Utah Risk Factor Study
For Inspections Conducted in 2016
Analysis Conducted in 2017

Foodborne illnesses continue to be a public health concern in Utah. Utah's local health departments are responsible to inspect food service businesses in Utah and to respond to foodborne illness complaints or outbreaks. The Utah Department of Health (UDOH) provides training and support to the local health departments. In addition, UDOH oversees and administers rules and policies that provide regulatory standards of operation for food safety and authority for local health departments to enforce those standards. The UDOH conducted an analysis of data from retail food inspections conducted in 2016 by local inspectors. This analysis was done through a cooperative agreement with the Association of Food and Drug Officials (AFDO) administering a grant from the U.S. Food and Drug Administration (FDA).

Purpose:

The purpose of this analysis is to evaluate trends, patterns, and correlations of food code violations with the intent of finding ways of improving the efficacy and efficiency of food establishment inspections by local departments, and to identify priorities for focused training and policy development by UDOH.

Method:

Food establishment inspection data were collected from local health departments. Data were made available for approximately 85%[1] of the population of Utah in 2016. Submission of inspection data was voluntary by Utah's local health departments

Three primary analyses were conducted as part of this report. First, overall line item violation frequency distributions were measured. Second, line item violation rates were compared between summer and non-summer months. Third, the correlations between line item occurrences were measured.

Frequency of Observed Violations

This analysis measured the frequency distribution of line items selected as violations on local inspection forms. Line items were then matched to equivalent line items on the FDA's standard form. Emphasis was given to the frequency of items associated with the five risk factors most associated with foodborne illnesses as identified by the U.S. Centers for Disease Control and Prevention (CDC) and the five main interventions for these risks as identified by the FDA.

Foodborne Illness Risk Factors and Food Code Interventions

CDC's 5 Risk Factors	FDA's Interventions
Improper Holding Temperatures	Demonstration of Knowledge
Inadequate Cooking	Employee Health Controls
Contaminated Equipment	Controlling Hands as a Vehicle of Contamination
Unsafe Sources	Time/Temp. Control of Pathogens
Poor Personal Hygiene	Consumer Advisory

The frequency distribution of risk factors and interventions (with their associated line numbers) was also stratified by establishment category. Establishments were grouped into one of four categories, dependent on the type of establishment or foods served.[2] Categories 1 to 3 represented establishments with increasing risk, with Category 3 representing establishments with the highest risk. Category 4 represented establishments with strict controls in place for the populations they serve. Examples of

[1] See Appendix B for participating local health departments.
[2] See Limitations for issues with grouping of establishments.

Category 4 items include schools, jails, child care centers, hospitals, and assisted living centers. Bar charts of the top ten violations in each category can be found in Appendix A.

Establishment Categories

Category 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.
Category 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.
Category 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.
Category 4	Examples include preschools, hospitals, nursing homes, and establishments serving a highly susceptible population.

A total of 48,592 food inspection violations were reported as part of approximately 22,946 inspections in 17,349 establishments (not including temporary establishments). Inspections where no violations were recorded were not included. During the study time period, there were approximately 495 enforcement actions taken, which include closures, hearing, notices, and citations.

Comparison of Violations Frequencies Between Summer and Non-Summer Months

Anecdotal evidence suggested that there may be seasonal variations in the frequency of line item violations. To test this, rates of individual line items were compared between summer and non-summer months. Summer months were defined as June, July, and August, with all other months categorized as non-summer. Rate ratios between both time periods were compared using a 95% confidence interval.

Correlation of Line Items

An analysis was done to determine if certain line items were more likely to occur given the marking of a different line item. Correlations among pairs of line items 1 through 56 from the FDA form were compared using a Phi correlation coefficient. Only line item pairs with $-0.80 => r >= +0.80$ were reported as being meaningful. This cutoff was chosen to focus on the strongest line item pair correlations.

Results:

Violations per Category (See Appendix A for the bar charts and comparisons)

Linking line items to either a risk or intervention resulted in 40 of the 56 line items being considered by this study to be significant enough to contribute directly to either a risk or intervention.[3] These 40 items accounted for 56% of all violations marked in 2016. The FDA form's first 29 items, the FDA's "Foodborne Illness Risk Factors and Food Code Interventions", accounted for 43% of all violations marked in 2016.

Of note were line items representing 'Physical Facilities Installed, Maintained, and Clean' (55), 'Food and Non-Food Contact Surfaces Cleanable, Properly Designed, Constructed, and Used (47), and 'Non-Food Contact Surfaces Clean (49). In every category where all marked line items were considered, these three line numbers (55, 47, and 49) were found to be among the top five most marked violations

[3] See Limitations for a table of which line items were associated with what risk/intervention.

and accounted for 22% of all violations marked. For Category 4, they were the top three items marked. These three line items are not considered to be related to any risk or intervention.

Line 8 (Hands Cleaned and Washed) and line 1 (PIC) only showed up in the top ten for Category 1 establishments, while line 10 (Adequate Hand Sinks; Accessible) was in the top ten for all categories. Half or less of the top ten violations marked would be considered associated with a risk factor or intervention.

When looking at risk factors across all establishment categories, line 16 (Food-Contact Surfaces: Cleaned/Sanitized) was the most marked violation. Line 10 was the most marked violation for interventions across all establishment categories.

Summer vs Non-Summer

Given that a violation occurs during an inspection, four line items were found to occur more frequently during summer months compared to non-summer months. No line items were found to be marked more frequently in non-summer months as compared to summer months.

Occurrence of Line Item Violations, Summer Months Compared to Non-Summer Months, 2016

Line Item	Rate Ratio	95% LCL	95% UCL	P-value
22	1.37	1.23	1.52	p < 0.005
28	1.15	1.02	1.28	p < 0.025
33	1.50	1.22	1.86	p < 0.005
36	1.23	1.04	1.45	p < 0.025

alpha = 0.05 Summer months defined as June, July, and August

MORE LIKELY VIOLATION IN SUMMER

22 Proper cold holding temperatures
28 Toxic substances properly identified, stored, and used
33 Proper cooling methods used; adequate equipment for temperature control
36 Thermometers provided & accurate

Correlated Line Items

No line item pair correlations were found to meet the threshold of -0.80 => *r* >= +0.80. Ninety-one percent of correlations were found have a coefficient close to zero (-0.20 =< *r* <= 0.20).

Limitations:

Of the 13 local health departments, seven volunteered data for use in this study. More than half of the local health departments currently use a method for storing inspection data digitally; the rest keep inspection hard copies. One health department sent in scanned copies of inspection data, which needed to be inputted manually. The time and labor involved with sending, collating, and scanning in copies of paper inspections likely limited broader participation by the local health departments.

This analysis is dependent on the ability to categorize establishments based on inherent risk due to populations served, types of food served, and type of food preparation techniques used. Though the rationales for categorizing establishments were inconsistent from one health department to another, each did use a classification system using some form of risk. The types of classifications being used by the local health departments included groupings due to square footage of the establishment, number of seats available, custom risk point systems, or a separation of establishments into three, nine, or

undefined number of categories and subsequent subcategories. These custom classifications were each recategorized to match one of the four aforementioned establishment risk categories.

