

# Food Emergency Response Network (FERN)

U.S. Food and Drug Administration  
Office of Regulatory Affairs

## Food Emergency Response Network



Presented by:

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USFDA - Pacific Region  
Oakland, CA

## Mission of FERN

- Integrate the nation's food-testing laboratories for the detection and identification of threat agents in food at the local, state, and federal levels.
- Includes biological, chemical, and radiological threat agents.

## Homeland Security Presidential Directive

HSPD-9: Defense of U.S. Agriculture and Food (1-30-04)

**Secretaries of Interior, Agriculture, Health and Human Services, and Administrator of EPA ... shall build on and expand current monitoring and surveillance to :**

- Develop robust, comprehensive, and fully coordinated surveillance and monitoring systems, including international information, for animal disease, plant disease, wildlife disease, food, public health, and water quality that provides early detection and awareness of disease, pest, or poisonous agents;

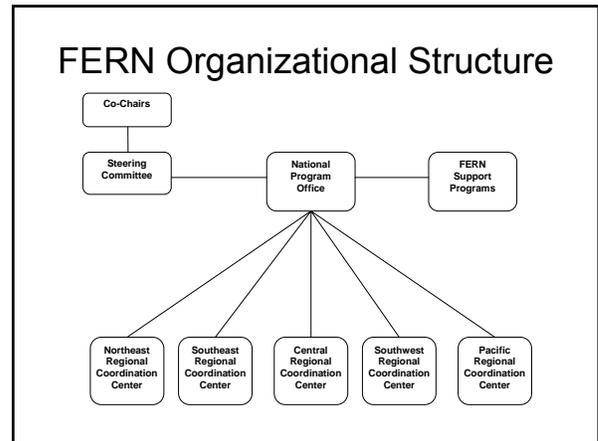
## Homeland Security Presidential Directive:

HSPD-9: Defense of U.S. Agriculture and Food (1-30-04)

- Develop systems that, as appropriate, track specific animals and plants, as well as specific commodities and food;
- Develop nationwide laboratory networks for food, veterinary, plant health, and water quality that integrate existing Federal and State laboratory resources, are interconnected, and utilize standardized diagnostic protocols and procedures.

## FERN Objectives

- **Prevention – federal/state surveillance sampling programs**
- **Preparedness – strengthening lab capabilities/capacities**
- **Response – surge capacity**
- **Recovery – provide assurance to the consumer**



- ## FERN Steering Committee
- **Federal**
    - HHS, FDA-ORA, FDA-CFSAN, CDC
    - USDA-FSIS, USDA-APHIS, USDA-AMS, USDA-ARS, USDA-GIPSA
    - US Customs, DoD, FBI, EPA, DHS
  - **State**
    - Agriculture
    - Public Health
    - Veterinary Diagnostic
    - Environmental

- ## FERN National Program Office (FERN NPO)
- Co-located in Rockville, MD and Athens, GA
  - Responsible for day to day operation of FERN
  - Manage and coordinate FERN Support Programs
  - Coordinate the national laboratory emergency response
  - Coordinate Regional Coordination Center (RCC) activities

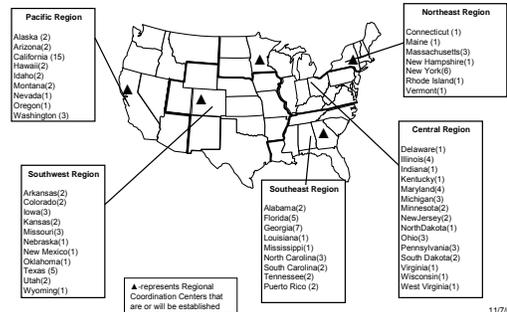
- ## Regional Coordination Centers (RCCs)
- Five RCCs will be located through the U.S. and will be staffed by FDA and USDA.
  - Ensure adequate screening, confirmatory and forensic capacity within the region
  - Identify needs of the region and convey those needs to the NPO
  - Coordinate regional response of laboratories during an emergency

- ## FERN Support Programs
- Laboratory Outreach
  - Method Development/Validation
  - Training
  - Proficiency Testing
  - Surveillance
  - Electronic communications

## Laboratory Outreach

- 122 Laboratories representing 50 States and Puerto Rico have satisfactorily completed FERN Laboratory Qualification Checklists
  - Affiliations – 27 Federal (FDA, USDA/FSIS, USDA/AMS, DHS, CBP); 86 State; 9 Local
  - Disciplines – 89 Chemical; 93 Microbiological; 27 Radiological

