Standard 8

Current Standard 8 Model

- **Purpose regarding staffing levels:**
  - Assesses the adequacy of a health department's staffing levels, by calculating if it has *an inspection to FTE ratio* within the specified FDA range
    - The range is **280 – 320 inspections per inspector**

- **Problem 1:**
  - This range was created with the belief that every food inspection regardless of establishment type would take **4 hours**. This is problematic as health departments (HD) have establishments that vary by type and risk category making the required time to complete inspections also vary.

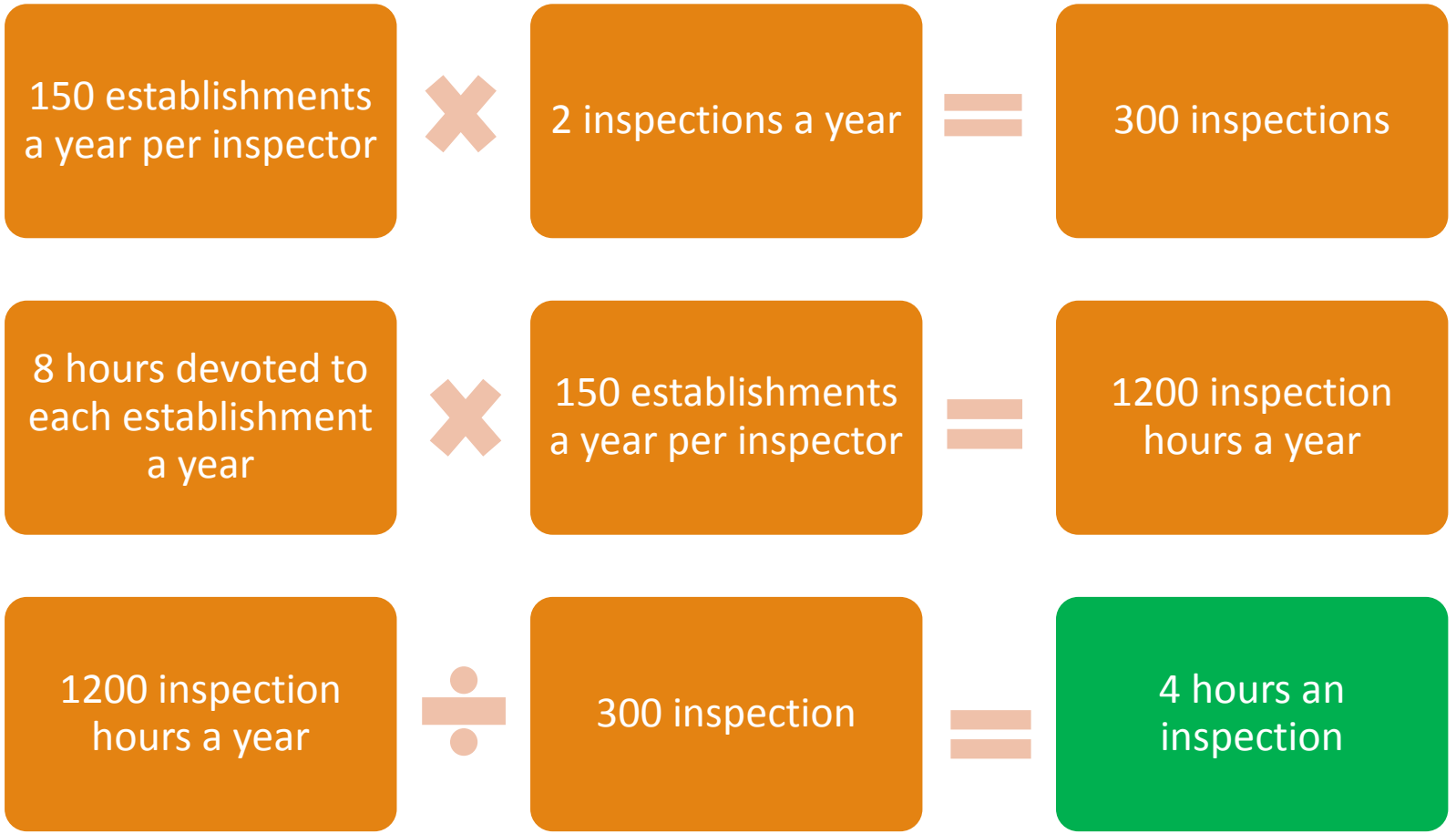
- **Problem 2:**
  - The very existence of a range creates the possibility that a HD can appear to be **overstaffed**. This creates the potential for that HD to have an *inspection to FTE ratio* that goes below the bottom value of the 280-320 range (thus making the HD fail to meet the standard). Standard 8 is evaluating if a HD has the "necessary" staff to perform the required number of inspections. If a HD has a unique need and the resources available to hire more staff than Standard 8 would require, it is not consistent with the intent of this standard to fail them.

