

Risk Factor Study Sharing Session
Panel Discussion Session II-Questions and Answers

Background:

The [first NACCHO Risk Factor Study Sharing Session](#) focused on the purpose, objectives and benefits of conducting a risk factor study in your jurisdiction. The session also covered the specific criteria within Standard 9 of the Voluntary National Retail Food Regulatory Program Standards.

The second session focused on the mechanics of actually conducting a study based on the experiences of two very different jurisdictions. What did they have to plan and decide before starting the field data collection part of the study? This discussion will hopefully help jurisdictions in designing and conducting a risk factor study. Every jurisdiction has different needs and different levels of resources to conduct a study. There is no one set way to conduct a study. Jurisdictions must make the best choices based on the resources and limitations within their programs.

Facilitator and Panelist Backgrounds:

Donna Wanucha served as the facilitator. Mrs. Wanucha is a Retail Food Specialist in the U.S. Food and Drug Administration's Office of State Cooperative Programs. She is responsible for supporting state, local and tribal retail food programs through their involvement in the Voluntary National Retail Food Regulatory Program Standards and adoption of the FDA Food Code. Mrs. Wanucha has worked for FDA since 2004, and previously worked at state and local health departments and in the food industry. She graduated from The Ohio State University with a degree in Microbiology and served in the US Army.

Panelists

Christine Sylvis began her career in Environmental Health after earning her Bachelor's degree in Biology from the University of Nevada, Las Vegas. She was hired by the Southern Nevada Health District (SNHD) in 1999 where she worked for many years in the Food Operations Program. She transferred to the Training Office in 2008 where she is currently an EH Supervisor. Her responsibilities include supervising the HACCP/Special Processes Team, providing continuing education and training for all EHSs, grant coordinator for multiple grants, overseeing continuous improvement on Retail Food Program Standards, providing industry training, and serving on the SNHD Accreditation and Quality Improvement and Training teams. She has been a FDA Standardization Officer since 2009, was a member of Council 2 for the 2014 & 2016 Conference for Food Protection (CFP), is active on 2 CFP committees, and has been an active member of NEHA, NVEHA, and the Nevada Food Safety Task Force since 2006.

Meg McGuire is the Environmental Health Programs Coordinator for Environmental Health in Rockingham County, North Carolina and has been an Environmental Health Specialist for 16 years. She supervises three Registered Environmental Health Specialists who conduct Food, Lodging, Institutions, Child Care Center, School Building, Public Swimming Pool and Tattoo inspections along with conducting Lead Poison Investigations within the Food Protection and Facilities Program. Rockingham County enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards September 2014 and currently meets Standards 1 and 4. They have completed their Risk Factor Study and are preparing to submit it for verification.

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Jurisdiction Backgrounds:

Southern Nevada Health District (SNHD): Speaker is Christine Sylvis

- The SNHD is the local health authority for Clark County, Nevada; in fact we used to be called CCHD. Our jurisdiction includes not only the Las Vegas metropolitan area, but 5 incorporated cities and many unincorporated communities, most of them in rural areas of the county. As the nation's 14th largest county, Clark County covers approximately 8,000 square miles and serves a population of more than 2.2 million residents representing almost 75% of the state's population. In addition, Las Vegas averages of over 46 million visitors per year.
- We are governed by a Board of Health with representatives from all major cities and Clark County, as well as professional representatives.
- The Southern Nevada Health District's mission is "To assess, protect, and promote the health, the environment, and well-being of Southern Nevada communities, residents, and visitors" in support of the vision "healthy people in a healthy Southern Nevada."
- Within the Environmental Health Division we have 154 staff to support our programs which include solid waste management, childcare, tattoo/body piercing, public accommodations, mobile home parks, schools, aquatic health, vector control, Facilities Design Assessment and Permitting (plan review), training, special processes (who approve HACCP plans and waivers), and of course our largest program Food Operations.
- The Food Operations Program is responsible for regulating approximately 20,000 annual permits and more than 5,000 temporary food establishments per year. Food facility staff is 89 strong consisting of 51 Environmental Health Specialists (district inspectors), their management team of 5 Senior EHSs, 5 supervisors, and one manager. Also supporting food operations are 10 staff in Facilities Design Assessment and Permitting, 10 staff in Special Programs, 7 staff in Training and Special Processes, and one director.
- We regulate all food facilities including packaged food stores, drinking establishments, processing facilities, warehouses, mobile vending, and restaurants. Las Vegas is one of America's hottest restaurant markets. Of course the chef's are very innovative, keeping us on our toes with special processes. Not only will you find celebrity-chef restaurants, (I've recently heard them referred to as destination restaurants), mega-buffets that serve thousands of covers per day, five-level nightclubs offering an "all-encompassing nightlife experience", but also vibrant international cuisine representing nearly every ethnicity. Las Vegas has one of the nation's top-rated Chinatowns and is known as Hawaii's unofficial 9th island.
- We write our regulations which are approved by the Board of Health and the State of Nevada. We are in the process of updating the regulations, but our current version was last updated in 2010 and incorporated mainly the 2005 FDA Food Code with a few parts of the 2009 FDA Food Code.
- As for our history with the Standards... well it's been a bit complicated. We enrolled in 2001 and completed an initial self-assessment in 2003. Then, due to numerous circumstances, opted out of the Program standards in 2009. In 2012, we were in a better place and had a new management team, so we re-enrolled and completed a self-assessment in 2015. I offer that information for those who may not be active in the Standards, don't dismay, you can always revitalize your efforts.

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- I'd like to take a second to recognize and thank the NACCHO Mentorship program. In Cohort 4, we were a mentee with the goal of completing a self-assessment and it was a great experience that I encourage everyone to apply for.
- Being involved in the program really jump-started our work on the Standards. Without applying for the program, I don't know if we would have completed our self-assessment in time which allowed us to apply for the FDA 5-year cooperative agreement which we were awarded. We have also been lucky enough to be a mentor in Cohorts 5 and 6 of the NACCHO Mentorship Program.

Rockingham County, North Carolina: Speaker is Meg McGuire

- Rockingham County is as far opposite of Southern Nevada Health District as you can get.
- Rockingham County is one of 100 counties in the state and encompass 573 sq. miles with a population around 93,000 and are located at the Virginia State line just below Martinsville and Danville Virginia and just above Greensboro North Carolina
- The county is governed by a Board of County Commissioners and a County Manager and also have an advisory Board of Health and Human Services which is made up of medical professionals, engineer, consumers and County Commissioners
- The Office consists of an Environmental Health Director, 2 Environmental Health Programs Coordinators (one in OSWW & Wells and one in Food, Lodging, Institutions, Child Care Centers, Public Swimming Pools, Tattoos and Childhood Lead Prevention Programs) and 6 Environmental Health Specialists (3 in each program).
- The Food, Lodging, Institutions, Child Care Centers, Public Swimming Pools, Tattoos and Childhood Lead Prevention Programs is responsible for regulating 292 retail food establishments which includes restaurants, food stands, meat markets, school lunchrooms, hospital/nursing home cafeterias, mobile food units/pushcarts and amateur athletic concession stands which is about 809 inspections a year. The program also issues around 60 temporary food establishment permits at local festivals each year. In total, the staff conducts about 1,200 inspections each year and issue about 145 permits.
- Rockingham County enrolled in the Program Standards September 2014. They completed their first self-assessment August 2015 and currently meet Standards 1 and 4 and are waiting on a verification audit of Standard 9.

Questions and Answers Topics

1. Initial Steps
2. Study Design
3. Choosing Staff
4. Training Staff
5. Time Commitment
6. Lessons Learned
7. Final Thoughts
8. Miscellaneous

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Question 1: Embarking on the risk factor study involves many decisions being made regarding how you chose to design your study, selecting staff and training them as well as keeping quality assurance on track. To begin our conversation, can you each talk a bit about the initial steps you made once you decided to move forward on conducting a risk factor study?

