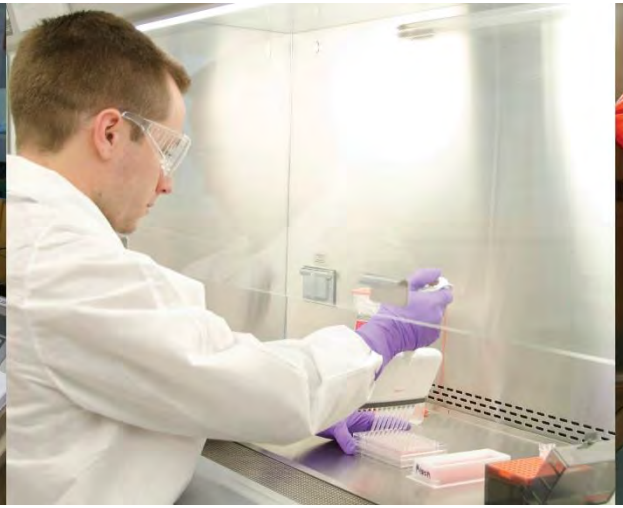
CDC PUBLIC HEALTH GRAND ROUNDS

Strengthening a Culture of Laboratory Safety

Accessible version: https://youtu.be/kyTy1wJD0cI

December 15, 2015

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Evolution of Laboratory Safety Standards




Steve Monroe, PhD

Associate Director for Laboratory Science and Safety

Centers for Disease Control and Prevention

Origins of Laboratory Science at CDC

1942 **Malaria Control in War Areas**
1943 **Communicable Disease Center**
1970 **Center for Disease Control**
1992 **Centers for Disease Control and Prevention**

Dr. Joseph W. Mountin

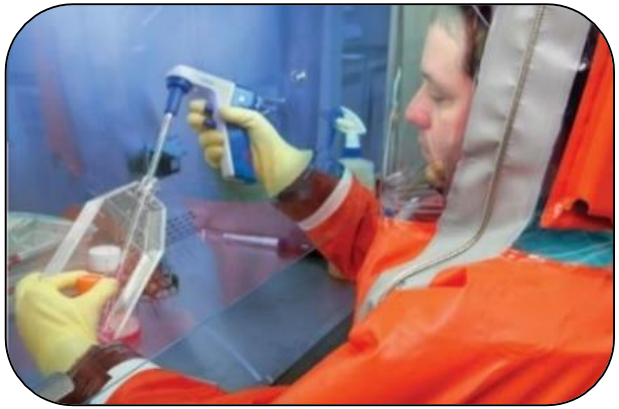
Class of state laboratory personnel at the Communicable Disease Center

cdc.gov/about/history/ourstory.htm

PHIL ID 17644, 13150

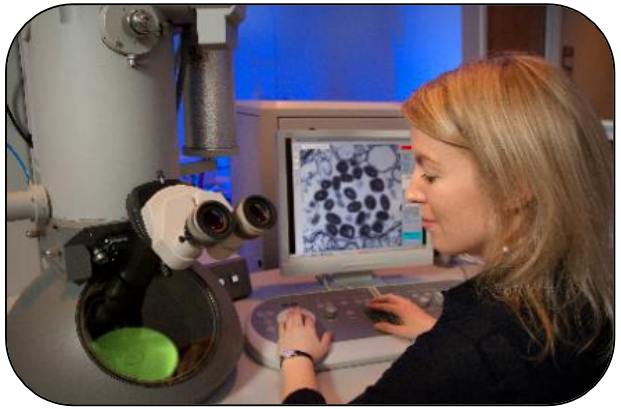
Current Scope of Laboratory Science at CDC

- **CDC's laboratory work now includes:**
  - Infectious diseases
  - Noninfectious diseases
  - Environmental health
  - Occupational health
  - Laboratory systems (e.g. standards, quality guidelines)



Viral Special Pathogens Branch

Tobacco and Volatiles Branch



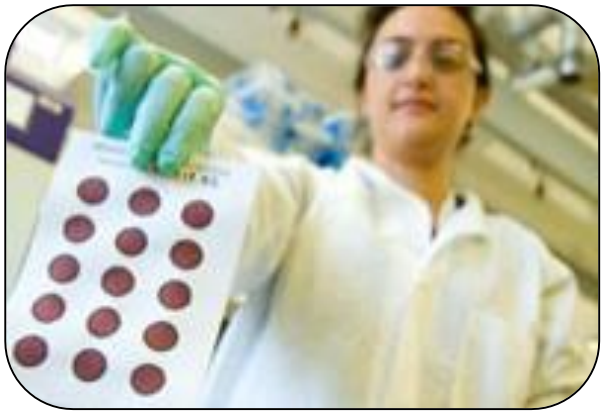
Infectious Diseases Pathology Branch

Current Scope of Laboratory Science at CDC

- Outbreak investigations
- Emergency response
- Population health studies
- Laboratory quality improvement
- Advanced Molecular Detection
- Genetic studies
- Biomonitoring
- Vaccine development
- Pathogen discovery
- Newborn screening

The National Institute for Occupational Safety and Health

Poxvirus and Rabies Branch



Newborn Screening and Molecular Biology Branch

www.cdc.gov/amd
www.cdc.gov/cdcgrandrounds/archives/2013/december2013.htm

PHIL ID 19381, 19896

Present-Day Scope of Laboratory Science at CDC

Over 2,000 laboratory staff

Laboratory Staff

- Biologists
- Chemists
- Veterinarians
- Engineers
- Medical technologists
- Biosafety experts
- Quality managers

Present-Day Scope of Laboratory Science at CDC

Over 2,000 laboratory staff

Over 150 laboratory groups

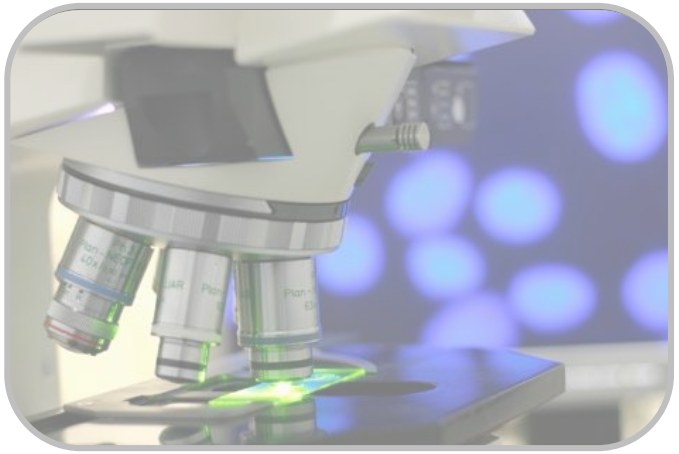
Biosafety Level (BSL)

- **BSL-1:**
  - Low potential of disease and risk to environment
- **BSL-2:**
  - Moderate potential of disease and risk to environment
- **BSL-3:**
  - Serious or potentially lethal disease after inhalation
- **BSL-4:**
  - High risk of disease through aerosol exposure, causing severe to fatal illness with no vaccine or treatment available

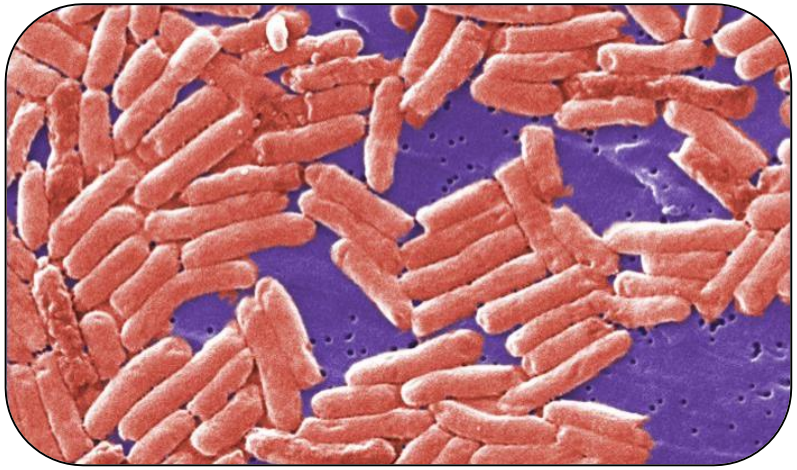
Present-Day Scope of Laboratory Science at CDC

Over 2,000 laboratory staff

Over 150 laboratory groups



Over 200 infectious pathogens



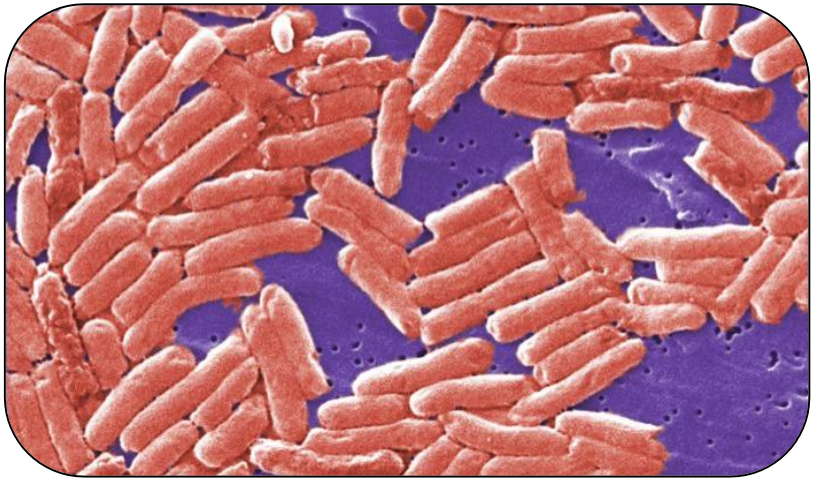
Pathogens

- Viruses
- Bacteria
- Parasites
- Fungi
- Prions (infectious agents composed of misfolded protein)