The Logic Behind the 280-320 FTE Inspections Per Year Range

- **VNRFRPS Clearinghouse Work Group agreed that 1,120 – 1,280 inspection hours a year per one FTE "represents a reasonable range" of annual productive hours -VNRFRPS 2019 https://www.fda.gov/media/86864/download**

- This then "allows for the **same unit of measure** to be applied to all jurisdictions regardless of their procedures and processes"-**VNRFRPS 2019 https://www.fda.gov/media/86864/download**

The Logic Behind the 4 Hour Inspection



Potential Problem with these Figures

- **150 establishments a year per inspector** came from the 1961 International City Managers' Association the *Administration of Community Health Services https://babel.hathitrust.org/cgi/pt?id=mdp.39015072177739&view=1up&seq=177* book sharing that "there is no widely accepted formula on which to base the number of staff persons" but that "some local agencies" use 150
- **2 inspections a year** came from the *1976 Food Service Sanitation Manual https://babel.hathitrust.org/cgi/pt?id=umn.31951002840720j&view=1up&seq=29* that acknowledges the above 150 establishment number and adds without justification that "a minimum of two inspections of each establishment per year is required"
- **8 hours devoted to each establishment** comes from the 1997 FDA Food Code https://wayback.archive-it.org/7993/20170113023657/http:/www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm054458.htm which suggests "8 to 10 hours be allocated per establishment year" also without evidence or clear reasoning

Conclusion: There appears to be no strong justification for any of these values based on real data and research making it problematic that they are the criteria from which the 4 hour inspection time is based

Our Solution

- **It is more accurate to assess a health department's staffing levels by:**

  1. categorizing establishments into **3 risk categories**: low, moderate, high
  2. use a **standardized frequency** each risk type should be inspected a year
  3. use a **standardized inspection time** required for each risk type
  4. calculate how many FTEs it "should" take to complete all of these inspections.
  5. calculate how many FTEs the health department *"currently"* has
  6. If the health department currently has an equal or greater number of FTEs than our new standard would require they would be considered sufficiently staffed

Note: The inspection to FTE ratio and the range which sets the standard would no longer be needed and would be removed from the Standard 8 Staffing Level assessment

Why Categorize Establishments

- Standard 8 states that a "process should exist for the regulated food establishments to be grouped into at least 3 categories based on food safety risk" – VNRFRPS 2019 https://www.fda.gov/media/86864/download
- The FDA recommends categorizing food establishments into risk categories because:
  - "By focusing inspections on the control of foodborne illness risk factors, inspectors can be assured that they are making a great impact on reducing foodborne illness" – FDA Food Code 2017 https://www.fda.gov/food/fda-food-code/food-code-2017
  - "Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the population served all have a bearing on the occurrence of foodborne illness risk factors in retail and foodservice establishments" – FDA Food Code 2017
  - "With limited resources, creating a variable inspection frequency for each category will allow inspection staff to effectively spend more time in high risk establishments that pose the greatest potential risk of causing foodborne illness." – FDA Food Code 2017

