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***FOCUSING ON RISK FACTORS: STUDIES FROM
REGULATORY PARTNERS***

STANDARD 9: PROGRAM ASSESSMENT

Risk Factor Study ~ A study on the occurrence of foodborne illness risk factors within a jurisdiction

- Food from unsafe sources;
- Inadequate cooking;
- Improper hot/cold holding + Time/temperature;
- Poor personal hygiene; and
- Contaminated equipment/protection from contamination

Intervention Strategy ~ Targeted intervention on those risk factors identified during the study

SCDHEC completed its Risk Factor Study in 2019 and was partnered with PDA as they started theirs this year (2021)

STUDY REQUIREMENTS AND VARIABLES

STUDY VARIATION EXAMPLES

- Workplan and timeline
- Resources
- Definitions of facility classifications
- Exclusion criteria
- Facility randomization process
- Forms (Inspection and data input)
- Amount of inspectors and training criteria
- Marking instructions/guidelines for inspectors

STUDY REQUIREMENTS

- Must focus on the 5 risk factors
- Must include data for each facility type regulated by the jurisdiction
- Must format observations with IN, OUT, NA, NO
- Must analyze and report results
- Must create and implement measurable intervention strategies

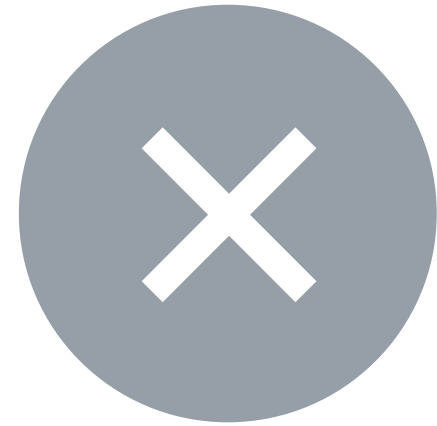
AN IDEAL MATCH FOR STANDARD 9



STATE-WIDE
JURISDICTIONS



STATE BROKEN DOWN
INTO REGIONS



FACILITY CLASSIFICATION
CHALLENGES

TIMELINES (SCDHEC)