Present-Day Scope of Laboratory Science at CDC

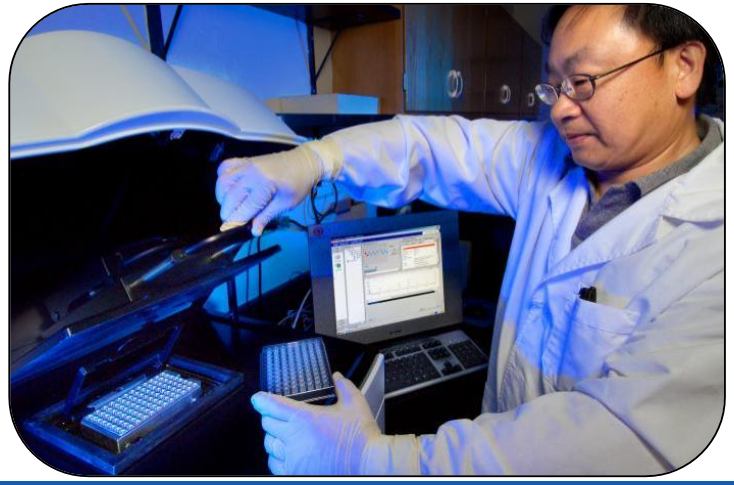
Over 2,000 laboratory staff

Over 200 infectious pathogens



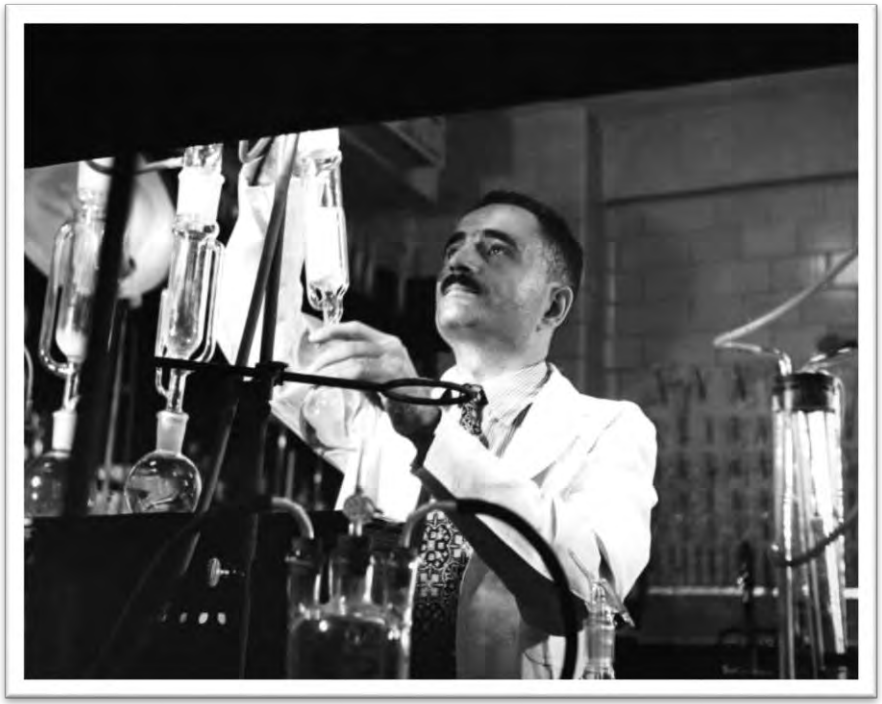
Over 150 laboratory groups

Over 5,000 samples processed per day



Laboratory Safety Standard Evolution

Safety standards change as new information becomes available



A scientist in 1943 works with potentially dangerous chemicals without modern personal protective equipment (PPE)

Two scientists in 1967 using practices no longer considered appropriate today

PHIL ID 9770, 12155

Laboratory Safety Standard Evolution

Evolving Practices

A scientist works with infectious influenza virus without modern personal protective equipment (PPE)

Today, scientists use biological safety cabinets (BSC) and powered air purifying respirators (PAPR) when working with highly pathogenic avian influenza virus

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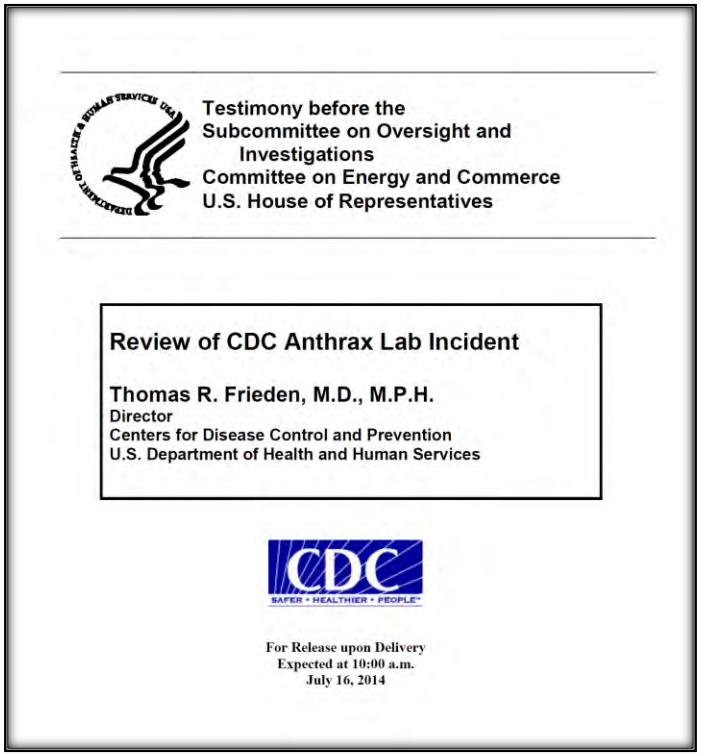
2014 Laboratory Safety Incidents

"What we're seeing is a pattern that we missed, and the pattern is an insufficient culture of safety."

– Dr. Thomas Frieden, Director, CDC



Testimony before the
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives

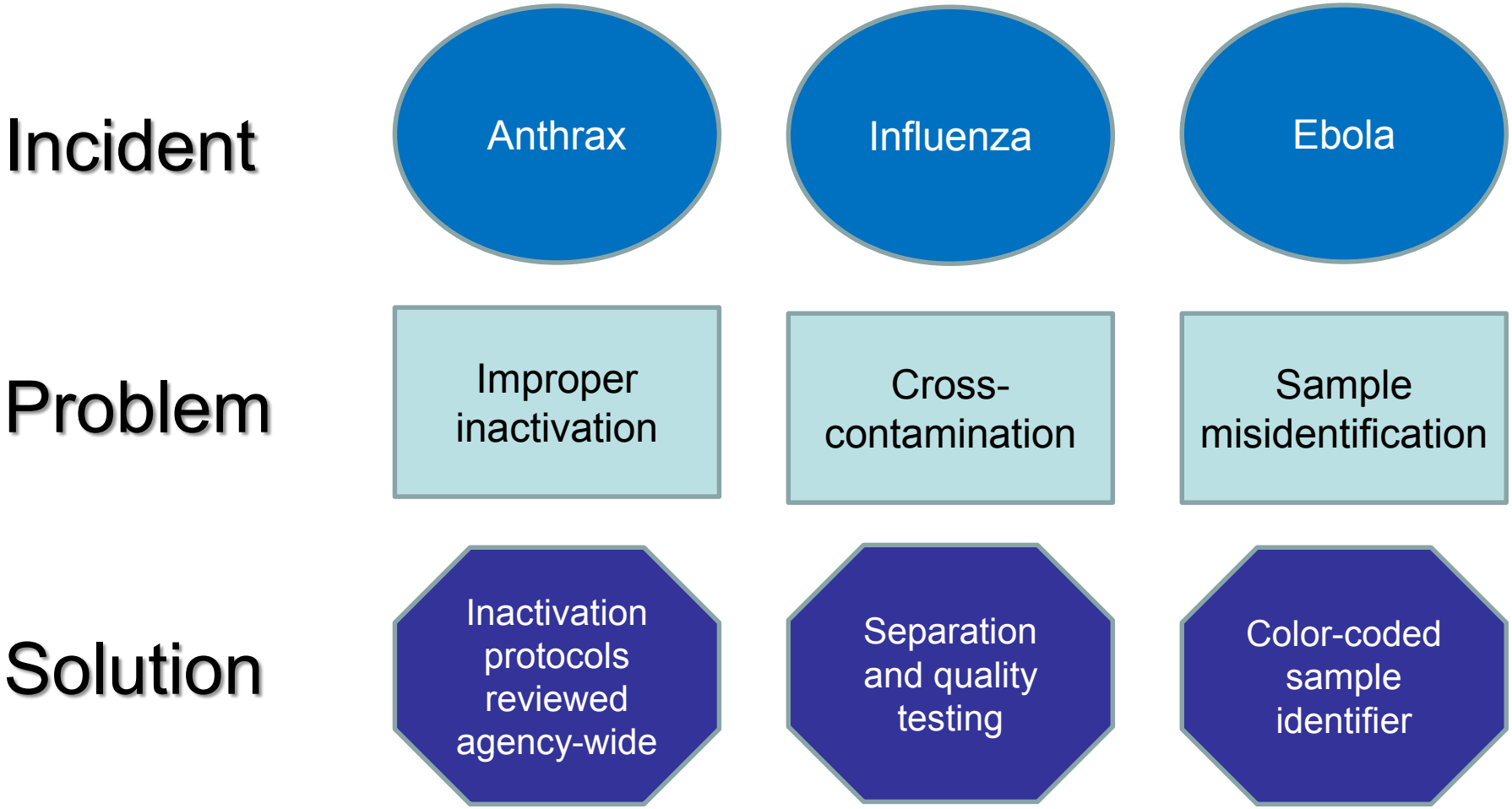
Review of CDC Anthrax Lab Incident

Thomas R. Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

CDC
SAFER • HEALTHIER • PEOPLE™

For Release upon Delivery
Expected at 10:00 a.m.
July 16, 2014

2014 Laboratory Safety Incidents



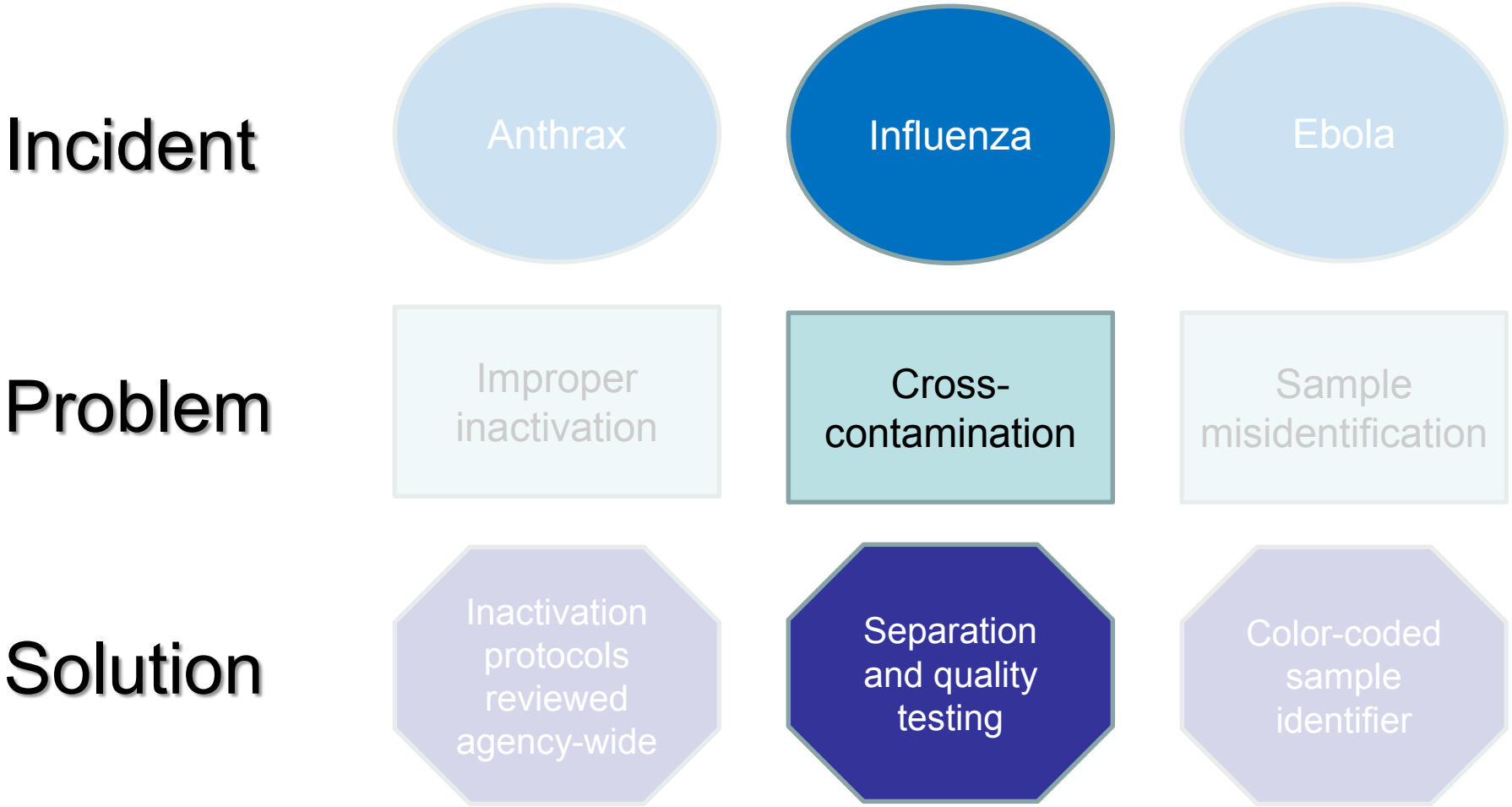
cdc.gov/about/lab-safety/reports-updates.html