Follow Other FDA Recommended Inspection Standards

- **FDA's *Manufactured Food Regulatory Program Standards 2016***

Appendix 8.2: Calculation for determining a required number of inspectors
https://www.fda.gov/media/100421/download

Risk category	Number in inventory	Inspection frequency	Average inspection time (includes travel)	Reinspection frequency
High		12 months	7.2 hours	10%
Medium		18 months	5.7 hours	10%
Low		24 months	4.2 hours	10%

- Formula: (high risk inspection hours + medium risk + low risk = total inspection hours required/**1200 inspection hours**) = **# FTEs required**

- *Note: Average Inspection times came from Department of Health and Human Services https://oig.hhs.gov/oei/reports/oei-01-98-00400.pdf study of 37 states' inspection. 5.7 hours was the state average with a standard deviation of 1.5.*

How Our FTE Model Categorizes

1. Following FDA recommendations it would require that a health department (HD) group their establishments into 3 risk categories**: low, moderate, and high risk**

2. If a HD is unsure how to put their current risk category scale into a 3 category model, refer to **Annex 5 – Risk Categorization of Food Establishments Table https://www.fda.gov/media/110822/download**. In this table there are 4 risk categories with descriptions. Risk category 1 would be low risk. Risk category 2-3 would be moderate risk. Risk category 4 would be high risk.

3. If a HD **only has 2 risk categories** put them in the most appropriate categories out of low, moderate, or high. E.g. low and high, moderate and high, etc

Annex 5 Descriptions of Risk Categories

Risk 1: Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, non- time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed, TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.	**Risk 2:** Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.
Risk 3: An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.	Risk 4: Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.

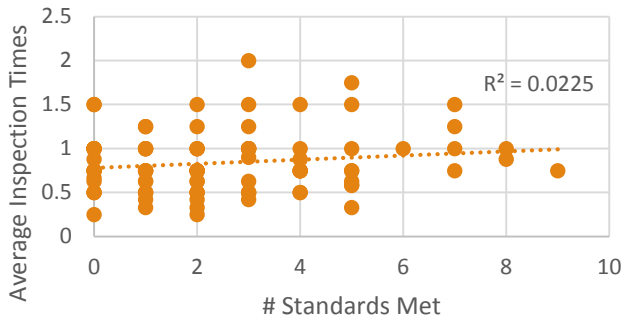
Creating the Standard for Frequency and Inspection Time by Risk Category

Methodology:

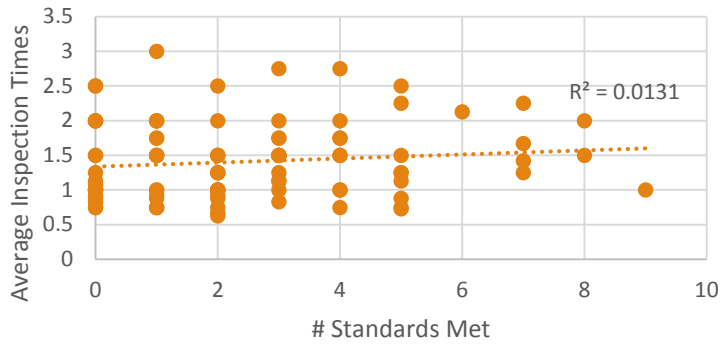
- In 2017 HCPH surveyed 390 health departments (HD) across the country asking them for average inspection times and frequencies per the 3 risk categories. 100 complete responses were received.
- To create a standard we categorized these HDs by the # of standards they achieved and evaluated if HDs with more standards met had inspection times and frequencies different from HDs with less standards met.
- **Statistical techniques demonstrated** that their was **no relationship** between the # of standards a HD achieved and their times or frequencies
- Thus there is no rational for emphasizing inspection times of HDs that passed more standards from the data we obtained
- Therefore it made the most sense to use the average or median inspection times and frequencies per risk category of all the HDs that responded as a standard. Now these values would be based on real data from a diverse group of HDs.

