

Food Emergency Response Network (FERN)

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

Food Emergency Response Network



Presented by:

**Tom Sidebottom
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

Food Laboratories are Mission-Critical Resources

Food Laboratories:

- Environmental
- Veterinary Diagnostic
- Agricultural
- Clinical
- Federal



Proficiency Testing



Method Validation



Consumer Complaints



Regulatory Compliance



Training



CT Surveillance



Routine Surveillance

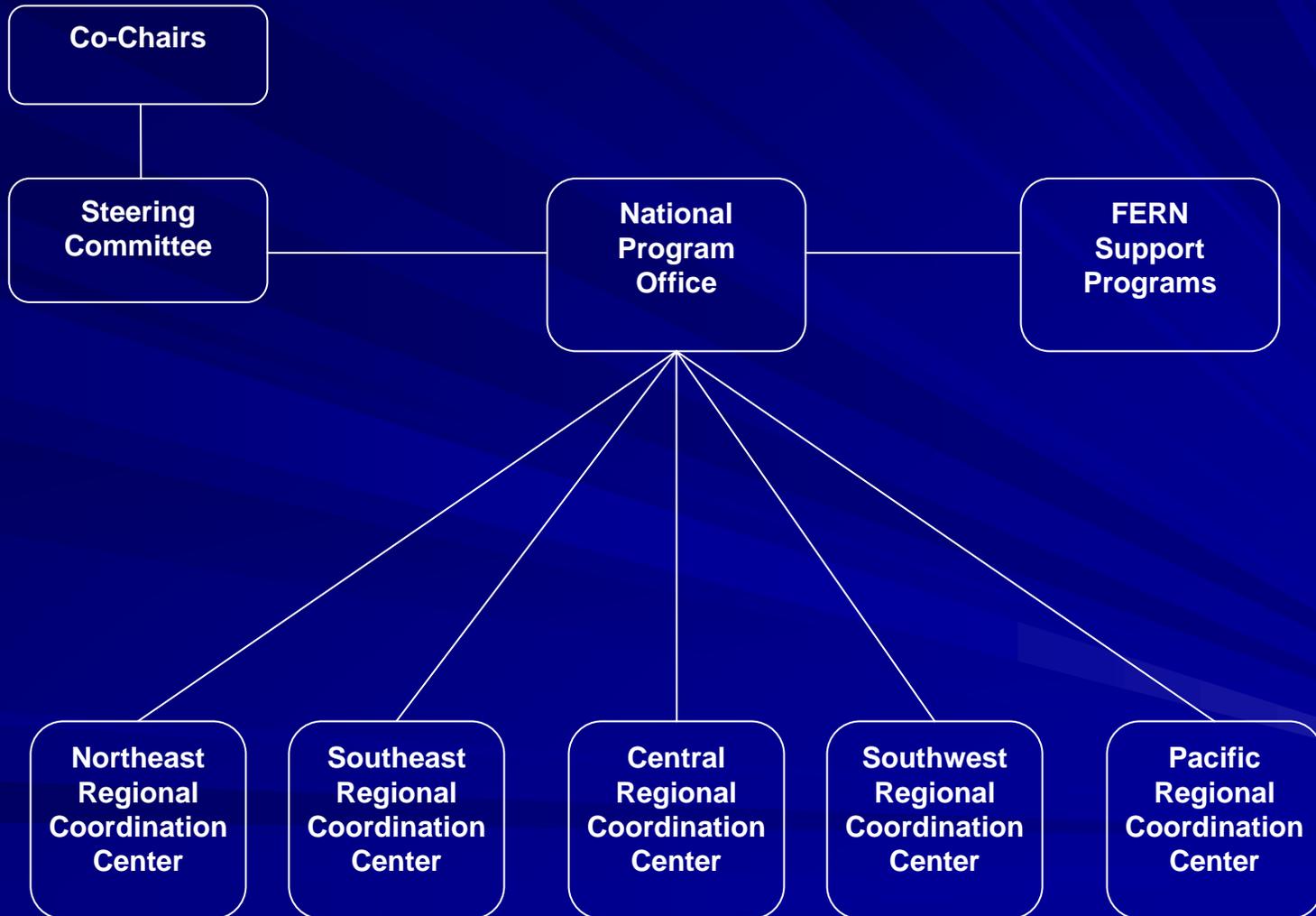


Outbreak Investigation



Emergency Response

FERN Organizational Structure



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

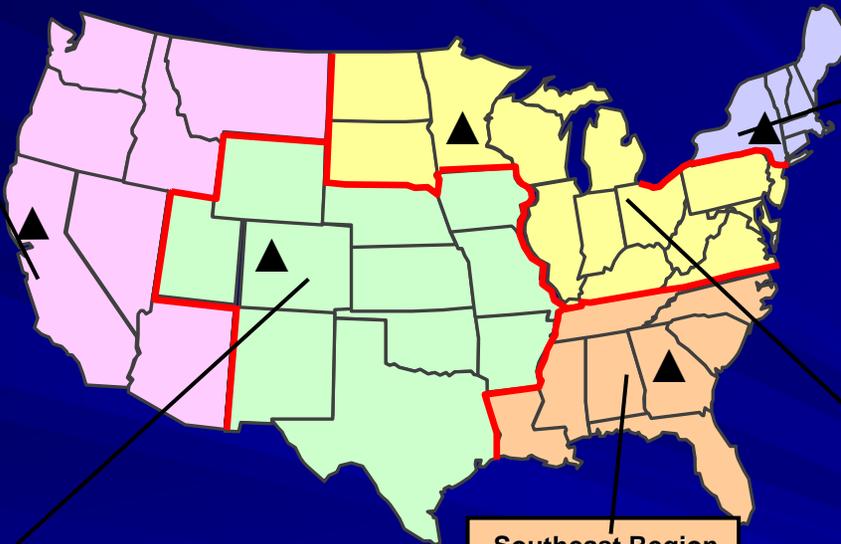
- 122 Laboratories representing 50 States and Puerto Rico have satisfactorily completed FERN Laboratory Qualification Checklists
 - Affiliations – 27 Federal (FDA, USDA/FSIS, USDA/AMS, DHS, CBP); 86 State; 9 Local
 - Disciplines – 89 Chemical; 93 Microbiological; 27 Radiological