## Food Emergency Response Network Federal, State, and Local Laboratories



11/7/05

## Laboratory Outreach - Regional Coordination

- 2 Meetings were held in Fiscal Year 05
  - August 11-12, 2005 – Central RCC in Madison, WI
  - August 22-24, 2005 – Pacific RCC in Richmond, CA
- 3 Meetings were held in Fiscal Year 04
  - July 26-27, 2004 - Northeast RCC in Amherst, MA
  - September 14-16, 2004 - Southwest RCC in Denver, CO
  - September 28-29, 2004 - Southeast RCC in Athens, GA

## Methods Development/Validation

- Standard Operating Procedure for FERN Methods Evaluation has been established and has been posted on eLEXNET.
  - Process ensures based on minimum standards, methods will provide consistent repeatable results in food matrices
  - Collaborative efforts (i.e. NMSU) will provide effective means to evaluate potential FERN Methods.
  - FERN Methods have also been shared with CDC/LRN.
- 31 FERN Methods have been developed and posted on eLEXNET. – 8 Microbiological, 22 Chemical, & 1 Radiological

## Training Performed

- Developed a training plan which includes both web-based and face-to-face training on methods, BSL-3 level laboratories, tour of FERN, etc.
- Since 2003, over 200 participants have been trained from over 35 States

## Proficiency Testing

- Standard Operating Procedures developed by FERN sub-committee.
  - Process ensures participating laboratories can demonstrate ability to successfully conduct the analysis of CT samples.
- First Microbiological PT sample for *Bacillus anthracis* issued November 29, 2004. *This was a joint PT sample with LRN involving 66 laboratories.*
- Two Radiological PT samples for Cesium have been issued in FY 2005: December 2004 & September 2005 .
- Three Chemical PT samples will be issued in FY 2005
  - Colchicine in February 14, 2005 to 35 chemistry laboratories with LC/MS capabilities
  - LC/MS & GC/MS Poison Screen for unknowns Sept. 2005
  - ICP/MS Toxic Elements Screen for unknowns Sept. 2005

## Surveillance

- The Interstate Travel Program (ITP) was issued on May 3, 2005 to 5 FDA FERN labs and to 8 USDA and State labs. The ITP was the integration of Food Defense into an assignment.
- The Food Security Surveillance Assignment (FSSA) was issued October 12, 2004 to 9 FDA FERN labs and 7 USDA and State labs. During FSSA, FERN demonstrated the ability to function as an integrated network through federal-federal and federal-state interactions as well as through coordinated communication and data reporting.

## Surveillance

- FERN Surveillance Assignment was issued September 8, 2004 with 40 participating Federal and State laboratories.
- This assignment
  - Assessed and demonstrated the effectiveness and capabilities of the FDA FERN Chem/Micro and Rad laboratories
  - Tested the operating mechanisms and protocols of the network

## Electronic Communication

- The data capture and exchange mechanism for the FERN is the Electronic Laboratory Exchange Network
- For more information go to:  
[www.eLEXNET.com](http://www.eLEXNET.com)  
or  
Contact Ellen Olson  
([ellen.olson@fda.gov](mailto:ellen.olson@fda.gov))

## Electronic Communication

- The data capture and exchange mechanism for the FERN is the Electronic Laboratory Exchange Network (eLEXNET).
- eLEXNET is an integrated, secure system designed for multiple government agencies involved in food safety activities



## How does the FERN use eLEXNET?

- Collaboration:
  - FERN National Program Office shares current information, meeting minutes, documentation, and guidance information
  - FERN Subcommittees conduct discussions, disseminate information, and develop documentation
  - FERN Participants have a central location to check for information regarding activities
- Data Sharing:
  - Participants can review information on samples that have been submitted by eLEXNET's participating laboratories
  - FERN Pilot: FERN related data can be captured and reported independently

## eLEXNET's GIS Reporting Functions



## Methods Module

- Allows laboratories to rapidly enter, search, access, review, and print methods and method-related information
- Users can review and evaluate a variety of methods and technologies in order to identify and implement methods that meet their needs



## Integrated Consortium of Laboratory Networks (ICLN)

- **FERN is represented on the ICLN Network Coordinating Group (NCG)**
- **The NCG has developed several technical working groups that include proficiency testing, methods, training, information technology (IT), quality assurance and scenarios/prioritization**

## ICLN

- Purpose: to set out the Federal relationships required to establish an ICLN by providing an information sharing structure and describing the commitments undertaken by the signatories
- Reflects intent to work cooperatively to optimize national laboratory preparedness and provide mutual support wherever possible

