

# Regulations

What agencies regulate the Public  
Health and Environmental  
Laboratories?

# Regulations

## Federal Agency

- **US Department of Health and Human Services**
  - CMS-CLIA: PHEL Certificate of Compliance
  - CDC & APHIS-Division of Select Agents and Toxins 42 CFR part 73
- **US Food & Drug Administration**
  - FDA-Milk Testing
- **US Department of Agriculture-Animal & Plant Health Inspection Service**
  - APHIS Certificate-Mosquito and Select Agents Program Organisms and Vectors permit 9 CFR part 122
- **US Environmental Protection Agency**
  - EPA-Drinking Water
- **US Department of Justice**
  - Drug Enforcement Administration-Controlled Substance Registration Certificate
- **US Department of Transportation**
  - Pipeline and Hazardous Materials Regulations for transport of infectious substances 49 CFR parts 171-178

# Regulations

## State Agency

- **NJ State Department of Health**  
CLIS - PHLS
- **NJ Department of Environmental Protection**  
NJDEP Office of QA–Drinking and Non-Drinking Water for PHLS  
and ECLS  
NJDEP Radioactive Materials Program
- **NJ Department of Law and Public Safety**  
NJ Office of Attorney General – Controlled Dangerous  
Substances

# Regulations

What agencies does the Public Health and Environmental Laboratories regulate?

# Regulations

- **CMS CLIA and NJ CLIS**
  - Clinical Laboratories
  - Clinical Specimen Collection Stations
  - Blood Banks, Dialysis Centers, Transfusion Centers
- **NJ Public Laws N.J.S.A. 26:2-110 N.J.S.A. 26:2-111, NJAC 8:18**
  - Requires all NJ newborns to be screened for 55 disorders from specimens sent from hospitals or other birthing centers.
  - Identified borderline or presumptive cases are followed up by a Program in the Department's Division of Family Health Services.

# Public Health Careers: Networks, Fellowships, and Certifications

May 22, 2018



# Public Health Organizations, Networks & Associations

- Centers for Disease Control & Prevention

- Federal government
- Provides resources and funding to state public health laboratories
- High end reference lab testing



- Association of Public Health Laboratories

- Non-profit, membership organization
- Promotes role of public health laboratories; promotes policies, programs and technologies to assure continuous improvement in quality of lab practices and health outcomes



- American Society for Microbiology

- Non-profit, professional organization
- Promotes and advances microbial science



# Fellowships & Internships: CDC

CDC: On site or on location (domestic and international)

- Short-term
  - 10-12 week programs
  - Often include pay
  - Many different concentrations/applications
    - Many target students of underrepresented populations
- Long-term/Full-time
  - 1-3 year programs, all paid
  - Bioinformatics, infectious disease, management/leadership or general research tracks
  - Doctoral or Master's degree requirements
- For more information: search "CDC Fellowships"; can sign up for email updates



# Fellowships & Internships: APHL

- All laboratory fellowships co-sponsored by CDC; Master's and Doctoral level scientists
- Prepare scientists for careers in public health laboratory science
  - ❖ Antimicrobial Resistance Fellowship
  - ❖ Bioinformatics Fellowship
  - ❖ Environmental Public Health Lab Fellowship (Master's)
  - ❖ Infectious Diseases Lab Fellowship (Master's)
  - ❖ Newborn Screening Fellowship

Placement within a state public health laboratory (1-2 year tenure)

# Fellowships & Internships: ASM

- ASM/CDC Program in Infectious Disease and Public Health
  - Currently on hiatus
  - Headquartered at CDC, with focus on infectious disease research
- CPEP (Committee on Postgraduate Educational Programs)
  - Two year program, culminates in American Board of Medical Microbiology board certification (required for many hospital laboratory positions)
  - Prepare scientists for leadership roles in medical/public health laboratory microbiology or immunology professions
  - Most graduates work in arenas involved in direct patient care

# Certifications

Often specific requirement for Laboratory Directors

- Diplomate of American Board of Medical Microbiology: D(ABMM)
  - Recognizes as highest, most widely acknowledged credential for doctoral level microbiologists
  - Requires re-certification every three years
- American Board of Bioanalysis offers certification in:
  - High-complexity Clinical Laboratory Director, Public Health Laboratory Director, Bioanalyst Clinical Laboratory Director, Technical or General Supervisor
    - Minimum requirements for years of experience (performing testing and directing/supervising testing)
    - Two exams: General Knowledge and test specific to certification
- 6 other accrediting agencies recognized by national regulatory body Centers for Medicare & Medicaid Services (CMS)