2014 Laboratory Safety Incidents

Incident	Anthrax	Influenza	Ebola
Problem	Improper inactivation	Cross-contamination	Sample misidentification
Solution	Inactivation protocols reviewed agency-wide	Separation and quality testing	Color-coded sample identifier

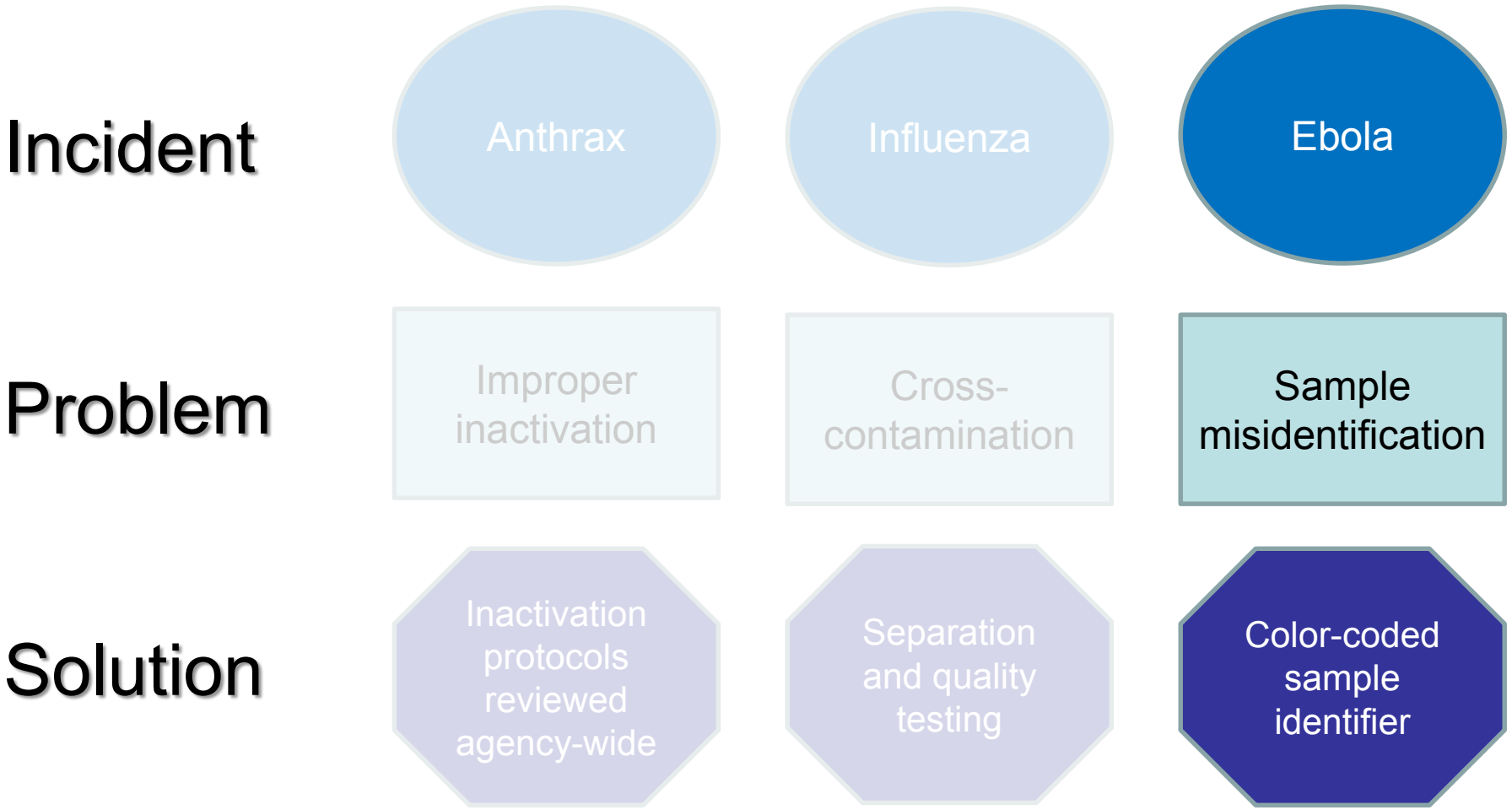
cdc.gov/about/lab-safety/reports-updates.html

2014 Laboratory Safety Incidents



cdc.gov/about/lab-safety/reports-updates.html

2014 Laboratory Safety Incidents



cdc.gov/about/lab-safety/reports-updates.html

Changes Implemented at CDC in Response to External Review Findings

- **Established clear laboratory leadership**
  - Provide scientific, technical, and managerial guidance to enhance science, safety and quality
  - Advocate for laboratory science within the agency
- **Revised laboratory competency training**
  - Laboratory Safety Training Board to develop and update courses to support a standardized, competency based CDC curriculum
- **Creating a "CDC Way" of performing risk assessments**
- **Pursuing external accreditation**
  - Identify best practices for broad QMS implementation across CDC
- **Clarified incident notification**

cdc.gov/about/lab-safety/laboratory-safety-workgroup/workgroup.html
QMS: Quality Management Systems

New Laboratory Science and Safety Leadership

- **Vision**
  - Make CDC labs the gold standard for scientific excellence and safety
- **Goals**
  - Leadership
  - Policy and compliance
  - Communication and collaboration
  - Laboratory improvement
  - Training

OADLSS

Office of the Associate Director for Laboratory Science and Safety

cdc.gov/about/lab-safety/index.html

Laboratory Leadership Service

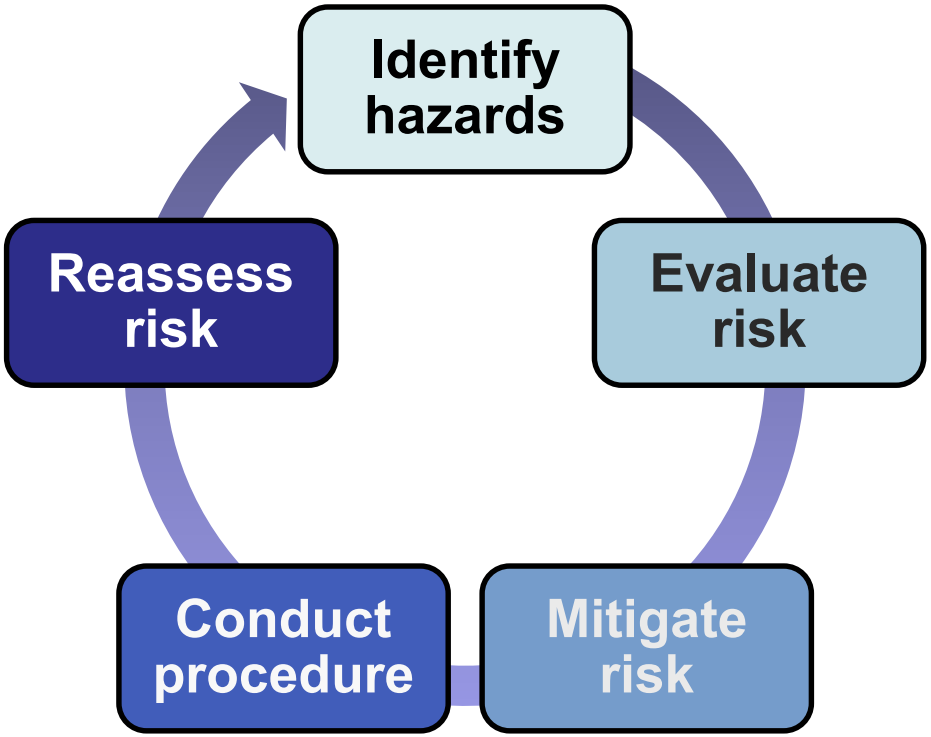
- **Mission**
  - Develop future public health laboratory leaders who integrate laboratory safety and quality as a principal standard of practice in every facet of their work
- **Laboratory Leadership Service Principles**
  - Integrate safety and quality into laboratory science
  - Provide training through service
  - Promote applied public health laboratory research
  - Produce future public health laboratory leaders

Inaugural LLS Fellowship Class of 2015

LLS: Laboratory Leadership Service
cdc.gov/lls/

Reinforcing the CDC Way of Risk Assessment

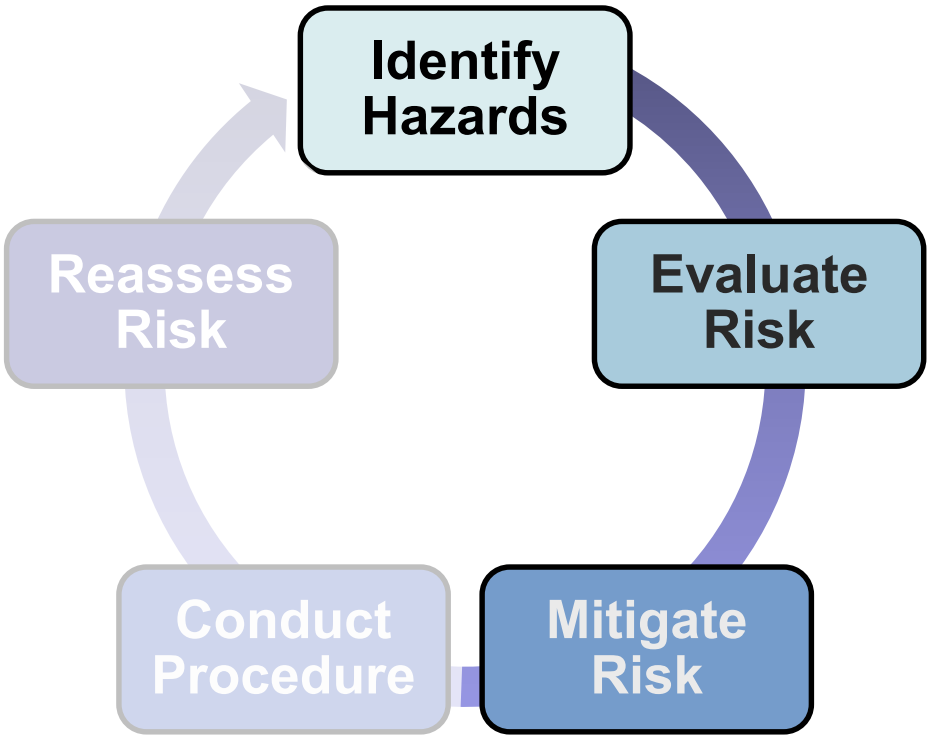
Risk Assessment Process



Reinforcing the CDC Way of Risk Assessment

Before

- Ensure research benefits outweigh the risks
- Explore safer alternatives
  - Use of non-pathogenic strains
- Predict potential problems