Answers 1:

Meg (Rockingham County, NC)

- I discussed with the Environmental Health Director in September 2015 about the value of completing a Risk Factor Study now that we had completed our first self-assessment to use as a baseline of where our program was at the beginning of our enrollment in the Program Standards and also pointed out that it could be used for Accreditation Activity 4.2 which is the requirement in North Carolina for Local Health Departments to monitor exposure to Environmental Health Risks. For our next step we discussed it with our Health and Human Services Director who gave us permission to apply for a grant through NACCHO and if awarded permission to proceed with the study.
- Rockingham County was awarded a NACCHO Grant of \$7,000 in November 2015 and we were partnered with Fairfax County Virginia to give us guidance on completing our Risk Factor Study
- We also talked with our FDA Retail Food Specialist early in our planning stages.

Christine (SNHD):

- We were fortunate in that conducting a Risk Factor Study was in our strategic plan and a grant deliverable, so we already had support from management.
- Early on in the planning stage, we talked to our FDA Retail Food Specialist and he reminded us that we could do all facility types at once or we could split up the facility types into different years... for instance year 1 restaurants, year 2 institutions, year 3 retail food stores.
- We knew that we wanted to closely mirror the FDA methodology for selecting facility types and collecting data. First, we had to determine how many fast food and full service establishments we have since we do not categorize them that way. We use Risk Categories based on FDA definitions. So, we had to use our data management software to run a report on the specific Risk Category 2 and 3 restaurants we were looking for then had to manually go through over 5,000 facilities to determine if they were full service, fast food, or did not qualify using the FDA definition from their risk factor study. For full service restaurants, customers usually order from the table and pay after the meal; for fast food restaurants, customers pay before the meal, usually at a counter.
- After we determined how many of each type of establishment we had, we met with the EH Director, EH Manager, and an informatics specialist from Community Health to decide the confidence level we were comfortable with and how many staff to use to gather RF data. I'll let you know the result of that meeting in a moment.

Question 2:

Study design is a big part of preliminary work, how did you make your decision to perform a separate study rather than inspectional data? What resources did you have to conduct the study (IT, staff) Design of the data collection tool? Determining sample size? Categorization of facilities? Paper vs. tech data collection tool?

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Answers 2:

Christine (SNHD)

- From the very begging, we developed an action plan, as advised by our FDA Retail Specialist, which included action steps for each planning milestone, persons involved, and completion dates to keep us on track.
- We have been using EnvionConnect data management software by Acella (formerly Decade), since 2011, but have only been fully electronic using tablets in the field since 2016. However, since our inspection report combines some of the risk factor study data points we wouldn't be able to get the detail we wanted if we used historical inspectional data. For example, handwashing and bare hand contact are under the same violation number on our inspection report. So, under handwashing, we would not be able to differentiate between a failure of when to wash and how to wash or the difference between compliance in handwashing and bare hand contact... the software is not able to separate that data. We decided that we wanted more specific data and to stay consistent with the FDA's Risk Factor Study questionnaire.
- In this step of the planning phase we were not sure how many data collection surveys we would be able to conduct so we determined sample sizes for 4 confidence levels to give us an idea of what kind of a time commitment we were looking at. You can see the results on the slide. After the manual calculations, we came up with 2,362 fast food permits and 2,159 full-service permits we determined sample sizes for 4 confidence levels that qualified for the RFS. You will have to stay tuned to see what we chose.

