FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Food Defense During a Radiological Emergency

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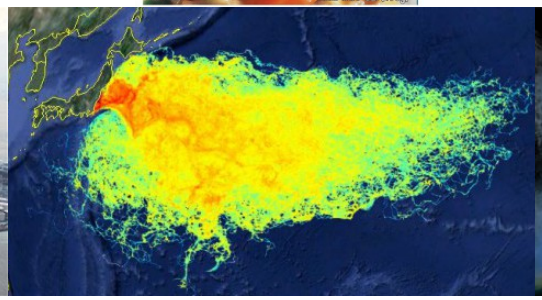


Outline

- FDA regulatory program for radionuclides in foods
- What is the Food Emergency Response Network
- Radiological FERN Network
  - Past
  - Present
  - Future

FDA Radionuclides in Foods

- Imported foods from Europe (Chernobyl)
  - Gamma (Cs-137)
    - Derived Intervention Level (Cs-137+134): 1200 Bq/kg
  - Beta
    - Sr-90 DIL: 160 Bq/kg
- Total Diet Study
  - Surveillance of Radionuclides in the Environment/ Food Supply Background
- Nuclear Reactor Surveillance (4 per year)

Emergency Response

- Additional Methods for alpha emitters
  - Po-210
  - Pu
  - Am

What is **FERN**?

Food **E**mergency **R**esponse **N**etwork

A network of State, Private, and other Federal Laboratories available to aid each other in Emergency Response and Emergency Preparedness Activities related to the food supply.

Original FERN Mission - 2002

Integrate the nation's food-testing laboratories for the detection of intentionally added threat agents in food at the local, state, and federal levels.

A *comprehensive effort* aimed at the detection of biological, chemical and radiological agents in the full range of food commodities.

Expanded Mission of FERN

Integrate the nation's multilevel food-testing laboratories to detect, identify, respond to and recover from a bioterrorism or public health emergency/outbreak involving the food supply

Mission Expansion

- Transition from exclusively bioterrorism to inclusion of food safety
- Utilization of FERN cooperative agreement labs
- Integrated Food/Feed Safety System

Food Defense vs. Food Safety

- *Food defense* – the protection of food products from *intentional adulteration* by biological, chemical, physical or radiological agents
- *Food safety* – the protection of food products from *unintentional contamination* by agents
- Combination now: Food Protection