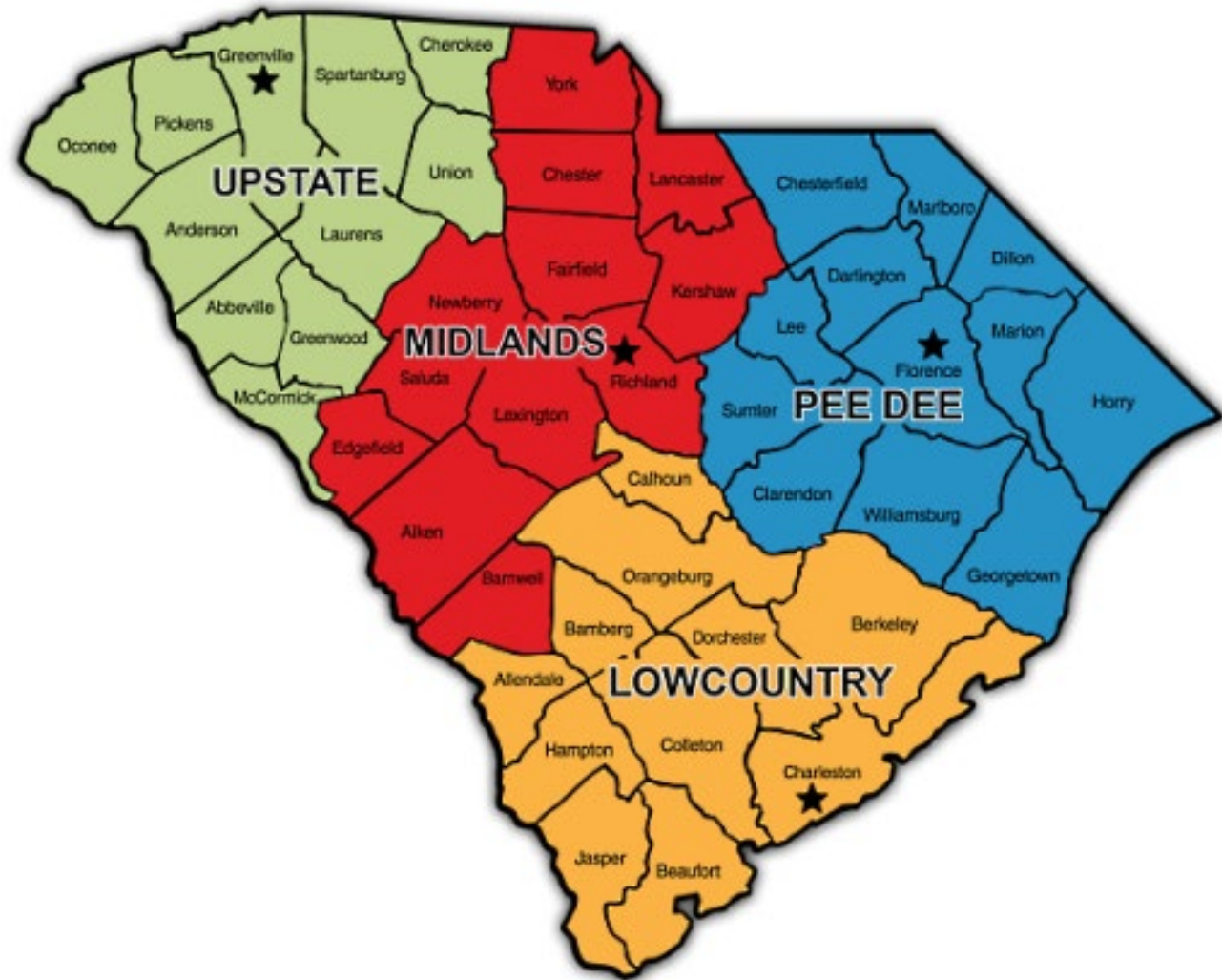
Sampling Period	Training Period	Data Collection Period	Data Analysis/Report Writing Period	Intervention Strategy Period
January – February 2019	March 2019	March – June 2019	July – August 2019	September 2019 – June 2024

TIMELINE(PDA)

Creation of Sample	Form + Field Training	Data Collection	Data Analysis and Report	Intervention Strategy Period
January – February 2021	March 2021	March – June 2021	July – August 2021	September 2021-June 2026

