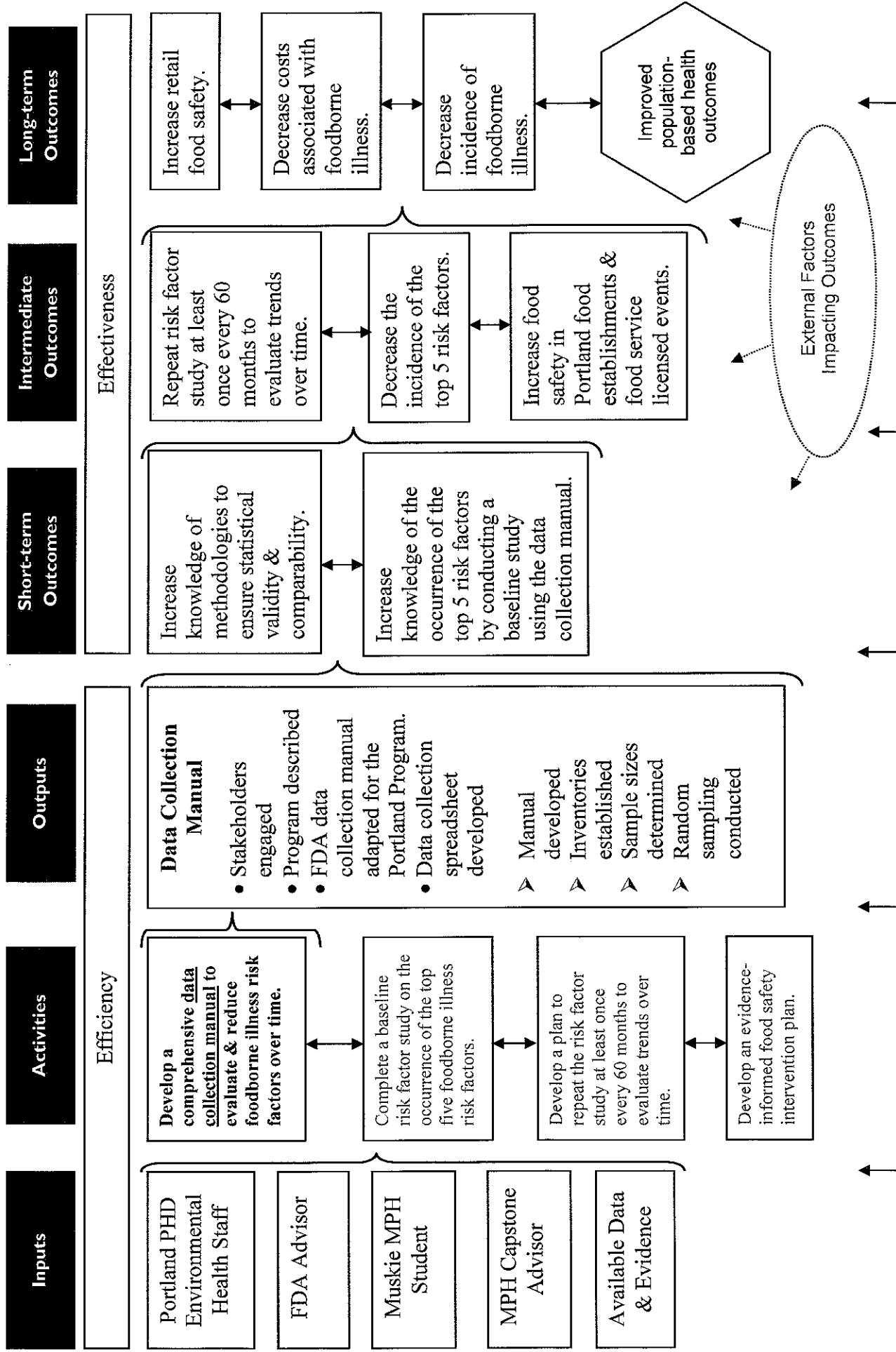


Table C: Inventory Development Summary and Abbreviation Keys

Categories of Portland Program Tracking Sheet, was not intended to be an "inventory"

Insp	EID	S	T	Name	Address	HOO	Insp Date	Last	Previous		O	L/T	H	V	Email	Exp Date
									A	B	C					

2013 Master Inventory

Count	#	Risk Cat.		FSE Name	specific Date	Result		LicType	Facility Type			
		H	M			P	F		K-5	FF	FS	OT
1	1											
2	1											
3	1											
	3											

2013 Full Service Inventory-High and Medium Risk Only

Count	#	RiskCat		FSE Name	Inspection Date	Result		LicType
		H	M			P	F	
								FS

Data Collection Spreadsheet-2013 Baseline Study

Count	#	RiskCat		FSE Name	Inspection Date	Result		FollowUp		RiskV	Item 1				Item 2			
		H	M			P	F	Y	N		IN	Out	NA	NO	IN	Out	NA	NO

<b>Table C—Abbreviation Key: Food Service Establishment (FSE) &amp; Survey Inventories</b>	
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<b>Count</b>	Assign unique number to each FSE (in preparation to random selection) Example: 1, 2, 3, 4.....
<b>#</b>	Always enter 1; counts each FSE in the inventory

<b>RiskCat</b>	<b>Risk Category</b>
H	High Risk--inspected every 4 to 6 months
M	Medium Risk—inspected once per year
L	Low Risk—inspected once within every two years (exclude from survey inventory)

<b>Inspection Date</b>	
	Date of initial, routine inspection; do not include inspections due to complaints or follow-up.

