

Laboratory Safety in a Hybrid Research and Development Work Environment



New approaches to safety culture and practices

National Emerging Infectious Diseases Laboratories
Boston University

Kevin Tuohey
Executive Director, NEIDL Research Compliance &
Chief Safety Officer
ketuohey@bu.edu

NEIDL

Combating Disease. Creating Cures.



Infectious disease research for the local, national, and global good.



Boston University National Emerging
Infectious Diseases Laboratories



NEIDL Location on the BU Medical Campus



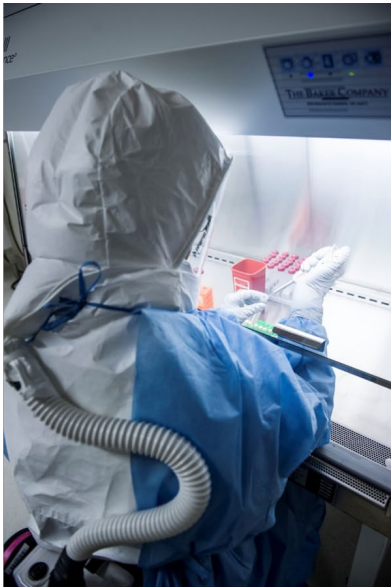
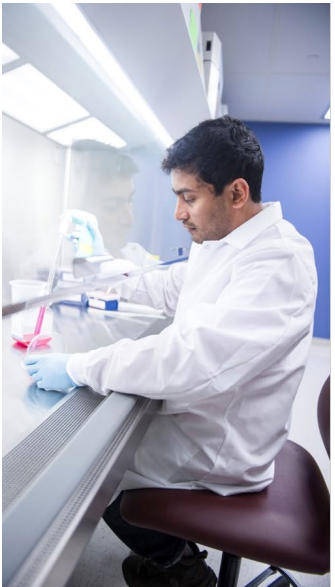
Boston University National Emerging
Infectious Diseases Laboratories

Mission of the NEIDL

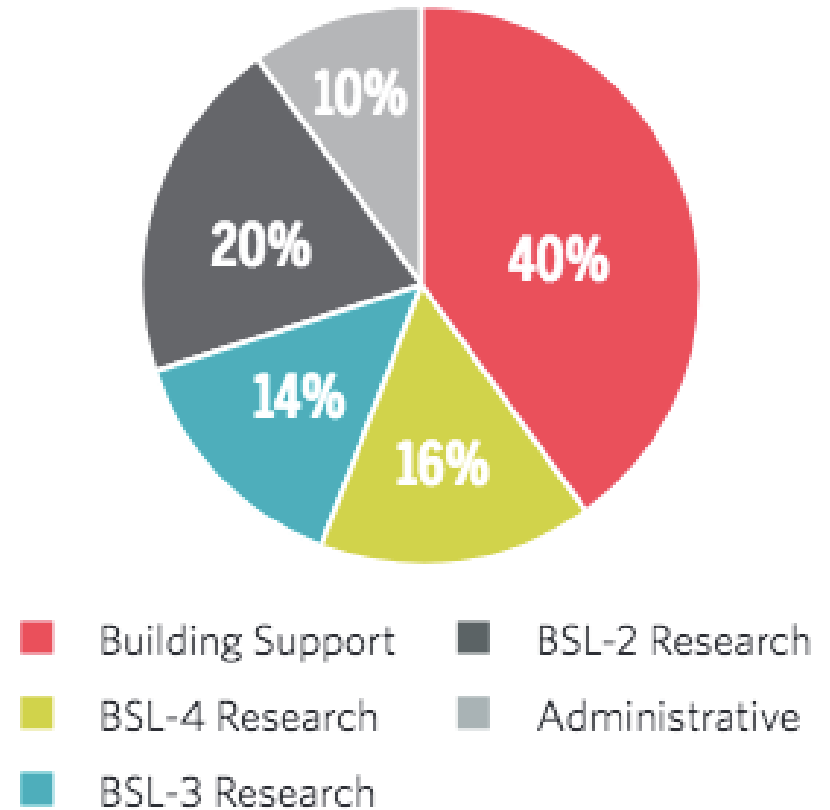
- The NEIDL conducts research to investigate and understand emerging pathogens and the diseases they cause
 - *Uses fundamental knowledge to develop and/or test diagnostics, vaccines, and therapeutics for EID to promote the public's health*
 - *Train the next generation of researchers for careers in EID*
 - *Operate a research facility with highest attention to community and laboratory safety and security*
- As an academic research center, research programs and capabilities parallel the expertise and interests of the faculty
 - ❖ *Committed to transparency. No classified research*