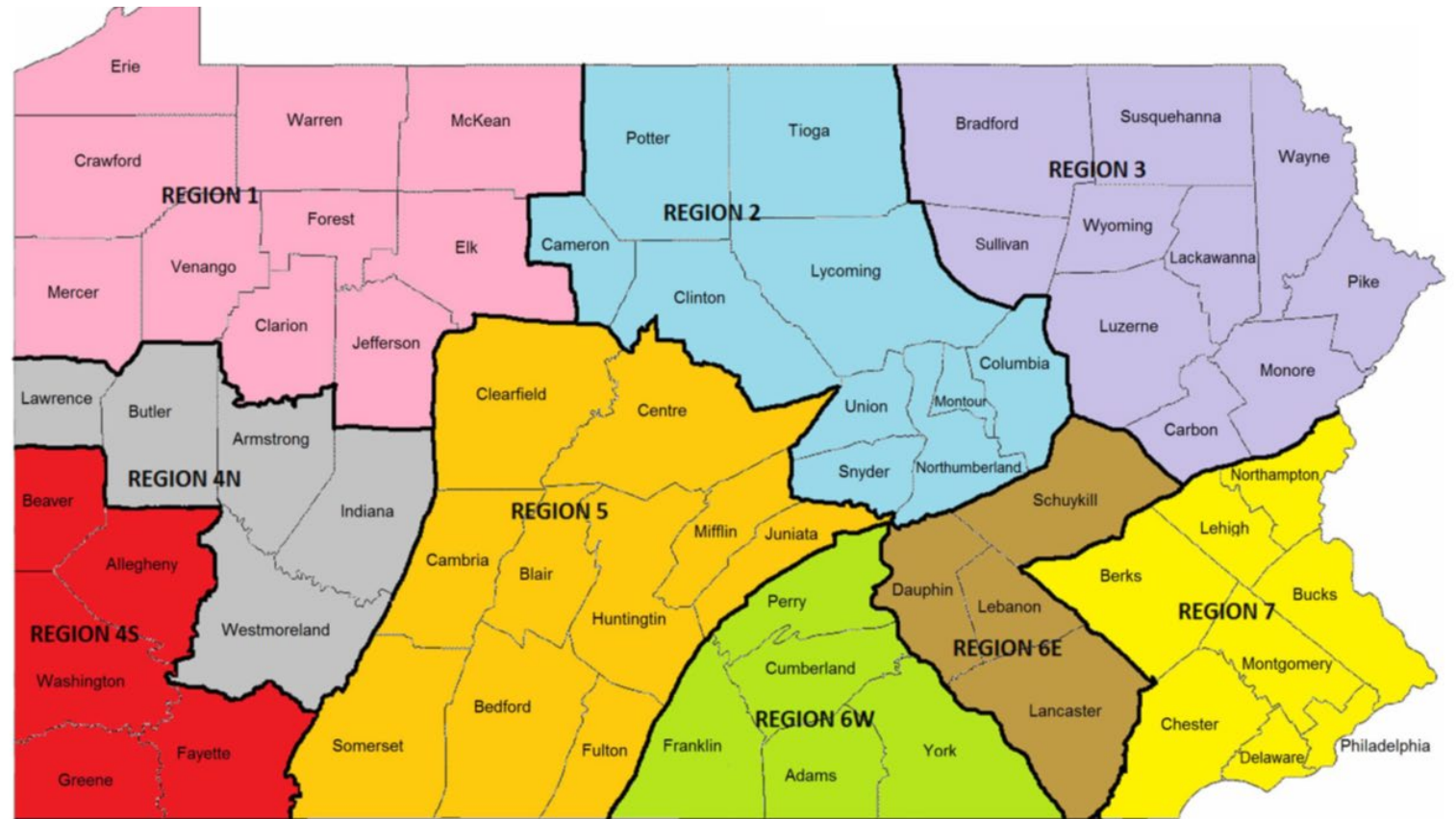
SCDHEC OVERVIEW

- Statewide jurisdiction
- 4 regions
- 16 food teams
- Over 20,000 retail food facilities
- 81 food inspection staff



PDA OVERVIEW

- Statewide jurisdiction
- Over 30,000 retail food facilities
 - 19,338 inclusion for study
- 80 inspectors cover retail, manufacturing, milk and produce
 - 26 inspectors for study
- Does not include local health (over 45,000 retail) and HSP



CHOOSING LOCATIONS (SCDHEC)

Cities =

- Highest density of retail food facilities
- Highest foot traffic (Charleston + Myrtle Beach are tourist hubs)
- Best way to maximize our data collectors' time



SAMPLE SIZE AND FACILITY SELECTION(SCDHEC)

Sample:

- 90/10 Confidence Interval
- 228 total facilities

Facility Types:

- Full Service Restaurants (17 per city)
- Fast Food Restaurants (15 per city)
- Retail Food Store Delis (12 per city)
- Schools (13 per city)

Biggest challenge: Fast Food Restaurants



SAMPLE SIZE AND FACILITY SELECTION (PDA)

Sample

- 90/10 confidence interval
- 216 facilities
- Sample locations across all 9 PDA regions statewide

Facility Types

- Retail Food Stores(8 per region)
- Restaurants (8 per region)
- Schools (8 per region)

Due to classification issues in our electronic database, these facility types were not further broken down prior to selecting facilities

Selection Process

- Exported facility list from electronic data base by facility type
- Online number generator to choose facilities
- If not obvious, inspector further verified according to definitions provided
- **Biggest Challenge:** Retail Food Stores-Finding facilities that met the definition including a deli, produce, seafood department.