Food Emergency Response Network

Federal, State, and Local Laboratories

- Pacific Region**
- Alaska (2)
 - Arizona(2)
 - California (15)
 - Hawaii(2)
 - Idaho(2)
 - Montana(2)
 - Nevada(1)
 - Oregon(1)
 - Washington (3)

- Northeast Region**
- Connecticut (1)
 - Maine (1)
 - Massachusetts(3)
 - New Hampshire(1)
 - New York(6)
 - Rhode Island(1)
 - Vermont(1)



- Southwest Region**
- Arkansas(2)
 - Colorado(2)
 - Iowa(3)
 - Kansas(2)
 - Missouri(3)
 - Nebraska(1)
 - New Mexico(1)
 - Oklahoma(1)
 - Texas (5)
 - Utah(2)
 - Wyoming(1)

- Central Region**
- Delaware(1)
 - Illinois(4)
 - Indiana(1)
 - Kentucky(1)
 - Maryland(4)
 - Michigan(3)
 - Minnesota(2)
 - New Jersey(2)
 - North Dakota(1)
 - Ohio(3)
 - Pennsylvania(3)
 - South Dakota(2)
 - Virginia(1)
 - Wisconsin(1)
 - West Virginia(1)

- Southeast Region**
- Alabama(2)
 - Florida(5)
 - Georgia(7)
 - Louisiana(1)
 - Mississippi(1)
 - North Carolina(3)
 - South Carolina(2)
 - Tennessee(2)
 - Puerto Rico (2)