NEIDL Facilities

- Laboratory and laboratory support space
 - BSL-2, BSL-3, and BSL-4 laboratories
 - ACL2/3 insectary
- On site Facilities, Security, IT and Safety Professionals



NEIDL: TOTAL BUILDING AREA



BSL-4 Support Space

40% of building space is dedicated to support of the laboratories



HEPA filtration deck for BSL-4



BSL-4 Effluent Decontamination System (EDS)

NEIDL BSL-4 Facilities

Chemical Shower



BSL-4 Laboratory



Central Corridor

BSL-3 (5 suites)



Federal Select Agent Program

The following is from <https://www.selectagents.gov/overview/index.htm>

- *The Federal Select Agent Program (FSAP) regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. Examples of select agents and toxins include the organisms that cause anthrax, smallpox, and foot-and-mouth disease, the plant pathogen *Ralstonia solanacearum*, as well as the toxin ricin.*
- *While potentially dangerous, work with select agents and toxins provides important scientific discoveries that have led to improved detection, prevention, diagnostic, and treatment options for diseases considered to be some of the most threatening to public, animal, and plant health. FSAP allows laboratories to conduct lifesaving research on these potentially dangerous materials while making sure it is done as safely and securely as possible.*
- *The program is managed jointly by:*
- *The **Division of Select Agents and Toxins (DSAT)** at the Centers for Disease Control and Prevention (CDC), which is part of the U.S. Department of Health and Human Services (HHS).*
- *The **Division of Agricultural Select Agents and Toxins (DASAT)** at the Animal and Plant Health Inspection Service (APHIS), which is part of the U.S. Department of Agriculture (USDA).*



Boston Public Health Commission

The following is from <https://www.boston.gov/government/cabinets/boston-public-health-commission/healthy-homes-and-environment/biological-safety>.

BIOLOGICAL SAFETY

The Biological Safety Program enforces regulations to ensure safe operation of biological research laboratories in the City of Boston.

The following biological research laboratories operating, or proposing to operate, in Boston must get an annual operating permit from the Boston Public Health Commission (BPHC):

- *Labs operating at biosafety level 3 and above: BSL-3/ABSL-3, BSL-4/ABSL-4*
- *Labs working with recombinant DNA (rDNA) materials at biosafety level 2 (BSL-2/ABSL-2) and above.*
- *The Biological Safety Program administers this permitting. It also leads the Boston Biosafety Committee oversight advisory group and coordinates internal and external multidisciplinary teams. This program ensures safe operations in Boston's biological research laboratories.*



Boston University National Emerging
Infectious Diseases Laboratories

Culture of Safety – Training Programs

	<u>Before</u>	<u>During</u>	<u>After</u>
Online	online	online	online
In Person	in person	hybrid	hybrid
Mentoring	in person	in person	In person



Online training (# increased)

- 20 lab safety courses
- 23 Agent Specific trainings

Individual Training Plan (ITP)/ Training Requirements:

Stage I Hands-on BSL-3/4 Training: introduction to working in a BSL-3/4 laboratory environment and the proper donning and doffing, and entry and exit procedures.

Stage II Hands-on BSL-3/4 Training: will include review of incidents, accidents, and emergency procedures.

Mentored Specific Training to the BSL-3/4 Laboratory: the trainee will be paired with an approved mentor who will provide mentorship training in the form of entries/hours which will be documented.

Annual Refresher Training: Following a lecture and review of NEIDL SOPs delivered via online training, a written exam (passing score of 80% required).

90 Day Refresher Training: If personnel go at least 90 consecutive days without entering the BSL-3, refresher training will be required before entry.

6 Month NTAC Reassessment: If personnel do not enter the BSL-3 for a period of 6 months or longer, the NTAC will perform a reassessment of degree of refresher training would be required to enter containment.