<b>Result</b>	
P	Pass
F	Fail

<b>LicType</b>	<b>License Type</b>
P	Permanent
M	All Other

<b>Facility Type</b>	
H	Hospital
K-5	Kindergarten through grade 5
FF	Fast Food = self-serve
FS	Full Service restaurant = wait staff
OT	Other (catering, coffee shops, ice cream shops, mobile)(exclude survey inventory)



**Table C—Abbreviation Key: Survey Inventory**

<b>Count</b>	Assign unique number to each FSE (in preparation to random selection) Example: 1, 2, 3, 4.....
<b>#</b>	Always enter 1; counts each FSE in the inventory

<b>RiskCat</b>	<b>Risk Category</b>
H	High Risk--inspected every 4 to 6 months
M	Medium Risk—inspected once per year
L	Low Risk—inspected once within every two years

<b>Inspection Date</b>	
	Date of initial, routine inspection; do not include inspections due to complaints or follow-up.

<b>Result</b>	
P	Pass
F	Fail

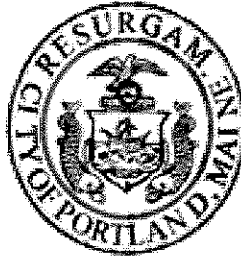
<b>LicType</b>	<b>License Type</b>
P	Permanent
M	All Other

<b>Facility Type</b>	
H	Hospital
K-5	Kindergarten through grade 5
FF	Fast Food = self-serve
FS	Full Service restaurant = wait staff
OT	Other (catering, coffee shops, ice cream shops, mobile)

<b>FollowUp</b>	Follow-up inspection
Y	Yes = exclude from data collection; only regular inspections are included
N	No = include in data collection

<b>RiskV</b>	<b>Risk Factor Violations (not required by FDA)</b>
#I	Number of risk factor/intervention violations
#R	Number of repeat risk factor/interventions violations

<b>Item #</b>	<b>Corresponds to question number on Maine Health Inspection Form</b>
IN	In compliance
Out	Out of compliance
NA	Not applicable
NO	Not observed



## Environmental Health & Safety Program

### Foodborne Illness Risk Factor Study

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# Data Collection Manual

Health Inspection Team Approval	
Original Date of Implementation	
Filed in the following location	

## Table of Contents

Statement of Need.....	3
Background.....	3
Goal and Objectives.....	4
Structure.....	4
Data Collection .....	5
Data Analyses .....	9
Continuous Quality Improvement.....	10

### Tables

Table 1: FDA Industry and Facility Definitions .....	12
Table 1A: Portland Industry and Facility Definitions.....	14
Table 2: FDA Minimum Sample Size.....	15
Table 3: Inventory Development Summary & Abbreviation Key .....	16
Table 4: How to Use Randomizer.org.....	19
Table 4A: Randomized Numbers List .....	20
Table 5: Identify an Opportunity and Plan for Improvement .....	21
Table 6: Logic Model—Risk Factory Study: Data Collection Manual .....	22

For complete inventory spreadsheets, see the Inspections folder located on the Division's o:drive

### Attachments

- Attachment A: FDA Voluntary National Retail Regulatory Program Standards-January 2011: Program Standard 9.
- Attachment B: FDA Data Collection Manual
- Attachment C: Embracing Quality in Public Health

## Statement of Need

Food comes from all over the world and is at risk of contamination from farm to consumption. However, more than half of all foodborne illness outbreaks in the US are associated with food prepared in restaurants.<sup>1</sup> Given that 80% of Americans eat out at least once per week; a better understanding of how and why transmission of foodborne diseases occurs in restaurants is needed to develop better prevention measures.<sup>1</sup>

### Risk Factors

Epidemiological outbreak data repeatedly identifies five major risk factors related to employee behaviors and preparation practices in retail and food service establishments as contributing to foodborne illness.<sup>2</sup>

- Improper holding temperatures;
- Inadequate cooking;
- Contaminated equipment;
- Food from unsafe sources; and
- Poor personal hygiene.

Appropriate hygiene and food handling processes in retail and food service establishments are critical to prevent the growth of microorganisms in foods which include but are not limited to *Salmonella*, *Vibrio*, *Campylobacter*, *E. coli* 0157, *Listeria*, and *Norovirus*.<sup>3</sup>

## Background

The FDA first implemented the Voluntary National Retail Food Regulatory Program Standards (Program Standards) in 2002 to establish a quality assurance and improvement strategy for regulatory authorities that license and inspect food service and retail food establishments.<sup>3</sup> As the title indicates participation in the Program Standards is voluntary and not required by federal or state law.

