

III. Methodology

In order to detect trends of improvement and/or regression from the 2010 baseline measurements, it was critical that the methodology used to collect data, as well as the study design, remained consistent for each data collection. The following sections of the report present an overview of the methodology used in this study.

A. Selection of facilities

For this study, nine facility types were chosen from three different segments of the foodservice and retail food industries. The selected industry segment samples provided coverage of general and highly susceptible populations, and also covered most of the industry segments regulated by the retail food inspection program. Highly susceptible populations are defined as a group of persons who are more likely than other individuals to experience foodborne illness because of their current health status or age.

The chart below reflects the 3 industry segments and 9 facility types selected for the survey. Sample sizes (n) for each type are shown. Using FDA's Data Collection Manual (2003), Wake County randomly determined the appropriate sample size to achieve statistical significance for each type facility for each industry segment, and randomly selected 447 facilities for the survey.¹

Industry Segment	Facility Type
Institutions	Hospitals (n=6) Nursing Homes (n=33) Elementary Schools (n=57)
Restaurants	Fast Food Restaurants (n=87) Full Service Restaurants (n=87)
Retail Food Stores	Delis (n=57) Meat Markets (n=59) Produce Departments (n=38) Seafood Markets (n=23)

Selection Criteria: Using the list of operating facilities in the county, each facility was categorized according to type and risk category (Appendix M). Using the definitions on the following pages, each establishment was categorized as a facility type. For each facility type, the following logic was used to select the group for consideration in the sample:

- **Hospital** food service establishments (n=6) were selected from those facilities that served each of the County's six hospitals. Hospital cafeterias in Wake County are

¹ FDA Data Collection Manual, "Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors," page 12.

classified by the North Carolina Department of Environment and Natural Resources (NC DHHS) types #01 or #16. Because of the low sample size, all hospital cafeterias were included in the study.

- **Nursing Home** food establishments (n=33) were selected based on the NC DHHS type #16. Each of these food establishments serves clients from nursing facilities.
- **Elementary School** food establishments (n=57) were selected from the list of private and public school lunchrooms with a risk category of 4. These facilities served school children from grades K-5.
- **Fast Food Restaurants** (n=87) were selected from NC DHHS types #01 and #02 that had a risk category of 2 or 3. The sample did not consider the type of service provided by the fast food establishment, i.e., counter, wait or drive-through service.
- **Full Service Restaurants** (n=87) were selected from NC DHHS types #01 and #02 that had a risk category of 4.
- **Delis** (n=57) were selected from the raw data by considering the word “deli” in the name of the establishment. These were most often associated with a retail grocery store. In addition, other facilities were selected based on the definition used in Annex 1.² Delis typically slice meats and cheeses; however, they may serve cooked foods and deli salads.
- **Meat Markets** (n=59) were selected from the NC DHHS type #30. Other facilities that sold raw meat or poultry directly to the consumer were also considered.³
- **Produce Departments** (n=38) were selected from facilities that cut, prepare, store or display produce. These facilities were often associated with retail grocery stores. Facilities were flagged for consideration if they had “produce” or “salad bar” in their facility name.
- **Seafood Markets** (n=23) were selected from facilities that sell seafood directly to the consumer, including raw and/or ready-to-eat product. Seafood restaurants were not considered for this category, but were considered for fast food or full service restaurants.

Risk categories: Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the populations served all have a bearing on the occurrence of foodborne illness risk factors in retail and foodservice establishments. The 2015 Wake County baseline survey used the State’s category flow chart in Appendix M.

² FDA Data Collection Manual, “Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors,” page 43.

³ Ibid.

B. Random Selection of Establishments

The project manager generated a list of types of facilities, and then randomized the list in a Microsoft Excel spreadsheet. A sample number was assigned to each facility, including the first 10 substitutes, which were numbered sequentially. Data collectors were assigned facilities to evaluate. If a facility was no longer in business, the surveyor would be assigned the next substitute on the list.

Staff completed the surveys for each facility type before proceeding to the facility type. This allowed staff to focus on similar process associated with a facility type.

C. Selection of Data Collectors

The same survey team from 2010 was used to conduct the surveys in this study. Staff was trained by the FDA regional retail food specialist who initially accompanied staff to several facilities to perform surveys.

Staff met weekly to discuss the process, clarify questions, and review colleagues' data collection forms. Throughout the process, staff consulted with the FDA regional retail food specialist.

D. Geographical Locations

To minimize travel costs, staff was assigned facilities in a particular geographic area. Staff surveyed the sample in the following order: Institutional (Hospitals, Nursing Home Kitchens, Elementary School Cafeterias), Restaurants (Fast Food and Full Service) and Retail Food Stores (Deli, Meat, Produce and Seafood). Retail food stores were grouped by address, and all types located at that address were surveyed at a single visit.

E. Baseline Data Collection Procedure

The 5 major risk factors contributing to foodborne illness identified by the CDC provided the foundation for the data collection inspection form. See Appendix O, "2015 Data Collection Form". For each risk factor, Food Code requirements were identified and grouped into individual data items on the inspection form. See Appendix N, "2015 Reference Sheet." An additional risk factor, "Other," was used to capture the potential food safety risks related to possible contamination by toxic or unapproved chemicals in the establishment. Data related to Certified Food Protection Manager (CFPM) was also captured.

Unannounced visits to selected establishments were designed to be observational rather than regulatory. The surveyor was not the regularly assigned staff person for that facility. If observations merited regulatory action, the survey representative would ask for correction of the condition and follow up with the environmental health specialist (EHS) assigned to that facility to ensure long term correction.

F. Baseline Data Collection Form

The 2015 Data Collection inspection form (Appendix O) contained 46 individual data items. For each of the 46 observations, the EHS determined whether the item was:

- IN=Item found “in compliance” with 2013 FDA Food Code provisions.
- OUT=Item found “out of compliance” with 2013 FDA Food Code provisions. An explanation was provided in the comment section on the data collection form for each “out of compliance” observation.
- NO=Item was “not observed.” The “NO” notation was used when an item was a usual practice in the food service operation, but the practice was not observed during the time of the inspection.
- NA=Item was “not applicable.” The “NA” notation was used when an item was not part of the food service operation.

The same data collection form was used at each establishment. The completed data collection inspection forms were sent to a project manager. Before data entry, the project manager thoroughly reviewed each form to ensure reporting consistency.

G. Quality Control

To ensure quality control, staff met weekly to discuss issues and to ask questions. Staff consulted with the FDA regional retail food specialist frequently for interpretation. E-mails have been archived for future reference.

After the data sheets were collected and reviewed, the project managers cross-referenced the entries on the raw data sheets with the electronically entered data to ensure accuracy in transfer to the electronic database. Final tabulations were audited by an outside staff person to confirm the results of the study.

H. Average Time per Data Collection

During data collection, Wake County tracked the actual time spent in each of the inspected establishments. Table 6, that appears on the following page, presents the average data collection time, in minutes, for each of the facility types and compares the 2015 study and the 2010 baseline study. Travel time and off-site report preparation were not included in the time assessment.

Table 6

**Average Inspection Time per Establishment for each of the 9 Facility Types
(Total MINUTES per Establishment)**

	Average Inspection Time (In Minutes)		
Facility Type	2015 Wake County	2010 Wake County	2008 FDA
Hospitals	64	79	138
Nursing Homes	58	56	81
Elementary Schools	33	40	91
Fast Food Restaurants	35	39	73
Full Service Restaurants	51	55	106
Deli	46	50	80
Meat & Poultry	30	28	36
Produce	29	26	33
Seafood	32	29	41