Confidence Level	# of Fast Food Permits	# of Full Service Permits	Total # of Data Collections
95%±5%	331	327	658
90%±5%	243	241	484
95%±10%	93	92	185
90%±10%	66	66	132

- As a large health department, we have an IT staff of 22, but they were not needed since we fortunate to have the FDA ask us to beta test the FoodSHIELD database. We made a "cheat sheet" to gather information and take notes during the data collection. Some chose to use their tablet with wifi to enter the data into FoodSHIELD immediately after the survey while on-site (like you would an inspection), and some did several surveys with detailed notes then entered them into the database back in the office.
- Another decision we had to make during study design was how to handle differences between our regulations and the Food Code. As I mentioned before, we write our own regulations and there are a few items that are different from the Food Code. We wanted to have consistent data that would be comparable in the next iteration of the study. Since we are in the process of updating our regulations and expect them to match the Food Code even more closely, we expect to meet Standard 1, we chose to use the 2009 FDA Food Code as the standard for the Risk Factor Study to allow for better comparison to national data.
- Another tool to create sample sizes is <https://www.surveymonkey.com/mp/sample-size-calculator/>.

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Meg (Rockingham County, NC)

- At the time of our study we were down one inspector and decided that the best way for us to complete all of our inspections as required in North Carolina, we would combine the regular compliance inspection with the survey.
- In the early stages of our planning, we had to determine how many retail food establishments we had in each of the 4 FDA facility types (Restaurants – Full-Service or Fast Food, Institutions, School Cafeterias and Retail Food – Delis and Meat Markets). This was a little challenging because it was slightly different from how establishments are categorized in North Carolina (Restaurants, Food Stands, Mobile Food Units, Push Carts, Limited Food Stands). At the time of our survey, Rockingham County did not have any permitted produce or seafood markets.
- I use Microsoft Excel to keep track of all of our establishments in Rockingham County by having a Master Establishment list that I keep current and normally use that data each year to create establishment inspection lists for each of the 3 inspectors. Using this Master List, I was able to create a new Establishment list with the FDA Facility types that was numbered showing the total number of establishments in each Facility types. Using www.randomizer.org, I was able to create randomized numbered lists which determined the establishments that would be surveyed in our study along with alternates.
- Once we had our randomized lists, we then were able to determine our sample sizes and then which sample size we wanted to use. We decided to use the 95/10 sample size due to staffing shortage.

Facility type	Establishment inventory	Sample size (95/5)	Sample size (95/10)
Full service restaurants	94	76	48
Fast food restaurants	92	75	48
Schools	26	25	21
Hospitals	2	2	2
Nursing homes	12	12	11
Deli	10	10	10
Meat	15	15	14
Total	251	215	154

- We also decided to use the paper surveys for our study. They were easy to carry and jot down notes during the survey. During our training with our FDA Regional Specialist, she told us that we did not have to make a decision at the time of the survey as to whether or not an item was in/out of compliance based on the current FDA Food Code (2013) which is slightly different than NC regulations that are based on the 2009 Food Code. We could just take notes during the survey and complete the form later. That was very helpful when we had questions and could send them to our FDA Regional Specialist for clarification.

Question 3: What about choosing staff to conduct the study? Did everyone participate or just a few?

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Answers 3:

Meg (Rockingham County, NC)

- Since we are a small county with a staff of 4 (3 at the time of the survey) food inspectors, we decided that all of retail food inspection staff would work on this study.

Christine (SNHD)

- The Food Operations leadership team was included on deciding how many staff to use to conduct the study since it impacted their staff. We settled on a small number of data collectors for consistency, and the impact to the offices. One EHS from each of the 5 Food Operations offices, plus a back-up in case they were not able to participate, were designated by the supervisor as a data collector ... so a total of 10 data collectors were trained with expectation of using up to 5.
- Back to that meeting with Informatics and EH Management, we came up with a unique approach to conduct the Risk Factor Study. Random lists were developed to cover the 658 restaurants required to achieve a confidence level of 95% ± 5%. Here's where it gets interesting...we decided on a two phases approach: In phase one, only two of the five data collectors would collect data on the first 132 facilities to achieve a confidence level of 90% ± 10%. Once phase one was complete, a determination would be made as to the feasibility of completing the remaining 526 restaurants by the other 3 data collectors.
- Although we were using a small number of EHSs for data collection we wanted all inspectors to have the opportunity to experience the risk factor study survey and observe the information that was collected first-hand. All inspectors were encouraged to accompany the data collectors on a survey. We also assigned new hires in training to accompany the data collectors. As a result, the data collectors had someone to take notes on the cheat sheet for them on the majority of the surveys which was a huge help to them.