The City of Portland has made a significant commitment to public health and food safety by adopting its own food code and health inspection program. To further this commitment, the Portland Environmental Health & Safety Program enrolled in the FDA

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<sup>1</sup> Jones T, Vugia D, Selman C, Angulo F, and the EIP FoodNet Working Group (2002). Eating in restaurants: a risk factor for foodborne illness? Findings from FoodNet to be explored by EHS-Net. Presented at the International Conference on Emerging Infectious Diseases, Atlanta, March 2002.

<sup>2</sup> US Department of Health and Human Services, Food and Drug Administration (2013). FDA Food Code 2013 Recommendations.

<sup>3</sup> US Department of Health and Human Services, Food and Drug Administration (2013). Voluntary National Retail Regulatory Program Standards-January 2011. Retrieved on 3/10/14 from <http://www.fda.gov/Food/GuidanceRegulations/RetailFoodProtection/ProgramStandards/default.htm>

Program Standards in 2014. This data collection manual is designed to meet the requirements of Program Standard 9: Program Assessment which focuses on the process used to measure the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors.<sup>3</sup>

## Goal and Objectives

**Goal:** To reduce foodborne illness risk factors in food service establishments (FSE) inspected by the Portland Environmental Health & Safety Program to improve food safety.

**Objective 1:** To maintain a comprehensive data collection manual to guide studies that monitor trends in the occurrence of foodborne illness risk factors.

**Objective 2:** To conduct risk factor studies to determine the occurrence of the top five foodborne illness risk factors at least once every 60 months beginning with calendar year 2013 (baseline).

**Objective 3:** To maintain an evidence-informed food safety intervention plan to address risk factors identified by the risk factor studies.

Source: FDA Voluntary National Retail Regulatory Program Standards-January 2011; Program Standard 9, see Attachment A.

## Structure

The Food and Drug Administration (FDA), in collaboration with subject matter experts from the Center for Food Safety and Applied Nutrition's (CFSAN) Division of Mathematics, developed a data collection instruction manual<sup>4</sup> to ensure statistical validity of conclusions derived from the analysis of data collected during the baseline study (Attachment B).

The FDA manual is approximately 100 pages long and not all information is applicable to the Portland Environmental Health & Safety Program (Portland Program). The Portland Program integrated the FDA's sample methodology and the four basic comparability principles into the data collection manual to ensure statistically valid compilations and comparability at the national level. The Comparability Principles<sup>5</sup> are:

Principle 1: Retain the 42 data items in the FDA's Baseline data inventory.

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<sup>4</sup> US Department of Health and Human Services, Food and Drug Administration, (2003). Voluntary National Retail Regulatory Program Standards-Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors: Data Collection Instruction Manual. Retrieved on 7/15/14 from FDA technical assistance CD.

<sup>5</sup> FDA Data Collection Manual, page 37

- Principle 2: Retain FDA facility types; do not merge facility types with each other or with new ones.
- Principle 3: Retain the four marking options for assessing individual data items in compliance (IN), out of compliance (OUT), not applicable (NA), or not observed (NO).
- Principle 4: Incorporate new data items without altering the original 42 data items.

The Portland Program also conducts studies of other licensed retail food vendors which are not included in the facilities defined by the FDA. Data regarding these additional vendors are separated from the FDA baseline study and are not included in reports required by the FDA.

The Portland Public Health Division has submitted an application and expects to be accredited by the Public Health Accreditation Board (PHAB). The Portland Program shall incorporate PHAB Standards (Version 1.0)<sup>6</sup> and documentation guidelines whenever possible. Additional details are provided in the Continuous Quality Improvement section of this manual.

## **Data Collection**

A meaningful baseline upon which to measure the occurrence of foodborne illness risk factors relies upon a consistent approach to data collection.<sup>7</sup>

### Data Source

Retrospective reviews of routine health inspection reports, which are publically available, are the data source for Portland's risk factor studies. This eliminates the need to distinguish between data collection and regulatory compliance oversight. An inspection report completed due to a complaint or as follow-up to a routine health inspection will not be used as a data source.

The Portland Program uses the health inspection form required by the State of Maine. This form uses the naming conventions of IN (in compliance), OUT (out of compliance), NA (not applicable) and NO (not observed) which match the FDA's naming convention (Principle3). The "not applicable" notation is used when an item is not part of the food service operation.<sup>8</sup> The "not observed" notation is used when an item is a usual practice of the food service operation but the practice was not observed during the time of inspection.<sup>8</sup> Using NA or NO are necessary for statistical validity even if a jurisdiction chooses to design its own data collection form.<sup>8</sup>

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<sup>6</sup> Public Health Accreditation Board (2011). Standards and measures, version 1.0. Retrieved on 09/8/2014 from <http://www.phaboard.org/wp-content/uploads/PHAB-Standards-and-Measures-Version-1.01.pdf>

<sup>7</sup> FDA Data Collection Manual, page 32

<sup>8</sup> FDA Data Collection Manual, page 35

The FDA Baseline Data Collection Form contains 42 individual data items<sup>9</sup>; the State inspection form contains 54 data elements.<sup>10</sup> The two forms have been compared and the elements have been cross-referenced to ensure national comparability (Principle 1). The broad categories are the same for both forms; it is the subcategories that create the difference in data items.

