Biorisk Assessment Models (BioRAMs)

Sandia National Laboratories' International Biological Threat Reduction Department (SNL/IBTR) has an ongoing mission to reduce biological risks. In that mission, IBTR has been actively developing biorisk assessment methodologies and tools. These methods and tools will aid laboratories seeking to implement biorisk mitigation measures in a manner advocated by the World Health Organization. IBTR has two biorisk models and software tools for conducting laboratory biosafety and biosecurity risk assessment.

The biorisk assessment models were designed for use by biorisk officers at laboratories and provide visualization of the relative risks, and help to identify risk mitigation measures. These models have incorporated IBTR and international biorisk officer experience in drafting sets of criteria, prioritizing the criteria, and outlining scoring functions for the criteria. The main objective of these models is to help strengthen risk governance in the laboratories by providing assessment methods that are is standardized, systematic, and repeatable. Biorisk subject matter expertise was critical in the development of these models, as there currently is no straight imperial data for laboratory biorisks.

Risk is defined by likelihood and consequences. For biosafety, likelihood is defined by the likelihood of infection and exposure via an infectious route of a biological agent. Consequences are defined as the consequences of disease to the at risk population. The populations of concern include persons in and around the laboratory, the human population outside the laboratory, and the animal community outside the laboratory. For biosecurity, likelihood is defined as the likelihood of theft of a biological agent and the severity of the consequence of an attack with that agent.
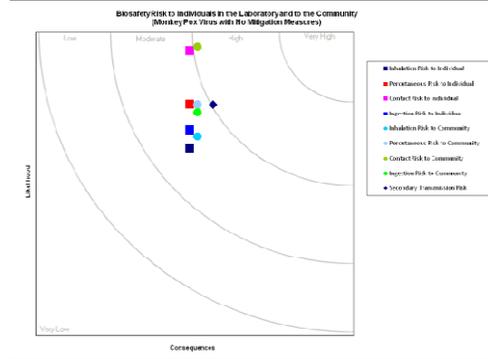
The assessment process is broken into components:
> Evaluate the biological agents that exist at the facility.
> Evaluate the facility processes and procedures.
> Evaluate the in place biorisk mitigation measures.
> For Biosecurity, evaluate the potential adversaries of the facility.

Within each component are several criteria and sub-criteria that are scored independently. These scores are weighted and then rolled up to provide the overall consequence and likelihood score. This method is based on a Multi Criteria Decision Analysis (MCDA) scheme, quantifying the various aspects of biorisk using qualitative definitions.

The final results show the relative risk of agents at the given facility, and give program management a mechanism to determine risks that are unacceptable. This scheme can aid program management in allocating recourses to mitigate facility biorisks; or to assess current biorisk program management effectiveness.

BIOSAFETY RAM
Example

Agent factors which impact the biosafety risks to humans

Is this agent known to cause infection via inhalation in humans (to cause infection via droplets or droplet nuclei that have entered the upper or lower respiratory tract) in a laboratory setting?
4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is this agent known to cause infection via inhalation in humans(to cause infection via droplets or droplet nuclei that have entered the upper or lower respiratory tract) in the natural environment?
4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans?
4 = Yes
2 = No
0 = If this is not an infectious route

Is this agent known to cause infection via percutaneous exposure in humans (to cause infection through compromised skin direct injection into the blood stream) in a laboratory setting?
4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is this agent known to cause infection via percutaneous exposure in humans (to cause infection through compromised skin direct injection into the blood stream) in the natural environment?
4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans?
4 = Yes
2 = No
0 = If this is not an infectious route

Biosafety Risk to Individuals in the Laboratory and to the Community (Monkey Pox Virus with No Mitigation Measures)

BIOSECURITY RAM
Example

Likelihood of Outsider targeting and successful theft from a facility

What level of physical security exists at the facility to keep unauthorized persons from accessing the agent?
4= There is no formalized physical security program at the facility
3 = There is limited perimeter security at the facility
2 = There is physical security to prevent the general public from accessing the laboratory areas
1 = There is physical security to limit access to the laboratory to only authorized laboratory personnel
0 = There is physical security to limit access to the agent to only authorized personnel

What level of personnel verification exists at the facility?
4 = Persons' identities are not systematically verified at the facility
1 = Verification of a person's identify and level of authorized access is confirmed prior to receiving access to the agent (via electronic badge access controls or guard verification)

What level of security management is in place at the facility?
4 = Management has not made a commitment to security at the facility
2 = Management has stated a commitment to security and is working to implement security, but it is still in process
1 = Management has clearly defined roles and responsibilities for all aspects of security, there is a clear commitment to security by management, documentation is maintained and secured as appropriate, personnel are trained, and the security system is reviewed periodically

Biosecurity risk of targeting, successful theft, and malicious release of a biological agent directed to the human population