

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

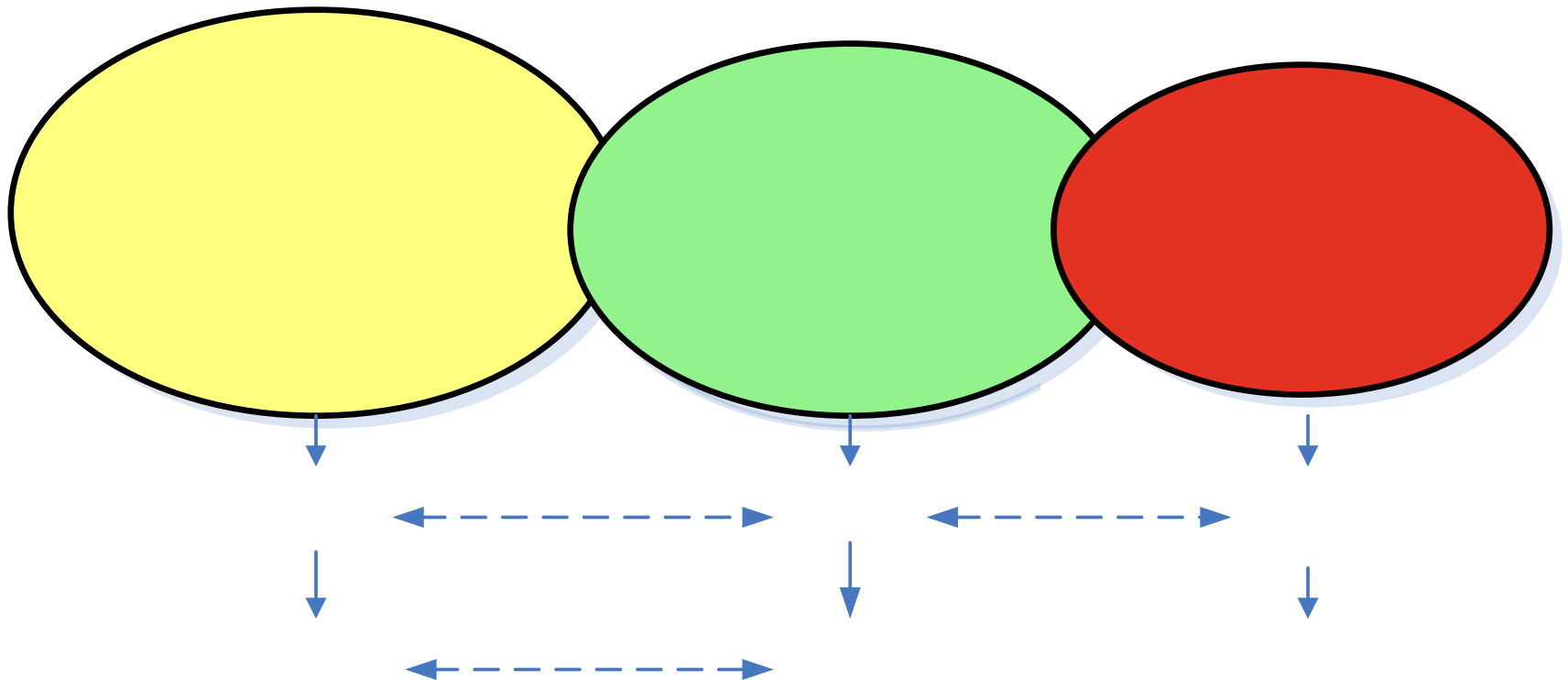
Biosecurity Program

- 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
 - Policy on ongoing suitability assessment and monitoring procedures
 - Behaviors of concern
 - Voluntary opt out process

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



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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