CDC Risk Factors	CDC/FDA-1997		Maine-2013	
	Data Items	# Items	Data Items	# Items
Food from unsafe sources	1A – 3C	7	1A – 3C	7
Inadequate cooking	4A – 5D	12	4A – 5D	12
Improper holding temperatures	6A – 9D	10	6A – 9D	10
Contaminated equipment	10A – 11A	5	10A – 11A	5
Poor personal hygiene	12A – 15B	5	12A – 15B	5
Other: Foreign Substance	16A – 16C	3	16A – 16C	3
	Total Items	42		42

### Data Collectors

When possible, the Portland Program will seek technically qualified “third party” or “independent” personnel who are not responsible for conducting regulatory health inspections to minimize potential bias in data collection.

### Data Collection Form

The Portland Program developed a standardized Microsoft Excel spreadsheet to overcome the difference between the State and FDA data points. The spreadsheet also contains formulas to automatically calculate items for analysis. The four principles of comparability have been retained to ensure comparability and measurement of trends.

### **Step 1: Determine Inventory**

The Portland Program food service establishments (FSE) inventories will include:

- The three industry segments and facility types defined by the FDA. For the Portland Program, there will be a minimum of four inventories.
- Additional FSE within the City of Portland’s jurisdiction that are not part of FDA facility types.
- Only inspection reports for “regular” inspections. Reports based on re-inspection or complaints will not be used.

<sup>9</sup> FDA Data Collection Manual, page 34

<sup>10</sup> Maine Department of Health & Human Services, Health Inspection Program, (2013). Maine Food Code 22 MRSA §2496. Retrieved on 3/10/14 from <http://www.maine.gov/dhhs/mecdc/environmental-health/el/index.htm>

- d) Only FSE determined to be high or medium risk as defined by the Portland Program. Facilities in the low risk category are not included in the risk factor studies.
- e) Count the number of FSE, based on facility types, to determine sample size.

### Industry Segment and Facility Types

The FDA constructed its baseline using three industry segments comprised of nine facility types,<sup>11</sup> see Table 1: FDA Industry Segments and Facility Types. To assure baseline comparability, industry segments and facility types will not be merged (Principle 2). As few as one facility type can be used to make a baseline measurement that has value and can be compared with the FDA's baseline.<sup>12</sup> According to the FDA guidelines, a jurisdiction may add other facility types; these would be excluded from national comparisons.

For the Portland Program, there will be a minimum of four inventories, see Table 1A: Portland Industry Segments and Facility Types. The Portland Program does not inspect nursing homes or facilities that have meat, seafood, deli, and produce departments and does not need to incorporate special considerations for facilities of this type, Portland Health Inspectors also do not inspect food service facilities located in gas stations or convenience stores; that type of facility is licensed and inspected by the Maine Department of Agriculture. As the inventories evolved, the data elements changed. A summary of these changes and the associated abbreviation keys are available in Table 3.

### Risk Categories

The FDA divides food establishments into five risk categories based on type of food prepared. The State of Maine follows the FDA risk category definitions. However, FDA Program Standard 3 allows jurisdictions to define their own risk categories. Risk category definitions are not part of the FDA's four comparability principles.

The Portland Program has developed its own risk category definitions. With 2.0 full-time equivalent (FTE) health inspectors, time must be prioritized for those facilities in most need of public health interventions. From a practical perspective, defining risk category based on a food service establishment's (FSE) inspection history addresses foodborne illness risk factors more than how food is prepared or served. The Portland Program risk categories are:

- **High Risk:** A FSE with a history of one or more failed inspections, confirmed complaints, suspected or confirmed foodborne illness or imminent health hazards within two years of the most recent inspection. High Risk FSE are inspected every six months.

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<sup>11</sup> FDA Data Collection Manual, page 9

<sup>12</sup> FDA Data Collection Manual, page 10



- **Medium Risk:** A FSE that serves potentially hazardous food (i.e. time and temperature controlled) with no history of one or more failed inspections, confirmed complaints, suspected or confirmed foodborne illness or imminent health hazards within two years of the most recent inspection. Medium Risk FSE are inspected once per year.
- **Low Risk:** A FSE that serves non-potentially hazardous food (e.g. donuts) and/or has a history of active managerial control (e.g. McDonald's) and no history of one or more failed inspections, confirmed complaints, suspected or confirmed foodborne illness or imminent health hazards within two years of the most recent inspection. Low Risk FSE are inspected once every two years.

## Step 2: Determine Sample Size

To assist jurisdictions in determining a statistically valid minimum sample size, the FDA developed a table of minimum sample sizes, see Table 2. In anticipation that one or more FSE may be randomly selected that should be excluded, substitute FSE should also be randomly selected. The substitute FSE is selected at the same time as the primary sample and shall equal 10% of the minimum sample to ensure an adequate pool of substitute establishments. For each risk factor study, FSE inventories should be summarized as illustrated below.