Where a local health department's categorization schema sorted establishments into types, the establishments were put into one of the four categories that best matched their schema's categorization. The rest of the establishments grouped otherwise were assigned to Category 1,2, or 3 based on the level of risk assigned by their jurisdiction. For example, in jurisdictions where establishments are categorized based on square footage, large establishments receive more frequent inspections and were thus chosen to be put into Category 3. Establishments that would meet the criteria for being in Category 4 needed to be manually separated from the rest of the data in most cases regardless of the categorization schema being used.

Of the participating local health departments, all but two currently use an inspection form based on the 2009 food code, meaning that their forms do not match the 2013 FDA form. Due to this, most line numbers in the submitted data needed to be translated to match the 2013 FDA form. Consequently, there will be few instances of line numbers 2 (Certified Food Protection Manager) or 5 (Clean-up of Vomiting and Diarrheal Events) being shown as marked as these do not exist on most forms currently being used. This does not mean these items are not being checked during inspections, but that they are being marked as part of other line items.

This analysis only represents a single year of inspection data. This single year of violations data may not be entirely representative of larger trends. Additional data will be needed for future investigations. This analysis only looks at the frequency of violations marked on the inspection form. Due to inadequate information, it is not possible to include in this study the precise reasons for why these line items were marked. There can be many varying rationales for the marking of any given line item.

UDOH was unable to find a listing that delineated which line numbers on the FDA form corresponded to either a risk factor or an intervention. On the FDA's form, as found in Annex 7, Form 3A, of the 2013 FDA Food Code, the first 29 line items are grouped together as the "Foodborne Illness Risk Factors and Food Code Interventions", but no further information is available on how these items correspond to either a risk or intervention. Below is listed how UDOH delineated which line numbers corresponded to which risks or interventions, with some items being chosen as both a risk and intervention. In addition, some of the line items in the Good Retail Practices section were noted to be part of the risk or intervention categories. All line item numbers over 29 are found in the Good Retail Practices.

UDOH's Classification of Line Items and Associated Risk Factors or Interventions

CDC's 5 Risk Factors (CDC Surveillance Report 1993-1997)	Associated FDA Line Numbers
Improper Holding Temperatures	21, 22
Inadequate Cooking	18, 19
Contaminated Equipment	15, 16, 17, 28, 43, 44, 45
Unsafe Sources	11, 12, 13, 14, 31, 32, 26, 27
Poor Personal Hygiene	6, 7, 8, 9, 10, 40,

UDOH's Classification of Line Items and Associated Risk Factors or Interventions

FDA's 5 Main Interventions From 2013 FDA Food Code	Associated FDA Line Numbers
Demonstration of Knowledge	1, 2, 29
Employee Health Controls	3, 4, 5
Controlling Hands as a Vehicle of Contamination	8, 9, 10
Time/Temp. Control of Pathogens	18, 19, 20, 21, 22, 23, 24, 33, 34, 35, 36, 37
Consumer Advisory	25

Discussion:

Most concerning are the high occurrences of lines 55, 47, and 49 being marked as compared to line items associated with risk factors or interventions. These line items concern themselves with the maintenance of the facility and general cleanliness and are not associated with any risk factor or intervention. As noted previously, there is no correlation between line items. It is not likely that these are being picked in tandem with each other, or conversely, they are being picked frequently, but not at the same time during an inspection. It's possible these line items are being used as a catch-all for when an inspector sees something broken or dirty and they are not sure where to mark it.

The frequency of line numbers 55, 47, and 49 being marked highlights a concern that has been growing among regulators and the FDA that inspectors are focusing on items that are not posing a direct risk to consumers. As noted above, proper hand washing was only noted in the top ten violations for Category 1 establishments which are the lowest risk establishments. Out of all inspections conducted in 2016, proper hand washing violations are only marked in 4% of inspections where a violation occurred. This supposes that either there is little to no problem with proper hand washing, or inspectors are not focusing on the items most likely to contribute to foodborne illness, such as proper hand washing. This has been highlighted in conversations between FDA Trained State Standards and the local trainer/Standardee when doing standardization exercises. A frequent item discussed during these exercises is the hand washing violations observed by the Standard while the Standardee is looking at something else. These results would suggest that more in-depth training on risk based inspections may be needed.

The higher likelihood of cooling and cold holding violations (line items 33 and 22 respectively) during summer months, while intuitively unsurprising, is concerning. This should not be the case as all facilities should have adequate ventilation as required in 6-304.11 of the 2013 FDA Food Code. The indoor temperature of a restaurant should be independent of out door temperatures. The serving areas are normally temperature controlled, but anecdotal evidence suggests that kitchen temperatures of over 90°F are not uncommon. A simple understanding of the mechanics of refrigeration would conclude the existence of a limit for ambient temperature past which cooling equipment would become inefficient, increasing the likelihood of temperature abused food. The efficacy of cooling equipment with food directly exposed to ambient air is especially impacted. Consideration should be given during plan reviews to how ambient temperatures in food preparation areas will be controlled.

Line items 28 and 36 were found to also be marked more frequently in summer months. More data is needed before formulating a rationale for why the use or storage of toxic substances (line 28) would be found in violation more frequently in summer months. This may also apply to line 36 (Thermometers provided and accurate), though it may be that inspectors are looking at an establishment's thermometers more frequently in summer months due to increased observations of temperature violations.

The frequency in which line number 20 was marked also raised some questions. Marking this as a violation requires direct observation of time and temperatures requirements being out of compliance. An inspector would need to take measurements and note observations at the start and end of either of the cooling steps outlined in 3-501.14 of the 2013 FDA Food Code. The time to do this could take 2-6 hours, making it unlikely that this line item is being marked correctly. Observations prompting the marking of line item 20 may be better marked under line items 22 (Improper cold holding), 33 (inadequate equipment; proper cooling methods), or 23 (improper date marking).

Line items 10 (Adequate hand sinks; accessible) and 16 (Food-contact surfaces: Cleaned/Sanitized) being in the top ten in all categories indicates issues with operators and employees not making hand sinks readily available (i.e. keeping dishes in the hand sink or getting to the hand sink difficult due to clutter). This also possibly indicates and on-going problem with dishwashers being properly maintained and/or dishes being found with food debris. As noted previously, though, a precise reason for why these line items are being marked would require further research.