TRAINING

SCHDEC

- Group Form training with FDA Specialist
- Practice Data Collection Training
 - Retail Store Deli data collection
 - One training per city (Greenville, Columbia, Charleston, Myrtle Beach)
 - All data collectors in each city participated

PDA

- Virtual Risk Factor Study Overview with FDA Specialist
- Internal PDA Virtual Training
 - Guidelines and marking instructions
 - Explaining how our forms will be used for the study
 - Importance of focusing on risk factors
 - Any additional information gathered in report's comment

*No in-person training due to COVID-19

FORM SELECTION (SCDHEC)

- Lots of internal debate/discussion!
- Ultimately, we went with the FDA Data Collection Form
- Routines were conducted alongside data collections as a compromise

DATA COLLECTION AND QUALITY CONTROL (SCDHEC)

- A total of 15 DHEC Food Safety Inspectors participated in data collection.
- Upon completion of data collection, inspectors sent the completed Risk Factor Study Data Collection Form to Central Office for review and data entry.
- FoodShield Risk Factor Study Site was used for data entry.
- FDA's Retail Food Specialist was contacted by Central Office when additional guidance was required.

FORM SELECTION (PDA)

- Decided to use our own inspection forms instead of FDA Form

Pros

- Saved time/resources
- Inspectors already have knowledge of our inspection forms
- Able to add “Risk Factor Study” into our electronic database as an inspection reason.
 - Easier to track/search
- If a randomly selected facility was due within 90 days of the study, we were able to keep the routine regulatory inspection instead of scheduling a new “risk factor only” inspection.

FORM SELECTION CONS (PDA)

Cons of using our own inspection reports:

- Can't compare exactly to FDA's risk factor study
 - Report shows results using form criteria and comparing to FDA risk factory study
- Not as many resources/examples for using regulatory inspection form for risk factor study
- Can't utilize food shield for entering report data
 - Had to manually create spreadsheets for data collection input
 - Quality assurance

DATA COLLECTION AND QUALITY CONTROL (PDA)

- 26 Inspectors
- Regulatory and Risk Factor Only inspections all used the same form
- Inspections were approved by their direct supervisors
- Inspections were emailed to PDA retail specialist
- PDA Retail Specialist monitored inspection completions, emailed reminders, quality assurance
- PDA Retail Specialist entered inspection information manually into excel forms mirroring FDA's auto populated form

OVERALL CHALLENGES (PDA & SCHEC)

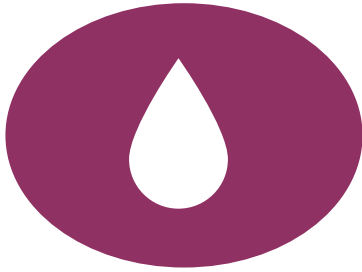
- Facility classification issues
- Quality Assurance
- Time
 - Learning about risk factor study/standard 9
 - Facility selections
 - Data collection input
 - Report

*COVID closures

FINDINGS - SCDHEC

OUT %	Full Service	Fast Food	Retail Food Store Delis	Schools
Poor Personal Hygiene	48% OUT	41% OUT	33% OUT	19% OUT
Contaminated Equipment/Protect from contamination	13% OUT	10% OUT	7% OUT	5% OUT
Improper Holding Time/Temperature	37% OUT	22% OUT	26% OUT	25% OUT
Inadequate Cooking	8% OUT	7% OUT	4% OUT	6% OUT

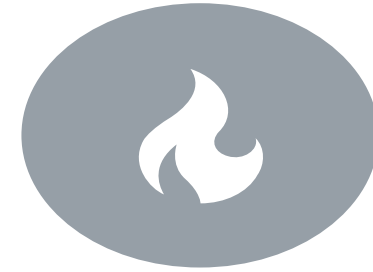
FINDINGS - SCDHEC



1. HANDWASHING



2. COLD HOLDING



3. HOT HOLDING

**WHILE THESE THREE WERE COMMON ACROSS ALL
INDUSTRY SEGMENTS, EACH INDUSTRY SEGMENT HAD
SPECIFIC PROBLEMS THAT REQUIRE INTERVENTION.**

INTERVENTION CRITERIA

- If an item got $\geq 30\%$ OUT, that item requires intervention.
- A description of planned intervention strategies are included in the Risk Factor Study report.
- These strategies are subject to change/modification depending on their efficacy over the current five-year period.
- At the end of this five-year period, another Risk Factor Study will be performed to measure improvements.