Facility Type	2013 FSE All Risk Levels	2013 FSE High & Medium Risk Only	Minimum Sample Size	Substitutes = 10% of Sample Size
Hospital	5	4	4	0
Elementary Schools (K-5)	3	3	3	0
Fast Food Restaurants	172	84	48	5
Full Service Restaurants	140	137	59	6
<b>Total</b>	<b>320</b>	<b>228</b>	<b>114</b>	<b>11</b>
Source: Portland Health Inspection Inventory, FSE inspected in calendar year 2013.				

If the sample size is less than 9 FSE, 100% of the facilities are selected and there would be no substitutes. As few as one facility type can be used to make a baseline measurement that has value and can be compared with the FDA's baseline.<sup>10</sup> While there are more than 500 permanent food service establishments inspected by the Portland Program, the sample size is a smaller subset that meet the inclusion criteria.

## Step 3: Random Selection of Establishments

For each facility type, FSE are randomly selected to cover the minimum sample size and substitute establishments. Random numbers will be obtained from Research Randomizer; see Table 4 for a screen shot containing directions. Two randomized sets per FSE type should be prepared; one for the primary sample and one for substitutes, see Table 4A.

## Data Analysis

The purpose of the risk factor studies is to identify risk factors most in need of correction, to monitor trends over time and to measure the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors.<sup>3</sup> At a minimum, data analyses will determine the following:

- A count of the occurrence of the top 5 risk factors that contribute to foodborne illness in calendar year 2013 (baseline) for the facilities within Portland's jurisdiction.
- The overall percent of observable and applicable data items in compliance (as noted on the completed inspection forms) for each facility types defined by the FDA.
- The percent of total observations in compliance for each of the facility types for each identified risk factor.
- The individual data items with the highest out of compliance observations for each facility type.
- A plan to repeat the risk factor study at least once every 60 months to monitor trends over time.

### Analysis Report

Standard 9 requires a report on the outcomes and conclusions of the risk factor study. A narrative is not necessary; however, the analysis must identify risk factors most in need of intervention.<sup>13</sup>

### Statistical Limitations<sup>14</sup>

The precision of the percentages calculated from the data is directly related to the number of observations included in the analyses; the more observations, the greater precision. Given the diversity within retail operations, it is anticipated that many individual data items will have relatively small numbers of observations. In designing the baseline, more emphasis will be given to analysis of the collection of data items within the five major risk factor categories (food from unsafe sources; inadequate cooking; improper holding temperatures; contaminated equipment; and poor personal hygiene).

It is more statistically reliable to group the data items into the risk factors because a larger pool of observations is attained. For any one of the 42 individual data items, the percentage in compliance is less precise due to the fewer number of observations available for analysis. It is important to note that baseline data collection is not designed to determine an individual establishment's compliance with regulatory requirements. Rather, the intent is to establish a baseline of compliance with Food Code provisions that address CDC-identified foodborne illness

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<sup>13</sup> US Department of Health and Human Services, Food and Drug Administration (2011). Voluntary National Retail Food Regulatory Program Standards, January 2011, Standard 9, page 11.

<sup>14</sup> FDA Data Collection Manual, page 41

risk factors to track the change in the occurrence of risk factors through future comparison studies.

### Risk Category Limitation

As previously noted, the FDA divides food establishments into five risk categories based on type of food prepared; the State of Maine follows the FDA risk category definitions. However, risk category definitions are not part of the FDA's four comparability principles and FDA Program Standard 3 allows jurisdictions to define their own risk categories. The Portland Program has chosen to define its own risk categories based on a food service establishment's inspection history. Therefore identified risk categories are not uniform and comparability is limited at the national level. Unless the Portland Program changes its risk categories, however, it will remain comparable with itself over time.

## **Continuous Quality Improvement (CQI)**

The Environmental Health & Safety Program (Portland Program) is committed to continuous quality improvement for all aspects of its program. Quality improvement initiatives, within key functional areas, shall focus on efficiency, effectiveness, accountability, outcomes and other indicators of quality. Standards may be selected from national, state, scientific guidelines, or by benchmarking against itself or similar organizations. Priority is given to performance standards set by regulatory and contractual requirements. This data collection manual has incorporated the requirements for both programs listed below.

<b>Source</b>	<b>Domain</b>
FDA Voluntary National Retail Food Regulatory Program, January 2013 <sup>3</sup>	<p>Standard 9: Program Assessment</p> <p>Required documentation:</p> <ol style="list-style-type: none"> <li>1. Survey reports on the occurrence of risk factors and Food Code interventions.</li> <li>2. Survey collection tools or inspection sheets used for the data collection.</li> <li>3. Documentation that each facility type regulated is surveyed during the 60-month survey cycle.</li> <li>4. Documentation of performed interventions, actions or activities designed to improve the control of risk factors.</li> <li>5. Documentation that the effectiveness of performed interventions is evaluated.</li> </ol>
Public Health Accreditation Board (PHAB) Standards and Measures, Version 1.0 <sup>6</sup>	<p><u>Standard 2.1.1A</u>: Conduct timely investigations of health problems and environmental public health hazards.</p> <p><u>Standard 9</u>: Evaluate and continuously improve health department processes, programs and interventions.</p>

The Portland Program has also selected the Plan, Do, Study, Act (PDSA) system as its primary CQI model, see Table 6. Once an opportunity for improvement has been identified and approved, staff will implement the PDSA process. The handbook, Embracing Quality in Public Health: A Practitioner's QI Handbook (Attachment C) serves as the primary staff resource.