## Laboratory Networks

- **Food Emergency Response Network**
- **Laboratory Response Network**
- **National Animal Health Laboratory Network**
- **National Plant Diagnostic Network**
- **Environmental Network**

## For Further FERN Facts

- National Program Office  
[ORAHQFERNNPO@fda.gov](mailto:ORAHQFERNNPO@fda.gov)

USDA, FSIS, OPHS, FERN, NPO  
950 College Station Road  
Athens, Georgia 30605

706-546-3578

FDA, ORA, DFS, FERN, NPO  
5600 Fishers Lane  
Rockville, Maryland 20857-0001

301-827-1037

## FERN RCC Contacts

## FERN: Pacific RCC Contact & ?'s

**Tom Sidebottom**  
Special Asst. for Science  
USFDA  
Pacific Region  
[Tom.Sidebottom@fda.gov](mailto:Tom.Sidebottom@fda.gov)  
510-637-3960 xt.130

**FERN National Program Office:**  
[ORAHQFERNNPO@fda.gov](mailto:ORAHQFERNNPO@fda.gov)



**Division of  
Human Resource Development**



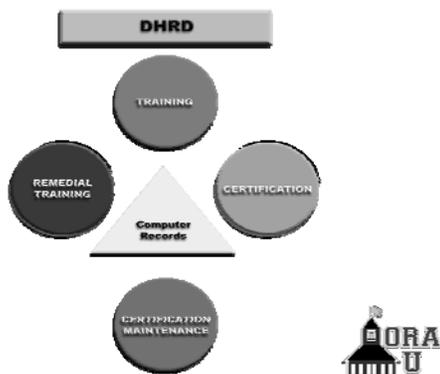
## Division of Human Resource Development

- State Training Team (State, local, tribal regulators)
- Regulatory & Science Team (FDA investigator & analyst)
- Distance Learning Team (Satellite, web, Strategic Systems Team - computer systems)
- Certification Team
- Resource Group



[www.fda.gov/ora/training/course\\_ora.html](http://www.fda.gov/ora/training/course_ora.html)

## How the Pieces Fit



## Course Structure

- CEU's thru the International Association of Continuing Education & Training
- CEU Application
  - Need & Target Audience
  - Course Objectives
  - Instructor Bio's & Agenda
  - Learning Support
  - Assessment of Learning Outcomes
  - Course Evaluation
  - Satisfactory Completion = Attendance + Participation + Assessment



**The assessment tools must match course objectives**

## Training Needs

Do FDA/State/  
Local/Tribal employees  
have the knowledge and  
skills to carry out their  
job of protecting the  
public health?



## More Training Related Needs ...

- Succession Planning
- Basic Knowledge/Skills
- Uniformity
- Updates - Cutting Edge Science/Technology
- Recruitment/Retention Tool
- Reduce Training Costs
- Right Training, Right Time, Right People

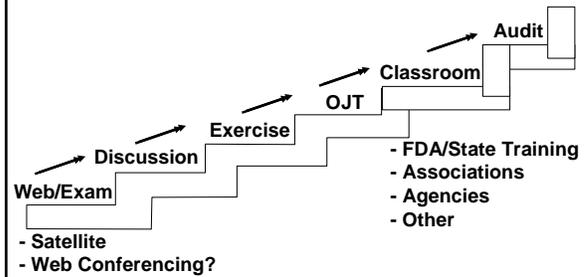
## Why?

It has to be safe...

They wouldn't allow it  
to be sold if it wasn't.



## Blended Learning



## Curriculums & Certification

### FDA Investigators & Analysts:

- Since 1995
- Mandatory Level I for New Hire w/in first 12 Months (1,070 as of Dec 2004)
- Voluntary Level II & III

### Level II Investigators (as of Dec 2004):

- Devices - 120
- Drugs - 21
- Blood Products - 42
- Seafood Products - 26
- Cooperative Programs Retail Foods, Shellfish, Milk - 24

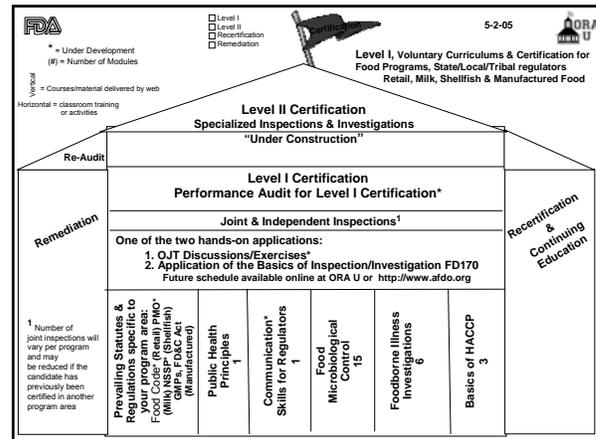
## Progress Through 2004

- Level I Analysts - 351
- More to Come
  - Bimo
  - Imports
  - PAS

## Voluntary Curriculums & Certification

State, Local & Tribal:

- Retail Foods
- Shellfish
- Milk
- Manufactured Foods (acidified, LACF, seafood HACCP, juice HACCP)
- Feed Control Officials (vet med)



## How are web courses developed?

CRADA with EduNeering:  
(Cooperative Research & Development Agreement)



- FREE access for:  
FDA, State, Local & Tribal regulators
- All other federal, industry, academia, etc. must inquire with EduNeering at:  
[www.EduNeering.com](http://www.EduNeering.com)

## Web Courses

- 110 on-line now
- 80+ in the queue
  - 2005 Food Code
  - Communication Skills for Regulators
  - Allergens
  - Plumbing & Cross-Connections
  - Basic LACF
  - Basics of Auditing for Regulators
  - Shellfish Overview
  - Shellfish Plants
  - Shellfish Growing Areas, Basics
  - Tracebacks
  - Basic Drugs
  - Basic Devices

## Continuing Education Online

- (New) An Introduction to Food Security Awareness
- Courtroom Testimony (60) MP6053
- Destruction and Reconditioning (60) MP6025
- Evidence and Proof (60) MP6009
- Food Labeling (60) FD3014
- Interviewing Techniques (60) MP6022
- Recalls of FDA Regulated Products (60) MP6010
- Risk Management 1: Key Concepts & Definitions (60) MP6069
- Sample Collection (90) MP6021
- Expected Conduct of FDA Personnel (90) MP6009
- FDA Establishment Inspection (90) MP6003
- FDA Establishment Report Writing (60) MP6023
- FDA 483s: Inspectional Observations (60) MP6011
- Recalls of FDA Regulated Products - FDA24 Version 2

## Continuing Education Web

### Traceback Investigations:

- Introduction
- Point of Service (POS) Investigations
- Distributor Investigations\*
- Eggs & Other Commodities\*
- Concluding the Investigation & Reporting the Results\*

### Food & Drug Law:

- FDA Jurisdictions (60) MP6014
- Prohibited Actions (60) MP6015
- Criminal Acts Violations (45) MP6016
- Judicial Actions (60) MP6017
- Imports & Exports (90) MP6018

## Web Course Status

- 80,000 web modules completed in 12 months (by 1,000 FDAers!)
- 7,989 FDAers signed on
- 8,000 plus - State/Local/Tribal Regulators
- "Some of the best training..."

## Classroom Courses (Retail, Manufactured Food)



- Low Acid Canned Foods FD103
- Food Processing & Distribution FD104
- Temporary Food Establishments FD108
- Food Code FD112
- Foodborne Illness Investigations FD325
- Acidified Foods FD202
- Plan Review FD207
- Managing Retail Food Safety FD215
- Preparation for Retail Food Standardization FD316

## "Collaborative" Classroom Courses

- ORA U & interested party develop course
  - CEU application, audience, objectives, agenda, etc.
  - Presentations w/ notes pages
  - Exercises & assessment tools w/ instructions
  - Handouts, user aids
- ORA U recognizes the course & interested party delivers



## "Collaborative" Classroom Courses



### Interested Party:

- May obtain collaborative course on CD or in a box
- Administer & deliver course
- Agenda: May localize or add content, but not remove content (CEUs remain the same)
- Sends ORA U the agenda & speaker bio's for CEU application addendum (prior to the course)
- Provides course logistics, materials & handouts
- Tracks participant's attendance, participation & meet assessment criteria
- Sends ORA U course evaluations & summary, sign-in sheets, registration forms

## "Collaborative" Classroom Courses



### ORA U:

- Processes agenda & bios for CEU application
- Provide electronically: sign-in sheets, registration forms, course evaluation summary sheet
- Processes registration & enters data for transcript
- E-mails certificates to successful participants
- Process course summary & evaluations
- Audit a number of collaborative courses
- Keep courses current

## Accessing Web Courses & User ID's

- On-line registration
- Send questions to: [ORAU@ora.fda.gov](mailto:ORAU@ora.fda.gov)
- Take a sample course "Tour of the FDA" at <http://www.eduneering.com/fda/courses/fdatour/welcome.html>