# **Authentic (vs. Idealized) Aspects of Public Health Program Management**

**Sherman Hom, PhD**

**Program Manager,**

**Specimen Receiving and Central Services**

**May 22, 2018**



# Necessary Ingredients for Success

- **Leadership – Communicate, Coordinate, Troubleshoot,.....**
- **Human Resources –Teamwork**
- **Customer Service – Internal/External**
- **Partners – Private/Public**
- **Financial Issues**
- **Legal/Regulatory Issues**
- **QA/QC → Quality Results meeting TAT**



# West Nile Virus Testing Laboratory

- **“TC”**: Validate RTPCR test & test 16,000 mosquito pools in 5 months
  - ❖ Automated Instrument - RNA isolation, assay set-up (20 ul/384)
  - 7900HT RTPCR Platform

## Issues

- **Staff**:  $1 + 1 + 2 = 4 \rightarrow$  “Not all of us worked 7 hrs/day”
- **Customer Service**: NJ State Mosquito Commission
  - Financial**: Created a template to determine cost/test
  - Validated 10 ul assay  $\rightarrow$  lowered cost by 40%



# BioThreat Response Laboratory

- **TC**: Post-Anthrax Outbreak Building Cleanup – test 30,000 samples  
RTPCR and confirmatory tests (agar plates)
- **Issues**
  - **Financial** - \$3M CDC Supplemental Grant  
Hiring Staff – Civil Service Commission  
Purchasing – Capital Equipment
  - **Regulatory** – Select Agent Program (SRA+, SOPs, Drills, BioSafety,...)
  - **Sample Receipt** – Chain of Custody
  - **Partners** – CDC, FDA, NJSP, FBI, Coast Guard, NJDOH Epi & E.R., APHL



# Drugs of Abuse Screening Laboratory

- **TC:** 170K U/OF Specimens/yr → 900K immunoassays
- **Issues**
  - **Staff:** 17 (2 programs cooperating)
  - **Customer Svc:** >100 clients (probation, courts, DOC,...)
  - **Partners:** Reference Labs, NJDOH Legal
  - **Create Inventory Tracking Sys.:** Maintain inventory/reduce wastage
  - **Legal/Reg.:** MOA, COC, Litigation Pkgs, Expert Witness, CLIA





# Start a Cannabis Analytical Laboratory

- **TC**: Validate analytical 3 assays to det. cannabinoids, metals, mycotoxins
- **Project Management**
  - **Form workgroup**: Upper Managers, ECLS (CT, Inorg, QA), NJDOA
  - **Legal**: Testing regulations, DEA permits,
  - **Customer Service**: NJMMP, patients
  - **Partners**: NJSP Forensics Lab, NJ State Library, USDEA, U Miss
  - **Financial**: Purchasing Schedule 1 cpds (standards, controls, etc.)



# NJ Public Health and Environmental Laboratories Grant Funding: Competitive/Noncompetitive Grant

**Tina Fan, Ph.D.**

Director, Environmental Chemical Laboratory Services

Rutgers GSBS Graduate Student Tour

NJDOH/PHEL

May 22, 2018



# The NJDOH Public Health and Environmental Laboratories (PHEL)

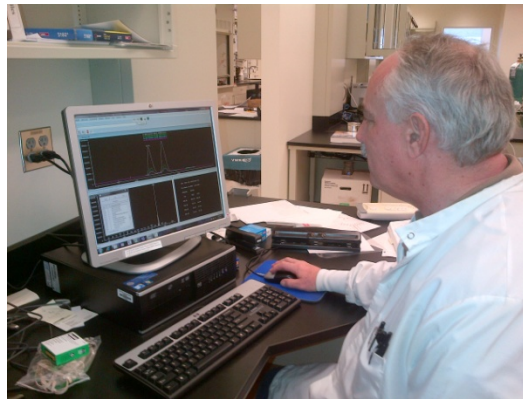
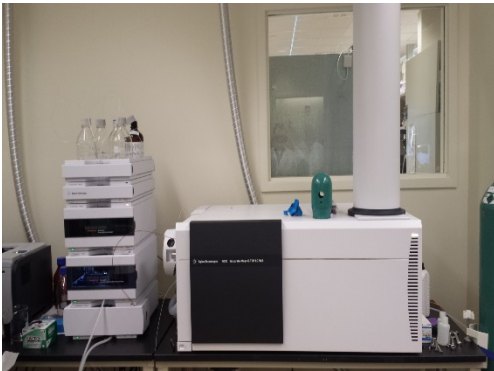
PHEL comprises five service areas:

- Public Health Laboratory Services
- Environmental Chemistry Laboratory Services
- Clinical Laboratory Improvement Services
- Policy Planning and Regulatory Compliance
- Administrative/Financial Services

PHEL provides diagnostic services to the residents of New Jersey through its programs of newborn screening, bio and chemical threat preparedness, ensuring water quality and identifying infectious disease outbreak.