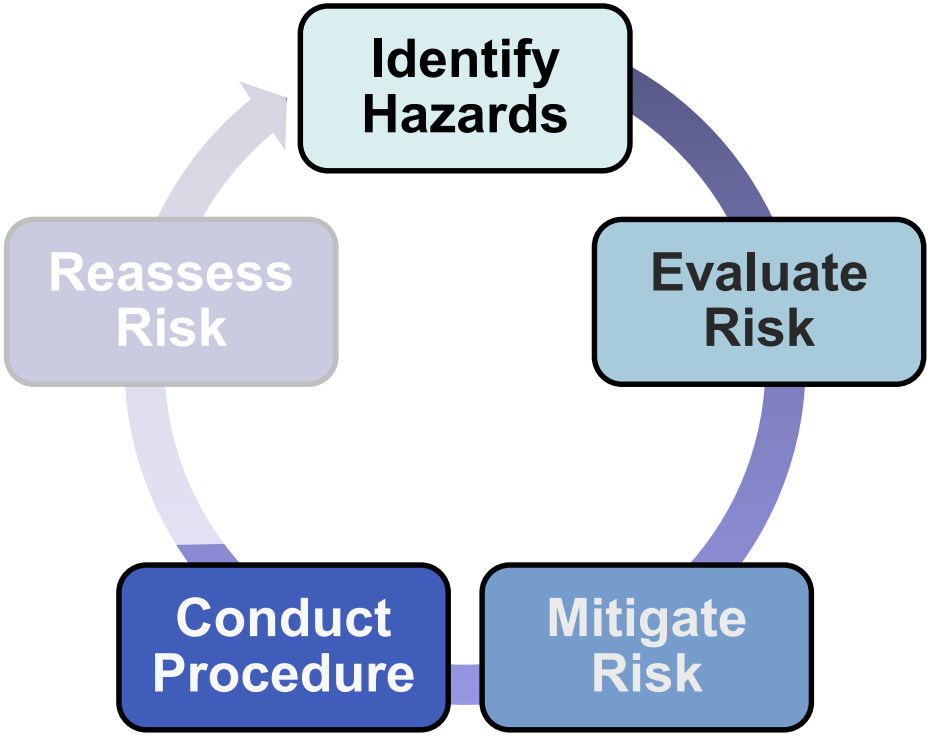


cdc.gov/about/lab-safety/reports-updates.html

Reinforcing the CDC Way of Risk Assessment

During

- Have a contingency plan
- Prompt notification of incidents and near misses

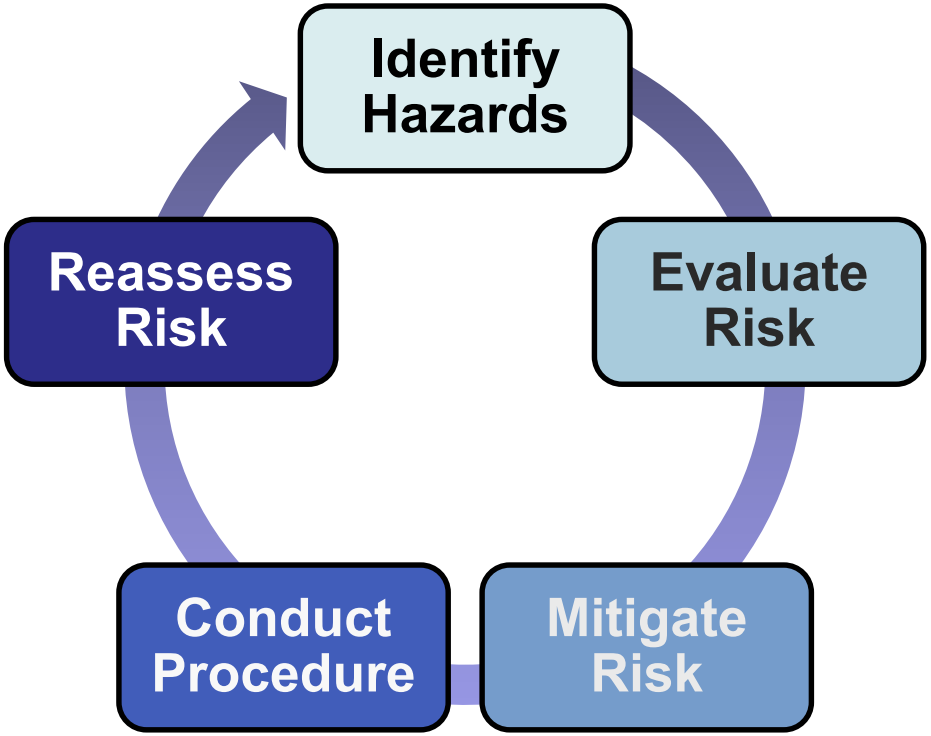


cdc.gov/about/lab-safety/reports-updates.html

Reinforcing the CDC Way of Risk Assessment

After

- Use lessons learned
- Reassess the risk



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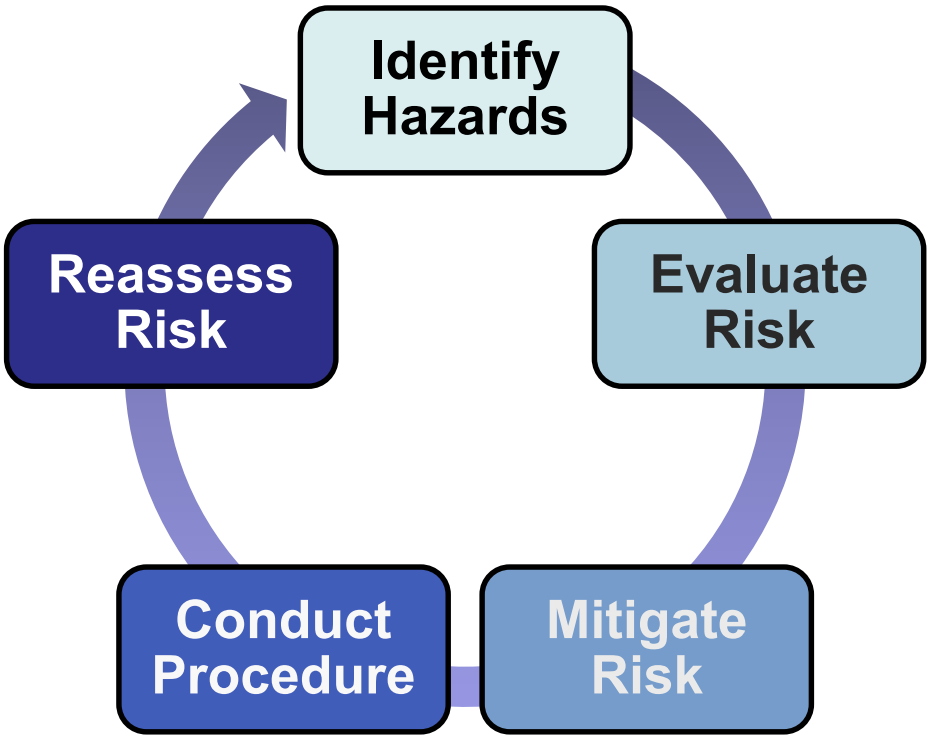


cdc.gov/about/lab-safety/reports-updates.html

Conclusions

- Laboratories and lab scientists are essential to all aspects of public health
- CDC laboratories have a unique scope of work
- CDC laboratory science has the opportunity for improvement in safety and quality of work
- Risk assessment is critical at the agency, individual laboratory, and worker level

Quality, Safety and Public Health Impact of Laboratory Science: A Case Study




Conrad P. Quinn, PhD

Chief, Meningitis and Vaccine Preventable Diseases Branch
Division of Bacterial Diseases
National Center for Immunization and Respiratory Diseases
Office of Infectious Diseases

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

The CDC Anthrax Vaccine Research Program: A Congressional Mandate

- **Designed, managed, analyzed, and reported under CDC sponsored Investigational New Drug application**
- **Why CDC?**
  - High public trust
  - No conflict of interest
  - Quality of science
- **Comprehensive and collaborative**
  - Laboratory scientists
  - Clinical practitioners
  - Statisticians
  - Academics
  - Interagency partners

The CDC Anthrax Vaccine Research Program: A First for CDC

- **Regulatory compliant**
  - Good Clinical Practice (cGCP)
  - Good Laboratory Practice (cGLP)
  - Quality assured laboratory data
- **Data submission to FDA**
  - Manufacturer's supplemental BLA
  - Basis for regulatory action