In Conclusion:

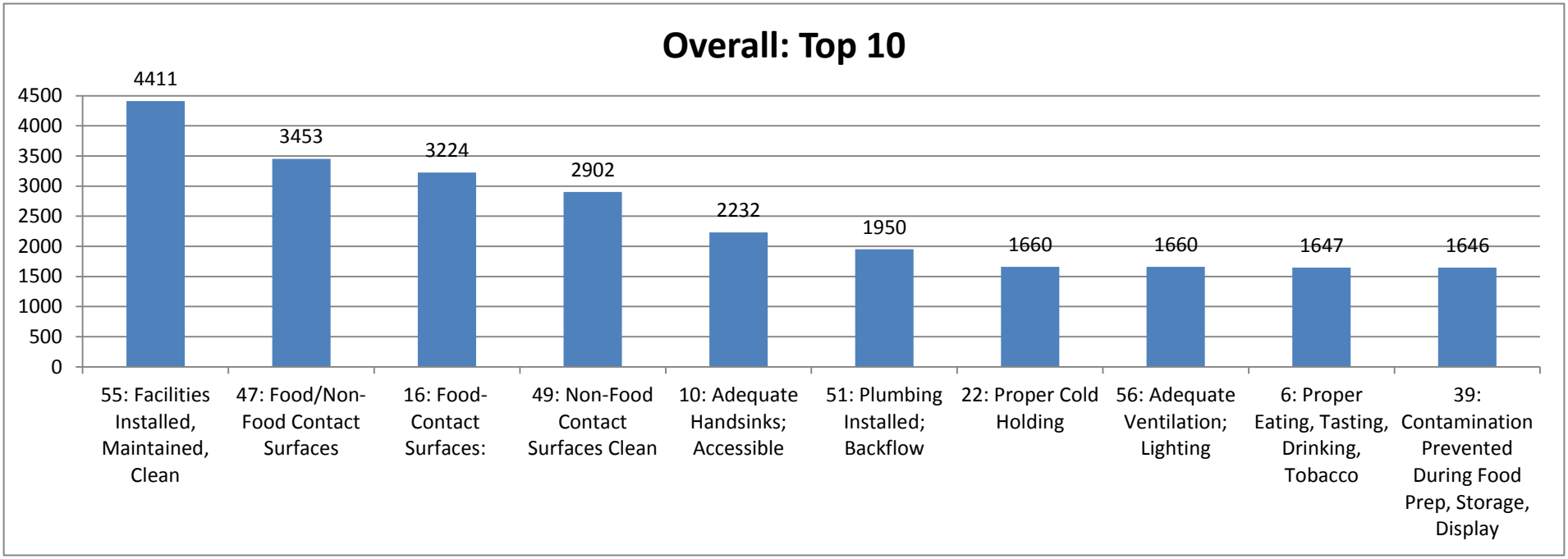
The primary conclusion from this study is that more training needs to be done with inspectors on risk based inspection methods. Such training should include some of the training given when doing standardizations, specifically training on the use of the FDA form. Additional information may be needed to be given to inspectors on when certain line items should be marked.

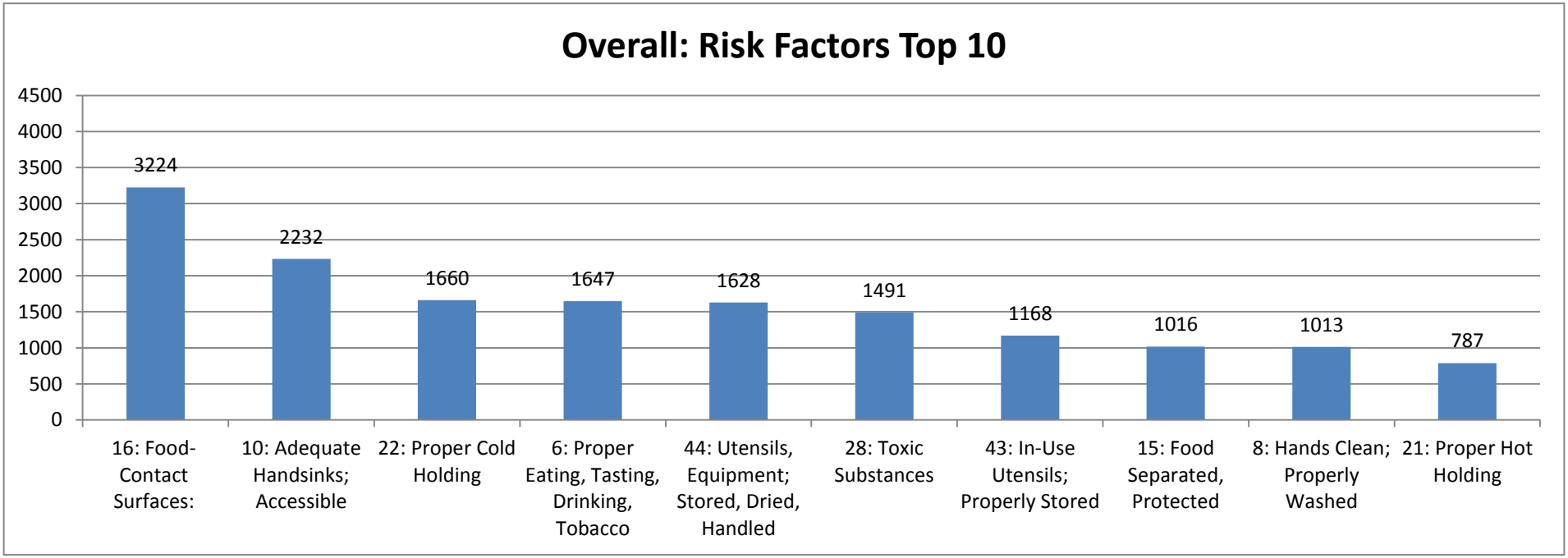
These results also highlight the need for greater awareness among operators of the importance of keeping their kitchens cool and of adequate ventilation. Also, keeping hand sinks clear of clutter and knowing how to maintain their dishwashers should be emphasized. These conclusions will be discussed with the local health department along with potential future training opportunities.

This study has highlighted the vast differences in how local health departments keep inspection data and how they categorize establishments. No two departments categorized their establishments the same, and few use the same digital system.

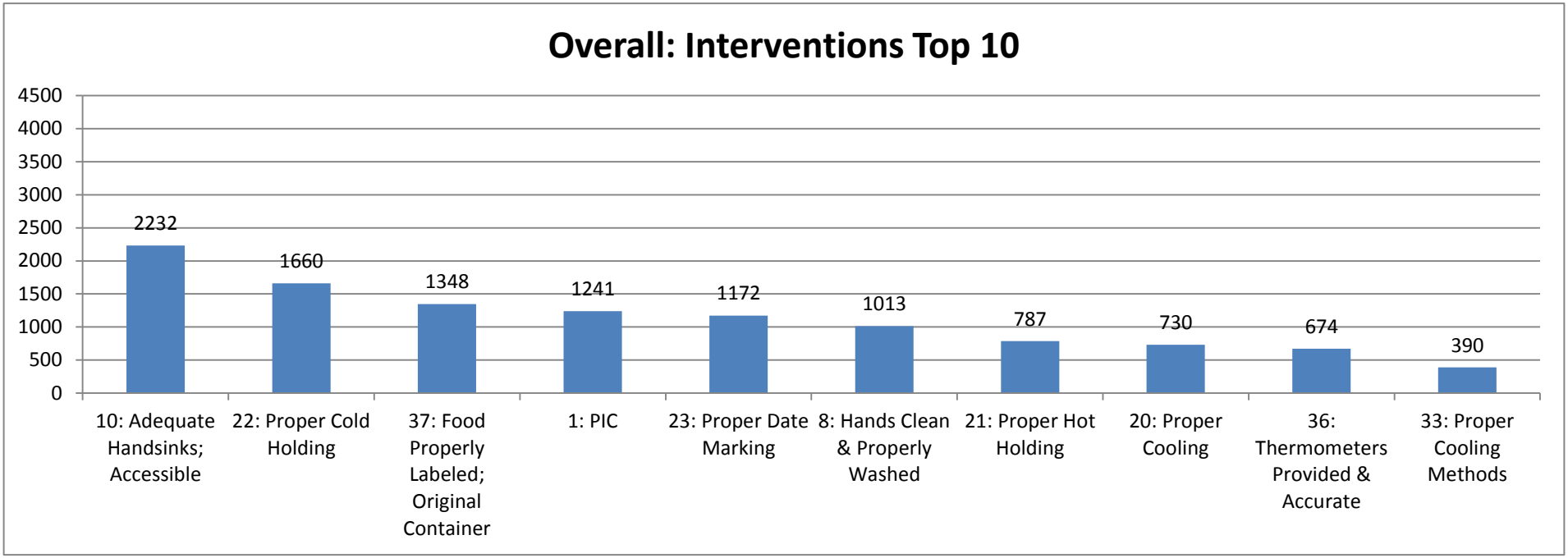
Appendix A: Charts

The following are the top 10 items marked on inspections forms from all categories:



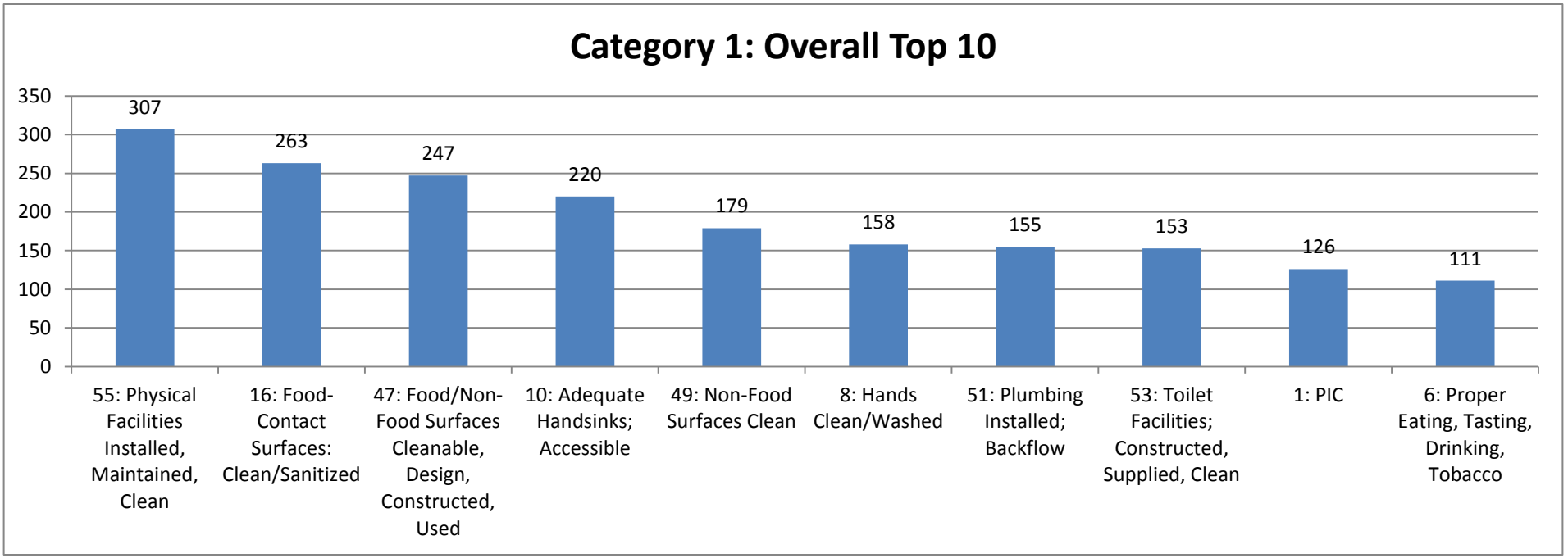


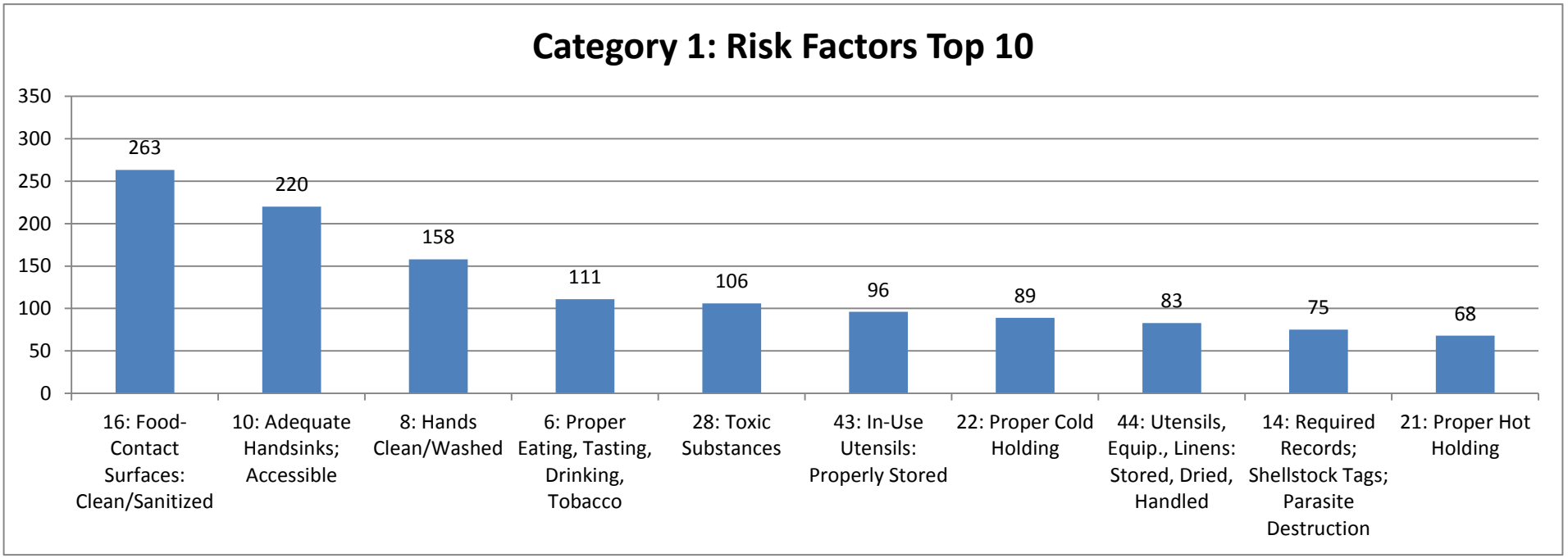
Appendix A: Charts



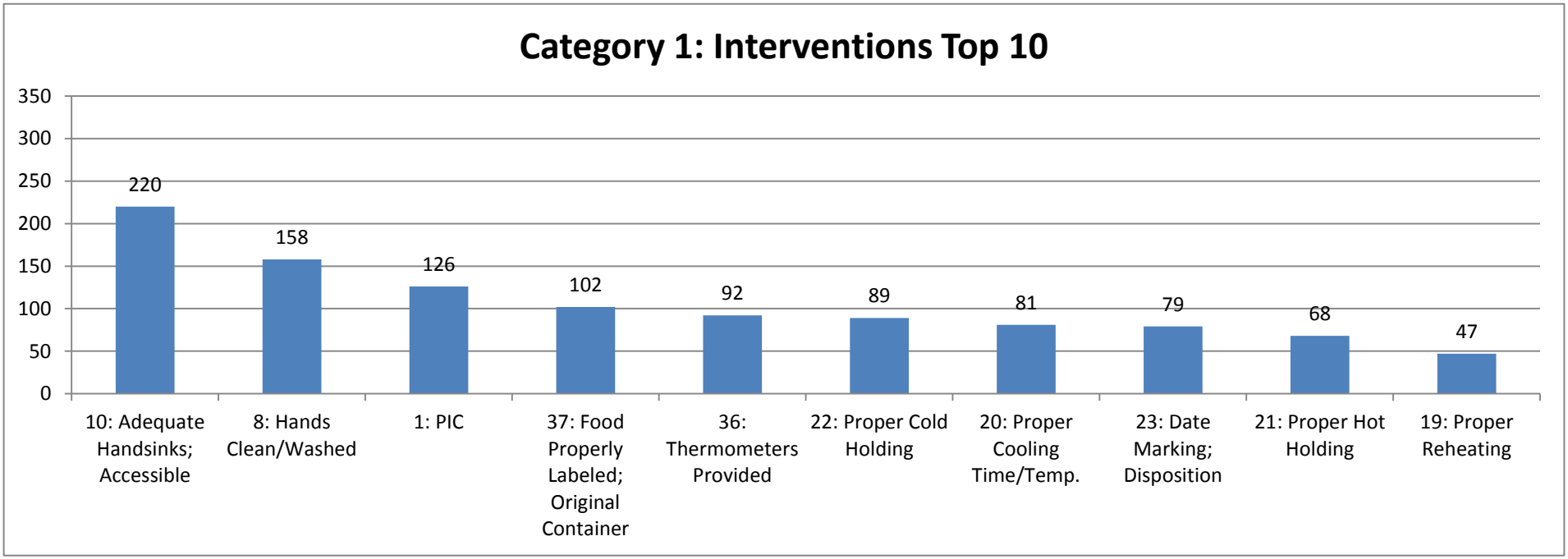
Appendix A: Charts

Top violations from **Category 1** establishments. Category 1 establishments represent the lowest risk establishments, as determined by either square footage, limited menus involving limited or no cooking, or those places that only serve non-TCS foods.