Plots of # of Standards Met by Inspection Times and Frequencies Demonstrating no Relationship,

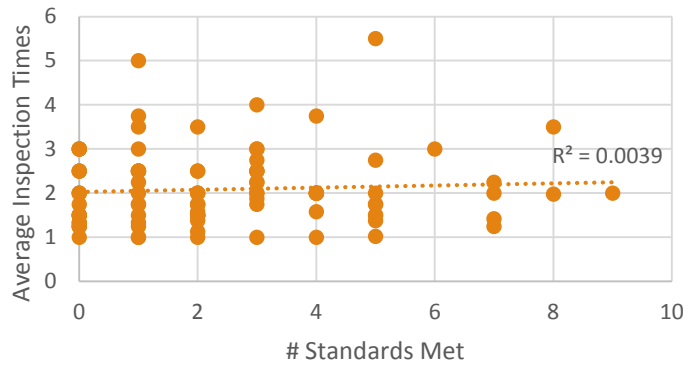
Low Risk Inspection Times



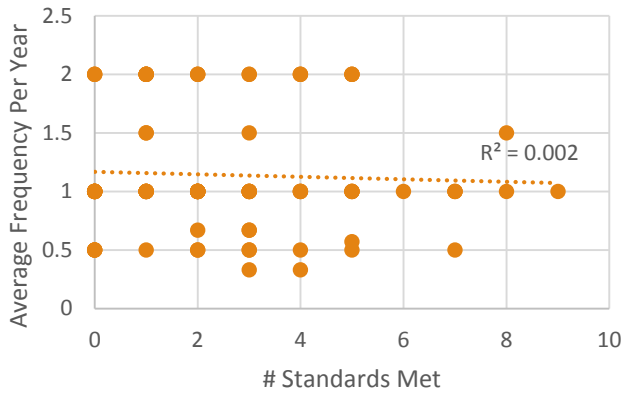
Moderate Risk Inspection Times



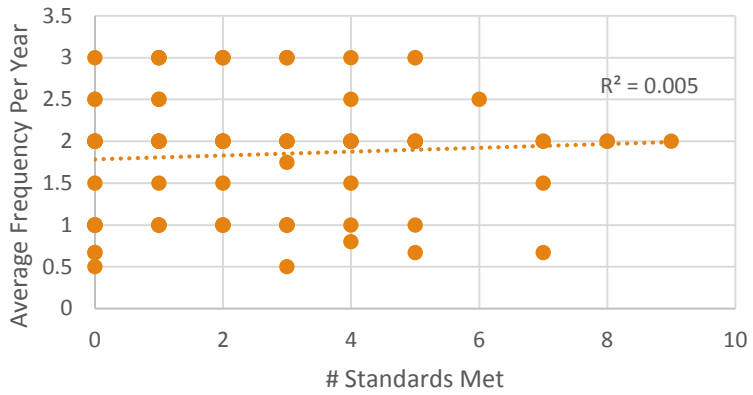
High Risk Inspection Times



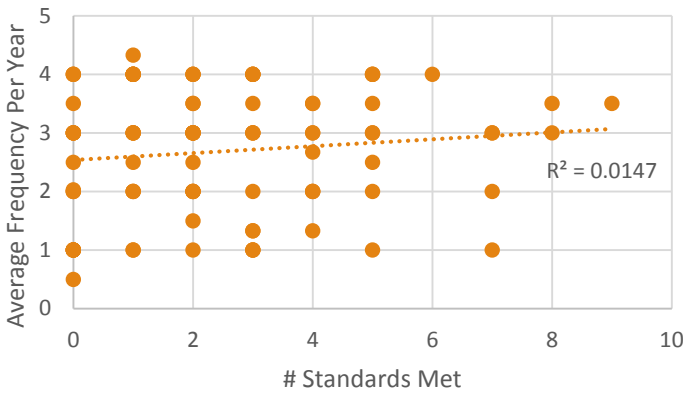
Low Risk Inspection Frequencies



Moderate Risk Inspection Frequencies



High Risk Inspection Frequencies



Bivariate Linear Regression Results and Correlation Coefficients

Independent Variable	Dependent Variable	P-Value	Pearson's Correlation Coefficient
# Stds. Met	Low Risk Freq.	0.67	-0.05
# Stds. Met	Low Risk Time	0.15	0.15
# Stds. Met	Mod Risk Freq.	0.49	0.07
# Stds. Met	Mod Risk Time	0.27	0.11
# Stds. Met	High Risk Freq.	0.24	0.12
# Stds. Met	High Risk Time	0.54	0.06

