

Security Policies and Procedures for FSIS Laboratories/Select Agent Rule Implementation

Patrick C. McCaskey

Assistant Deputy Administrator

U. S. Department of Agriculture

Food Safety and Inspection Service



Overview of FSIS Laboratories

- **3 Regulatory Laboratories**
- **Microbial Outbreaks and Special Projects Lab**
- **150,000 samples per year**
- **700,000 analyses**
- **Micro, Residues, Pathology**



Security Policies and Procedures for Laboratories/Select Agent Rule Implementation

Recent Legislation/Policies

- **USA Patriot Act**
- **Public Health Security and Bioterrorism Preparedness and Response Act of 2002**
- **Possession, Use and Transfer of Select Agents and Toxins (CDC)**
- **Agricultural Bioterrorism Protection Act of 2002, Possession, Use and Transfer of Biological Agents and Toxins (APHIS)**

Recent Legislation/Policies (cont.)

- **Biosecurity Requirements for BSL-3 Pathogens and Facilities (USDA Dept Manual 9610-1)**
- **Biosafety in Microbiological and Biomedical Laboratories, Edition 4, CDC**

The FSIS approach...

FSIS has a leg up...



*All FSIS Labs are Accredited to
ISO Standard 17025*



ISO Standard 17025

- **International Organization for Standardization**
- **“Gold Standard” for testing laboratories**
- **Internationally developed/accepted**
- **Specific requirements**
- **Quality system**
- **32 lab-wide SOPs**
- **600 work instructions**
- **800 forms**

ISO Standard 17025

- **Say what you do**
- **Do what you say**
- **Prove it**

ISO Accreditation/ Select Agent Rule Implementation

- **Seek advice from experts**
- **Identify what needs to be done**
- **Agree on how things need to be done**

ISO Accreditation/ Select Agent Rule Implementation

- **Divide and conquer**
- **Assign responsibilities**
- **Agree on deliverables**
- **Set timeframes**
- **Don't re-invent the wheel**
- **Plagiarize the work of others**

FSIS Activities

- **Join the Laboratory Response Network (LRN)**
- **Create food component of LRN**
- **Due Diligence Checklist enhancements**
- **Training**
- **Method validation efforts**

FSIS Activities (continued)

- **Security plans**
- **Assessments of facilities**



FedEx

Federal Express

The World On Time

1-800-Go-FedEx
www.fedex.com

1E1 MC50 8082

AIS 112006



RUSH LABORATORY SAMPLES

RUSH LABORATORY SAMPLES

ALTERNATE ROUTING FOR
DIRECTOR'S OFFICE
OR
LABORATORY

New Tamper-Evident Tape



FSIS Activities (continued)

- **Continuity of Operations Plans**
- **Enhance surge capacity**
- **Construction of BSL-3 laboratory**

Other activities

- **eLEXNET (electronic Laboratory Exchange Network)**
- **eCAM (electronic Compilation of Analytical Methods)**
- **LabDir (Laboratory Directory)**