Strengthening the Disaster Resilience at an Academic Maximum Containment Laboratory: Biosafety and Biosecurity Preparedness

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University-Wide Emergency Response Plan

- Establish SOPs to mobilize BU resources and communicate with the University community in efficient and orderly manner
- Promote effective triage of University resources with minimal disruption to normal operations

- NEIDL comprehensive emergency management program (CEMP)
  - Designed to prevent, prepare for, respond to, and recover from any threat, emergency, or disaster that could disrupt operations
  - Policies, procedures, plans, and internal and external outreach strategies
  - Multi-year strategic planning
Plan-Do-Check-Act Management System

• Planning the response to emergencies
• Evaluation and drills
• After-action reviews designed to check performance
• Modify as appropriate
NEIDL CEMP

- Defines who does what, when, where, and how in order to prevent, prepare for, respond to, and recover from natural and manmade emergency incidents
  - Prevent: eliminate or reduce the probability of disaster
  - Prepare for measures to preserve life and minimize damage
  - Respond during emergencies and provide assistance to prevent loss of lives and property
  - Establish a recovery system in order to return to a normal state of affairs
    - Short and long term activities
    - Return all systems to normal, or improved standards
    - Continuity of Operations Program
NEIDL CEMP

• Three separate exercises each year
  – Research-related risk such as exposure
  – Building-related risk such as utility loss
  – Security-related risk such as theft/loss of agent
  – One joint full scale exercise conducted with Boston emergency responders

• After Action Report and Improvement Plan done following each exercise, as well as large and/or significant events, to assess the effectiveness of the response
Hazard Vulnerability Assessments & Risk Analysis

- Conducted annually

- Take into consideration the likelihood of what events may occur in the Boston area and weigh them accordingly. Including:
  - Cybersecurity
  - Nuclear
  - Pandemic
  - Chemical
  - Biological
  - Radiological
  - Explosive

- Issues Considered:
  - Probability
  - Property
  - Internal Resources
  - Response
  - Business Impact
  - External Resources
  - Human Impact
  - Preparedness
Hazard Vulnerability Assessments & Risk Analysis

• Highest relative risks become the design criteria for training and drills & exercises
• Information from regulatory and law enforcement bodies are included
• Annual Hazard Vulnerability and Risk Assessment results shared with various University and external emergency responders
Capability Assessment

- Do we have plans to respond to the hazards identified through the HVA?
- Is there an organization available to execute those plans?
- Is that organization properly equipped?
- Has the organization been trained on the equipment and plans?
- Has the organization exercised those plans?
Safety at the NEIDL

- Is of primary consideration and is integrated into every aspect of its design and operations
  - All systems built with both engineered and operational redundancies
  - Reviewing all protocols and procedures and mitigating potential hazards
  - Providing all employees with extensive training and awareness programs
  - Establishing a comprehensive oversight program
  - Continuously improving safety, health, and environmental protection practices
  - Maintaining transparency and informing the community of its activities
  - Creating an environment where individuals are empowered to recognize and to report errors or near misses without fear of reprimand or punishment
  - Committing resources to address safety concerns
Biosecurity Program

• The ongoing management of safe and compliant programs within a secure and productive facility includes recognition of the importance of research within a culture of trust

• In order to achieve the necessary balance, the following are required for an effective, ongoing biosecurity program:
  – Personal responsibility
  – Communication and transparency
  – Periodic evaluation
  – Privacy and confidentiality
  – Ongoing monitoring
  – Fairness and flexibility
  – Engaged leadership
  – Appropriate training
Biosecurity Program

1. Security systems
2. Ongoing education and training
3. Personnel suitability and reliability
Biosecurity Program
NEIDL Mitigation Strategies

• NEIDL-specific construction design
  – 100-foot set-back
  – Designed according to Massachusetts Building Codes for Seismic Category D
  – The BSL-4 suites are structurally separated from the adjoining floors
  – BSL-4 suites have 12-inch thick reinforced concrete walls with special epoxy covering
  – N+1 redundancy
  – Critical utilities that support the building can be generated onsite in addition to being delivered from external sources
NEIDL Mitigation Strategies

- Entry requirements (BSL-4 and BSL-3 Select Agents)
  - Criminal Background Check
    - BU Public Safety (Federal, state, and local)
    - Department of Justice (including fingerprinting)
  - Credential checks
    - Social Security Number
    - Academic
    - Past employment
    - Licenses and credentials
    - Sexual Offender Registry Information
    - Credit history check
    - RMV/DMV driving record, if required
NEIDL Mitigation Strategies

