DEVELOPING A BIOSAFETY RISK ASSESSMENT METHODOLOGY (Biosafety-RAM)

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Sandia National Laboratories International BIOLOGICAL THREAT REDUCTION

Enhancing US and International Security by Reducing Biological Threats Globally

SAND Number: 2008-6747C

Project Origins:
2nd Biorisk Management Workshop, 2007

- **Held at the Canadian Science Centre for Human and Animal Health**
  - **Organized by the National Microbiology Laboratory's Office of Biorisk Management (part of the Public Health Agency of Canada)**
  - **Winnipeg, Manitoba, February 2007**
- **Participants charged with discussing and, if possible, developing a common approach to biological risk assessment for the laboratory**
- **From the workshop report: "The current lack of a clearly quantifiable processes makes biological risk assessment a predominantly qualitative approach and, as such, potentially highly subjective, variable, and inconsistent."**
  - **Next steps include "the establishment of a comprehensive toolkit for biological risk assessment"**
- **Following the workshop, Sandia sought and received three years of internal R&D funding to develop a quantitative biosafety risk assessment methodology and software tool**
  - **Biosafety RAM**
- **"Biological Risk Assessment in the Laboratory: Report of the Second Biorisk Management Workshop," *Applied Biosafety,* Vol. 13, No. 3, 2008**

Collaborative Effort Required to Advance the Project

- **Project is a collaborative effort among ABSA, the Canadian Science Centre for Human and Animal Health, and Sandia National Laboratories**
  - The biosafety community and the microbiology community are key contributors
- **Upon completion, the methodology will be made publicly available**
- **The prototype software tool will be tested and reviewed by members of the biosafety and microbiology community**
- **The production version of the software tool will be made publicly available**

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3rd Biorisk Management Workshop, 2008

- **Held at the Canadian Science Centre for Human and Animal Health**
  - Organized by the National Microbiology Laboratory's Office of Biorisk Management (part of the Public Health Agency of Canada)
  - Winnipeg, Manitoba, March 2008

- **International participants charged with outlining the criteria and developing risk definitions for the Biosafety RAM project**
  - 13 participants from the US, Canada, Japan, and Singapore

Project Goals and Milestones

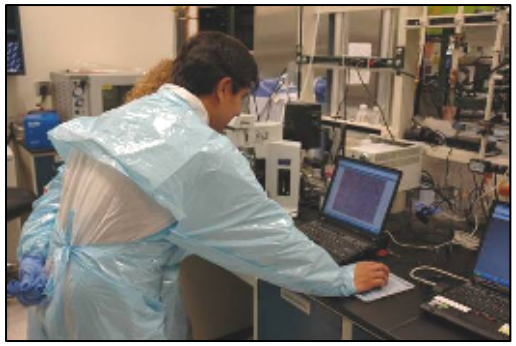
Goal	Milestone	Completion Date
Outline Methodology	***Review method with SMEs***	***03/2008***
Establish criteria	*Agent hazard criteria*	*05/2008*
	Laboratory hazard criteria	*05/2008*
	Hazard mitigation criteria	05/2008
Determine relative importance among criteria	Determine relationship among the criteria	06/2008
	Weight the criteria	**10/2008**
Create prototype model	Create prototype model	11/2008
	Test model with SMEs	**1/2009**
	Present overall methodology/model for peer review	03/2009
Develop software tool	Develop alpha software tool to implement model	09/2009
	Validate software tool	**12/2009**
	Finalize software tool and implement revisions	04/2010
Final report and tool		**09/2010**

Expected Project Results

- **Deliver a quantitative, repeatable biosafety risk assessment methodology and associated software tool**
- **Promote the use of the tool throughout the international bioscience community**
  - Especially in the many new high containment laboratories around the globe
  - Increase standardization of biological safety risk assessments
- **Improve understanding that there is no such thing as zero biosafety risk in biocontainment facilities**
  - Help to articulate and communicate the real risks at these facilities -- to users, managers, and the public
- **Develop a methodology that is flexible and allows for modification**
  - Biosafety RAM tool will be based upon this methodology
- **Strengthen the practice of biosafety and improve the reliability of infectious disease research, outbreak response, and diagnostics globally**

Biosafety Risk Assessment Methodology (RAM)

- **This methodology will be the basis for a systematic, standardized tool that includes**
  - Accepted criteria for assessing the risk
  - A “scoring system” for evaluating the situation against the criteria
  - Relative weights for the criteria
  - An equation that combines the criteria scores and the relative weights to produce a measure of risk



Why Risk Assessment?