FDA: Food and Drug Administration
BLA: Biologics License Application

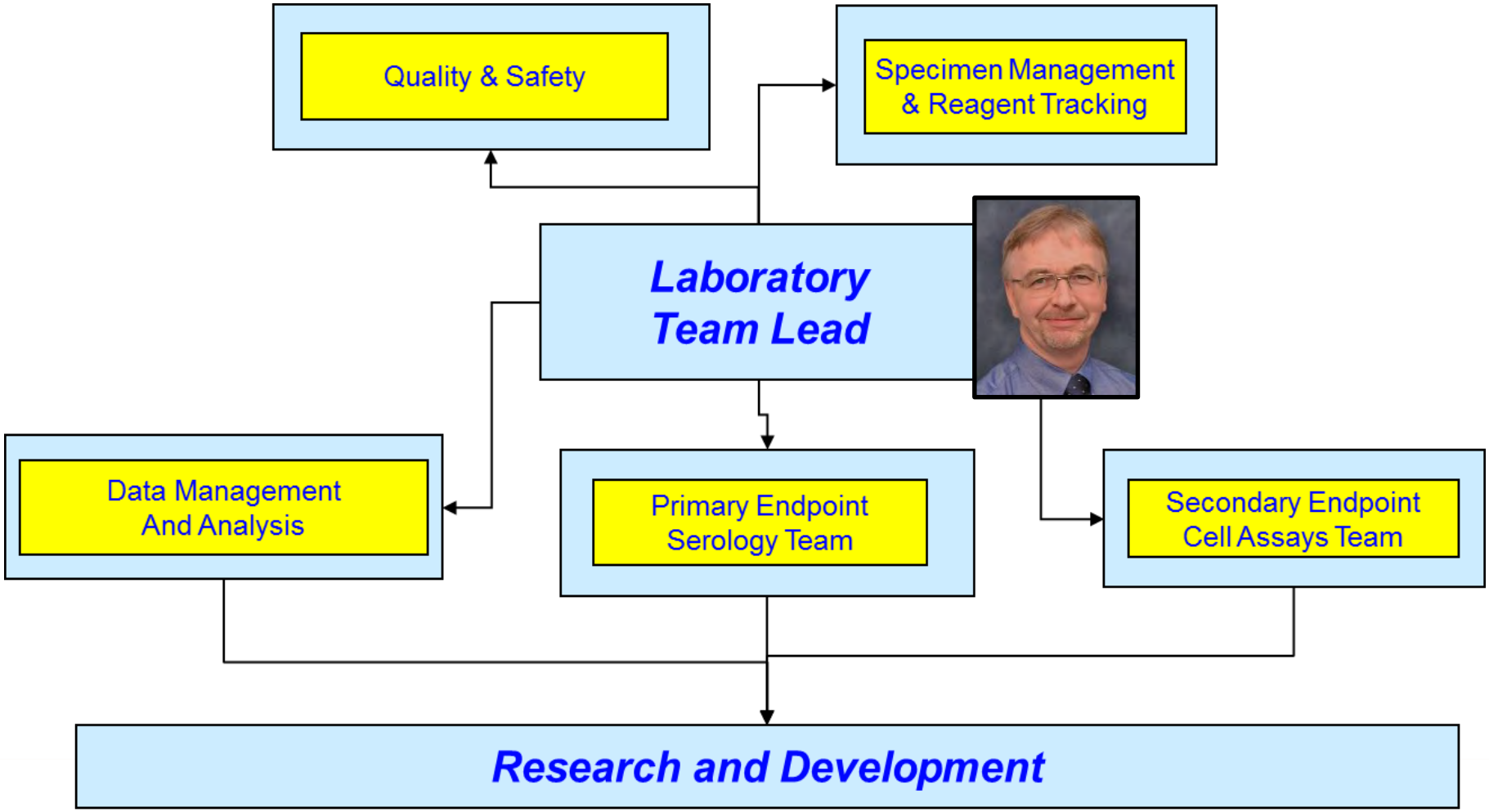
The Laboratory Component

- **Microbial Pathogenesis and Immune Response (MPIR) laboratory**
  - Established February 2001
  - Laboratory support to AVRP
  - To build human clinical trials capability
  - Expertise of Anthrax disease development
- **Build and apply a customized QMS**
  - CLIA, ISO-9000, 21 CFR Part 58, CDC
- **Quality and safety are integral and inseparable**
  - Regulatory compliant methods validation—ICH
  - QMS controlled and monitored processes and procedures

AVRP: Anthrax Vaccine Research Program
QMS: Quality Management System
CLIA: Clinical Laboratory Improvement Amendments

ISO-9000: International Organization for Standardization-9000
CFR: Code of Federal Regulations
ICH: International Conference on Harmonization

Embracing a Culture of Laboratory Quality and Safety from Day 1



An Effective QMS Encourages Public Trust in CDC Science and Recommendations

- **Team development was guided by**
  - Recognition that high public trust in CDC was an earned privilege
  - Functional structure
  - Specialized staff for specialized activities
    - Safety and quality management
    - Specimen management
    - Data management
    - Laboratory science
- **QMS documented evidence**
  - Processes and procedures
  - Competent and proficient
  - Primary record data

QMS: Quality Management System

An Investment of Leadership and Management

- Ensure support from management
- Create the proper environment
- Craft a strategy
- Lead by example

ISO 9000: 2000 QUALITY MANAGEMENT PRINCIPLES

- Principle 1: Customer Focus
- Principle 2: Leadership
- Principle 3: Involvement of people
- Principle 4: Process approach
- Principle 5: Systems approach for management
- Principle 6: Continual improvement
- Principle 7: Factual approach to decision making
- Principle 8: Mutually beneficial supplier relationships.

"Perfection is not attainable, but if we chase perfection we can catch excellence"
– Vince Lombardi

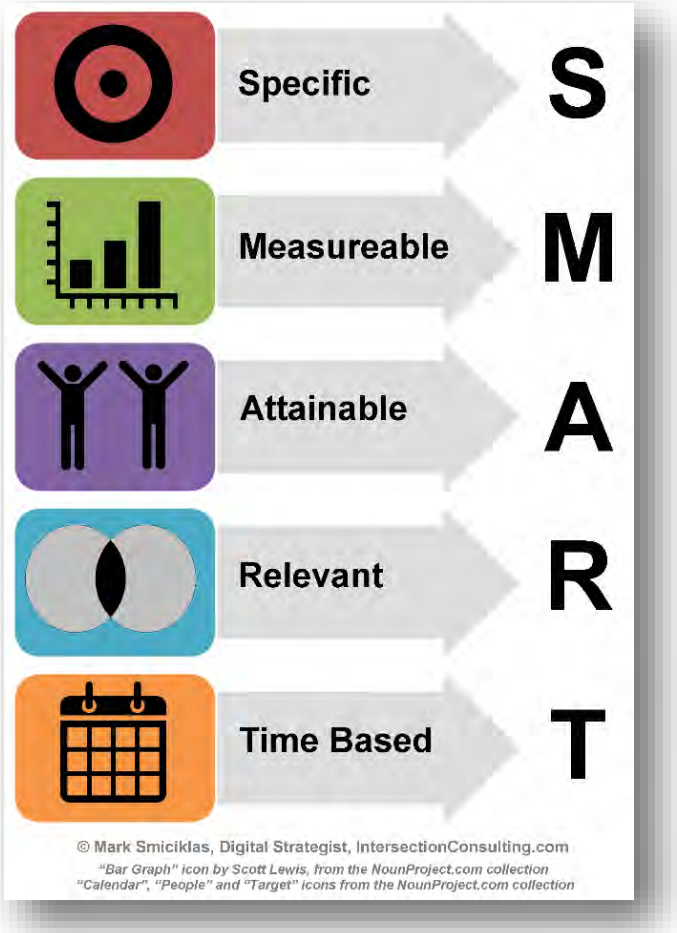
ISO: International Organization for Standards
Verma U. www.slideshare.net/mtaram/total-quality-management-presentation-949360
linkedin.com/pulse/20141106190850-228512303-the-role-of-leadership-in-total-quality-management-tqm

What Leaders Must Understand First

- What does the project I am leading involve?
- What are the benefits from success?
- Who benefits from success?
- What does my team need to succeed?

Flaherty C. wwwn.cdc.gov/cliac/pdf/Addenda/cliac0208/Addendum%20T.pdf

What Gets Measured, Gets Done



Leaders Should Designate Resources Based on Initial Assessment

- **Make investments that are**
  - Tangible
  - Sustainable
- **Develop assets including**
  - Personnel
    - Roles and responsibilities
    - Training
    - Skillsets
  - Equipment
  - Reagent standards
  - Quality controls
  - Standardized technologies
    - Data reduction and analysis

Soroka SD, Schiffer JM, Semenova VA, et al. *Biologicals*: 2010; 38(6): 675-683.

Resources Must be Valued and Protected

- **People are our most valuable resource**
  - Practice accountability and empowerment
  - Know where you fit
  - Own what you do
  - Establish study-specific role descriptions
  - Maintain training and competency records
- **Protecting our state of the art facilities and equipment**
  - Perform preventative equipment maintenance
  - Monitor performance
  - Manage facilities and equipment

Quality Management Systems (QMS): Building on Existing Expertise

- **Implementation of enterprise level LIMS**
  - Specimen and data management
  - Study data management, analysis and reporting
  - Specimen and critical reagent inventory
- **Use existing agency expertise**
  - Specimen barcoding
  - CASPIR inventory
  - Information management
  - Facilities management

LIMS: Laboratory Information Management System
CASPIR: CDC/ATSDR Specimen Packaging, Inventory and Repository

Quality and Safety are Integrally Linked

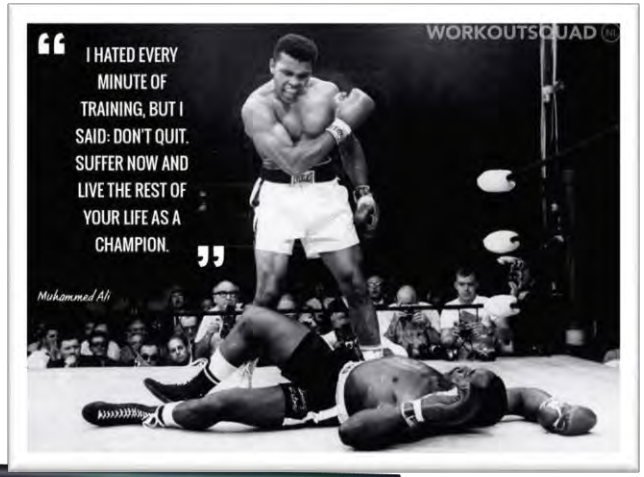
- **Quality managers, safety liaisons, and team members should engage in**
  - Developing risk assessments
  - Managing content
  - Controlling documents
  - Monitoring compliance
    - Requirements
    - Frequency
    - Competency

i.ensohaber.com/resimler/galeri/komik_bebekler_7.jpg

Laboratories Should Train With Intent

A core safety training curriculum is critical

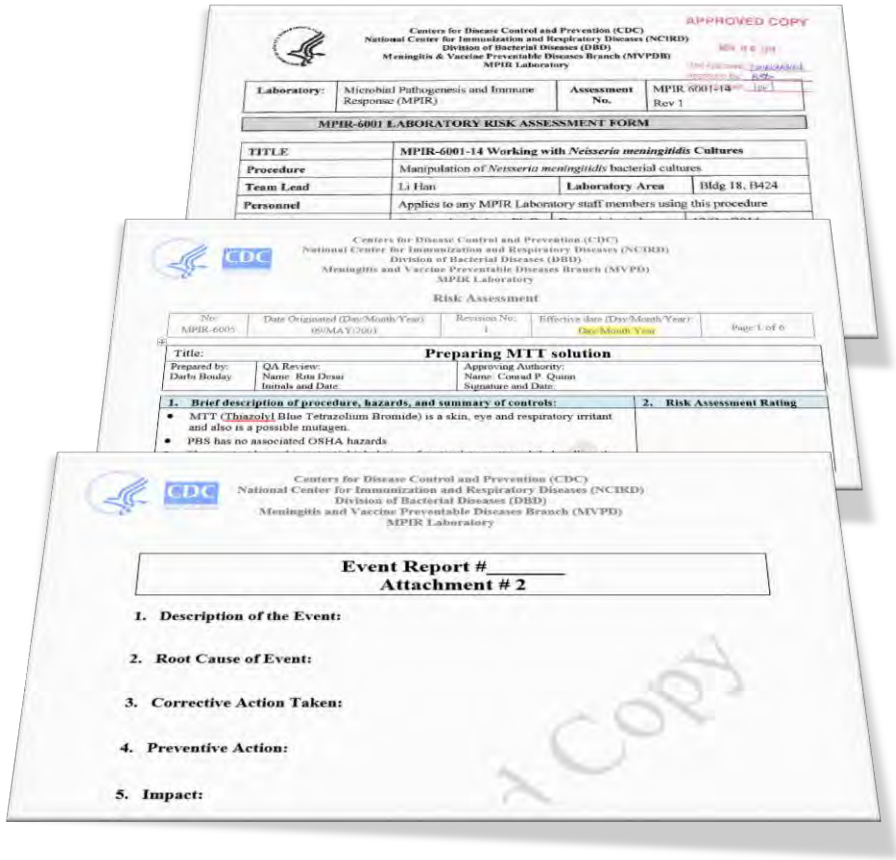
- **Train like you fight, fight like you train**
- **What training do I need?**
  - Know where I fit
  - Set clear expectations
- **What am I trained to do?**
  - Defined curriculum
  - Defined outcomes
- **How do I know I am trained?**
  - Competency based outcome and proficiency measures



medium.com/homeland-security/train-like-you-fight-and-fight-like-you-train-1787c0b78fde#.mctsiqn31
origami.about.com/od/History-Of-Origami/a/Akira-Yoshizawa-Origami-Biography.htm