Question 4: How did you train staff on the data collection tool? How did you ensure everyone stayed on the same page (QA)?

Answers 4:

Christine (SNHD):

- Fortunately, our FDA Specialist was available to come train our staff on using the data collection form. During the training, interpretation of the data items, marking instructions, and how to conduct the data collection was explained in detail. He was also able to conduct webinar training on data entry into FoodSHIELD. Also, each data collector was given a hard copy of the *FDA Protocol for the Data Collection in Restaurant Facilities* which contains marking instructions in Appendix A that they could reference to properly mark the form IN, OUT, NO or NA.
- For quality assurance, the data collectors and I, as the project coordinator, conducted a few of the initial surveys together, each taking the lead with the others observing. In the middle of the study, I went out with each of the data collectors again to evaluate consistency. Since we only had a few data collectors, they communicated with each other often and would talk about how they handled the unique situations they encountered.

Meg (Rockingham County, NC):

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- When we called our FDA Retail Specialist early in the planning stages, she was able to sign us up for a webinar training about using the new FoodSHIELD Risk Factor Database and she was also able to come to our county to train myself and my staff on how to correctly fill out the survey forms. She was also able to with us on our first surveys and make sure we were filling out the form correctly.
- It was a little challenging in the beginning because we had to remember that the surveys were based on the most current version of the Food Code and not on North Carolina regulations. The main difference for us was that North Carolina still allows cold holding at 45F instead of 41F.
- Since there were only 3 of us working on the surveys, we checked each other's survey forms for errors before entering into FoodSHIELD.

Question 5: Time management - how long did it take you to complete the data collection? How many facilities were in your study and how many people were collecting the data?

Answers 5:

Christine (SNHD):

- Before starting the RFS we wanted staff to know what was going on and allow them to have input, so an informational briefing describing the Study, its importance, and the general plan to accomplish it as delivered to the Food Ops Leadership Team. Once they were on board, the briefing was presented to EHSs during a Staff Meeting in December 2015. This way all staff were informed and could talk to their supervisor if they were interested in participating. In January 2016, the FDA protocol was issued to 10 data collectors, assigned by their supervisors, for their review followed by the 5-hour training session with our FDA Retail Food Specialist. In February 2016, the meeting with Informatics and EH Management was held resulting in the two-phase plan I discussed earlier. Also in February, the data collectors attended an FDA webinar to learn to use FoodSHIELD, the web-based database. Between February 22 and July 19, 2016, data was collected on 66 full service and 68 fast food facilities (134 facilities total). In the middle of that timeframe, a third data collector was added in order to meet timeline in the action plan. At that time, it was determined to use the 90% ± 10% confidence level and conclude the data collection. The official Risk Factor Study Report was completed on September 19, 2016.
- The data collection surveys took about double the time as a routine inspection. In addition, entry into Food SHIELD took about 20 minutes per survey.
- Since we worked so hard to gather this information, we wanted to share it. The results of the Study were presented to Food Ops staff during a staff meeting, to the BOH at one of their meetings, and to industry during a Food Safety Partnership Meeting.

Meg (Rockingham County, NC):

- Since we completed the surveys as part of our regular compliance visits, the surveys added about 20-30 minutes to our inspections once we got familiar with the questions and form.
- We completed 156 surveys total in approximately 5 months (mostly due to completing them during regular compliance visits)
- Entering the surveys into FoodSHIELD also took us about 20-30 minutes, longer if there were errors. FoodSHIELD has its own QA check, so sometimes if you did not enter a temperature or

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comment for one of the questions when it was required, it would not accept the survey until corrected. I entered the majority of the surveys into FoodSHIELD when I had office time which took approximately 3 months. I started to enter them while still collecting the surveys and had them completely entered two months after we had completed the surveys.