Note:

Statistically Significant Relationship = P-Value < .05

Pearson's Correlation Coefficient: Perfect positive relationship =1, Perfect negative relationship = -1

Creating Standard Inspection Times by Risk Category

Median

Low Risk: 45 minutes

Mod Risk: 75 minutes

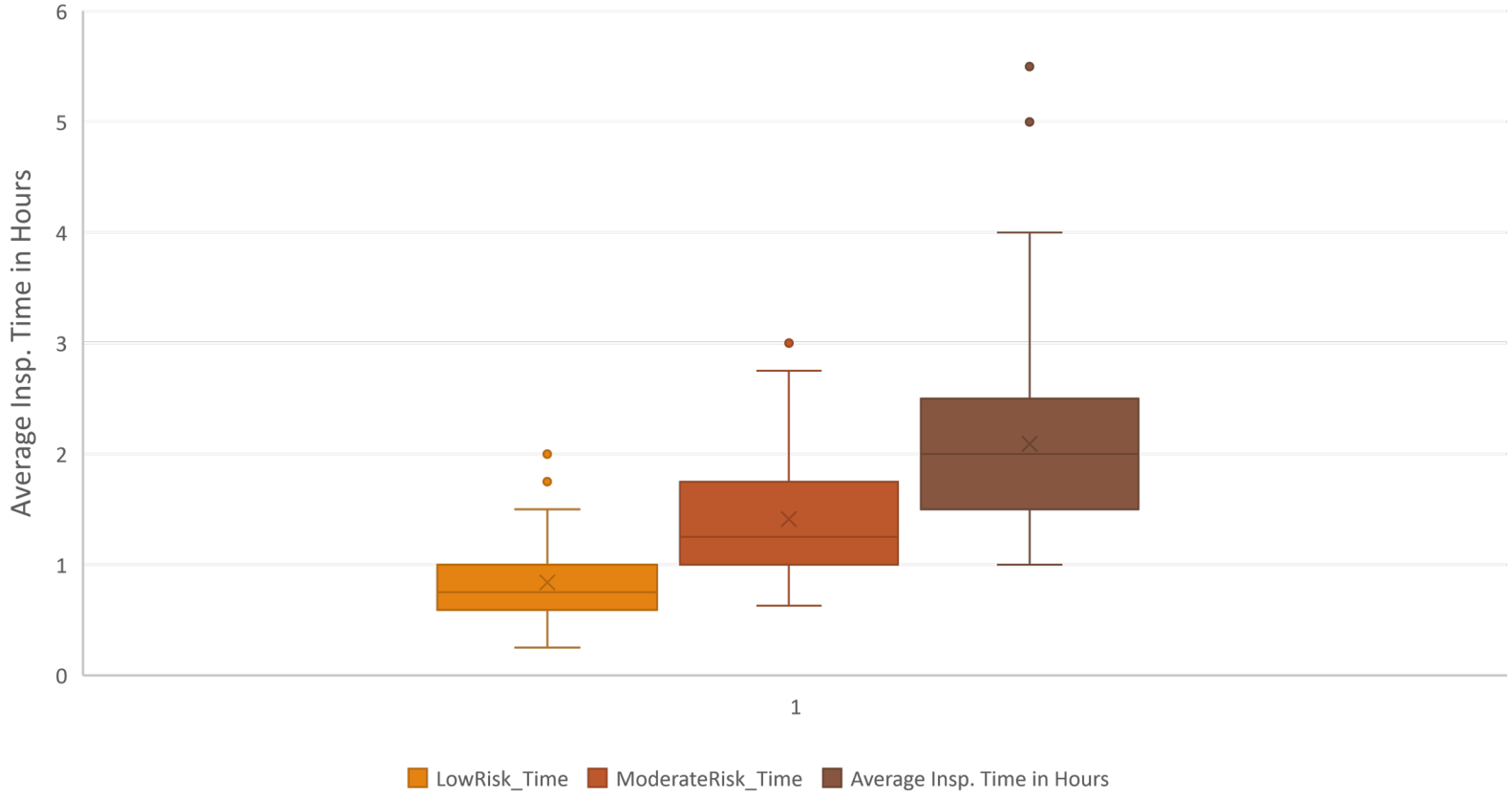
High Risk: 120 minutes

Average

Low Risk: 50 minutes

Mod Risk: 85 minutes

High Risk: 125 minutes



Creating Standard Inspection Frequencies by Risk Category

Median

Low Risk: 1 insp.

Mod Risk: 2 insp.

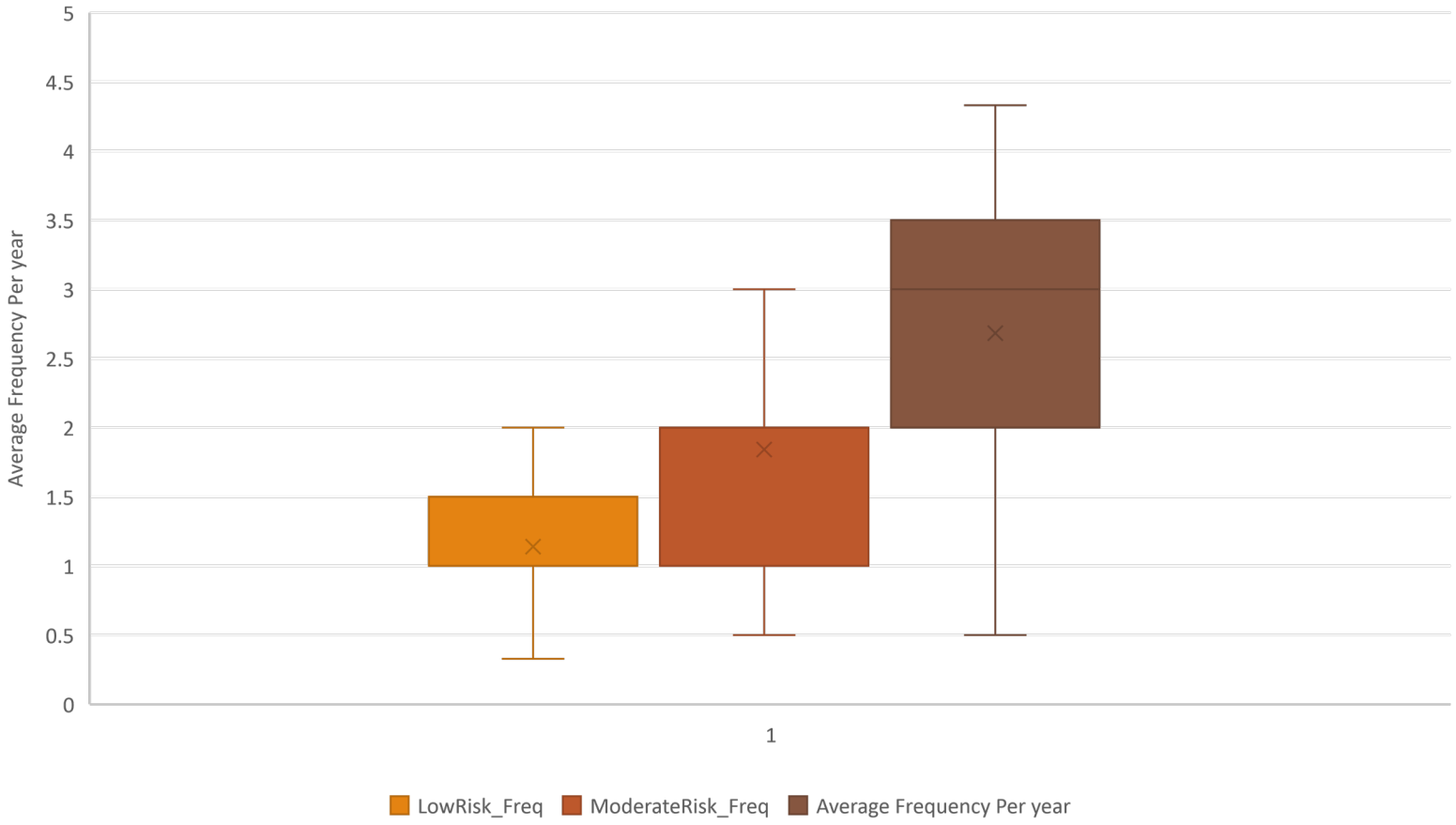
High Risk: 3 insp.