Documenting Safety and the Quality of Science

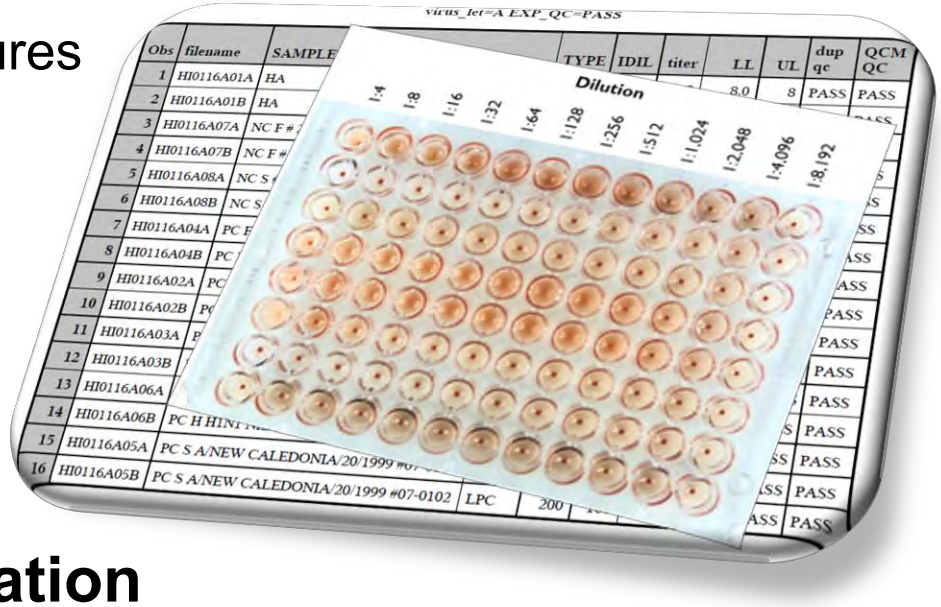
- **Document control system**
- **Laboratory risk assessments**
  - Process linked
  - Biological and chemical hazards
  - Risk mitigation and response
- **Event and incident reporting**
  - Root cause analysis
  - Impact assessment
  - Corrective action
  - Preventative action



CDC MPIR-6001 Laboratory Risk Assessment
CDC MPIR-6005 Chemical Risk Assessment
CDC MPIR-7075 Event Reporting Form

Validated Science Adds Value and Confidence

- **Documented validation**
  - Defined performance characteristics
  - Established acceptable measures of confidence and uncertainty
- **Data management**
  - Traceable
  - Transparent
  - Reliable
- **Secure reporting**
- **Evidence-based interpretation**



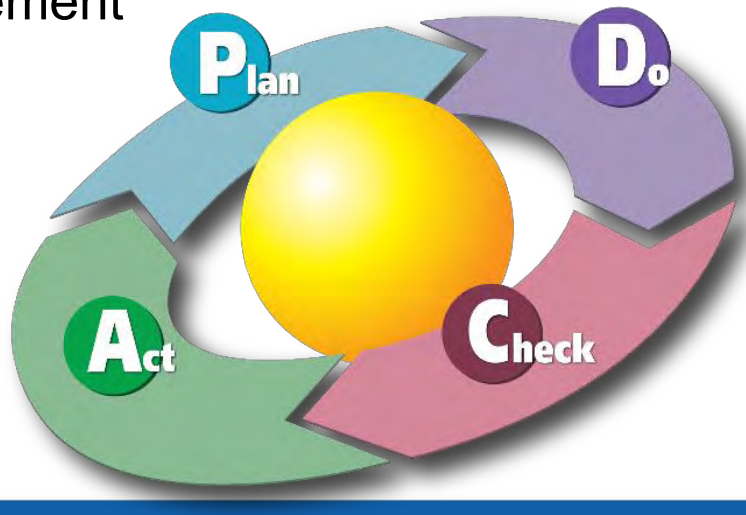
pH1N1 Hemagglutination Inhibition Assay and Statistical Analysis System-generated data report

Be Flexible

"Effective leadership is putting first things first. Effective management is discipline, carrying it out"
– Stephen Covey

The Plan–Do–Check–Act Cycle

- **A process for implementing change**
  - **Plan:** Recognize an opportunity and plan a change
  - **Do:** Test the change – start small
  - **Check:** Review, analyze, and identify lessons learned
  - **Act:** Take action based on lessons learned
  - **Repeat:** Promotes continuous improvement
- **Set targets – quality indicators**
- **Measure progress**
- **Adapt to improve**



AVRP Demonstrates that Attention to Quality and Safety Does Not Compromise Productivity

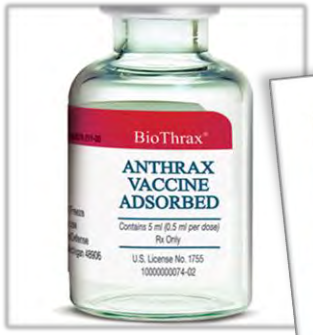
- Laboratory tests for diagnosis and patient management
- Analysis models for immune correlates of protection
- A basis for regulatory action
- More than 70 laboratory specific publications
- More than 10 Patents
- Nine Shepard Award nominations

Marano N, Plikaytis BD, Martin SW, et al. *JAMA*. 2008;300(13):1532-1543.
Wright JG, Plikaytis BD, Rose CE, et al. *Vaccine. 2014;32*(8): 1019-1028.
Schiffer JM, Chen L, Dalton S, et al. *Vaccine*. 2015;33(31): 3709-3716.

AVRP: Anthrax Vaccine Research Program

A Congressional Mandate Fulfilled

- **A first for the anthrax vaccine**
  - Only data-driven changes in AVA use in 38 years
- **Improved safety profile – 2008**
  - Change to intramuscular injection route
  - Reduction in frequency, severity and duration of injection site adverse events
- **Simplified regimen – 2012**
  - Reduction in priming series to 3 doses IM
  - Protection in 6 months
- **Correlates of protection in humans**
  - Application of the *Animal Rule*
- **sBLA for booster schedule reduction – 2016**



AVA: anthrax vaccine adsorbed
IM: intramuscular
sBLA: Supplemental Biologics License Application
Wright JG, Quinn CP, Shadomy S, et al. *MMWR*. 2010:59(6):1–36.

MPIR Laboratory Contributions to Enhancing Research and Collaboration

- **Emergency response capacity**
  - Anthrax letter attacks of 2001
  - Pandemic H1N1 response contributions 2009
  - STRIVE and Phase 1 Ebola vaccine studies
  - Laboratory surge capacity
- **Expertise**
  - PEP anthrax vaccine optimization
  - Pertussis and bacterial meningitis
- **Technology**
  - Methods development and technology transfer
  - Emergency response laboratory capability
- **Reputation**
  - Associated funding
  - Research-base expansion

Agrawal A, Lingappa J, Leppla SH. et al. *Nature.* 2003;424:329-334.
Veguilla V, Hancock K, Schiffer J, et al. *Journal of Clinical Microbiology*. 2011;49(6):2210-2215.
Fay MP, Follmann DA, Lynn F, et al. *Science translational medicine*. 2012;4(151):151ra126.

MPIR: Microbial Pathogenesis and Immune Response
STRIVE: Sierra Leone Trial to Introduce a Vaccine against Ebola
PEP: post-exposure prophylaxis

Inspire Your Team

- **Recognize the value your team contributes to quality, safety, and public health or patient impact**
- **Share the vision you see for what the laboratory team can accomplish, and how it can best achieve its goals**
- **Articulate the importance of attention to safety and quality best practices**
  - Catch people being good—recognize exemplary practices and performers
- **Continue to improve**

Embracing a Culture of Quality and Safety

"Change will not come if we wait for some other person or some other time."
— Barack Obama

"The illiterate of the 21st century will not be the person who cannot read. It will be those who cannot learn, unlearn and relearn."
— Alvin Toffler

blogs.reuters.com/great-debate/files/2013/07/obama-best.jpg
upload.wikimedia.org/wikipedia/commons/e/e1/Alvin_Toffler_02.jpg

Establishing a Culture of Safety in an Academic Research Institution: Teaching Safety to Scientists




Joseph Kanabrocki, PhD, NRCM(SM)

Associate Vice-President of Research Safety

Professor of Microbiology

University of Chicago

Chair, External Laboratory Safety Workgroup, CDC

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Building A Culture of Responsible Science

- **People**
  - Provide leadership and support at all levels, especially high levels
  - Develop and track training needs
  - Support development of laboratory professionals
- **Institutional infrastructure and oversight**
  - Use institutional controls to assess and monitor risk
  - Improve biosafety procedures
  - Encourage reporting of incidents
- **Knowledge, awareness, and communication**
  - Engage broader community
  - Increase awareness through multiple media

Leadership and Governance for Lab Safety at the University of Chicago

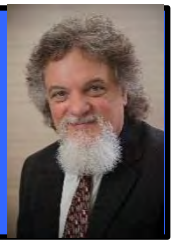
University of Chicago President

Provost

Research Safety Policy Council

VP Research

Associate Vice-President of Research Safety,
Office of Research Safety established 2014



VP Finance and Administration

AVP Safety and Security

Director, Environmental Health and Safety

AVP: Associate Vice-President

University of Chicago
Office of Research Safety

Provost's Research Safety Policy Council

AVP Research Safety

Environmental Health and Safety

Research Safety Fellow

Office of Research Safety Department Administrator

IT and Training Coordinator

Biosafety

- Biosafety Officer/ARO (PhD Microbiology) DURC Admin.
- Biosafety Officer/ARO (PhD Microbiology)
- Biosafety Officer (PhD Cell & Molecular Biology, MBA)
- H.T. Ricketts Laboratory Biosafety Officer/ARO (IH)

Lab Compliance

- Director, Regulatory Compliance for Lab Programs (IBC, IACUC, DURC)
- 3 IBC/IACUC Administrators

Chemical Safety

- 2 Chemical Safety Officers (PhD Chemistry)

Radiation and Laser Safety

- Radiation and Laser Safety Officer
- Administrative Ass't
- 3 Health Physicists
- Laser Safety Specialist