[www.fda.gov/ora/training/course\\_ora.html](http://www.fda.gov/ora/training/course_ora.html)

**FDA U.S. Food and Drug Administration** Department of Health and Human Services

OFFICE OF REGULATORY AFFAIRS

FDA Home Page | Federal/State | Import/Program | Compliance | Inspection | Science | OBA Search

**Training Contents**

- ORA U Start Page
- What's New
- Web-Based Courses
- State & Other Classroom Training
- Computer Training
- Broadcasts & Videoconferences
- State, Local, Tribal Certification
- Registration & Records
- Library
- Helpful Info
- Contact Us
- FAQs



ABOUT ORA **State, Local, and Tribal Regulators** FDA Employees

Click Here 

**FDA U.S. Food and Drug Administration** Department of Health and Human Services

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- Consumer Information
- Industry Assistance
- Recall
- Reinspection
- Field Contacts
- OTD Reading Room

**State, Local and Tribal Regulatory Partners**  
Welcome to ORA U!  
Last Update: February 4, 2004

In support of our common public health mission, FDA's Office of Regulatory Affairs' university (ORA U) provides free training to state, local and tribal regulatory partners.

ORA U is able to offer continuous learning with a combination of online courses and classroom training. We are an authorized provider of continuing education units (CEUs).

FDA/ORA collaborates with its stakeholders and organizations such as the Association of Food and Drug Officials (AFDO) and the Association of American Food Control Officials (AAFCO) to develop suggested curricula to meet the training needs of our regulatory partners.

Our vision is for ORA U to serve you as a source of training, as well as, a provider of certification.

Read the full text of the [Welcome Message from ORA U's Director](#)

[Online Courses](#)  
[Curricula & Registration](#)  
[Classroom Training](#)

### On-Line Registration Form

ComplianceWire™

**Self Registration**

Welcome to the FDA/ORA U Self Registration Page!

Please enter your user information, then click register at the bottom of the page.

The web based courses available through this registration portal were developed via a Cooperative Research and Development Agreement between the Food and Drug Administration (FDA) and EduNeering, Inc. or Princeton New Jersey. This agreement provides free access to these courses to FDA, state, local and tribal officials engaged in the regulation of foods and drugs. Other governmental officials, industry, academia and the general public may access these courses for a fee by contacting EduNeering.



**User Information**

Enter the User information in the fields below. Required fields are marked with an asterisk (\*).

First Name\* Middle Name\* Last Name\*

You can include your user ID below. It can consist of any combination of letters and numbers, but cannot exceed 10.

User ID\* Company Code\*  
FDAORAU

Position Title\*

Organization/Agency\*

Supervisor Name\*

Supervisor Job Title\*

Supervisor e-mail address\*

Supervisor Phone\*

Approved Funding Funding

Street\*

City\* State\*

Country\* Zip/Postal Code\*

Home Phone\* Work Phone\*

Fax\* E-Mail\*

### Login Procedure

**EDU NEERING™**  
ASSURING COMPLIANCE THROUGH KNOWLEDGE™

**Client Login**  
[EduNeering Home Page](#)

**Welcome to ComplianceWire™**

To log on to ComplianceWire, enter your login information, review the terms of use, and click the "I Accept" button below.

User ID:

Password:  [Forgot your password?](#)

Company Code:

**Terms of Use:** [Please read these Terms of Use carefully before using this site](#)

By using this site, you signify your assent to these terms of use. If you do not agree to them, please [click here](#).

Do you accept the Terms of Use?  I Accept

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### “My Catalog”

#### Alphabetical Listing of all Courses

ComplianceWire™

Welcome Back, William  
Wednesday, April 07, 2004

**My Catalog** Keyword Search:   [Advanced Search](#)

Your search returned 482 record(s). Page 1 of 16 is displayed below.

Token#	Training	Category
1	A Step-by-Step Approach to Process Validation (PHDV73 ver.1)	General
2	A Tour of the FDA (PHOV50 ver.2)	Multi-program
3	A Tour of the FDA (Analysis - Discussion) (PHOV90A ver.1)	Multi-program
4	A Tour of the FDA (Analysis - Exercise) (PHOV90EA ver.1)	Multi-program
5	A Tour of the FDA - Discussion (PHOV90C ver.1)	Multi-program
6	A Tour of the FDA - Exercise (PHOV90E ver.1)	Multi-program
7	Access to Employee Exposure and Medical Records (EM001 ver.1)	General
8	Active Listening Skills (EM4002 ver.1)	General

Page 1 of 16

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