Average

Low Risk: 1.14 insp.

Mod Risk: 1.84 insp.

High Risk: 2.68 insp.



Calculating How Many FTEs a Health Department *"currently"* has

- *Note: This process uses the current Standard 8 model developed by the FDA with the sections devoted to the **inspection to FTE ratio removed***

- **The model now only needs to:**
  1. calculate the annual productive hours of one FTE
  2. calculate the total food inspection hours the health department currently conducts
  3. divide the total food inspection hours by the annual productive hours of one FTE to calculate how many overall FTEs the health department *"currently"* has

Total food inspection hours / one FTE's annual productive hours = Total FTEs

Calculating *"current"* FTEs

FTE DATA CALCULATION				
Calculate productive hours per year for an employee doing 100% food inspections				
Information For One Employee		**Hours/Year**	**Hours/Day**	**Total Hours**
Annual FTE Hours Per Year: Industry Standard				2080
	Local Holiday Hours Per Year	80		80
	Local Vacation Leave Hours Per Year	104		104
	Local Sick Leave Hours Per Year	78		78
	Local Family-Personal Leave Hours Per Year	0		0
Productivity Factoring Per Year				
	Travel Time For Inspection		1.5	1477
	Administrative Work (in-office work)	192		1285
	Training Time	20		1265
	Others	0		1265
Personal Development Time Per Year				
	Continuing Education Hours	12		1253
	Others	0		1253
Productive Annual FTE Hours Per Year (FTE Conversion Factor)				**1253**

Actual working days	Actual working weeks
227.25	45.45

FOOD SAFETY INSPECTION HOURS PER YEAR			
Position Category	**Food Safety Inspection Hours**	**Number of Employees**	**Total Hours**
Food/NNA	1239	31	38397
Food/Pools	831	2	1663
Supervisors	42	3	126
Total Food Safety Inspection Hours			**40186**
Total Local FTE			**32.1**

Calculating How Many FTEs a Health Department *"should"* have

- *Note: this process would be incorporated into the current Standard 8 model*
- **The steps of the new process are below:**

1. A health department will input the number of establishments they have into each of the **3 risk categories** of the table

2. The table will automatically calculate how many inspections should be conducted for each risk category using the **inspection frequency values** from the survey

3. The table will then automatically calculate how many total hours are required to complete these inspections using the **inspection time values** from the survey

4. The table will lastly divide these total inspection hours by the annual productive hours of one FTE (this value is already calculated in the previous section) to calculate how many overall FTEs the health department *"should"* have