Questions 6: What lessons did you learn in conducting your risk factor study? What changes did or do you plan to make for the next data collection? Why?

Answers 6:

Meg (Rockingham County, NC)

- The main thing we learned was that if you would like to use the Risk Factor Study to meet Program Standard 9, you need to add question 17 which covers Food from Approved Sources. The 10 core questions only cover 4 of the 5 CDC Risk Factors and you need all 5 to meet this Standard. We were fortunate that we had completed our compliance inspections at the same time as the surveys, so we were able to go back and answer this question for all 156 surveys.
- We would like to possibly add in some of the optional questions on our next study in 2021

Christine (SNHD)

- As the study was an extra responsibility on top of a large workload for the data collectors, it was important that their supervisor and fellow inspectors were supportive and willing to help keep up their workload.
- Splitting up the facility types into different years (year 1 restaurants, year 2 institutions, and year 3 retail food stores) was definitely the way to go for us. Using smaller sample sizes yearly is more achievable than a large sample size once. This will also allow us to repeat the study every 3 years rather than 5 if we decide to go that way. We feel that conducting the study more frequently will give us better data to ascertain if intervention strategies are effective.
- We are also happy with our decision to use a small number of data collectors. This carried over to institutions last year when we used 2 data collectors for the sample size of 52. We will also be using 2 data collectors this year for retail food stores. Although there is a great impact to the workload of the few data collectors, this can be absorbed by assistance within the office. Overall, this approach is a lesser impact to the Division as a whole compared to if we used a larger number of data collectors. Also, by default, it results in less training and more consistent data.

Question 7: Final words?

Answers 7:

Christine (SNHD)

- Update staff, Board of Health, and industry; publish the final report (The SNHD Risk Factor Study Report can be found at <http://www.southernnevadahealthdistrict.org/food-operations/index.php>). Don't forget to use the results to develop an intervention strategy - involve staff and the community
- Don't underestimate the time and energy it takes to write the report.

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- Recognize collectors: David Greer (also the project lead), Meredith Garman, and Mikki Knowles. Of course, CHO Dr. Iser and EH Director Jackie Reszetar for their support. And always John Marcello, our FDA Retail Food Specialist.

Meg (Rockingham County, NC)

- Write a report on the outcomes of the study and share them with your staff, facilities and Board of Health. You don't need to start from scratch, reach out to other jurisdictions that completed a risk factor study to see their reports and use them as a starting point for your own. You also don't need to write a long report, in order to meet the standards you just need to show the results of the study that you can get from running reports in FoodSHIELD.
- Link to Rockingham County's Report:
<https://rchealth.municipalcms.com/files/documents/2016RockinghamCountyRiskFactorStudyofFoodborneIllnessRiskFactors1037032039091417PM.pdf>

Additional Q&A's

Question 8: Where can I find the paper version of the risk factor study collection survey?

Answer 8: Please contact your regional Retail Food Specialist. Find your specialist at <https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm394716.htm>.

Question 9: When people are aware that they are being watched, they conduct a job-related tasks differently. What adjustments did you make to account for this?

Answers 9:

- Meg (Rockingham County, NC): This is something that we are accustomed as part of the normal inspection process. We tried to make observations that were not obvious to the employees, however, employees were probably on their best behavior because we are there. The best scenario would be to do the surveys separate from compliance inspections. Once employees know that your visit is non-compliance, they tend to behave like they normally do.
- Donna Wanucha (FDA): In my experience, even when people are being watched, although indirectly as we are doing other tasks such as taking temperatures, they revert back to their normal habits. Other studies of food employees on camera have noted the same response, they are alert at first but then relax and go back to their normal routine. The FDA risk factor study made no adjustment.
- Christine (SNHD): We took this into consideration when we decided to conduct data collections separately from routine inspections. Upon arrival to a randomly selected facility, we identified ourselves and stated the purpose for the visit as a data collection survey and educational opportunity for the operator. We explained that it was not a regulatory inspection and demerits would not be issued; we wanted to have a candid discussion and make observations to determine the risks in our community.

