Risk Factor Study Toolkit: Study Checklist

Preliminary Steps

Completed?	Step	Assigned to	Target Date
	Review Standard 9 in the Program Standards Manual		
	Recommended: Review FDA's Protocol for Data Collections		
	Recommended: Identify goals for your study. What questions do you hope to answer? How do you plan to use the data?		
	Identify which facility categories to include based on regulatory authority. Define the categories for your jurisdiction for consistent application. Consider additional segments of interest. *Restaurants (full-service and quick-service) *Healthcare (hospitals and long-term care) *Schools (K-12) *Retail Food Stores (deli, seafood, produce)		
	Recommended: Assign each facility a risk category (see Annex 5, page 595). Remove low-risk establishments where risk factor observations are less likely.		
	Confirm establishment inventory. Verify name, address, operational status. Ensure correct assignment of facility category.		
	Divide establishment inventory by facility category.		
	Assess data collection tool or current inspection form (for file study). *Does the tool/form assess compliance for all five risk factors? All risk factors need to be included. *Does the tool/form assess compliance using IN, OUT, N/O, N/A conventions? The form must use these conventions. If "no" to either of the above, a new form/tool is needed.		
	Assess data collection, storage, and analysis options. *Contact your Retail Food Specialist about the Retail Risk Factor Study Database. *Inspections forms/software *Statistics software		
	Determine study design (e.g., file study using routine inspection data, separate data collection, collect data alongside routine inspection)		
	Develop timeline for study design, training, implementation, analysis, and report writing. Note: Not all industry segments need to be completed in the same year (e.g., year one - restaurants, year two - healthcare)?		

New Data Collection

Completed?	Step	Assigned to	Target Date
	Take curated list of eligible establishments. Determine the number of eligible establishments per category.		
	Assign numbers to eligible establishments. (Easy option: Create a worksheet in Excel, a separate tab for each facility category. Copy and paste the establishment names into Column A for each tab and use the row numbers down the left-hand side.		
	Determine the confidence level and margin of error for your study. *Recommend using 95% confidence level with 5% margin of error.*		
	Use a sample size calculator to determine the number of establishments in total or per category, depending on study design, using your chosen confidence level and error. Note: inventories with less than 30 establishments you should assess in their entirety.		
	Use a random number generator to pull a list of numbers.		
	Create a sample list by matching the numbers pulled by the random number generator with the numbers previously assigned (e.g., row numbers).		
	Recommended: Run a second random number list to pull replacements when establishments in the sample is either closed or becomes ineligible during the data collection period.		
	Finalize the data collection tool/form.		
	Create marking instructions for the data collection. *Recommended: Review FDA's marking instructions--adopt/adapt.*		
	Train data collectors. A Retail Food Specialist can assist with training. *Recommended: assign a lead data collector who has been Standardized; other data collectors should meet training steps 1-3 in Standard 2.*		
	Designate and train quality assuarance personnel.		
	Recommended: After each data collector has completed a few collections, have the Lead Data Collector or a quality assurance person shadow them on a collection or review their reports and provide feedback.		
	Finish data collection.		
	Complete quality assurance review. *Recommended: complete quality assurance checks as data comes in.*		
	Complete entry of data into database		
	Analyze data. At minimum, determine the occurrence of each risk factor and identify priority areas. Have quantifiable measure of each to track trends over time.		
	Write report. Discuss findings and conclusions.		

Using Inspection Data

Completed?	Step	Assigned to	Target Date
	Assess current inspection procedures, marking policies, and form. * Which form items and violations will you use to measure risk factors? * Does your department use a risk-based inspection approach? * Are there differences between the approach for a routine inspection and the data collection procedures (e.g., cold temps not marked out when 1 degree over during routine)? Will these affect your study goals? * Are there any adjustments you would need to make to achieve your study goals? * Are all inspectors trained? Are there any quality assurance concerns with uniform inspections?		
	Assemble a quality assurance team. Train them on any adjustments that need to be made, as well as your marking procedures and uniform inspection protocols.		
	Enter data, if needed, into data analysis program.		
	Complete quality assurance review. *Recommended: complete quality assuarance checks as data is entered.*		
	Analyze data. At minimum, determine the items and risk factors most out of compliance. Have quantifiable measure of each to track trends over time.		
	Write report. Discuss findings and conclusions. Discuss challenges or limitations with using existing data.		

Intervention

Completed?	Step	Assigned to	Target Date
	Identify a risk factor in need of priority attention based on the study results.		
	Assemble an intervention development group.		
	Design an intervention for the identified area.		
	Set timeline for implementation.		
	Implement intervention.		

2nd Study

Completed?	Step	Assigned to	Target Date
	Repeat steps above for the method chosen ("New Data Collection" or "Inspection Data")		
	Measure the impact of your intervention using the data from your 2nd study or another method		
	Repeat steps above for "Intervention"		

3rd Study

Completed?	Step	Assigned to	Target Date
	Repeat steps above for the method chosen ("New Data Collection" or "Inspection Data")		
	Measure the impact of your intervention using the data from your 3rd study or another method		
	After data analysis for the third study, assess trends over the three data points		
	Include discussion in report.		