Laboratory Makeup

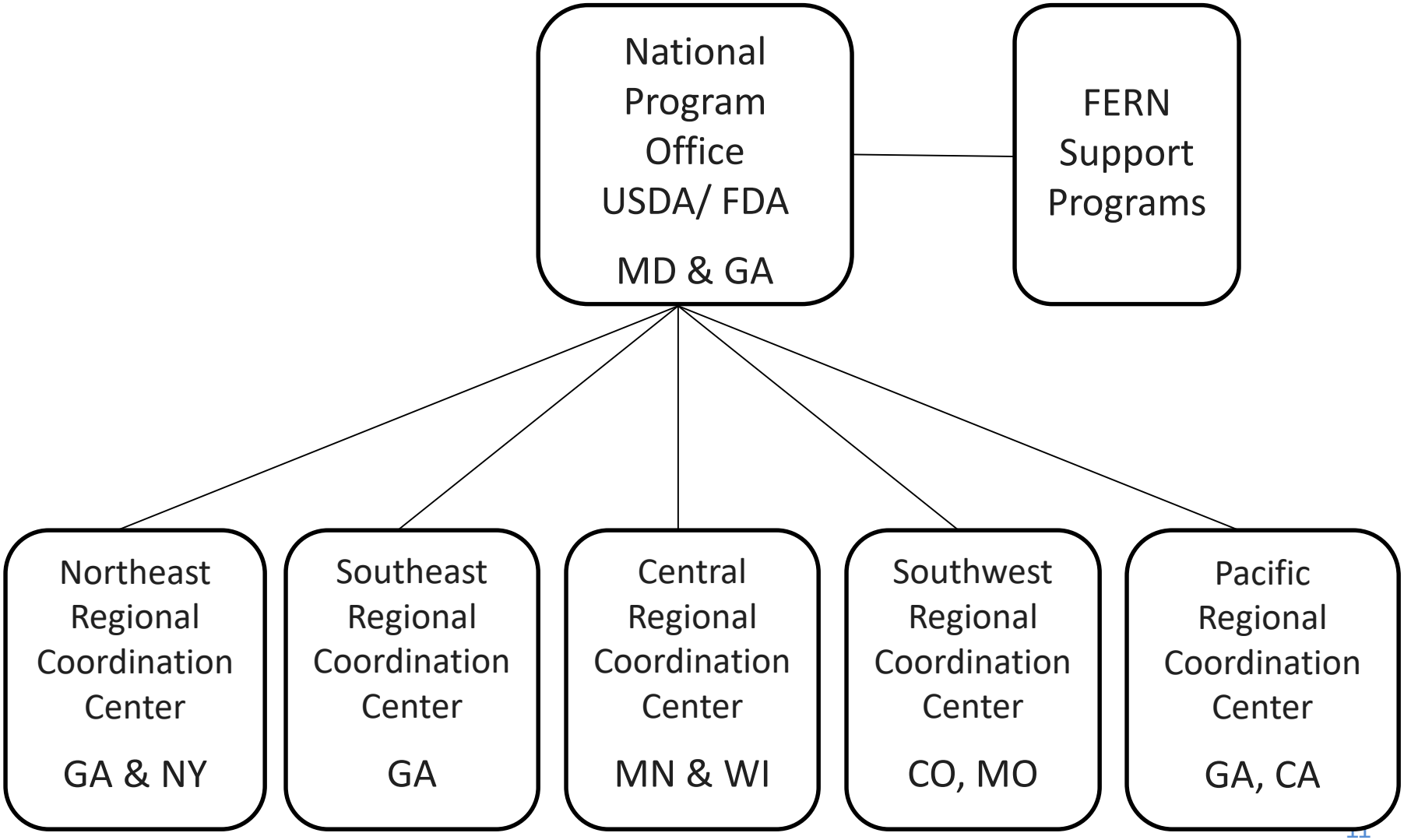
169 Laboratories

Affiliations	Disciplines	Lab Testing Types
39 Federal	113 Microbiological	115 Food Safety (Outbreak)
113 State	111 Chemistry	90 Food Safety (Regulatory/Routine
17 Local	31 Radiological	40 Agricultural Input
		22 Veterinary Diagnostic
		102 Environmental
		58 Clinical

FERN Objectives

- Detection: identification of biological, chemical, and radiological threat agents
- Prevention: operate targeted federal/state surveillance sampling programs
- Preparedness: strengthen laboratory capacities and capabilities
- Response: provide large-scale laboratory testing capacity
- Recovery: provide public assurance of food safety following an emergency

FERN Organizational Chart



Winchester Engineering and Analytical Center: Specialty Lab

- Engineering Branch
  - Medical devices
  - Electronic products

- Analytical Branch
  - Sterility of Medical Devices
  - Radiochemical Analysis of FDA regulated products
  - Technical Advisors of the Radiological FERN Network

Radiological FERN

- PAST (2002-2014)
- 5 FDA CAP Grant labs
- Equipment
  - Gamma Detectors and Liquid Scintillation Counters
- Exercises
  - Po-210
  - Empire ‘09
  - MENU 2010

Fukushima

- Increased demand for analysis of imported foods from Japan
- Radiological FERN Network Activated
- None of the FERN labs had been evaluated
  - Can the FDA accept data and make regulatory decisions with data from outside labs?
  - What is the data acceptance criteria?
  - How does data get reported?

FERN- Present

- RadEx Interlaboratory Comparison on Screening Alpha/Beta Radioactivity in Foods
- ICLN Full Scale Radiological Laboratory Exercise
- FERN Gamma Intercomparison Studies
- FERN Gamma class: LB517 FDA/FERN Gamma Spectroscopy-Analysis for Food
- FERN alpha/Beta class: LB523 FDA/FERN Screening for Alpha/Beta Radioactivity in Food

RadEx Interlaboratory Comparison on Screening Alpha/Beta Radioactivity in Foods

The Problem: FERN did not have rapid method and surge capacity for screening alpha/beta radionuclides in foods

