



Health, Housing &  
Community Services Department  
Division of Environmental Health

**California Conference  
of Directors of Environmental Health  
Excellence in Environmental Health Award 2017**

**Adopting and Sustaining  
a Risk-Based Retail Food Safety Program**

## Overview

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The Retail Food Safety Program (RFSP) has always been and will continue to be the most impactful Environmental Health program regulated by California REHSs. Food safety touches every person every single day. A wrong decision, or a failure to require immediate corrective action, can result in illness, injury, or death.

In late 2012, the City of Berkeley Environmental Health Division's (EHD) RFSP embarked on an ambitious project, funded in-part through cooperative agreement grants with the Food and Drug Administration (FDA), to develop and implement program improvements by adopting and sustaining the *FDA Voluntary National Retail Food Regulatory Program Standards (Standards)*. Project goals are to:

- *Improve RFSP effectiveness;*
- *Reduce frequency of CDC identified risk factors;*
- *Promote active managerial control (AMC); and*
- *Develop a strategy for long-term RFSP support by institutionalizing a risk-based food safety culture throughout City governing documents and agencies.*

Berkeley's RFSP has more than 1,000 fixed facility permits and a current staff of four Field Specialists and one Senior REHS; in addition, a part-time Senior REHS is project coordinator. A Supervising REHS and Division Manager provide oversight for all programs under EHD's umbrella.

Approximately 93% of fixed food facilities in Berkeley are owned and operated independent of national or regional chains. These facilities have little or no access to reliable food safety training materials and rely heavily on information shared by Field Specialists.

As an enrolled jurisdiction in the Standards, we conducted a self-assessment, or internal review, to determine whether our RFSP met any of the Standards. We were aware of some shortcomings, but thought our Field Specialists were conducting effective risk-based inspections (RBI) by following CalCode's *Food Inspection Data Field Marking Guideline*. However, the results of our self-assessment made it apparent we had large gaps to fill to make the entire RFSP fully "risk-based."

In years past, RFSP procedures and policy were generally created in response to a single challenge or concern; in many cases, only long-standing but unwritten protocol existed. This project worked to integrate risk-based concepts and update existing procedure into a limited number of comprehensive manuals that are more easily interpreted, cross-referenced, and maintained. Each is considered a "working document" to be updated when needed to incorporate new information and to reflect changes in regulations, best-practices, and most importantly, lessons learned.

- *Training and Standardization Procedures*
- *Risk-Based Inspection (RBI) Procedures*

- *Field Investigation Procedures*
- *Compliance and Enforcement (C&E) Procedures*
- *Quality Assurance Program (QAP) Procedures*

## **Partnerships and Collaboration**

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Throughout this project, we reached out whenever possible to capitalize on the knowledge and success of others. Examples of partnerships and collaboration include:

- Querying jurisdictions that had met multiple Standards regarding lessons learned.
- Working with our FDA Regional Specialist to adapt and customize FDA documents.
- Collaborating with Berkeley's Communicable Disease Control Program (CD) to improve communication and investigation protocol.
- Partnering with California Emerging Infections Program (CEIP) to investigate underreported but confirmed foodborne illnesses possibly linked to Berkeley facilities.
- Participating in a CDPH pilot project with other jurisdictions and the National Environmental Assessment Reporting System (NEARS).
- Working with FDA, California Department of Public Health (CDPH), and California Department of Food and Agriculture (CDFA) to provide onsite training.
- Utilizing staff to field-test documents and incorporate feedback prior to full implementation.
- Exchanging information and documents with other regulatory jurisdictions.

## **Sustained Improvements**

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Since embarking on this project, Berkeley has achieved full conformance and successfully passed a verification audit for five Standards:

- Standard 2 – Trained Regulatory Staff (October 2015)
- Standard 3 – Inspection Program Based on HACCP Principles (October 2015)
- Standard 4 – Uniform Inspection Program (June 2017)
- Standard 5 – Foodborne Illness and Food Defense Preparedness and Response (October 2015)
- Standard 7 – Industry and Community Relations (April 2015)

In addition, we anticipate conformance and a successful verification audit in late 2017 for:

- Standard 6 – Compliance and Enforcement

The outcome of meeting these Standards is that retail food safety in Berkeley is improved.

