

# Approaches For A Unified Laboratory Management Biorisk Framework



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## Problem

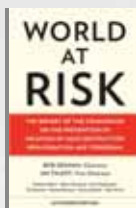
Biological weapons and their use or proliferation by States or non-State actors present a significant challenge to our national security.

The National Biodefense Strategy, as mandated by Homeland Security Presidential Directive (HSPD)-10, has one main goal: *PROTECT* against the misuse of the life sciences to develop or use biological agents to cause harm.

- Promote global health security
- Reinforce norms of safe & responsible conduct
- Obtain timely and accurate insight on current & emerging risks
- Take reasonable steps to reduce potential for exploitation
- Expand our capability to prevent, attribute, & apprehend
- Communicate effectively with all stakeholders
- Transform the international dialogue of biological threats

Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (*World at Risk*, December 2008):

- Terrorists more likely to be able to obtain/ use a biological weapon than a nuclear weapon
- Should be less concern that terrorists will become biologists, far more concern that biologists will become terrorists.
- Efforts critical to promoting culture of security awareness in life sciences community.



Unsecured biological material



Unsecured laboratory keys

## Approach

Laboratories that handle dangerous pathogens need to responsibly manage their safety and security risks (highlighted in the *World at Risk* report, which specifically called for bioscience laboratories handling dangerous pathogens to implement a unified management framework to enhance safety & security).

- Currently, many laboratories rely on ad hoc management systems to address these biorisks
- This project analyzed the value in implementing integrated formal biorisk management

Although safety and security pose separate risks and must be assessed independently, the system to manage these risks must be cohesive and unified to be effective from the laboratory perspective. A risk management framework has seven main phases:

- Pre-assessment
- Risk assessment
- Concern assessment
- Risk characterization
- Risk evaluation
- Decision-making
- Implementation



The bioscience community has tools for implementation and is developing tools for risk assessment.

- This project explored aspects of the other elements, especially approaches for pre-assessment & risk management.
- The ultimate goal of a biorisk management system should be to ensure an organization's biorisk management objectives are met in the most efficient & effective way; this project hopes to help institutions working towards this goal.

## Results

### Pre Assessment:

#### Biorisk cases:

- Under this project, 63 recent cases were analyzed and could be grouped into the following categories:
  - Laboratory exposure (actual or potential)
  - Unintentional release from facility
  - Theft
  - Inappropriate shipments
  - Inventory discrepancies
  - Unauthorized access
  - Unauthorized experiments
  - Inadequate biosafety measures
  - Inadequate biosecurity measures
  - Problems with documentation
  - Inadequate training



### Management:

The lack or insufficiency of appropriate training or reliability programs are two important gaps identified through this project & others.

### Training:

Retention can be explained by classifying tasks into skill sets:

- Physical and speed-based skills appear to be retained longer than cognitive & accuracy-based skills.
- Closed-loop skills, involving discrete responses that have a definite beginning & end, are retained longer than open-loop skills, which involve continuous, repeated responses with no definite beginning or end.

Three issues to consider when determining optimal refresher training interval: 1) how frequently is the skill practiced in the workplace? 2) how susceptible is that type of skill to decay? 3) how much retraining is necessary to restore effectiveness?

### Personnel Reliability Programs:

This project examined personnel reliability programs (PRPs) from a range of industries (nuclear, aviation, finance, and healthcare) to better inform and inspire the discussion of PRPs among biosecurity practitioners & to help us start identifying reasonable alternatives for biosecurity.

Component	Marker
Trustworthy	Criminal History
Physically Competent	Medical Evaluation
Mentally Competent	Mental Health History
Emotionally Stable	Psychological Evaluation
Financially Stable	Credit History
Responsible to uphold obligations to safety, public health, national security and scientific integrity	Drug Testing, Peer Review, Affiliations

### Measuring effectiveness of risk management systems:

A variety of measures were examined, including management performance indicators, operational performance indicators, & biorisk status indicators.

- Analysis of performance indicators in other industries (e.g., chemical)
- Ways to assess biorisk climate through questionnaires
- Behavior-based coaching processes
- Ways to strengthen incident reporting
  - Defining incident and level of risk
  - Notification & response protocol with risk-based tiers
  - Models for root cause analysis

## Significance

Risk governance is emerging as a global, holistic approach to manage issues like scientific uncertainty or preparedness to natural disasters or major sociological or economical events, as well as any situation that is submitted to risks that may impact an organization in a substantial way.

The risk governance approach provides effectiveness and legitimacy to risk management decision-making.

Due to the complexity and diversity of biological processes/ activities, & the multiplicity of associated risks & activities, biorisk management should certainly benefit from the precepts of risk governance.