# NJ Public Health Laboratories



# Overview of Grant Funding

## Sources

- Federal
- State
- Service Contract

## Type

- Competitive
- Non-Competitive



# Major Funding in PHEL

- **Clinical Laboratory Improvement Amendments (CLIA)-Federal**
  - Centers for Medicare & Medicaid Services ( <http://www.cms.gov>) regulates all laboratory testing (except research) performed on humans in the U.S. through the CLIA. In total, CLIA covers approximately 250,000 laboratory entities.
  - The objective of the CLIA program is to ensure quality laboratory testing – supports salaries, travel and vehicles for inspectors.
  - \$500k/year, non-competitive grant

# Major Funding in PHEL

- **Public Health Emergency Preparedness Cooperative Agreements (PHEP) -Federal**
  - Centers for Disease Control and Prevention (CDC) (<http://www.cdc.gov/phpr/coopagreement.htm>)
    - The objective of PHEP is to upgrade the health department ability to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events.
    - non-competitive
    - ~\$13 million/yr (a total of \$11 billion to State Depts. of health across the nation since 2002) – mainly passthrough dollars for locals – some support for public health laboratories for Biothreat and Chemical Threat testing and outreach to hospital laboratories
    - PHEP Ebola and Zika Supplemental funding also awarded

# Major Funding in PHEL-cont'

- **Biomonitoring (BM) Grant-Federal**
  - Centers for Disease Control and Prevention ([http://www.cdc.gov/biomonitoring/state\\_grants.html](http://www.cdc.gov/biomonitoring/state_grants.html))
  - Competitive
  - 5-year grant (2014-2019), \$800k/year
  - The goal of the BM grant is to increase the capability and capacity of states to conduct biomonitoring and state population-based biomonitoring surveillance to assess human exposure to environmental chemicals.

CA, MA, NH, NJ , VA, and UT-AZ-CO-NM (*as part of the Four Corners States Biomonitoring Consortium*)



# Major Funding in PHEL-cont'

- **FERN Cooperative Agreements (2015-2020) – Federal**

- USDA's Food Safety and Inspection Service (FSIS) (<http://www.federalgrants.com/FSIS-FERN-Cooperative-Agreements-49946.html>)

- Competitive

- \$250k for Level 1 Lab and \$60-80k for Level 2 Lab

The agreements will enhance the ability to analyze for microbiological, radiological and chemical threat agents utilizing FERN and other methods to improve laboratory capacities for food defense assignments and outbreak response.

- ECLS received ~\$80 k/yr to enhance the ability to respond to radiological threats.



# Major Funding in PHEL-cont'

- **The Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement - Federal**

- CDC (<http://www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html>)
- Goal: ELC provides state, local, and territorial health department grantees with the financial and technical resources to strengthen essential epidemiologic, laboratory, and health information systems to detect, prevent, and control infectious diseases.
- Semi-competitive – 45 project areas
- PHEL is awarded around \$1,000,000 annually

**ELC Ebola and Zika Supplemental Funding:** PHEL awarded \$500k each

(CDC provided \$184 million in funding to states, territories, local jurisdictions, and universities to support efforts to protect Americans from Zika virus infection and associated adverse health outcomes.



# Major Funding in PHEL-cont'

## Laboratory Service

- NBS funding
  - Testing for 100,000 newborn in NJ, ~\$9 million
  - State fund: >\$1.6 million
- ECLS funding
  - NJDEP water testing for elements (\$300k/yr)
  - DRBC –water testing for elements, radioanalytes and organics (~\$100k/yr)

# Fellowship Program

## The Emerging Infectious Diseases (EID) Laboratory Fellowship Program

- Association of Public Health Laboratories and CDC  
(<http://www.aphl.org/mycareer/fellowships/eid/pages/default.aspx>)
- Competitive
- 1- 2-year grant, \$45k for salary, plus fringe and other expense (admin through APHL, funded by CDC)

## The Public Health Associate Program (PHAP)

(<https://www.cdc.gov/phap/index.html>)

- Competitive
- 2-year grant, ~\$40k for salary, plus fringe and other expense



# Grant Application

## Competitive grant

- highly competitive
- based on an evaluation of the lab's specific proposal, past performance in the program (if applicable), and other relevant criteria (geographical considerations, testing capability, testing capacity, laboratory accreditation etc.)
- Preparation of application materials (narrative, budget, budget justification, resume, etc.)

# Grant Implementation

- Award
- Establishment of contract (external and internal contract)
- Project implementation (or perform proposed tasks)
- Progress report
- Grant renewal

# Thank you!



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