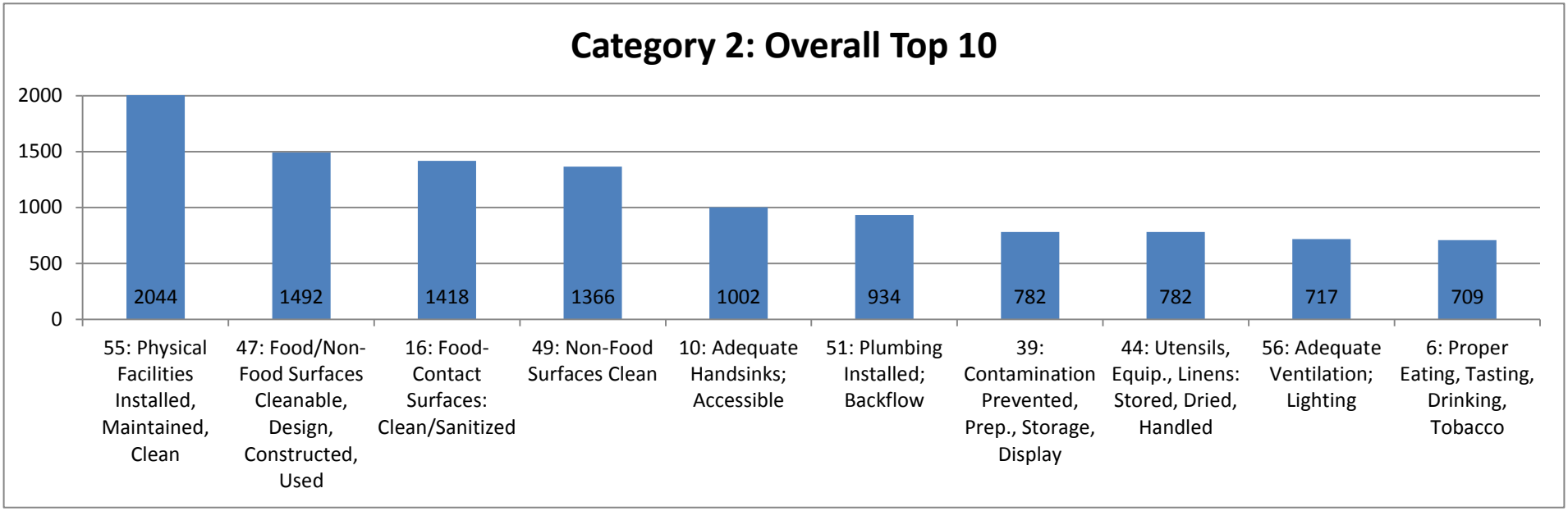


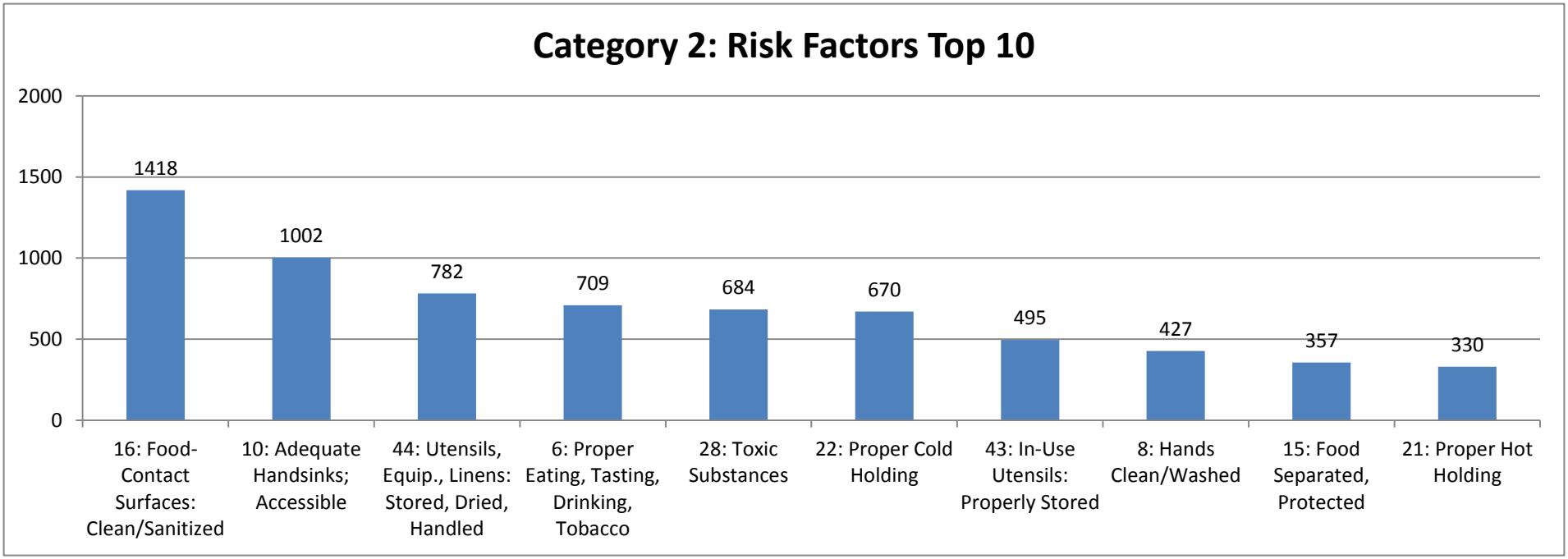
Appendix A: Charts



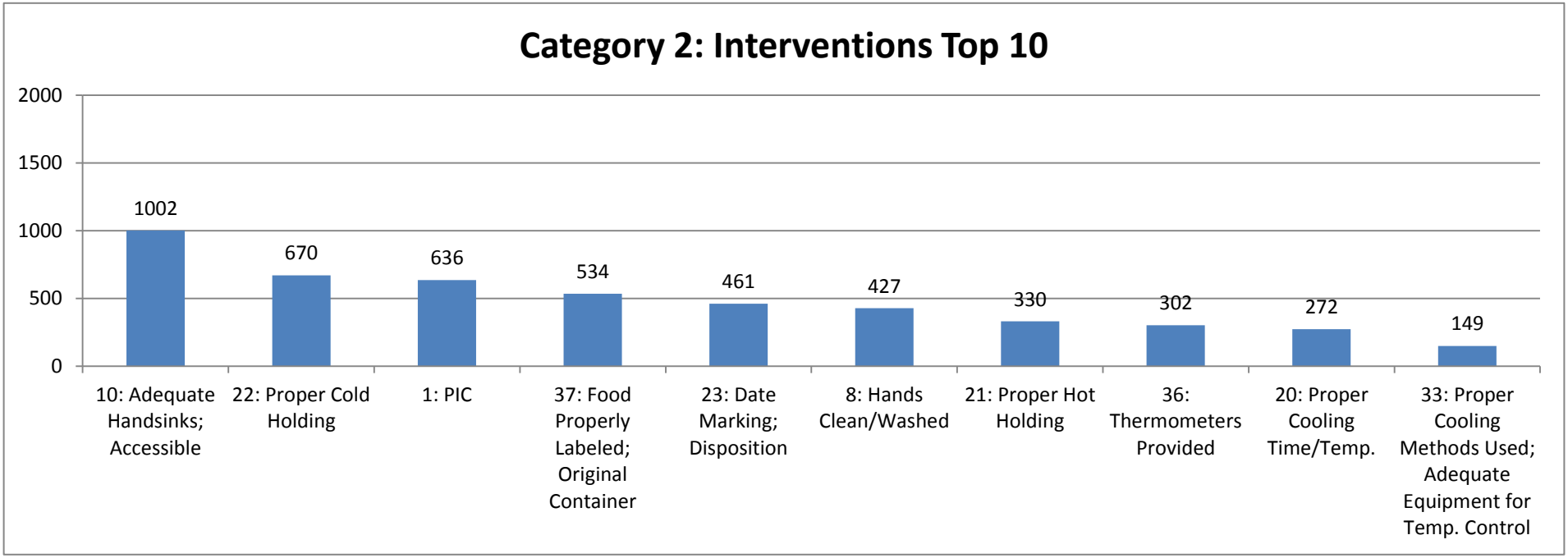
Appendix A: Charts

Top violations from **Category 2** establishments. Category 2 establishments represent medium risk establishments, as determined by either square footage, limited menus involving process 2 cook steps, or those places doing very little complex preparation of TCS foods. Will include fast food, carts, public lodging.