Calculating *"required"* FTE

STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION							
	Low Risk Establishment	**Frequency of Low Risk Est Inspections Per Year**	**Moderate Risk Establishment**	**Frequency of Moderate Risk Est Inspections Per Year**	**High Risk Establishment**	**Frequency of High Risk Est Inspections Per Year**	**Total Inspections**
Routine and Permitting	2090	1.00	6374	2.00	104	3.00	15150
Follow Up Inspections/Re-inspections (15%)							2550
Foodborne Illness Complaints (1%)							170
Other (10%)							1700
Median Hours Spent Per Inspection	0.75		1.25		2.00		
Total Inspection Time	1568		15935		624		24757
Total Required FTE							**19.76**
Standard 8 Criteria							**Standard met**

Notes:

- **Frequency of inspections - 2017 HCPH Survey 1 (100 responses)**
- **Median Hours Spent Per Inspection -2017 HCPH Survey 1 (100 responses)**
- **Follow Up Inspections % (out of total # inspections) - 2017 HCPH Survey 2 (60 responses)**
- **Foodborne Illness Complaints % (out of total # inspections)- 2017 HCPH Survey 2 (60 responses)**
- **Other % (out of total # inspections) E.g. from *Standard 8 Staffing Level Assessment Workbook, pg. 10* - complaints, outbreak investigations, risk assessment reviews, process reviews, variance process reviews, final construction inspections and "other direct establishment contact time"**

Meet or Not Meet Standard 8

- As demonstrated on previous slide, once the Standard 8 model is completed it will automatically calculate if a health department meets or does not meet the standard. E.g. below.

Jurisdiction X "*should*" have 5 FTE

Jurisdiction X "*currently*" has 4 FTE

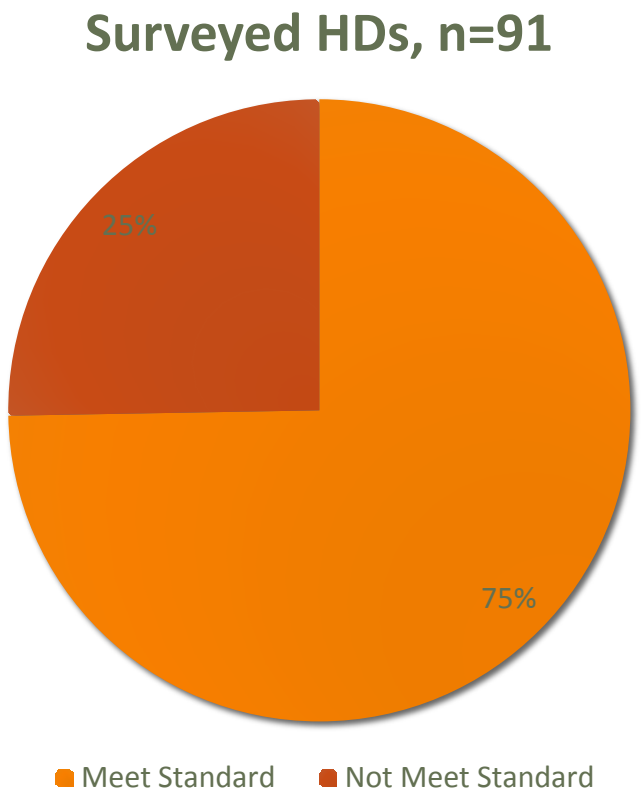
should have > currently have

Jurisdiction Y "*should*" have 20 FTE

Jurisdiction Y "*currently*" has 23 FTE

should have =< currently have

How Do Our Surveyed HDs Do?



Recommendation #1

- A HD can use their own method
- A HD can use the current assessment tool
- A HD can use the new proposed assessment tool that calculates staffing levels by risk category

Recommendation #2

- Use the new proposed model to determine staffing level
  - Option 1: use the standardized values from the survey
  - Option 2: use values that the HD determines to be appropriate for their program

Recommendation #3

- Pilot the new proposed model among HDs for a period of time

Conclusion

- The standard 4 hour inspection time needs to be updated
- Our survey demonstrates that inspection times and frequencies vary by risk category
- An *inspection to FTE ratio* is not necessary to asses a HD's staffing levels, in fact it creates the potential for failing a health department that is sufficiently staffed