FINDINGS (PDA)

RISK FACTOR OUT% BY INDUSTRY TYPE			
RISK FACTOR	RETAIL FOOD STORES	RESTAURANTS	SCHOOLS
POOR PERSONAL HYGEINE	1.5%	1.5%	1.4%
CONTAMINATED EQUIPMENT/PROTECTION FROM CONTAMINATION	9.7%	20.1%	4.9%
IMPROPER HOLDING TIME/TEMPERATURE	11.2%	1.4%	1.2%
INADEQUATE COOKING	0%	6.1%	0%

FINDINGS CONTINUED (PDA)

“Other Items” OUT% BY INDUSTRY TYPE			
Other Item	RETAIL FOOD STORES	RESTAURANTS	SCHOOLS
Adequate handwashing sinks properly supplied and accessible	8.3%	1.4%	1.4%
Good Hygienic Practices	1.4%	3.6%	1.4%
Consumer advisory provided for raw/undercooked foods	0%	7.1%	0%
Time as a public health control: procedures & records	14.2%	23.1%	0%
Thermometers provided & accurate	4.2%	12.5%	2.8%
Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan	35.4%	22.2%	16.7%
Food obtained from approved source	2.8%	0%	0%
Toxic substances properly identified, stored, & used; held for retail sale, properly stored	8.3%	8.3%	6.9%

FINDINGS-PDA

1. **Conformance with Approved Procedures/”other”** Element 25: Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan
 - **RETAIL FOOD STORES**
 - **RESTAURANTS**
2. **Protection from contamination:** Element 14: Food Contact Surfaces Cleaned and Sanitized
 - **RESTAURANTS**
3. **Conformance with Approved Procedures/”other”** Element 21: Time as a public health control: procedures & records
 - **RESTAURANTS**

INTERVENTION STRATEGY CRITERIA(PDA)

Intervention strategies are being developed for risk factors/items that are >20% OUT of compliance

Incorporate code changes, educational and training activities, enforcement and compliance strategies

Some intervention strategies can be immediately implemented, others will require strategic planning

Intervention strategy individual plans will show how they will be measured for record keeping

FINAL RECOMMENDATIONS (SCDHEC)

- Determine the level of statistical analysis you want to perform ahead of time.
- If you don't have a tool that automatically catches errors (i.e. <https://www.retailfoodriskfactorstudy.net/member/login/>) make sure you're vigilant.
- If you want to capture data on something not included in your routine inspection form, push hard for a custom data collection form.
- Use FoodShield as a resource.

FINAL RECOMMENDATIONS (PDA)

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- Pre-plan resources for time management!
 - For the first study, if you can determine facility classifications prior to starting the study it will save time!
 - Weigh the pros and cons of using your own regulatory form vs FDA form

RESOURCES

Websites for information on standard 9 and examples of forms, reports, etc. :

- FDA VNRFRPS: <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>
- AFDO: <http://www.afdo.wildapricot.org/resources/CustomPages/AFDO/index.htm>
- NACCHO: <https://www.naccho.org/programs/environmental-health/hazards/food-safety/retail-program-standards-mentorship?searchType=standard&lhd-state=PA#resource>
- FOOD SHIELD: <https://www.foodshield.org>
- Survey Monkey for sample size and confidence interval <https://www.surveymonkey.com/mp/sample-size-calculator/>
- Randomizing generator tool <https://www.calculator.net/random-number-generator.html>
- Data Entry when using FDA Form <https://www.retailfoodriskfactorstudy.net/member/login/>

People

- NACCHO Mentor
- FDA Specialist
- Supervisor/Management Staff
- IT Department

CONTACT US!

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