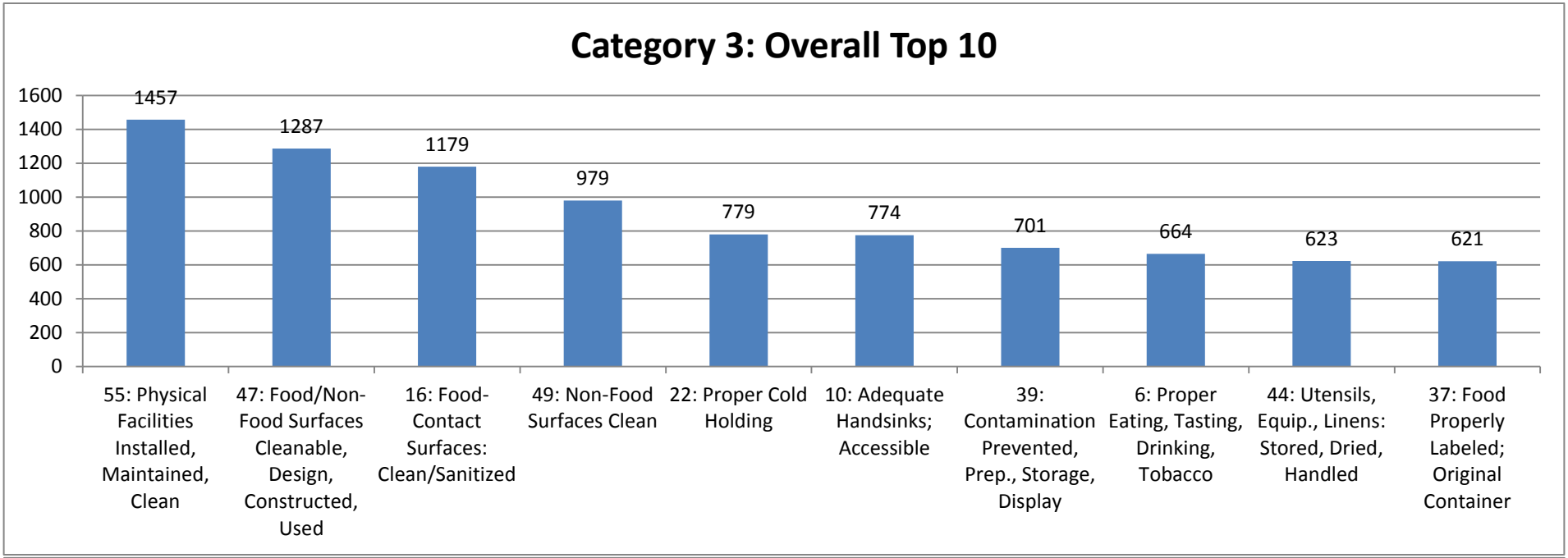


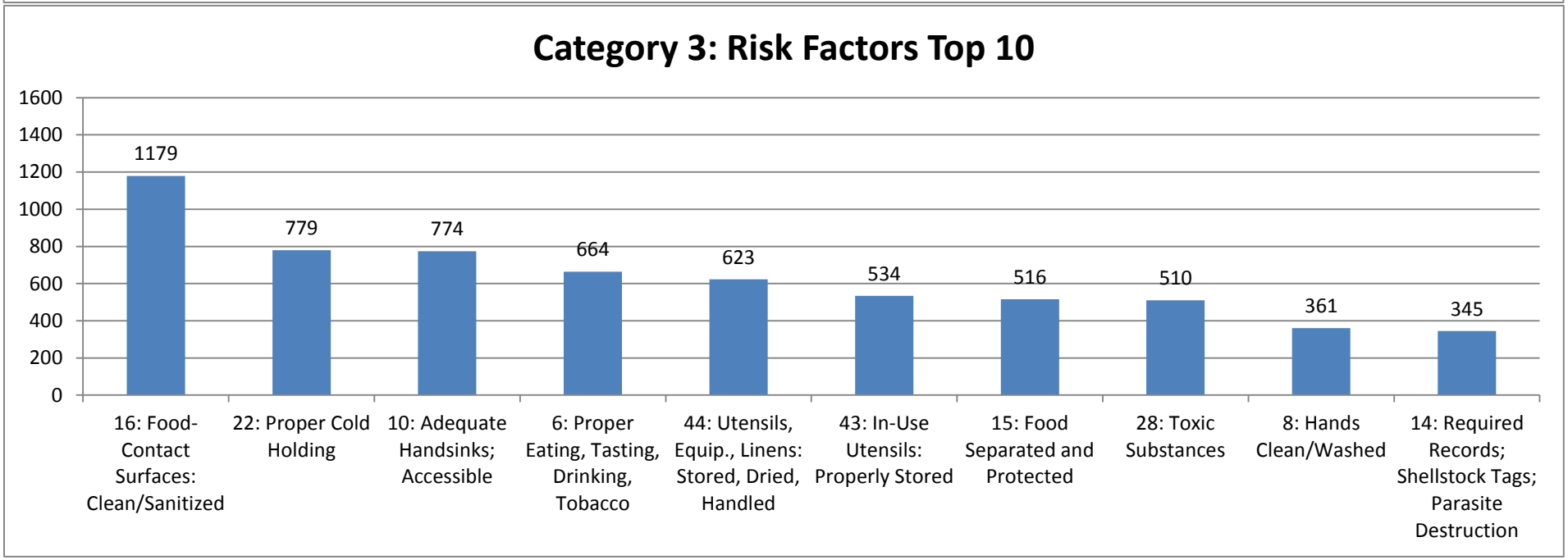
Appendix A: Charts



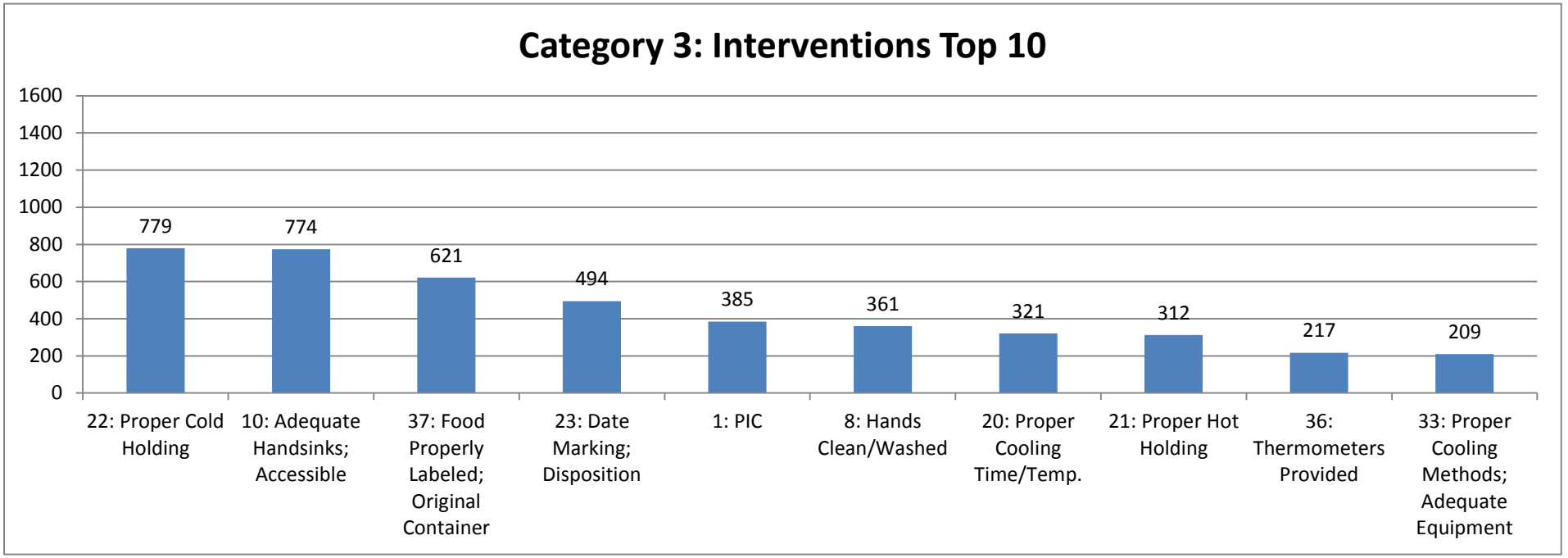
Appendix A: Charts

Top violations from **Category 3** establishments. Category 3 establishments represent highest risk establishments, as determined by either square footage, menus involving process 3 cook steps, or those places doing complex preparation of TCS foods. Will include full service, food trucks, commissaries.