With enhanced staff training and standardization, and by incorporating a risk-based philosophy to all aspects of inspection and investigation, the RFSP is more consistent, more focused, and more credible. Overall efficiency has been enhanced via a policy and procedure framework that minimizes "reinventing the wheel" at every turn. Moreover, by promoting AMC, Field Specialists provide operators with knowledge and tools to help minimize the occurrence of risk factors long after the inspection ends. Factored together, these changes offer improved service to the regulated community and the general public.

## **Summary of Innovations Implemented**

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It is recognized that a large volume of quality materials have been created by regulatory jurisdictions and available publically. This project utilized the Standards as a foundation and, whenever possible, incorporated best practices from other sources to help meet our needs.

When unable to find appropriate examples, we invested the time needed to develop customized and, at times, innovative documents, handouts, and field tools (see also attached document list).

## 1. Training and Standardization Procedures

The Supervising REHS serves as the Division's Training Standard and is standardized to both FDA Food Code and CalCode. All Field Specialists were standardized in 2015 to CalCode using procedures equivalent to *FDA Procedures for Standardization*.

- Developed procedures and documentation; including:
  - ✓ New-hire assessment of training needs based on California REHS competencies.
  - ✓ Affidavit of previous training and experience.
  - ✓ Verification of FDA ORA U course equivalency.
  - ✓ Training plan and field objectives with progressive responsibility identified for a California REHS, for Standard 2, and *FDA Procedures for Standardization*.
    - Reduces redundancy in using multiple protocols with similar criteria.
    - Ensures all requirements are included in initial training.
  - ✓ Customized assessment tools:
    - Part 1: required prior to conducting independent inspections of low risk facilities.
    - Part 2: required prior to conducting independent inspections of higher risk facilities.
    - Part 3: activities best assessed in a classroom/laboratory; required prior to conducting the specified activity.
    - Part 4: combined requirements from Parts 1 and 2. Required to assess an experienced REHS prior to conducting independent inspections; also required prior to initial standardization for all Field Specialists.
  - ✓ Standardization procedures and verification equivalent to FDA procedures.
  - ✓ Executive summary tracking training and continuing education from hire date to standardization and re-standardization.

## 2. Risk-Based Inspection (RBI) Procedures

- Provided 28-hours of in-house classroom training, including:
  - ✓ Theory, protocol, and practical application of RBI.
  - ✓ Regulatory code/policy review – consensus interpretation of “gray areas” and identification of “parking lot” topics.
  - ✓ Risk factors and interventions – major versus minor; immediate corrective action (ICA); temporary suitable alternatives (TSA); active managerial control (AMC).
  - ✓ Good retail practices (GRP) leading to a major violation.
  - ✓ Verbal and written communication skills.
  - ✓ Compliance and enforcement options.
- Developed *Criticality Matrix* to assess priority/criticality when observing more than one risk factor violation; compares urgency of correction and impact to public health.
- Developed tools to integrate RBI with AMC and procedures, training, and monitoring (PTM):
  - ✓ Tri-fold brochure introducing AMC and its benefits.
  - ✓ Comprehensive AMC self-assessment divided into categories: working with potentially hazardous foods, food workers, general activities.

- ✓ Abbreviated AMC self-assessment for facilities with repeat violation history.
- ✓ Adapted FDA materials to:
  - Provide questions/tips for assessing AMC.
  - Use AMC-PTM assessment to determine appropriate course of action.
- Developed HACCP and Variance field verification forms.
- Created new RBI data collection categories and reports:
  - ✓ Risk category assignment with auto-generated inspection frequencies.
  - ✓ “Corrected onsite” actions and “repeat” violations.

### 3. Quality Assurance Program (QAP) Procedures

- Developed protocol to help ensure a uniform inspection program:
  - ✓ Identified performance areas.
  - ✓ Designed field audit tool encompassing Standard 4 requirements in Standard 4 and Standard 2 re-standardization requirements; resulting in one activity meeting both Standards.
  - ✓ Developed documentation for auditor and Field Specialist comments/concerns, action plan, follow-up, and activity tracking.
- Established *Record of Communication* to document conversations with facility management and directives not documented during an inspection or investigation (e.g., phone conversations).