Boston University National Emerging Infectious Diseases Laboratories

NEIDL Safety Training
BSL-2 Laboratory Access
 Floors 4 and 5 (circle all that apply)

Instructions: Authorized trainer reviews each bullet point with individual, checking the box after each topic is sufficiently covered. Please provide a completed copy to the NEIDL Training Manager.

Name of Employee _____
 Core/Office/Affiliation _____
 Date _____
 Name of NEIDL Authorized Trainer _____

General Information

☒ Additional access requires PI/Manager request and additional training/hour
☒ Lab Attire and PPE

Required Training

☒ ROHP Clearance
☒ BioRAFT Trainings

- BSL-1&2 Training
- Chemical Safety Training
- Lab Safety Training
- Bloodborne Pathogens Training
- rDNA/IBC Policies Training
- Agent Specific Training

☒ Lab Specific Training

- Procedure Specific
- Equipment Specific

Hazard Communication

☒ Fire Extinguishers
☒ AED Locations
☒ Emergency Pull Alarms
☒ Egress/Evacuation Routes
☒ Rally Points

☒ Door Signage
☒ Chemical Labeling
☒ Hazardous Chemical Waste Procedures
☒ Biohazard Waste Procedures
☒ Universal Waste Procedures
☒ Report Incidents to PI and ROHP

Safety Equipment

☒ Emergency Eyewash/Safety Shower
☒ Spill Kits/Spill Response

Equipment Movement

☒ Decontamination Form
☒ Coordinate with EH&S and Facilities

Culture of Safety – Training through SOPs / protocols

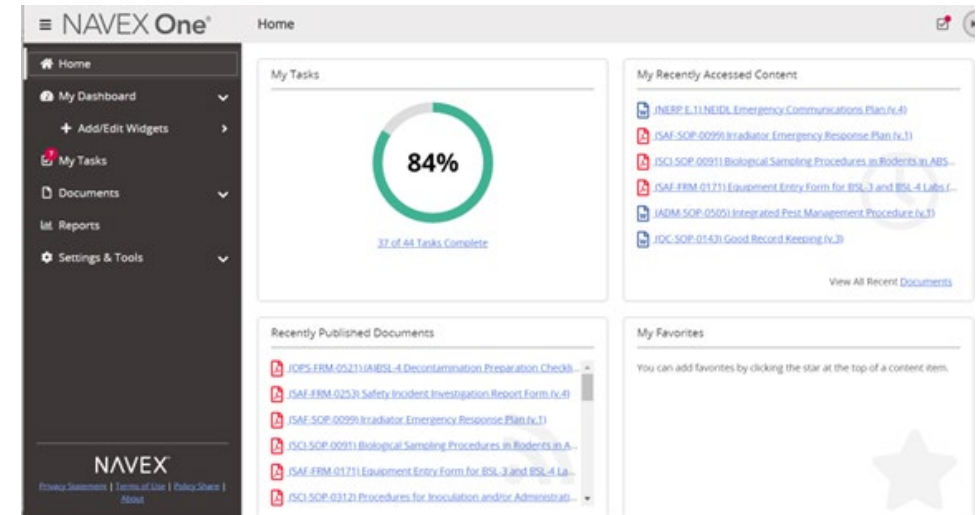
	<u>Before</u>	<u>During</u>	<u>After</u>
SOPs	both	On-line	On-line
Protocol Review	in person	virtual	virtual
Regulatory Review	in person	virtual	virtual