- **Risk is the likelihood an adverse event will occur**
  - A function of likelihood and consequences
- **Risk assessment**
  - Structured, analytical approach that can provide unbiased information to decision makers
  - Relies on factual information to the extent possible
  - Clearly delineates what is known and unknown about the problem
- **Cannot eliminate risk**
  - Need to recognize that we cannot protect against every conceivable adverse event
  - Need to distinguish between “acceptable” and “unacceptable” risks
- **Resources for risk mitigation are not infinite**
  - Risk assessments are a tool for determining and prioritizing risks
  - Risk assessment can help ensure that resources are used as efficiently as possible -- ensuring that protection measures, and their cost, are proportional to the risk

Risk Assessment Principles

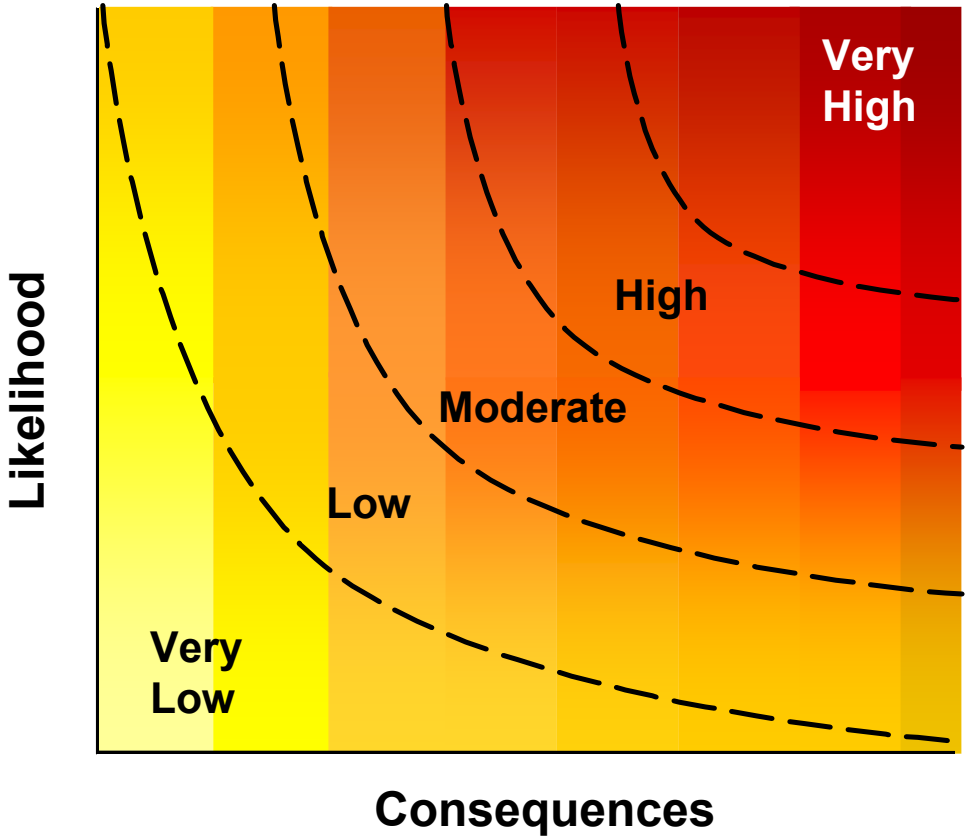
- **Define the problem**
- **The problem should drive the choice of method for the assessment**
- **The risk assessment method should be as simple as possible**
  - Elaborate when needed
- **Those conducting risk assessments should be explicit about uncertainties**
- **Risk assessment methods can incorporate one or more approaches**

Risk Assessment Schemes

- **All rely on:**
  - A set of well-defined criteria, which are
    - **measurable,**
    - **understandable,**
    - **relevant to the problem**
  - A standardized approach to evaluate an adverse event against the criteria ("scoring")