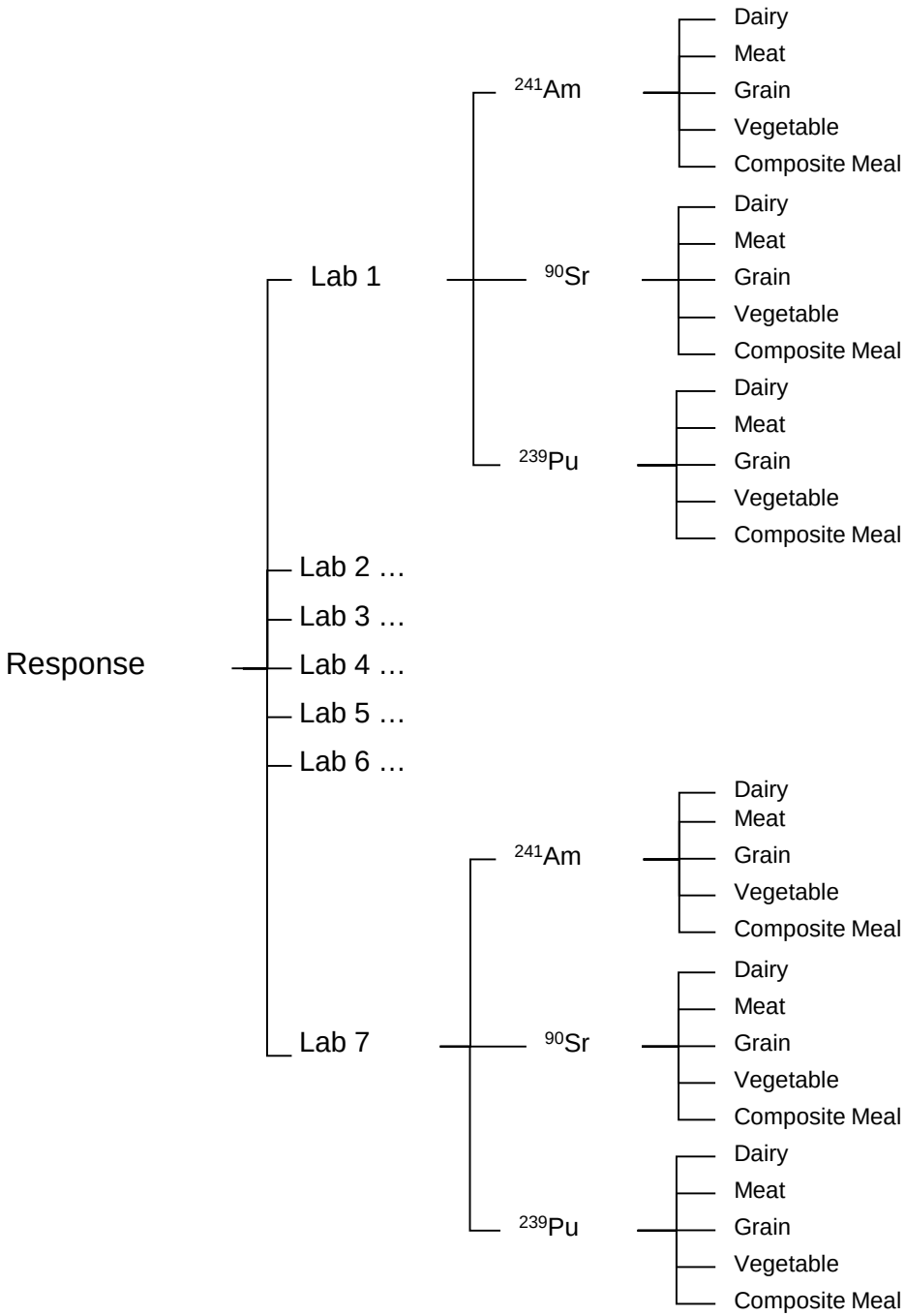
The Solution: Development of method using high selectivity solid-phase extraction and discriminative liquid scintillation spectrometry for alpha/beta radioactivity detection

The Approach: Identify radionuclides of most concern → Single laboratory development → Collaborative matrix extension study → Proficiency testing → Proven network capability and capacity

The Objective: Develop and implement a robust high-throughput alpha/beta screening method that ensures effective FERN radiological emergency response

RadEx Interlaboratory Comparison on Screening Alpha/Beta Radioactivity in Foods

- Method development at WEAC
  - Digestion of fresh food products in Nitric Acid
  - Solid Phase extraction using Eichrom DGA resin
  - Liquid Scintillation Counting
- Phase 1
  - Share method with FERN labs
  - Answer questions/ instrument calibrations