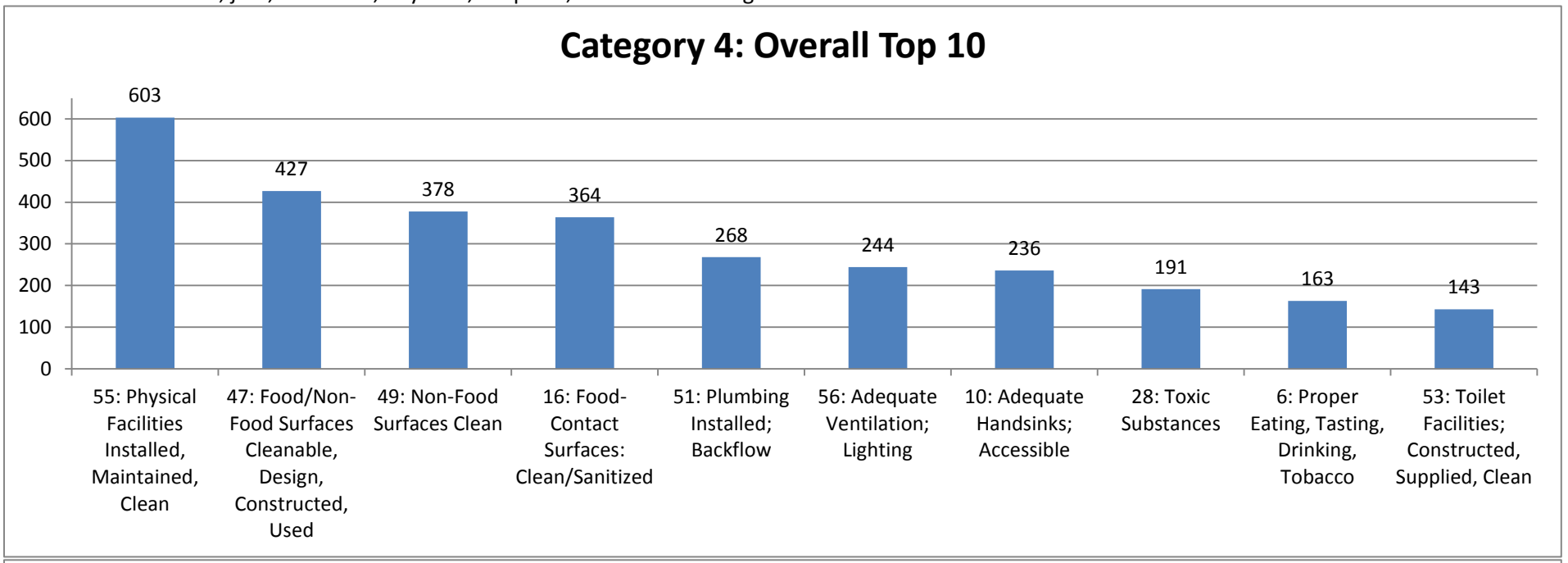


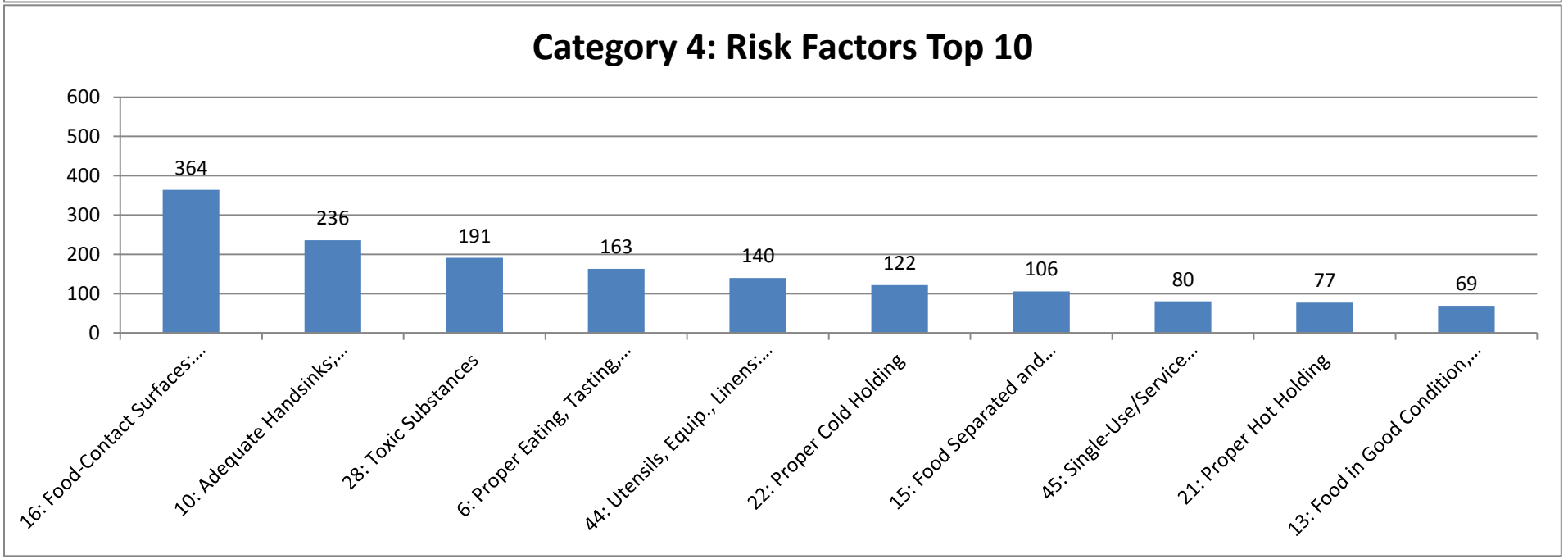
Appendix A: Charts



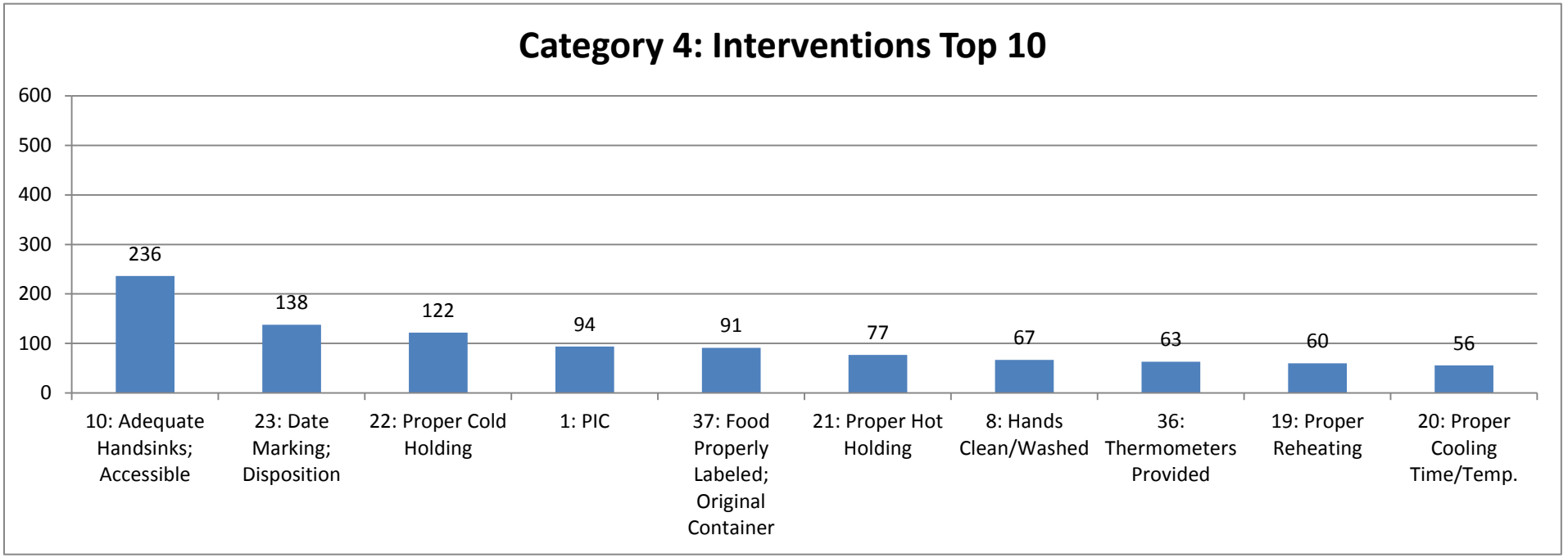
Appendix A: Charts

Top violations from **Category 4** establishments. Category 4 establishments includes establishments serving highly susceptible populations or are institutions. These includes schools, jails, child care, day care, hospitals, and assisted living centers.





Appendix A: Charts



Appendix B

Population information from the National Center for Health Statistics (NCHS) through a collaborative agreement with the U.S. Census Bureau. Retrieved on 25 October 2017 from Utah Department of Health, Center for Health Data and Informatics, Indicator-Based Information System for Public Health website: https://ibis.health.utah.gov.

Study Area Population, by participating local health jurisdiction, 2016

Local Health District	Population
Bear River HD	178,211
Davis County HD	342,281
Salt Lake County HD	1,121,354
Summit County HD	40,307
Utah County HD	592,299
Weber-Morgan HD	258,997
TriCounty HD	52,254
Total Study Area	*2,585,703*
Total State Population	*3,051,217*
	85%