• Entry Requirements (cont.)
  – Medical Clearance Process
    • Medical evaluation
    • Drug screening
    • Psychological screening
    • Immunization/titer level review
  – Training and education (annual)
    • Insider threat awareness
    • Self/peer reporting procedures
    • Corrective actions, procedures, and policies
    • Behaviors of concern
    • Voluntary opt out process
    • Policy on ongoing suitability assessment and monitoring procedures
NEIDL Mitigation Strategies

• Entry Requirements (cont.)
  – Visitors
    • Escorted at all times
    • Must be pre-authorized
    • Present government-issued photo ID for verification of identity and comparison against available public safety databases
NEIDL Mitigation Strategies

• Transportation of Select Agents (BSL-3 and BSL-4)
  – Upon arrival of the carrier at the delivery site
    • Ensure vehicle remains in a secured location
    • Check carriers’ driver’s licenses and verify that their identities match the photographs and names provided
    • Carriers stand by and do not depart until the package has been opened in the lab and verified
  – Public safety officer provides escort during the acceptance of the package and delivery to the final laboratory location
  – Public safety officer waits outside the laboratory while verification of the shipment occurs within the containment lab
NEIDL Mitigation Strategies

• Additional requirements of BU transportation policy that exceed the regulatory requirements:
  – Carrier uses dedicated vehicle with two qualified drivers
  – Carrier provides staffing that has undergone background checks
  – GPS tracking of packages and vehicles
  – BU-determined routes of travel
  – Carrier pre-designates an emergency response company
  – BU notified of any accidents or incidents during transport
  – State and local emergency response departments are notified of all BSL-3 and BSL-4 Select Agent shipments
  – Deliveries scheduled to arrive at off-peak traffic hours through the City of Boston to ensure transport and reduce the possibility of accident or delay due to traffic congestion
NEIDL Mitigation Strategies

• Inventory controls
  – All access to agents in storage is tracked and recorded in an electronic inventory control
  – Authorized personnel keep track of and record the transactions
    • Strain of agent
    • Amount added, removed, or destroyed
    • Name of persons conducting the transaction
    • Date and time of the transaction
  – Records are secured from electronic intrusions
  – Access to inventory storage requires two authorized personnel
NEIDL Mitigation Strategies

• Two-person guideline
  – Intended to mitigate safety and security risks associated with individuals working in BSL-3 and BSL-4 restricted access areas and not easily accessible to co-workers or first responders in the event of an accident, injury, and/or exposure
  – Risk assessments conducted to ensure that implementation in specific situations will not add additional risk to personnel
NEIDL Mitigation Strategies

- Building & Laboratory Access
  - ID verification entry controls
  - Proximity card readers
  - Biometric iris scanners
  - 24/7 security control by Public Safety Officers
  - Security controls programmed so employee can only access spaces that have been approved
    - Requested by supervisor, based on job function
  - Access records are reviewed monthly by the Responsible Official and Public Safety
  - BSL-4 entry for new employees requires supervised access with a mentor as part of the training program
  - Independent access/work in the BSL-4 laboratory assessed by mentor, BSL-4 trainer, and EHS
    - Assessment submitted to the NEIDL Training Advisory Committee, which provides final sign-off
NEIDL Mitigation Strategies

Orientation to the NEIDL

Application Review
Prior Experience

Stage I Positive Pressure Suit Training
1 week

Stage II Scenario-Based Simulations
1 week

Core- or Lab-Specific Training:
Mentored Work in BSL-4
(Minimum 10 entries and 25 hours)

BSL-4 Access

Annual Refresher Training

Mentor Training

Mentor
Personnel Reliability Program

- Mitigate potential risks of theft, loss, and intentional or accidental release of agents by individuals who have been approved for access in a manner that does not impede the progress of science
  - Strike the appropriate balance between personal privacy and safety & security
- Initial assessment with an ongoing evaluation and monitoring program
- Promote reporting of safety and security concerns based on a culture of trust, respect, cohesiveness, and responsibility
- Enable leadership to make timely operational decisions consistent with the highest standards of personnel reliability
- Provide tools for the employees to be able to recognize behaviors and conditions that may be detrimental to a safe and secure working environment, as well as an environment for reporting such situations in a manner that is supportive and free from fear of reprisal
Personnel Reliability Program

- Provide training and guidelines related to monitoring activities and expectations
- Assess employees’ behavioral suitability, reliability and willingness to comply with the heightened security and safety procedures required within the NEIDL
- Assess employees’ acceptance of responsibility with respect to safety and security requirements, as well as BU policies and procedures
- Provide plans for those that are temporarily or permanently denied access to NEIDL facilities
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Questions?
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