Protocol / Regulatory Review

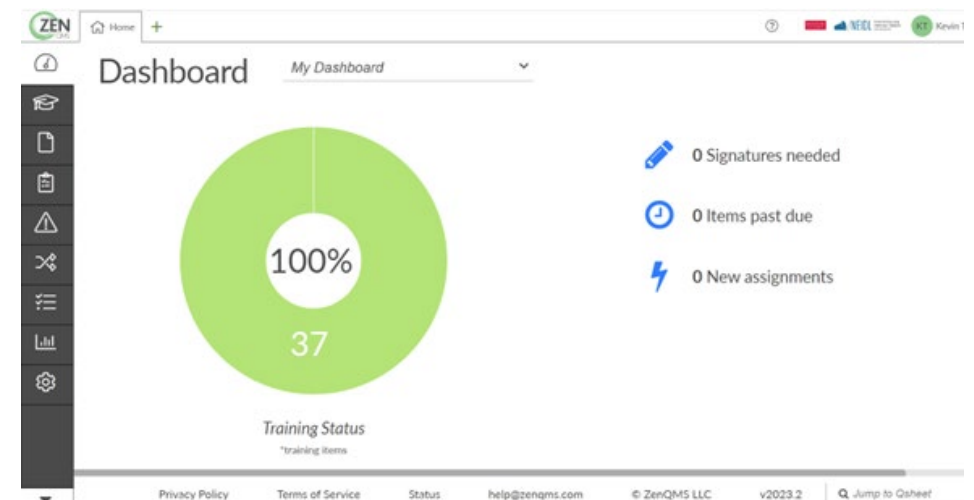
- Boston University Institutional Biosafety Committee (IBC) includes community members. Reviews were expedited, meetings increased in frequency, moved to virtual, quorum improved, open to public.
- Boston Public Health Commission (BPHC) led Boston Biosafety Committee (BBC) made up of volunteer SMEs and community members. Review of IBC approved protocols were expedited, meetings increased in frequency, moved to virtual, open to public.



Boston University National Emerging
Infectious Diseases Laboratories

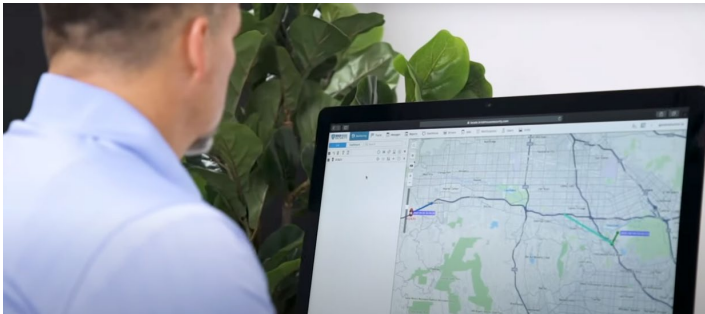
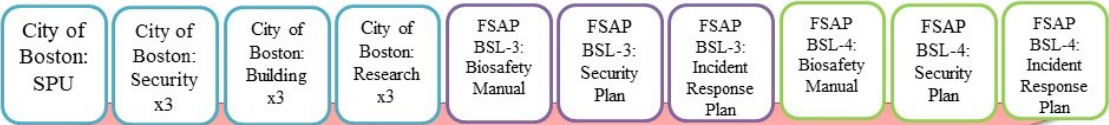


Approximately 300 documents in above,
approximately 180 documents in below



Culture of Safety – Training through Drills / Exercises

	Before	During	After
HVRA Process	in person	virtual	hybrid
Drills / Exercises	in person	hybrid	hybrid
Familiarization Training	in person	hybrid	hybrid
Command Center	in person	virtual	hybrid



Observation/Area for Improvement	Corrective Action
Quarantine living conditions checklist	Construction of a checklist for living conditions and considerations following a post-potential exposure incident.