AVP: Associate Vice-President
IBC: Institutional Biosafety Committee
IACUC: Institutional Animal Use and Care Committee
DURC: Dual Use Research of Concern
ARO: Alternate Responsible Official

Risk Assessments: Institutional Biosafety Committee (IBC)

- **IBC is responsible for all life-sciences research protocols at University of Chicago**
  - Review and approval
  - Surveillance
- **Review the use of biohazardous materials including**
  - Recombinant DNA
  - Infectious agents
    - Humans
    - Animals
    - Plants
  - Biological toxins

Laboratory Safety Training

- **Laboratory safety training designed to meet needs of personnel working on research**
  - Training requirements dictated by research description as detailed in IBC protocol
- **Variety of courses, matched to protocol needs**
  - Bloodborne Pathogens for Research Staff
  - BSL1 and rDNA
  - BSL2 and rDNA
  - Viral Vectors
  - Biological Toxins
  - Human Gene Transfer (in development)
  - Chemical Hygiene

IBC: Institutional Biosafety Committee
BSL: Biosafety Level
rDNA: recombinant deoxyribonucleic acid

Cognitive and Practical Biosafety Education for the Host-Pathogen Investigator

- **Intensive 4-day course**
- **Basic BSL3 lab safety, PPE, and respiratory protection**
- **Decontamination and disinfection**
- **History of biodefense programs, biologic toxins, biosecurity, and dual-use research**
- **Emergency response**
- **Epidemiology of lab-acquired infections**
- **Risk assessment of:**
  - Recombinant DNA and pathogenic microorganisms
  - Laboratory animals and exposure
  - Vivarium and zoonoses

BSL: Biosafety Level
PPE: Personal protective equipment

Cognitive and Practical Biosafety Education for Host-Pathogen Investigators

Learning How to Prepare to Enter Laboratory Environment

Cognitive and Practical Biosafety Education for Host-Pathogen Investigators

Learning how to put on personal protective equipment to enter BSL3 laboratory

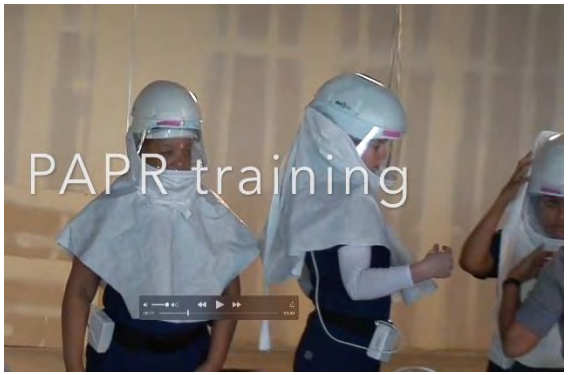
BSL: Biosafety Level

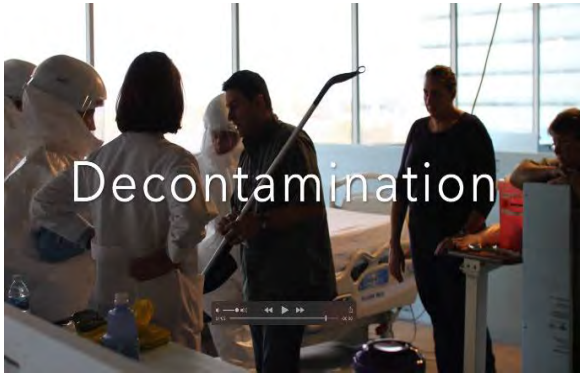
Working with First Responders to Improve Understanding Risks in Laboratory Setting

First responders from the Argonne National Labs being shown laboratory work environment

Responding to Ebola: Training Healthcare Workers How to Don and Doff PPE

- **Ebola PPE protocol for healthcare workers similar to those used by laboratory workers**
- **Biosafety personnel rapidly developed training for proper use of PPE, clinical procedures, decontamination**





PPE: Personal protective equipment
PAPR: Powered air purifying respirators

Shaping the Future: GLRCE Biosafety Research Fellow Program

- **One fellow per year in-residence program**
  - NIH stipend, plus benefits
- **Fellows support biosafety and IBC activities, with primary focus on laboratory and research safety**
  - IBC protocol review and risk assessment
  - Select Agent Program management
  - Laboratory inspections, including external inspections (USDA, CDC, FAA)
  - Training
  - BSL3 facility operations and maintenance
  - Emergency spill response
  - Export controls/DURC program and material transfer agreements

GLRCE: Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research
IBC: Institutional Biosafety Committee
USDA: U.S. Department of Agriculture
FAA: Federal Aviation Administration
DURC: Dual-Use Research of Concern

Additional Experience for GLRCE Biosafety Research Fellows

- **Fellows are expected to participate in applied biosafety research**
- **Fellows are encouraged to take advantage of resources and projects conducted at the H.T. Ricketts Laboratory (NIAID Regional Biocontainment Laboratory)**
- **Fellows attend and present at national and regional meetings**
- **Fellows prepare and sit for certification exams**
  - National Registry of Certified Microbiologists (NRCM) and Specialist in Microbiology (SM)

GLRCE: Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research
NIAID: National institute of Allergy and Infectious Diseases

Using Applied Biosafety Research to Improve Safety and Facilitate Research

- **Two previously established University of Chicago autoclave standard operating procedures**
  - Non-spore-formers: **40-min cycle at 121°C**
  - Spore-formers (*B. anthracis*): **180-min cycle at 121°C**
- **Study found**
  - 40-min cycle safely decontaminates all infectious waste generated at H.T. Ricketts Laboratory (HTRL)
  - Effective regardless of whether spores are in moist or dry waste
  - Reproducible using several different types of bacteria
- **New SOP with reduced autoclave times**
  - Approved by IBC
  - Increased efficiency and safety of operations

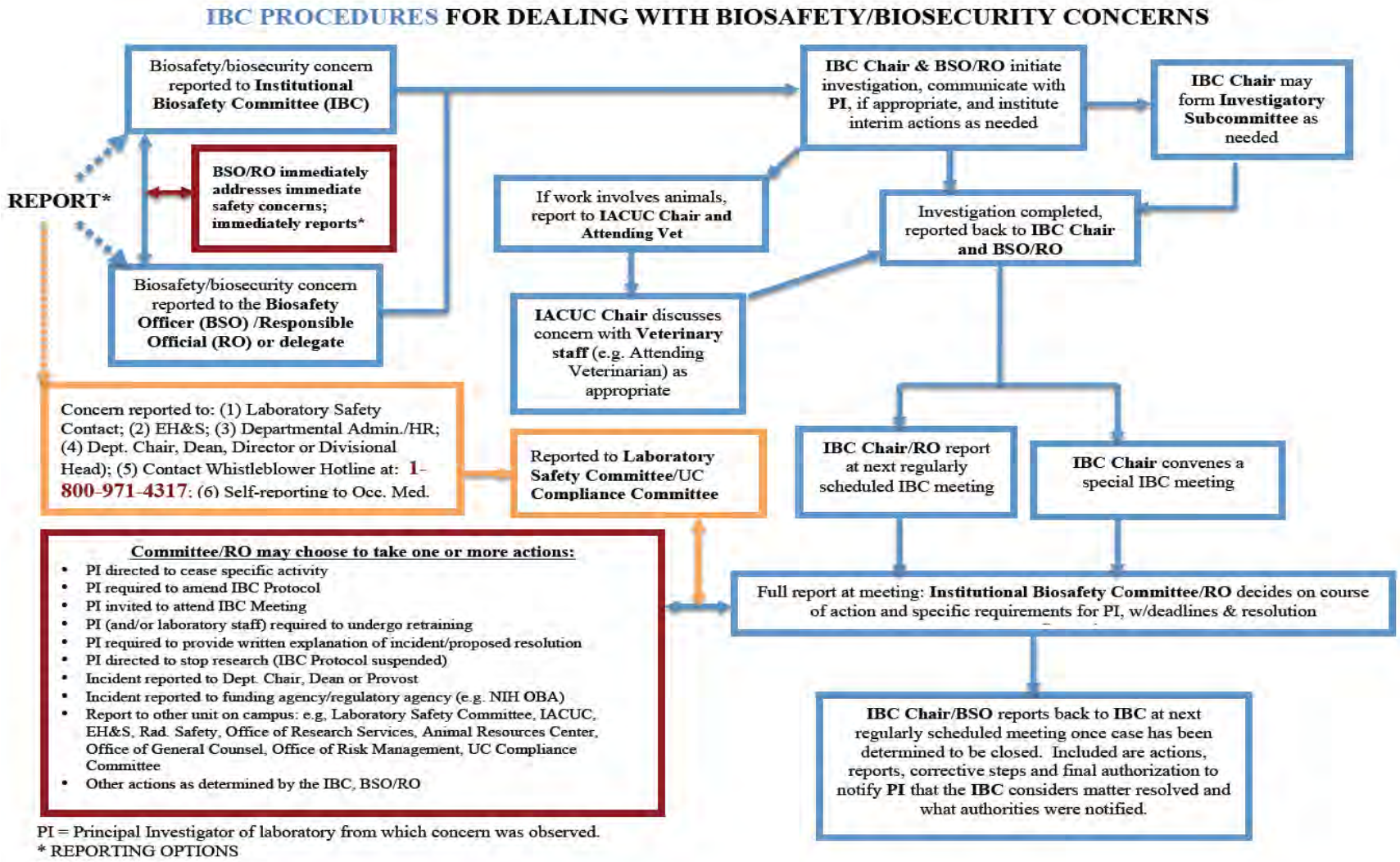
SOP: Standard Operating Procedure
IBC: Institutional Biosafety Committee
Helm RA. Unpublished data, reviewed by University of Chicago Institutional Biosafety Committee.