### 4. Field Investigation Procedures (foodborne illness, food emergency, special investigations)

- Updated intake interview to capture emerging/non-traditional sources (e.g., delivery, personal chefs, internet purchases, pop-ups, farmers markets, cottage foods).
- Established triage for alleged foodborne illness complaints and forms to standardize how investigations are conducted and documented.
  - ✓ *Level 1 – Risk Factor Assessment for Alleged Foodborne Illness (RFA:Epi):*  
Determines overall facility compliance with risk factors and closure criteria. Generally conducted when:
    - *only 1 person ill*
    - *multiple persons ill from same household*
    - *persons from different households ill, but NO common food (e.g. possible Norovirus; developed customized RFA:Noro)*
    - *persons from different households ill and multiple common foods (e.g., buffet)*
    - *large event with pending food history; investigation level may increase as information becomes available*
  - ✓ *Level 2 – Hazard Assessment:*  
Builds upon RFA:Epi (Level 1) by adding review of operational compliance of risk factors by evaluating process steps of identified food(s) (e.g., common food, ground beef). Generally conducted when:
    - *persons from different households ill and common food(s) identified*
    - *ill person age 9 or under and consumed ground beef*
    - *RFA reveals out-of-compliance risk factor related to menu item consumed by ill person(s)*

- ✓ *Level 3 – Epidemiological Investigation:*  
Builds upon Hazard Assessment (Level 2) by adding food handler interviews and complete review of suspect food item(s) and ingredients, including:
  - *Operational steps/processes*
  - *Method of preparation/equipment*
 Generally conducted ONLY with laboratory confirmed diagnosis.
- ✓ Environmental assessment and data collection documents:
  - *CDPH Data Collection* – transcribes investigation findings to required reporting categories.
  - *Field Notes Supplement* – investigations related to eggs, ground beef, or schools; required for National Outbreak Reporting System (NORS).
  - *Outbreak Environmental Assessment* – captures all NEARS required elements.
  - *NEARS “short form”* – abbreviated data collection tool.
- Utilized increased number of foodborne illness reports (via partnership with CEIP and clarifying intake procedures) to fine-tune investigation documents.
- Adapted tools from Alaska and Washington State to help focus foodborne illness investigations.
- Coordinated activities between CD and EHD:
  - ✓ Established roles, responsibilities, and lines of communication.
  - ✓ Developed secondary intake form when multiple people ill from common meal.
  - ✓ Established protocol for bodily fluid clean-up in a food facility.
- *Field Investigation Procedures* also include:
  - ✓ Restriction/exclusion of food employees
  - ✓ Food safety recalls and trace-back
  - ✓ Sampling protocol
  - ✓ Emergency response
  - ✓ Laboratory/communicable disease support
  - ✓ Management of media outreach/legal queries
  - ✓ Post-event hot wash
  - ✓ Data analysis/review
  - ✓ Contact lists
  - ✓ Color-coded charts to supplement narrative:
    - Triage criteria
    - Information flow
    - Data reporting
    - Required investigation documents
  - ✓ Complaint investigations will be incorporated at next update
- Developed *All Hazards Emergency Field Response* (currently in final draft) merging best practices for assessing food safety during emergency situations; not intended as a handout or to replace existing emergency response protocol.
  - ✓ Developed *Emergency Food Service Risk Control Plan* (EFS-RCP) – check-list of considerations when allowing food preparation/service under challenging conditions.

## 5. Compliance and Enforcement (C&E) Procedures

Procedures place emphasis on the distinction between “compliance” strategies and “enforcement” activities and transitioning from one to the other.