### Logic Model

A logic model provides a graphic depiction of the relationship between a program's goals, objectives, activities and stakeholder groups; Table 6: Logic Model—Risk Factor Study Data Collection Manual was created for this project.

### Documentation Guidelines

The Portland Program shall document and report progress in meeting performance management objectives, indicators, performance goals, benchmarks and trends. Documentation shall include:

1. Date: The date may indicate creation, implementation or other date important for document control.
2. Page Numbers: For any document more than one page long, page numbers shall be formatted at the bottom of each page.
3. Evidence of Authority: The most current Public Health Division logo or letterhead.
4. Meeting Minutes: A written record of CQI meetings shall include the names of those in attendance and a summary of discussion, decisions, and recommendations.
5. References: This may include the source of a specific requirement, literature, evidence-informed best practice or applied research and evaluation methodology.

### Evidence-informed Food Safety Intervention Plan

Standard 9 requires that targeted intervention strategies be developed, implemented and evaluated to reduce foodborne illness risk factors identified by the risk factor studies. Interventions may include policy, education, or compliance strategies to reduce the occurrence of the risk factors over time. These strategies will be developed after the baseline study is complete.

### Plan to Repeat Risk Factor Study

The plan to repeat risk factor studies at least once every 60 months will be developed after the baseline study is complete.

**Table 1: FDA Industry Segment and Facility Type Definitions**

INDUSTRY SEGMENT	FDA FACILITY TYPE	
<p><u><b>Institutions</b></u></p> <p>This segment includes food service to high-risk populations such as the elderly/older adults, the very young, and/or immune-compromised.</p> <p>Each facility type may include food service operations that prepare and serve food on-site, serve as central kitchens or are satellite kitchens served by central kitchens.</p>	Hospitals	Food service operations that serve patients, staff, and hospital visitors in a traditional hospital setting. Individuals who are acutely ill or those who are immune-compromised are a target population for data collection.
	Nursing Homes & Assisted Living Facilities	Food service operations that serve highly susceptible populations living in a group care setting. The elderly (55+ years) is a target population for data collection.
	Elementary Schools (K-5)	Food service operations that serve students from one or more grade levels from pre-school through grade 5. Young children are a target population for data collection.
<p><u><b>Restaurants</b></u></p> <p>Most establishments in this industry segment can be categorized according to the commonly understood distinctions between a full service and a fast food restaurant.</p> <p>For a few establishments, the appropriate category may not be as obvious. In these cases, one should use good judgment and the definitions provided to assign the facility type.</p> <p>The criteria used for selection of facility type should be applied consistently.</p>	Fast Food a/k/a quick service restaurant	<p>Establishments typically characterized by counter service and drive-thru operations. These establishments may or may not provide customer-seating areas.</p> <p>Food is typically prepared or cooked for immediate service with limited advance preparation or carry-over of prepared food from one day to the next. These establishments are also referred to as quick service restaurants.</p>
	Full Service	<p>Establishments typically characterized by the availability of table service and a wait staff.</p> <p>Buffet restaurants and cafeterias that prepare a variety of potentially hazardous foods and provide customer seating may also be categorized as full service restaurants.</p>
<p><u><b>Retail Food Stores</b></u></p> <p>The inventory of each of the four retail food</p>	Deli Department	The department in a retail food store where potentially hazardous foods such as luncheon meats and cheeses are sliced for the customer

**Table 1: FDA Industry Segment and Facility Type Definitions**

INDUSTRY SEGMENT	FDA FACILITY TYPE	
<p>store facility types should include individual departments that are part of a larger grocery store or supermarket, as well as, freestanding specialty markets that may sell foods from only one of the categories.</p> <p>Note: For data collection purposes, the salad bar is included with the department that is responsible for preparing the food items that will be offered at the salad bar. If the deli department prepares the items for the salad bar, then it should be included as part of the data collection for the deli department. If the produce department prepares the items for the salad bar, then it is included as part of the data collection for the produce department.</p>		<p>and where sandwiches and salads (such as potato salad and cole slaw) are prepared and displayed. Parts of a deli may also include:</p> <ul style="list-style-type: none"> <li>• Salad bars and other food bars maintained by the deli department manager</li> <li>• Areas where meat or poultry is cooked and offered for sale as ready-to-eat;</li> <li>• Pizza stands; and</li> <li>• Limited bakery operations attached to or adjacent the deli.</li> </ul>
	Meat & Poultry Dept.	The meat and poultry department in a retail food store as well as any freestanding meat market or butcher shop that sells raw meat or poultry directly to the consumer.
	Seafood Department	Seafood departments in retail food stores and freestanding seafood markets that sell seafood directly to the consumer include the preparation and sale of raw and/or ready-to-eat seafood. In-store sushi bars should be considered as part of the seafood department for purposes of the data collection.
	Produce Department	An area or department where produce is cut, prepared, stored or displayed. A produce department may include salad bars that managed by the produce department managers.
<p>Source: US Department of Health and Human Services, Food and Drug Administration, (2003). Voluntary National Retail Regulatory Program Standards-Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors: Data Collection Instruction Manual. Retrieved on 7/15/14 from FDA technical assistance compact disk.</p>		

**Table 1A: Portland Industry Segments and Facility Types**

The criteria used for selection of facility type should be applied consistently.