GLRCE Programmatic Legacy and Direct Impact: Biosafety Fellows

- **Previous fellows now work in key laboratory safety positions with various organizations including**
  - Universities
    - Massachusetts Institute of Technology
    - Northwestern University
    - University of Chicago-Hyde Park
    - University of Cincinnati
    - University of Illinois at Chicago
    - University of Nebraska-Lincoln
    - Washington University in St Louis
  - Research Institutes
  - Governmental Agencies (DHS)

GLRCE: Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research
DHS: Department of Homeland Security

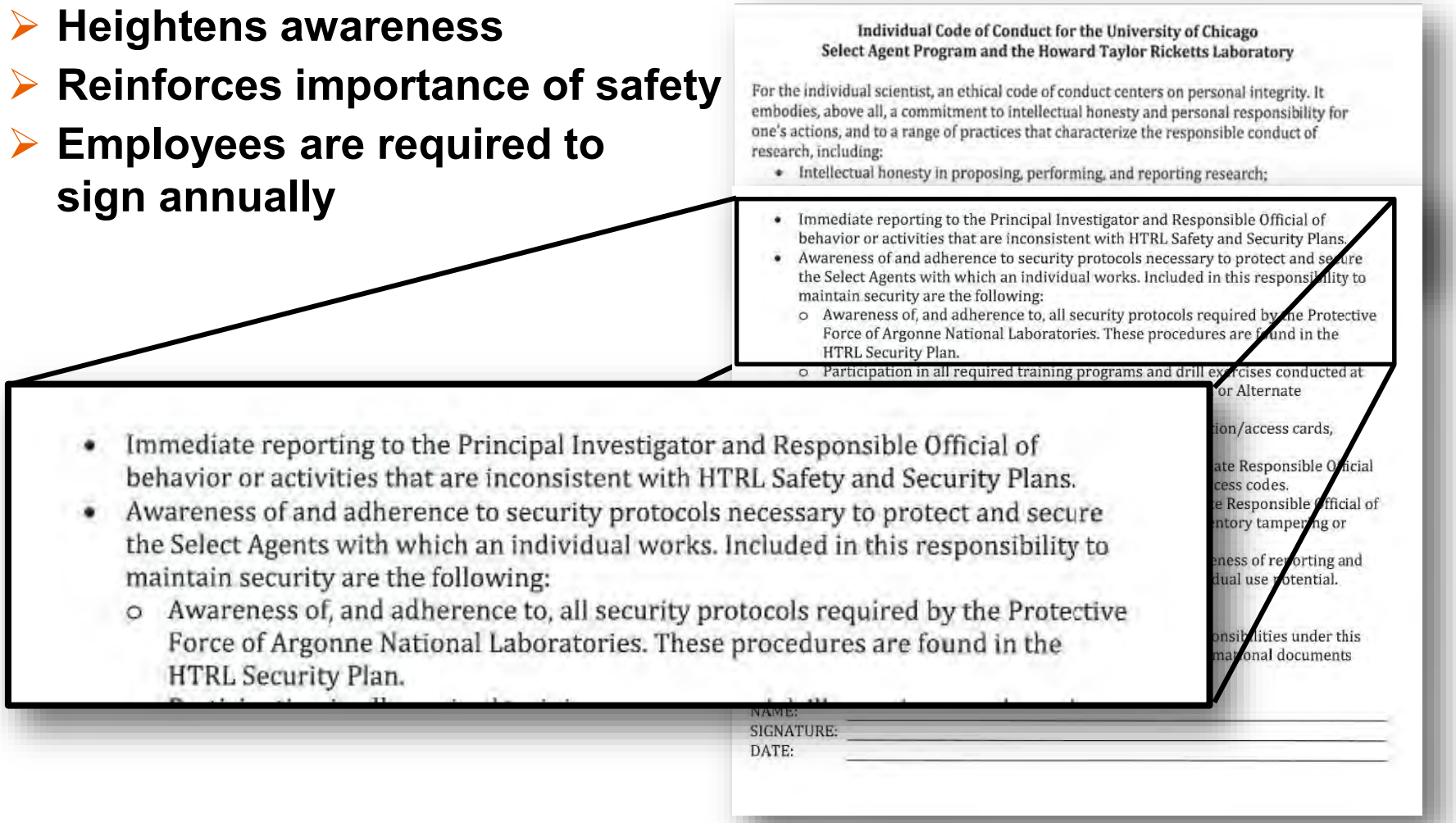
Incident Reporting Is Encouraged: Multiple Reporting Pathways Established



IBC: Institutional Biosafety Committee

Code of Conduct Includes Reporting Incidents

- Heightens awareness
- Reinforces importance of safety
- Employees are required to sign annually



Individual Code of Conduct for the University of Chicago
Select Agent Program and the Howard Taylor Ricketts Laboratory

For the individual scientist, an ethical code of conduct centers on personal integrity. It embodies, above all, a commitment to intellectual honesty and personal responsibility for one's actions, and to a range of practices that characterize the responsible conduct of research, including:

- Intellectual honesty in proposing, performing, and reporting research;
- Immediate reporting to the Principal Investigator and Responsible Official of behavior or activities that are inconsistent with HTRL Safety and Security Plans.
- Awareness of and adherence to security protocols necessary to protect and secure the Select Agents with which an individual works. Included in this responsibility to maintain security are the following:
  - Awareness of, and adherence to, all security protocols required by the Protective Force of Argonne National Laboratories. These procedures are found in the HTRL Security Plan.
  - Participation in all required training programs and drill exercises conducted at

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SIGNATURE:
DATE:

Services Provided by University of Chicago Office of Research Safety

"How do we get investigators to even know we exist?"

"How do we get investigators to realize we are here to help?"

Communication and Outreach to Frontline Laboratory Workers

DO NOT APPLY COSMETICS IN THE LAB

(THIS INCLUDES CHAPSTICK®)

DON'T EAT OR DRINK OR STORE FOOD IN THE LAB.

DON'T HANDLE CONTACT LENSES IN THE LAB.

http://biologicalsafety.uchicago.edu/

This message brought to you by the Office of Biological Safety and BSL Awesome Productions.

YOU SHALL NOT PASS

...IBC approval without the appropriate biosafety training.

biologicalsafety.uchicago.edu/ facebook.com/UChicagoBiosafety

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BSL Awesome

BY THE NIH GUIDELINES

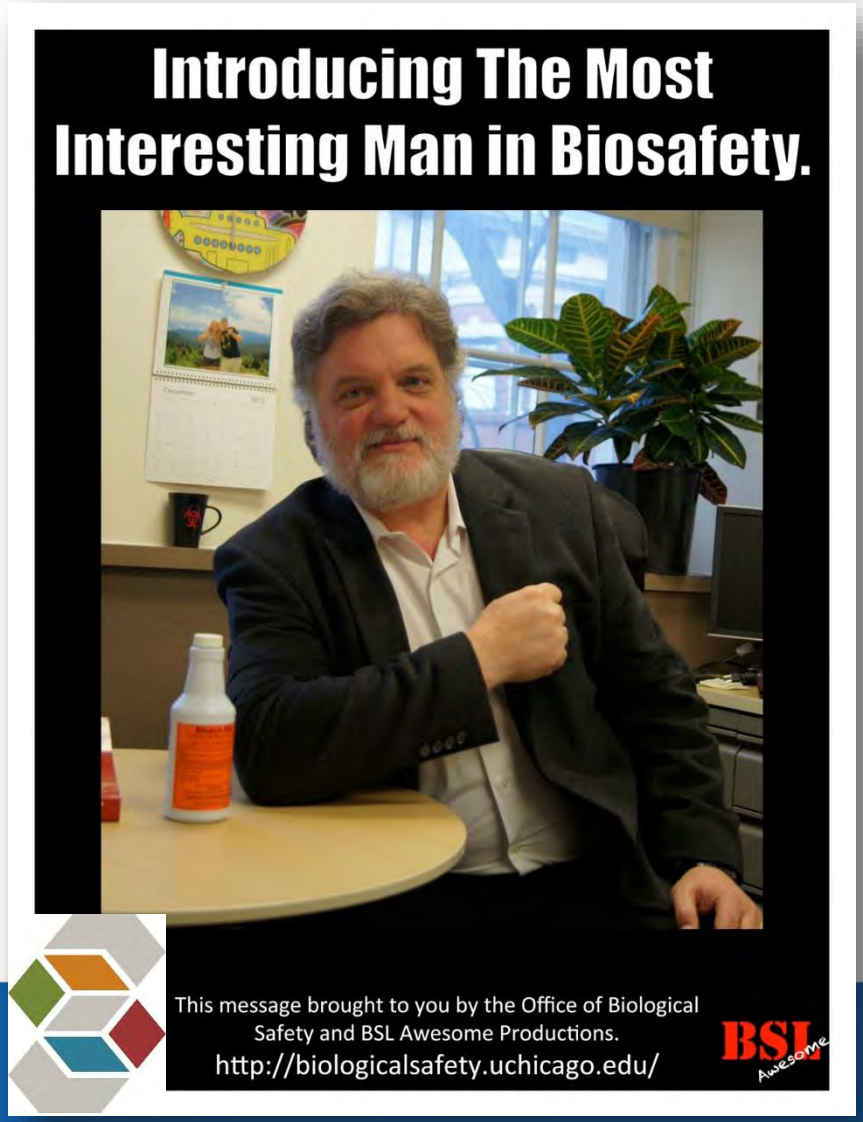
THE NIH GUIDELINES, OR THE NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT AND SYNTHETIC DNA MOLECULES, IF YOU'RE NOT INTO THE WHOLE BREVITY THING, APPLY TO ALL RESEARCH INVOLVING rDNA AND SYNTHETIC DNA REGARDLESS OF ITS FUNDING SOURCE.

FOR ANY QUESTIONS REGARDING COMPLIANCE WITH THE NIH GUIDELINES, CONTACT THE OFFICE OF BIOLOGICAL SAFETY

773.834.2707
biosafety@
bsd.uchicago.edu

BSL Awesome

Clever Posters Designed to Increase Awareness



… and Reinforce Good Behavior

How to Strengthen A Culture of Lab Safety

- **Leadership at high levels**
  - UC – Office of Research Safety
  - CDC – Office of the Associate Director for Laboratory Science and Safety
- **Developing future leaders**
  - UC – GLRCE Biosafety Research Fellows
  - CDC – Laboratory Leadership Service
- **Review mechanisms for lab safety**
  - UC – Institutional Biosafety Committee
  - CDC – Laboratory Safety Review Board
- **Engaging and proactive communication**

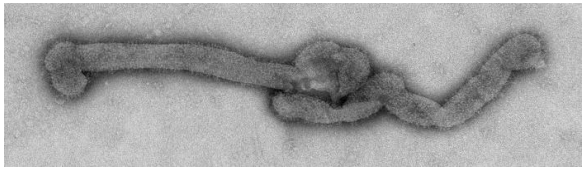
UC: University of Chicago

Questions?

Selected CDC Pathogen and Toxin Discoveries

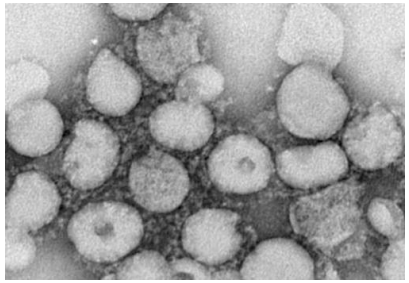
Akhmeta Virus

Legionella

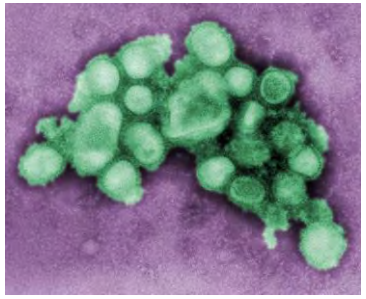


Bourbon Virus

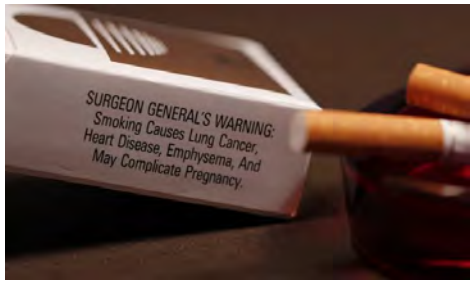
Lychee Nut Toxin



SARS



2009 pandemic H1N1 Influenza



Carcinogens in Smoke

For more information about CDC Laboratory Safety
www.cdc.gov/about/lab-safety/index.html

PHIL ID 14542, 11215, 15530, 11152, 19479