- Developed *Structural Evaluation Report* (SER):
  - ✓ Required prior to issuing a fixed facility permit to operate.
  - ✓ Used as periodic RBI supplement – documents compliance (or lack thereof) of physical structure, surface finishes, permanently installed equipment.
  - ✓ Establishes compliance schedule or restrictions for non-conformity.
  - ✓ Clarifies expectations for future compliance and consequences for non-compliance.
- Implemented *Pre-Permit Inspection* (PPI) requirement:
  - ✓ Review of facility file (electronic and paper).
  - ✓ Full menu review and equipment evaluation.
  - ✓ Comprehensive AMC self-assessment.
  - ✓ Risk factor assessment for a pre-permit inspection (RFA:PPI).
  - ✓ SER.
  - ✓ Verification of food safety manager and food handler certificates.
  - ✓ Verification of required consumer advisory.
- Established standardized narrative for enforcement actions, such as:
  - ✓ Cease and desist orders (CDO):
    - Impacted area
    - Construction
    - Menu change
    - Specialized process
  - ✓ Facility closure orders
- Established 4-step enforcement cycle:
  - ✓ *Step 1: Compliance Letter*
    - *Demonstrates seriousness of problem to help motivate compliance.*
    - *Indicates failure to comply will result in action to suspend or revoke permit.*
  - ✓ *Step 2: Notice of Violation (NOV)*
    - *Outlines repeat/recurring violation(s) with code reference(s) and required corrective action(s).*
    - *Establishes designated follow-up date and date/time of Administrative Hearing for Permit Suspension (Step 3) for failure to comply.*
    - *For repeat risk factor violation(s): indicates failure to comply will result in suspension of permit to operate.*
  - ✓ *Step 3: Administrative Hearing for Permit Suspension*
    - *For repeat risk factor violation(s): determines length of suspension and required corrective action(s).*
    - *For repeat GRP violation(s): outcome determined case-by-case (e.g., permit suspension, compliance schedule, menu modification, risk control plan, additional training).*
  - ✓ *Step 4: Administrative Hearing for Permit Revocation*
    - *Outcome options may include revocation or restriction of permit, remedial training, referral to City Attorney.*

## Metrics and Outcomes

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The original goals for this project were to achieve a specific reduction in risk factor violations over time. Monthly productivity reports have been generated and statistics and trends tracked. While providing a valuable management tool, this inspection data does not paint a true picture of actual outcomes of this project.

- Enhanced training and standardization of Field Specialists resulted in some out-of-compliance observations being reallocated to a different category.
- Because Berkeley is a small jurisdiction, the number of documented violations in many categories is so small that a percentage change is not an effective indicator.
- The implementation of multiple new policies caused short-term productivity challenges while staff endeavored to learn and follow new procedures; however, the long-term benefit is increased consistency regarding interpretation and enforcement.
- While individual productivity improved over time, multiple staff vacancies created fluctuations in aggregate productivity.

To monitor metrics and outcomes, performance indicators were established with a tracking tool indicating assigned responsibility and required deadlines.

## Continuous Improvement

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The challenge for Field Specialists to communicate food safety principles to a diverse audience – while assisting the operator to implement needed interventions *and* improve AMC – can feel overwhelming. Developing interventions and AMC-PTM materials for specific risk factors will greatly improve the Field Specialists' effectiveness. Collating these sample procedures, training materials, and monitoring tools into modules readily accessible to Field Specialists via existing tablet computers is underway.

In addition, a sustainability and resilience plan is being developed to identify crossover areas between the Standards and existing Berkeley initiatives (e.g., *100 Resilient Cities* project, Business Improvement Districts); and to explore avenues to increase visibility of the RFSP, the Standards, and risk-based best-practices within official City documents (e.g., Municipal Code, Citywide Work Plan).

The emphasis and focus of all improvement projects is to develop strategies and materials that reinforce, support, and institutionalize the Standards for the continuous improvement of Berkeley's Retail Food Safety Program.

This project would not have been possible without FDA funding or without the Standards as a framework. Our journey has had challenges. The FDA grant application process and reporting requirements are time-consuming. Modifying any given policy/procedure often required back-and-forth changes in other documents to ensure consistency. And, we continue to strengthen our internal work culture to embrace the changes. The end result, however, is extremely positive. Berkeley now has an integrated, fully risk-based RFSP lending credibility to our Division and to our Field Specialists as they do their job every day.