INDUSTRY SEGMENT	PORTLAND FACILITY TYPE	PORTLAND DEFINITIONS
<b>Institutions</b>  License Type: Permanent	<b>Hospitals</b>	Food service operations that serve patients, staff, and hospital visitors in a traditional hospital setting.
	<b>Elementary Schools</b>	Food service operations that serve students at least one grade from pre-school through grade 5.
	Middle Schools	Food service operations that serve students from one or more grade levels from 6-8.
	High Schools	Food service operations that serve students from one or more grade levels from 9-12.
<b>Restaurants</b>  License Type: Permanent	<b>Fast Food</b> a/k/a quick service	<p>Establishments typically characterized by counter service and drive-thru operations. These establishments may or may not provide customer-seating areas.</p> <p>Food is typically prepared or cooked for immediate service with limited advance preparation or carry-over of prepared food from one day to the next.</p>
	<b>Full Service</b>	<p>Establishments typically characterized by the availability of table service and wait staff.</p> <p>Buffet restaurants and cafeterias that prepare a variety of potentially hazardous foods and provide customer seating may also be categorized as full service restaurants.</p>
Mobile Food Vendors, by license type	Catering	To be determined
	Food Truck	To be determined
	Push Cart	To be determined
Temporary Food Licensed Events	Temporary Event	To be determined
Other FSE	License Type: Permanent	For a few establishments, the appropriate category may not be obvious. In these cases, use good judgment and the definitions provided to assign the facility type.

**Table 2: FDA Suggested Minimum Sample Size**

There will be an inventory and sample size per facility type.	
INVENTORY SIZE	SAMPLE SIZE
<9	All
9	8
10-12	9
13	12
14-19	14
20-24	18
25-28	23
29-31	24
32-36	27
37-43	29
44-51	33
52-58	38
59-73	42
74-81	44
82-96	48
97-103	53
104-133	57
134-148	59
149-163	63
164-186	68
187-261	72
262-291	74
292-328	78
329-373	83
374+	87
Source: US Department of Health and Human Services, Food and Drug Administration, (2003). Voluntary National Retail Regulatory Program Standards-Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors: Data Collection Instruction Manual. Retrieved on 7/15/14 from FDA technical assistance compact disk.	



**Table 3: Inventory Development Summary and Abbreviation Keys**

Categories of Portland Program Tracking Sheet, was not intended to be an "Inventory"

Insp	EID	S	T	Name	Address	HOO	Insp	Previous			Last	O			L/T	H	V	Email	Exp Date
							Date	A	B	C									

**2013 Master Inventory**

Count	#	Risk Cat.			FSE	Name	specifi	Result		LicType	Facility Type				
		H	M	L				P	F		K-5	FF	FS	OT	
1	1														
2	1														
3	1														
	3														

**2013 Full Service Inventory-High and Medium Risk Only**

Count	#	RiskCat		FSE	Inspection	Date	Result		LicType	FS
		H	M				P	F		

**Data Collection Spreadsheet-2013 Baseline Study**

Count	#	RiskCat		FSE	Inspection	Date	Result		FollowUp	RiskV	Item 1			Item 2		
		H	M				P	F			IN	Out	NA	NO	IN	Out

<b>Table 3-Abbreviation Key: Food Service Establishment (FSE) &amp; Survey Inventories</b>	
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<b>Count</b>	Assign unique number to each FSE (in preparation to random selection) Example: 1, 2, 3, 4.....
<b>#</b>	Always enter 1; counts each FSE in the inventory

<b>RiskCat</b>	<b>Risk Category</b>
H	High Risk--inspected every 4 to 6 months
M	Medium Risk—inspected once per year
L	Low Risk—inspected once within every two years (exclude from survey inventory)

<b>Inspection Date</b>	
	Date of initial, routine inspection; do not include inspections due to complaints or follow-up.

<b>Result</b>	
P	Pass
F	Fail

<b>LicType</b>	<b>License Type</b>
P	Permanent
M	All Other

<b>Facility Type</b>	
H	Hospital
K-5	Kindergarten through grade 5
FF	Fast Food = self-serve
FS	Full Service restaurant = wait staff
OT	Other (catering, coffee shops, ice cream shops, mobile)(exclude survey inventory)

**Table 3-Abbreviation Key: Survey Inventory**

<b>Count</b>	Assign unique number to each FSE (in preparation to random selection) Example: 1, 2, 3, 4.....
<b>#</b>	Always enter 1; counts each FSE in the inventory

<b>RiskCat</b>	<b>Risk Category</b>
H	High Risk---inspected every 4 to 6 months
M	Medium Risk---inspected once per year
L	Low Risk---inspected once within every two years

<b>Inspection Date</b>	
	Date of initial, routine inspection; do not include inspections due to complaints or follow-up.