▲-represents Regional Coordination Centers that are or will be established

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:**

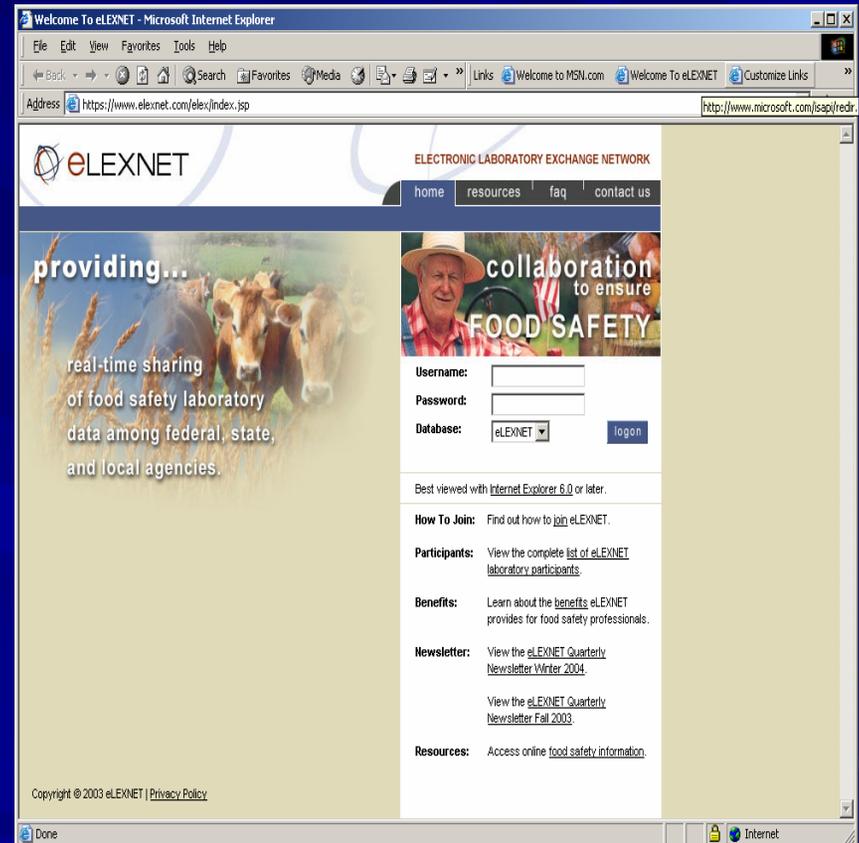
www.eLEXNET.com

or

Contact Ellen Olson
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?

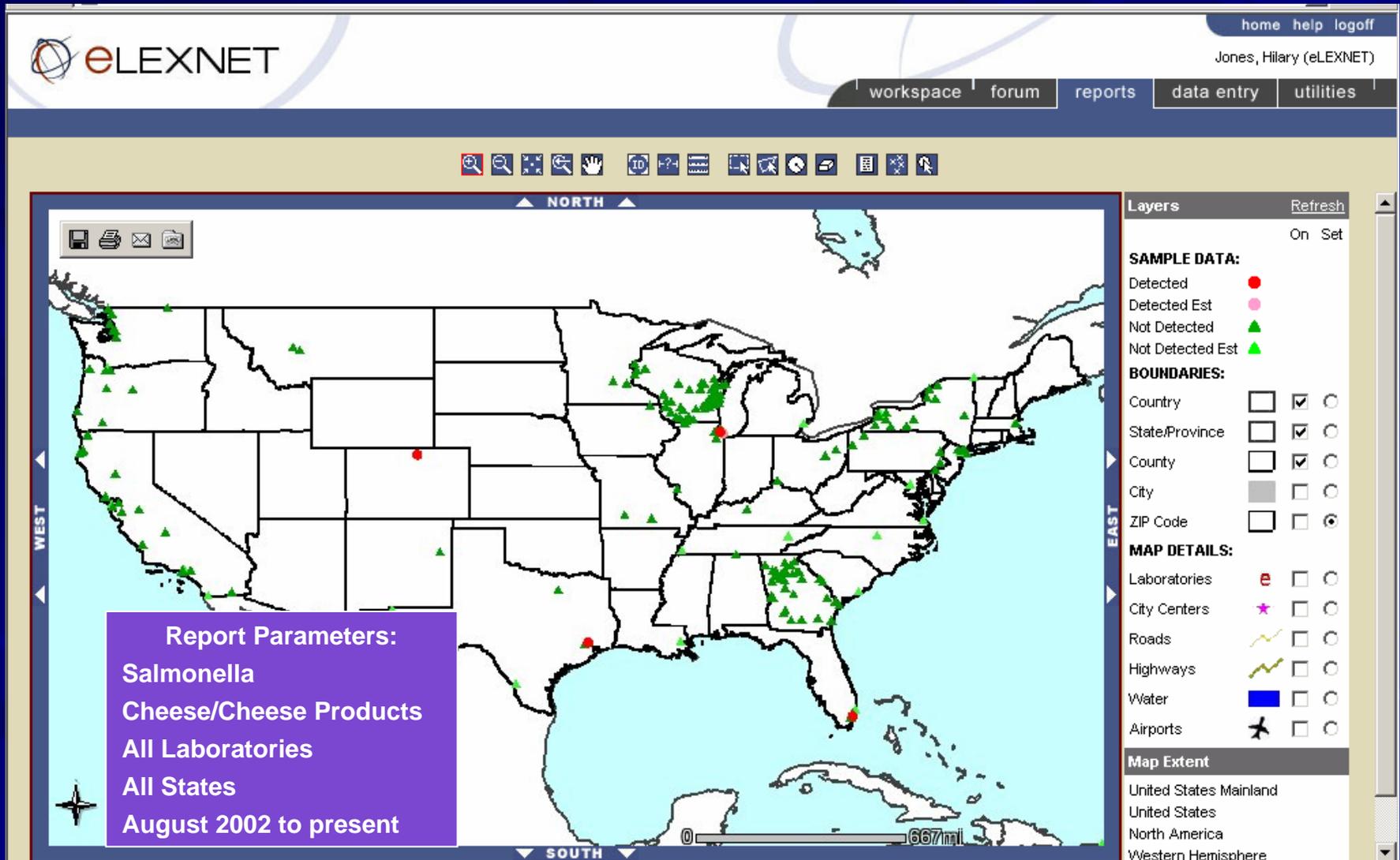
■ Collaboration:

- 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

The screenshot shows the eLEXNET web application interface in Microsoft Internet Explorer. The page title is "eLEXNET" and the user is logged in as "Submitter, Method (JA DA)". The navigation menu includes "workspace", "forum", "reports", "data entry", "utilities", and "methods". The "methods" section is active, showing a search form.

methods: search
Select multiple values in the Type of Method and Matrices fields by pressing the Ctrl key while clicking on the desired value.

Search

Source Organization:

Matrix:
ALCOHOLIC BEVERAGE
ANIMAL FEED (MEDICATED)
ANIMAL FEED (NON-MEDICATED)

Technology:

Analyte:

Type of Method:
CONFIRMATORY
DIAGNOSTIC
FORENSIC

Include All Versions

Include End-Dated Methods

Method Title ▲	Version	Type of Method ▾	Source Organization ▾	Technology ▾
No Results to Display				

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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

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

510-637-3960 xt.130

FERN National Program Office:

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

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

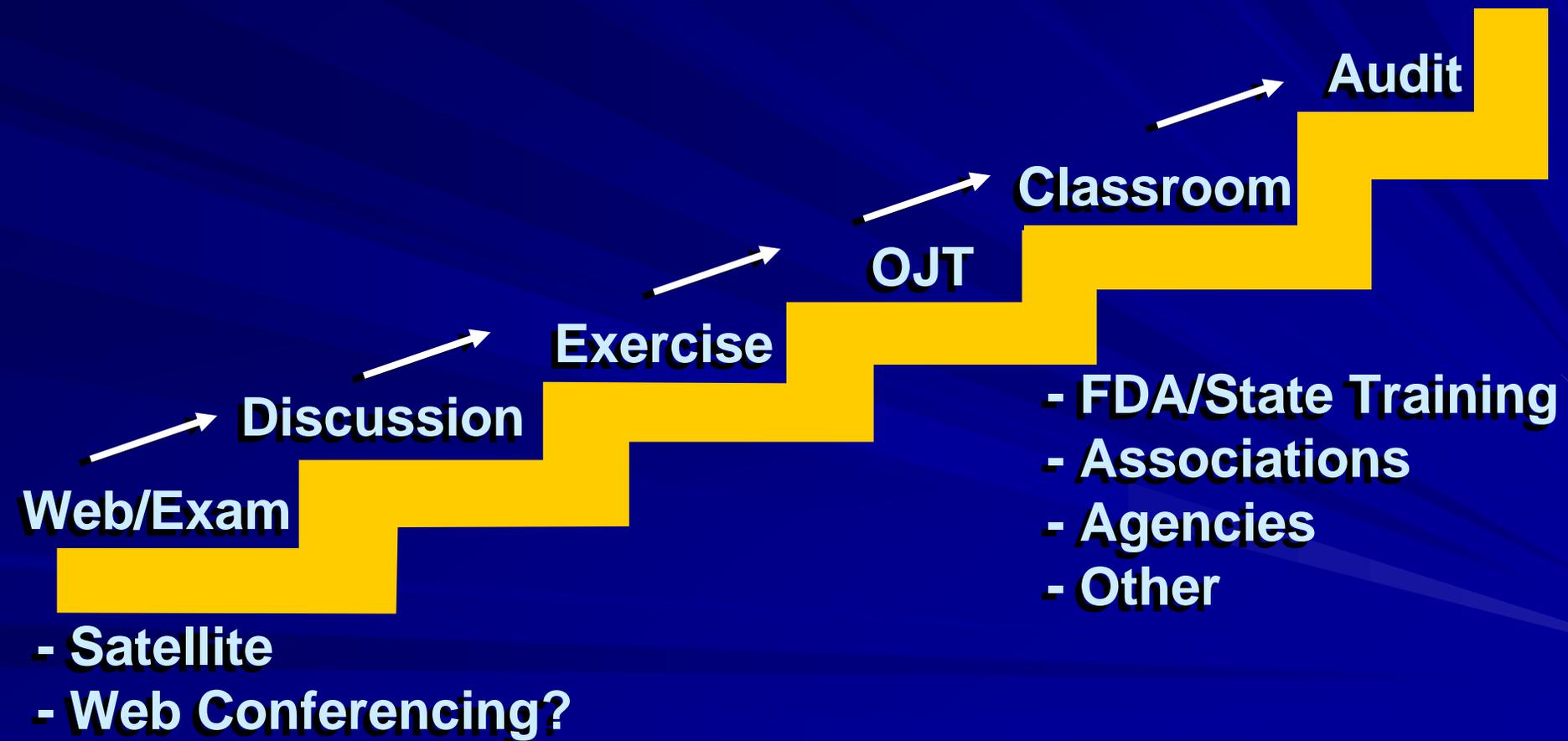
Why?