Phase 2

- Matrix extension utilizing FERN Labs
- Each lab assigned 3 matrices from each food group
- 15 matrices total per lab
- Each matrix analyzed for Pu-239, Am-241, Sr-90

Phase 3: Proficiency Testing and Evaluation

- 15 of 31 FERN rad labs equipped to analyze alpha/beta activity using this method
- The method is sensitive enough to allow the detection of ^{90}Sr at 1/3 FDA DIL
- The method offers sensitive detection of ^{241}Am and $^{238,239,240}Pu$, but sample size and count time must be cautiously determined to meet 1/3 FDA DIL
- Method performance is dependent on analyst skill level
- Training is necessary to ensure network capability of screening food for alpha/ beta emitters

The Integrated Consortium of Laboratory Networks (ICLN) Confidence Building Competency Test (CBCT)

- the ability of networks to perform a non-routine method on a non-routine matrix at an acceptable level of quality and the ability to combine information from several networks using prescribed data reporting and communication procedures
- FDA, CDC, EPA, DOE
- Funding from DHS

ICLN Exercise: FDA/ FERN Objectives

- ability of FDA's Food Emergency Response Network (FERN) to conduct food safety assessment and post-event food surveillance in a nuclear or radiological event that involves alpha and beta radioactivity
- Test FERN's ability to identify the analytical criteria required for participation in a united analytical effort
- Test FERN's ability to prepare and ship test samples
- provide instructions on how to report data, and merge data results using the ICLN minimum data elements (MDE) spreadsheet and/or the ICLN Portal Data Exchange Utility (DEU) in a realistic timeframe

ICLN Exercise

- Scenario
  - **DENVER:** Denver, Colorado was notionally impacted by an Radioactive Dispersal Device (RDD) containing strontium-90 (a beta-emitter)
  - **CHICAGO:** Chicago, IL (Chicago O'Hare Airport) was notionally impacted by an RDD containing plutonium-239 (an alpha- emitter)

ICLN Exercise

- The **early phase** begins at the time of release of the radioactive material and generally continues until the release has been controlled. During this phase, protective actions are generally based on the status of the situation and limited information on the type and quantities of materials present. This phase may last from hours to days.
- The **recovery phase** (also referred to as the late phase) is the period beginning when recovery action designed to reduce radiation levels in the environment to acceptable levels for unrestricted use are commenced, and ending when all recovery actions have been completed. This period may extend from months to years.

ICLN Exercise

- Samples prepared at WEAC
- 17 FERN Labs participated
- Apple juice spiked with known amounts of Sr-90 and Pu-239 for both phases

Considerations in Preparation of Test Samples

The test samples should be able to:

- Assess method detection capability for Sr-90 and Pu-239
- Assess frequency of false positive and false negative detections for the applied methods
- Assess conformity of sample analyses
- Assess minimum detection limit for the applied methods

