II. Methodology

A. Selection of facilities

The industry segments surveyed in Wake County's baseline risk factor study were institutional food service establishments, restaurants and retail food establishments. 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 458 facilities for the survey.[1]

Industry Segment	Facility Type
Institutions	Hospitals (n=7) 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=42) Seafood Markets (n=29)

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=7) were selected from those facilities that served each of the County's 7 hospitals. Hospital cafeterias in Wake County are classified by the North Carolina Department of Environment and Natural Resources (NC DENR) types of 01 or 16. Because of the low sample size, all hospital cafeterias were included in the study.

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

- ***Nursing Home*** food establishments (n=33) were selected based on the NC DENR type of 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 DENR 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 DENR 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 DENR type 30. Other facilities that sold raw meat or poultry directly to the consumer were also considered.[3]
- ***Seafood Markets*** (n=29) 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.
- ***Produce Departments*** (n=42) 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.

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 2010 Wake County baseline survey used the State's category flow chart in Appendix M.

B. Assignment of Facilities

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

[2] FDA Data Collection Manual, "Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors," page 43.
[3] FDA Data Collection Manual, "Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors," page 43.

10 substitutes, which were numbered sequentially. Data collectors were assigned facilities to survey. 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 next one. This allowed staff to ask questions and standardize the process each week.

C. Selection of Data Collectors

Staff with knowledge of the risk factors and the 2009 Food Code was selected to perform the data collection process. Eight county staff and one regional environmental health specialist assisted with the survey. Staff was trained by the FDA regional retail food specialist who 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. E-mail correspondence was archived and used for reference throughout the process.

D. Geographical Locations

Selected facilities were located across the county. 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, Seafood and Produce). 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 CDC provided the foundation for the data collection inspection form. See Appendix O, "2010 Wake County baseline survey instrument." For each risk factor, Food Code requirements were identified and grouped into individual data items on the inspection form. See Appendix N, "Baseline Data Collection 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.

Unannounced visits to the selected establishment 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 correction.

F. Baseline Data Collection Form

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

- IN=Item found "in compliance" with Food Code provisions.

- OUT=Item found "out of compliance" with 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.