<b>Result</b>	
P	Pass
F	Fail

<b>LicType</b>	<b>License Type</b>
P	Permanent
M	All Other

<b>Facility Type</b>	
H	Hospital
K-5	Kindergarten through grade 5
FF	Fast Food = self-serve
FS	Full Service restaurant = wait staff
OT	Other (catering, coffee shops, ice cream shops, mobile)

<b>FollowUp</b>	Follow-up inspection
Y	Yes = exclude from data collection; only regular inspections are included
N	No = include in data collection

<b>RiskV</b>	<b>Risk Factor Violations (not required by FDA)</b>
#I	Number of risk factor/intervention violations
#R	Number of repeat risk factor/interventions violations

<b>Item #</b>	<b>Corresponds to question number on Maine Health Inspection Form</b>
IN	In compliance
Out	Out of compliance
NA	Not applicable
NO	Not observed

Table 4: How to Use Randomizer.org



To generate random numbers, enter your choices below (using integer values only):

How many sets of numbers do you want to generate?

[Help](#)

1 set of numbers

How many numbers per set?

[Help](#)

Number in Sample Size

Number range (e.g., 1-50):

From:  To:  [Help](#)

Range of numbers in inventory

Do you wish each number in a set to remain unique?

☒ Yes [Help](#)

No duplicate numbers in the set

Do you wish to sort the numbers that are generated?

☒ Yes: Least to Greatest [Help](#)

How do you wish to view your random numbers?

☒ Place Markers Off [Help](#)

[Randomize Now!](#)

Press the Randomize Now

Version 3/17/2015

Conduct randomizer twice for each facility type:  
Primary Inventory  
Substitution Inventory

Source: Urbaniak, G. C., & Plous, S. (2013). Research Randomizer (Version 4.0) [Computer software]. Retrieved on 12/16/2014, from <http://www.randomizer.org/>

**Table 4A: Randomized Numbers Generated**

Results - Research Randomizer

Page 1 of 1



Print

Download in Excel

Close

### Research Randomizer Results

2 Sets of 48 Unique Numbers Per Set

Range: From 1 to 84 -- Sorted from Least to Greatest

Job Status: **Finished**

#### Set #1:

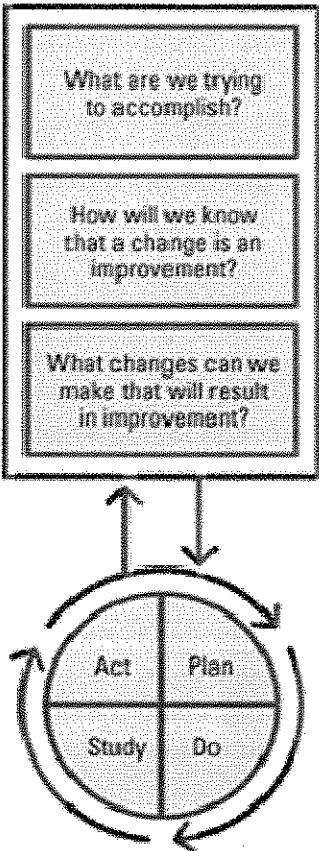
2, 4, 5, 7, 9, 10, 11, 13, 15, 16, 17, 19, 21, 22, 23, 24, 26, 30, 31, 32, 33, 34, 36, 37, 38, 40, 43, 44, 46, 49, 50, 51, 54, 55, 57, 59, 60, 61, 63, 65, 68, 71, 73, 74, 75, 79, 81, 83

#### Set #2: Substitutions

① 2, 4, 5, 6, 7, 9, ② 12, 15, 16, 17, ③ 18, 19, ④ 20, 25, 27, ⑤ 28, 31, 32, 33, 34, 36, ⑥ 39, ⑦ 41, ⑧ 42, 43, 44, 50, 51, 55, 56, 57, 58, 59, 60, 61, 62, 64, 66, 67, 68, 69, 79, 80, 81, 82, 83

FAST Food

**Table 5: Identify an Opportunity and Plan for Improvement**

	<p><u>PLAN</u></p> <ul style="list-style-type: none"> <li>• Step 1: Get Started</li> <li>• Step 2: Assemble the Team</li> <li>• Step 3: Examine the Current Approach</li> <li>• Step 4: Identify Potential Solutions</li> <li>• Step 5: Develop an Improvement Theory</li> </ul> <hr/> <p><u>DO</u></p> <ul style="list-style-type: none"> <li>• Step 6: Test the Theory</li> </ul> <hr/> <p><u>STUDY</u></p> <ul style="list-style-type: none"> <li>• Step 7: Study the Results</li> </ul> <hr/> <p><u>ACT</u></p> <ul style="list-style-type: none"> <li>• Step 8: Standardize the Improvement or Develop a New Theory</li> <li>• Step 9: Establish Future Plans</li> </ul>
<p>Source: Embracing Quality in Public Health: A Practitioner's Quality Improvement Guide, Ch 4, pages 28-39</p>	

**Table 6: Logic Model—Risk Factor Study Data Collection Manual**