ICLN Exercise

Sample Statistics

Early Phase: 48 hours to complete analysis and report data

Samples tested for alpha radioactivity = 76

Samples tested for beta radioactivity = 110

Recovery Phase: 1 week for analysis and data reporting

Samples analyzed for Pu-239 = 51

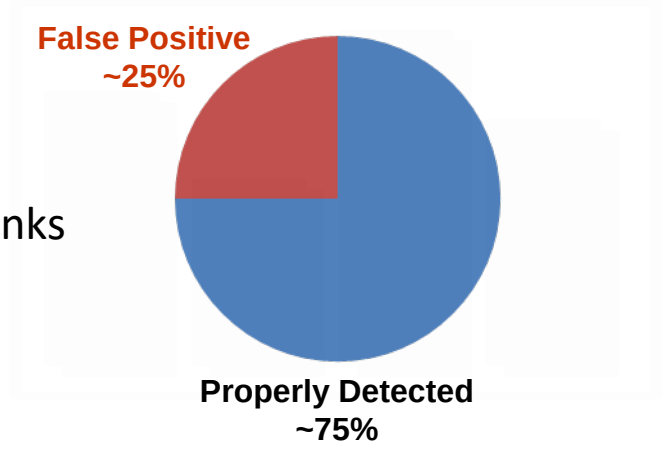
Samples analyzed for Sr-90 = 85

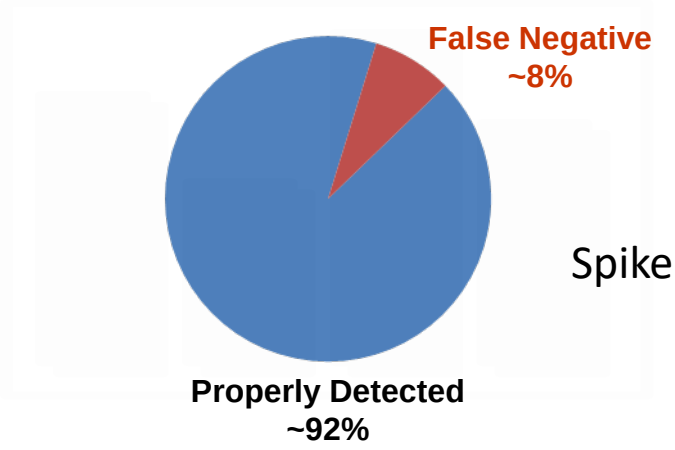
Total number of samples completed throughout the exercise
322

ICLN ‘s Expectation for FERN network
200 - 300

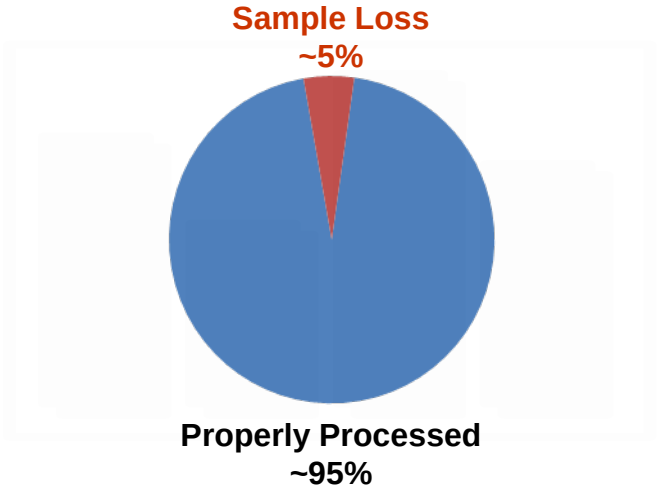
ICLN Exercise

Blanks





Spiked samples



ICLN Lessons Learned

- Data reporting issues – unable to upload spreadsheet into FERN Data Portal
  - FERN IT support had problem fixed by the time the data was due
- Not all data reported on time (2 labs late in early phase)
- False Negatives/ Positives
  - Method related

    GPC method needed

FERN Gamma Method Intercomparison Study

- 26 of 31 labs participating
- Food samples prepared, spiked and shipped from WEAC
- Samples spiked heterogeneously
  - Cs-134, Cs-137, Co-60, Ba-133
  - Amounts far below FDA action levels for each radioisotope

FERN Gamma Method Intercomparison Study

- Objectives
  - Allow labs to use routine methods
  - Control count time (10 minutes)
  - Evaluate labs ability to detect and identify a variety of radioisotopes of concern
  - Select variety of foods of varying density
  - Evaluate labs ability to homogenize sample

  * While labs were not evaluated based on ability to quantify radioactivity we did request this information in order to assess this capability

FERN Gamma Method Intercomparison Study

- Conclusions
  - Composite and homogenization of heterogeneously contaminated food products for gamma spectrometric analysis were realistically practiced
  - Sample homogenization methods used by some participating laboratories need improvement
  - All laboratory's methods were able to correctly identify gamma radionuclides presented in the test food samples
  - Radionuclides of interest were detectable down to 1/4 of regulatory limits with 10-min count time
  - Harmonization of uncertainty calculation is needed
  - Not all labs are correcting for density and coincidence summing

Training

- LB517:FDA/FERN Gamma Spectroscopy-Analysis for Food
- LB 523: FDA/FERN Screening for Alpha/Beta Radioactivity in Food

FERN Future

- Continue with exercises and training to improve network capability and performance
- Continue working with network to develop new rapid methods for emergency response
- Expand Intercomparison Studies to alpha and beta emitters (tritium, Sr-90, Pu, Am, etc.)

Questions?