THREAT LEVEL / HAZARD	CATEGORY	PROBABILITY <small>1=Rare 2=Doubtful 3=Possible 4=Probable 5=Unavoidable</small>	SEVERITY - MAGNITUDE OF IMPACTS						SEVERITY IMPACTS <small>Overall Impact (Average)</small> 1=Lowest 5=Highest	UNMITIGATED RISK 1=Lowest 25=Highest	PREPAREDNESS <small>1=Best 2=Fair 3=Good 4=Excellent 5=Outstanding</small>	RELATIVE RISK Unmitigated Risk / Preparedness	
			HUMAN IMPACT <small>Potential deaths or injuries</small>		FACILITIES IMPACT <small>Physical damage and costs</small>		INSTITUTIONAL IMPACT <small>Research/research & teaching; reputational damage</small>						
			Question 1	Question 2	Question 1	Question 2	Question 1	Question 2					
Natural Hazard	Technological	Human-Caused											
Community Epidemic Impacts on REEL	Natural		4.00	2.00	2.00	1.00	1.00	5.00	1.00	2.00	8.00	5.00	1.60
Community Epidemic Impacts on REEL	Technological	Human-Caused	3.00	1.00	2.00	2.00	1.00	1.00	2.00	1.50	4.50	3.00	1.50
Fire or Explosion	Technological		2.00	1.00	2.00	3.00	3.00	3.00	2.00	2.33	7.00	5.00	1.40
Laboratory Accidents	Technological		3.00	2.00	1.00	1.00	2.00	2.00	5.00	2.33	3.00	5.00	1.40
Loss of Data	Technological		3.00	1.00	1.00	2.00	2.00	2.00	1.00	1.67	5.00	4.00	1.25
Multiple Violence	Human-Caused		3.00	1.00	3.00	2.00	1.00	3.00	2.00	2.00	6.00	5.00	1.20
pH Neutralization Failure	Technological		3.00	1.00	1.00	1.00	1.00	2.00	1.00	1.32	3.50	3.00	1.17
Medical Emergency	Human-Caused		3.00	2.00	3.00	1.00	1.00	1.00	1.00	1.50	4.50	4.00	1.13
Information Systems	Technological		3.00	1.00	1.00	1.00	2.00	3.00	1.00	1.50	4.50	4.00	1.13
Hurricane	Natural		4.00	1.00	2.00	1.00	1.00	2.00	1.00	1.33	5.33	5.00	1.07
Autoclave Batch Failure	Technological		4.00	1.00	2.00	1.00	1.00	2.00	1.00	1.33	5.33	5.00	1.07
Vaccine Leak/Release	Technological		4.00	1.00	1.00	2.00	1.00	2.00	1.00	1.33	5.33	5.00	1.07
External Cyber Attack	Human-Caused		3.00	1.00	1.00	2.00	1.00	2.00	1.00	1.33	4.00	4.00	1.00
Severe Thunderstorm	Natural		5.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	5.00	5.00	1.00
Bleedout	Natural		5.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	5.00	5.00	1.00
Temperature Excursion	Natural		5.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	5.00	5.00	1.00
Quarantine Isolation Failure	Technological		3.00	1.00	1.00	1.00	1.00	2.00	4.00	1.67	5.00	5.00	1.00
Laboratory Medical Emergency	Technological		3.00	1.00	3.00	2.00	1.00	2.00	1.00	1.67	5.00	5.00	1.00
Chemical Incident	Technological		3.00	2.00	2.00	1.00	1.00	1.00	3.00	1.67	5.00	5.00	1.00

2022 NEIDL Drills and Exercise Plan

Testing BPHC Security Incident and CDC Security Plan

Testing BPHC Building Incident and CDC Incident Response Plan

Testing BPHC Research Incident and CDC Biosafety Plan



Boston University National Emerging Infectious Diseases Laboratories

Culture of Safety – Other Lessons

	Before	During	After
Emergency Pass / ID	none	provided	If need
Shared Calendar	none	provided	maintain
Daily Checklist	With EHS	Shared	Shared
Grand Rounds	in person	virtual	hybrid
Incident Management	in person	virtual	virtual
Personnel Suitability	in person	virtual	virtual

Daily Checklist - Required every 24 hours

– all critical and life safety systems.

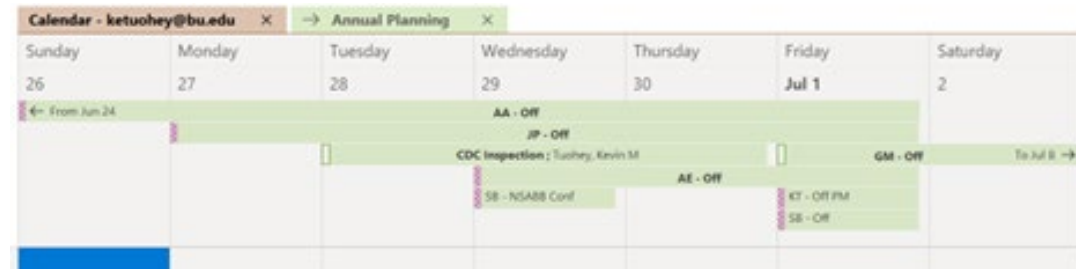
- Trained research staff to perform checklist
- Provided EHS support by phone
- Moved to more frequent checks (sometimes twice a day).