- **Schemes vary on:**
  - Approach to gathering data
  - Method for combining scores to reach a risk result

Characterizing Scenarios by Risk



- Protect against unacceptable risk scenarios

- Develop incident response plans for acceptable risk scenarios

Biosafety Risk Definitions

Risk = f (Likelihood, Consequence)

- **Likelihood**
  - Likelihood of infection based upon agent properties
  - Likelihood of exposure based upon laboratory hazards
- **Consequences are based upon agent properties**
- **Risk calculated independently for**
  - Individuals performing direct manipulation upon agent
  - Individuals also working in the laboratory
  - Individuals performing maintenance around the laboratory
  - Individuals with no laboratory access but also in the facility
  - The human community outside the laboratory
  - The animal community outside the laboratory (domestic, agricultural, and wildlife)
  - The risk of secondary transmission to both the human and animal community

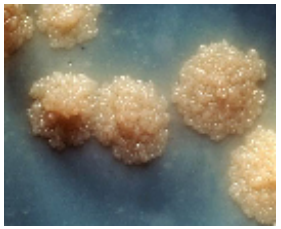
Biological Agent Properties

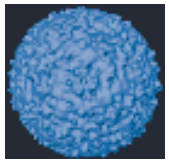
- **Properties that categorize an agent's**
  - Potential for infection
  - Consequence of infection
    - **Potential for secondary infection**
- **Bacteria, viruses, rickettsia, fungi, parasites, and prions**
  - Toxins are excluded except as byproducts of bacteria

Likelihood criteria classifications

  - Pathogencity
    - **Infectivity**
    - **Virulence**
    - **Existence of mitigation measures**
  - Laboratory routes of Infection

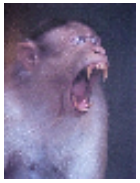
- **Consequence criteria classifications**
  - Pathogencity
    - **Virulence**
    - **Existence of mitigation measures**
  - Communicability
  - Natural routes of infection





Laboratory Hazards

- **Likelihood of exposure based upon the procedures**
  - Inhalation
    - **Aerosol generating procedures as byproducts of procedures**
    - **Accidental aerosol release**
    - **Animals**
    - **Aerosolization experiments**
  - Ingestion
    - **Splashes**
    - **Waste handling**
    - **Contaminated items with potential to enter mouth**
  - Percutaneous
    - **Animals**
    - **Sharps in laboratory**
    - **Waste**
  - Contact
    - **Splash**
    - **Spill**
    - **Containment surfaces**
    - **Animal**
    - **Waste**



- **Laboratory hazards include the vulnerabilities or gaps in biosafety controls**

Biosafety Gap Assessment

- **Performance-based control mechanisms that mitigate laboratory hazards (reduce likelihood of exposure)**

- **Criteria classifications for biosafety risk mitigation measures**
  - Engineering controls
  - Procedural/administration controls

- **Biosafety risk mitigation measures are designed for unique risks**
  - Mitigation measures are unique for each of the risk assessments
    - **E.g. air handling systems are designed to protect those not in the particular laboratory where the work is conducted**
  - Mitigation measures are unique to the exposure route
    - **E.g. proper sharps handling protects against a percutaneous exposure**

Project Scope

- **Results are agent/laboratory procedure based**
  - Assessing multiple research protocols in one assessment is feasible, but will blend the results, making management more difficult

- **Hazards beyond the defined laboratory activity are not specifically addressed, but information regarding those risks can be included**
  - E.g. if working with human blood, the risk assessment does not automatically include all potential blood and body fluid risks; however, those agents can be added into the assessment tool
  - E.g. if working with animals, the risks of animal bites/scratches beyond the agents identified in the assessment are not included; however, those additional risks can be added into the assessment tool

Summary and Next Steps

- **Members of the biosafety community and the microbiology community will be formally weighting the criteria**
  - Reno Oct 23-24
  - Additional meetings to follow as needed
- **Prototype model to be tested during the fall of 2009**
  - Finalized model and tool to be released in the fall of 2010
- **Preliminary methodology reports and trainings to be released prior to model prototype and finalization**
- **Community feedback and support are key!**
  - This is a community risk assessment methodology and tool