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)



- Level I
- Level II
- Recertification
- Remediation



5-2-05



Level I, Voluntary Curriculums & Certification for Food Programs, State/Local/Tribal regulators
Retail, Milk, Shellfish & Manufactured Food

* = Under Development
 (#) = Number of Modules

Vertical = Courses/material delivered by web

Horizontal = classroom training or activities

Level II Certification
Specialized Inspections & Investigations
“Under Construction”

Re-Audit

Level I Certification
Performance Audit for Level I Certification*

Joint & Independent Inspections¹

One of the two hands-on applications:

1. OJT Discussions/Exercises*
 2. Application of the Basics of Inspection/Investigation FD170
- Future schedule available online at ORA U or <http://www.afdo.org>

Remediation

Recertification & Continuing Education

¹ Number of joint inspections will vary per program and may be reduced if the candidate has previously been certified in another program area

Prevailing Statutes & Regulations specific to your program area:
 Food Code* (Retail) PMO*
 (Milk) NSSP* (Shellfish)
 GMPs, FD&C Act (Manufactured)

Public Health Principles
 1

Communication* Skills for Regulators
 1

Food Microbiological Control
 15

Foodborne Illness Investigations
 6

Basics of HACCP
 3



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

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:

1. Introduction
2. Point of Service (POS) Investigations
3. Distributor Investigations*
4. Eggs & Other Commodities*
5. Concluding the Investigation & Reporting the Results*

Food & Drug Law:

1. FDA Jurisdictions (60) MP6014
2. Prohibited Actions (60) MP6015
3. Criminal Acts Violations (45) MP6016
4. Judicial Actions (60) MP6017
5. 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
- Take a sample course “Tour of the FDA” at <http://www.eduneering.com/fda/courses/fdatour/welcome.html>





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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 Feed 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 FDAORAU 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. of Princeton New
Jersey. The 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 a red asterisk (*)

First Name:* **Middle Name:** **Last Name:***

You can create your own User Id below. It can consist of any combination of letter and numbers, but cannot exceed 50

User ID:* **Company Code:***

Position Title:*
Organization/Agency:*
Supervisor Name:*
Supervisor Job Title:*
Supervisor e-mail address:*
Supervisor Phone:*
Approved/Pending:

Street:

City: **State:***

Country: **Zip/Postal Code:**

Home Phone: **Work Phone:**

Fax: **E-Mail:***

Login Procedure



Client Login

 [EduNeering Home Page](#)

Welcome to ComplianceWire™

To log on to ComplianceWire, enter your logon 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

Do you accept the Terms of Use?

“My Catalog”

Alphabetical Listing of all Courses

Welcome Back, William

Wednesday, April 07, 2004

Instruction

- [My To-Do](#)
- [My Catalog](#)
- [My History](#)

My Catalog

Keyword Search:

Search

Your search returned 446 record (s). Page 1 of 9 is displayed below.

Advanced Search

Download

Print

Tokens	Training	Category	
	A Step-by-Step Approach to Process Validation (PHDV79 ver 1)	General	
	A Tour of the FDA (PHDV60 ver 3)	Multi-program	
	A Tour of the FDA (Analyst) - Discussion (PHDV60DA ver 1)	Multi-program	
	A Tour of the FDA (Analyst) - Exercise (PHDV60EA ver 1)	Multi-program	
	A Tour of the FDA - Discussion (PHDV60D ver 1)	Multi-program	
	A Tour of the FDA - Exercise (PHDV60E ver 1)	Multi-program	
	Access to Employee Exposure and Medical Records (EHS01 ver 1)	General	
	Active Listening Skills (EHS02 ver 1)	General	



Questions?