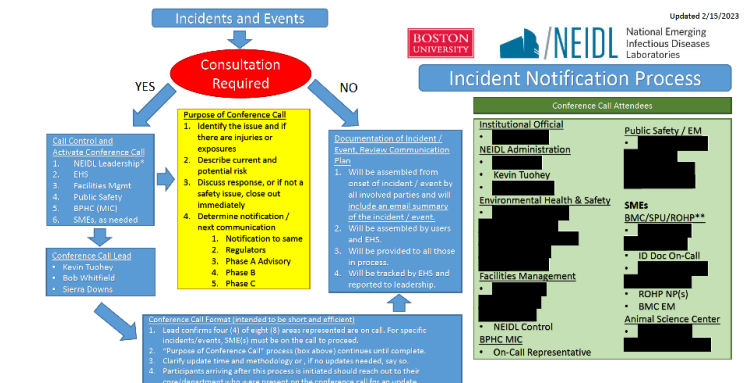
Boston University National Emerging Infectious Diseases Laboratories

Personnel Suitability Review Team

- Transitioned to virtual meetings
- Met more frequently and focused on supporting staff
- Revised policy.



Grand Rounds – moved to virtual. Focused on lessons learned



*Research leadership to communicate with the Office of Research, Operations leadership to communicate with BU wide Operations, Safety leadership to communicate with compliance and regulators. Emergency Management to determine if the NEIDL incident requires further university response.
 **For medical/exposure incidents involving personal health information, only individuals listed under the "BMC/SPU/ROHP" should remain on the line. All other groups shall drop off the call.

Maintaining a Culture of Safety - Summary

	<u>Before</u>	<u>Changes</u>	<u>After</u>
Online training	online	increased # of trainings	online
Building orientation	in person	hybrid	in person
Insider Threat	in person	online	online - reinforced in Grand Rounds annually
Grand Rounds	in person	virtual	combined - in person and virtual
Suit training	in person	in person	in person
Mentoring	in person	in person	in person
Standard Operation Procedures	in person development, online review	virtual development, online review	virtual development, online review
Protocol Review / Approval	in person	virtual	virtual
Regulatory Review / Approval	in person (CDC, BPHC)	hybrid (CDC , BPHC)	hybrid (CDC , BPHC)
Hazard Vulner & Risk Assess	in person	virtual	hybrid
Drills and Exercises	in person	hybrid	hybrid
Responder Familiarization Trng	in person	hybrid	hybrid
Incident Notification	virtual (specific to those notified)	virtual (group conference call/zoom)	virtual (group conference call/zoom)
Command Center Activation	in person	virtual	virtual or, if necessary, in person
Emergency Worker ID	did not exist	ID cards issued	to be determined based on need
Shared Calender	did not exist	shared calendar created	shared calendar
Daily Checklist	done by single department (safety)	expanded to other users to perform	includes others, may be more than 1 x day
Lab Inspection frequency	based on risk	increased due to COVID positive tests	based on risk
Personal Protective Equipment	defined in protocol based on risk (BSL-3)	N95 needed by HC -PAPR standardized	PAPR is standard
Personnel Suitability Team	in person	virtual - at greater frequency	virtual - as needed beyond meetings, 6 x YR

Lessons Learned

- Few of us are prepared to communicate effectively with the public – whether science, or risk communication
- There is no such thing as over-communicating, or even communicating enough
- We tend to view complex issues through our own lens, not those of the public
- We need to understand potential bias of audience and sources and antecedents of mistrust – address them
- Community members who disagree should not be dismissed.

Messaging Transparency

- Credibility is critical: “mean what you say, say what you mean”
- We can’t promise there will never be an “incident”, and don’t conceal things that happen
- Respond proactively to inaccuracies
- Communicate in different ways
 - IBC Minutes at: <https://www.bu.edu/researchsupport/compliance/ibc/about-the-ibc/ibc-meeting-minutes/>
 - Agent Specific Information at: <http://www.bu.edu/researchsupport/safety/rohpa/agent-information-sheets/>
 - Incident Reports at: <http://www.bu.edu/researchsupport/safety/rohpa/quarterly-incident-reports/>