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Question 10: Is it feasible to incorporate data collection into existing inspection workflow without a supplemental survey?

Answers 10:

- Meg (Rockingham County, NC): I think that you could incorporate the survey questions into inspections. That is one reason that we decided to do the surveys at the same time as our inspections because it felt like we were completing an inspection. You just need to be detailed about documenting violations and make sure that all questions are addressed during an inspection to use when filling out the survey form in FoodSHIELD.

Question 11: We completed the entire form, 19 questions and the Assessment for one Risk factor. Are you saying we only had to do questions 1- 10?

Answers 11:

- Meg (Rockingham County, NC): If you are using the new FDA protocol and FoodSHIELD, you are only required to answer questions 1-10 on the survey. I would add in question 17 for approved sources if you would like to use the survey towards meeting Standard 9.
- Donna Wanucha (FDA): In order to meet the requirements of Standard 9 you need to complete risk factor study of the 5 risk factors, analyze the data from the study (create a report), and design targeted interventions strategies based on the highest priority behaviors that the study has identified. The questions on the current FDA survey form that address the 5 risk factors are questions 1-10 and 17. Doing additional questions may provide other valuable data that you may use in formulating an intervention strategy for your highest out of compliance risk factors. Nothing was lost by doing the additional questions, rather information was gained that may provide more insight into the behaviors you have evaluated. Each jurisdiction must make their own best choices regarding study design based on the resources and limitations you have to complete a risk factor study and the information that you want to gather.
- Christine (SNHD): We used all 19 questions consistent with the FDA protocol.

Question 12: Have any other jurisdictions use their historical data to start their risk factor study?

Answer 12:

- Meg (Rockingham County, NC): We choose not to use historical data (past inspections) in our county for our first survey because we were not capturing all the data needed to correctly fill out the survey forms.

We also use an FDA inspection form with IN, OUT, NA & NO that is very similar to the one in the FDA Annex 7 (form 3-A), however we were not always as specific as we needed to be when recording temperatures. For example question 5 asks about cold holding and what type of cold holding equipment the food was stored in. It also wants to know what temperature raw shell

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eggs are stored at. In North Carolina, we still allow for cold holding at 45°F and on our past inspection forms this would have been marked as "In" but for the survey any food above 41°F would be out on the survey. So there were several items that we would not be able to accurately record on this question.

Question 7 is about cooling and until we were trained on how to fill out the survey, we had never calculated a cooling rate before on any of our previous inspections. For the survey, you will need to take two temperatures of cooling food and calculate the cooling rate.

Another reason is that it would have been just as time consuming going through our files to find the printed reports to pull the data from. We use an electronic program to complete our reports in the field, however, we cannot run reports for individual citations, only for the 54 items on the NC grade sheet that could possibly be marked for multiple citations each.

Question 13: When we conducted our baseline study in 2013, we used the 2003 FDA Data Collection Manual which included a table showing minimum sample size for each facility type. What confidence level was that table based on?

Answer 13:

- Donna Wanucha (FDA): The sampling approach in the 2004 FDA Date Collection Manual calculated sample sizes using the following criteria:

If a particular baseline item (observation) has a compliance rate of no more than 60 percent, we want to have a high level of confidence that our data will show a compliance rate that is no more than 70 percent.

This method does not specify a confidence level or a precision level. What it does is minimize the probability of having a sample with a compliance percentage of 70% or more when the population has a compliance of less than 60%. The converse is also true.