Biorisk Assessment: Methodologies and Models

4th Biorisk Management Workshop

Winnipeg, Canada

April 14th to 17th, 2009

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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

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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**

Public Health Agency of Canada

Agence de la santé publique du Canada

Sandia National Laboratories

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Enhancing US and International Security by Reducing Biological Threats Globally

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

Subject Matter Expert Meeting Oct 2008

- **Members of the biosafety community and the microbiology community formally reviewed, altered, and weighted the criteria**
  - Reno Oct 23-24
- **Weights collected and calculated for laboratory procedures and biosafety measures**
- **Criteria revised for biological agent parameters**
  - Scope revised to include recombinant DNA
  - Criteria re-categorized and more specifically designed

4th Biorisk Management Workshop, 2009

- **Desired outcomes**
  - Determination of relative importance of criteria for biosafety and biosecurity risk assessment methodologies
  - Determination of metrics for evaluating biosafety and biosecurity risk assessment criteria
  - Determining thresholds of acceptable and unacceptable risks
  - Developing roles and responsibilities for executing biosafety and biosecurity risk assessments

Project Goals and Milestones

Goal	Milestone	Completion Date
Outline Methodology	*Review method with SMEs*	*Completed 03/2008*
Establish criteria	*Agent hazard criteria*	*Completed 05/2008*
	Laboratory hazard criteria	*Completed 05/2008*
	Hazard mitigation criteria	*Completed 05/2008*
Determine relative importance among criteria	*Determine relationship among the criteria*	*Completed 06/2008*
	Weight the criteria	*Completed 10/2008*
Create prototype model	*Create prototype model*	*Completed 01/2009*
	Test model with SMEs	**In process 04/2009**
	Present overall methodology/model for peer review	**In process 04/2009**
Develop software tool	**Develop alpha software tool to implement model**	**10/2009**
	Validate software tool	**12/2009**
	Finalize software tool and implement revisions	**05/2010**
SAND report		**09/2010**

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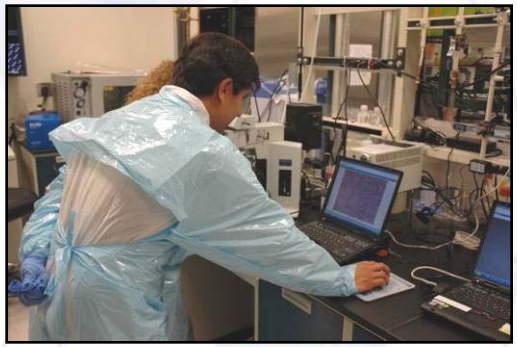
Expected Project Results

- **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



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Additional Tools Under Development

- **Biosafety Wiki**
  - Goal: centralized resource for data needed in biorisk assessment
- **Biosecurity Risk Assessment Methodology (BioRAM)**
  - Goal: Develop a tool to help community conduct biosecurity risk assessments

BIOSAFETY
Risk Assessment

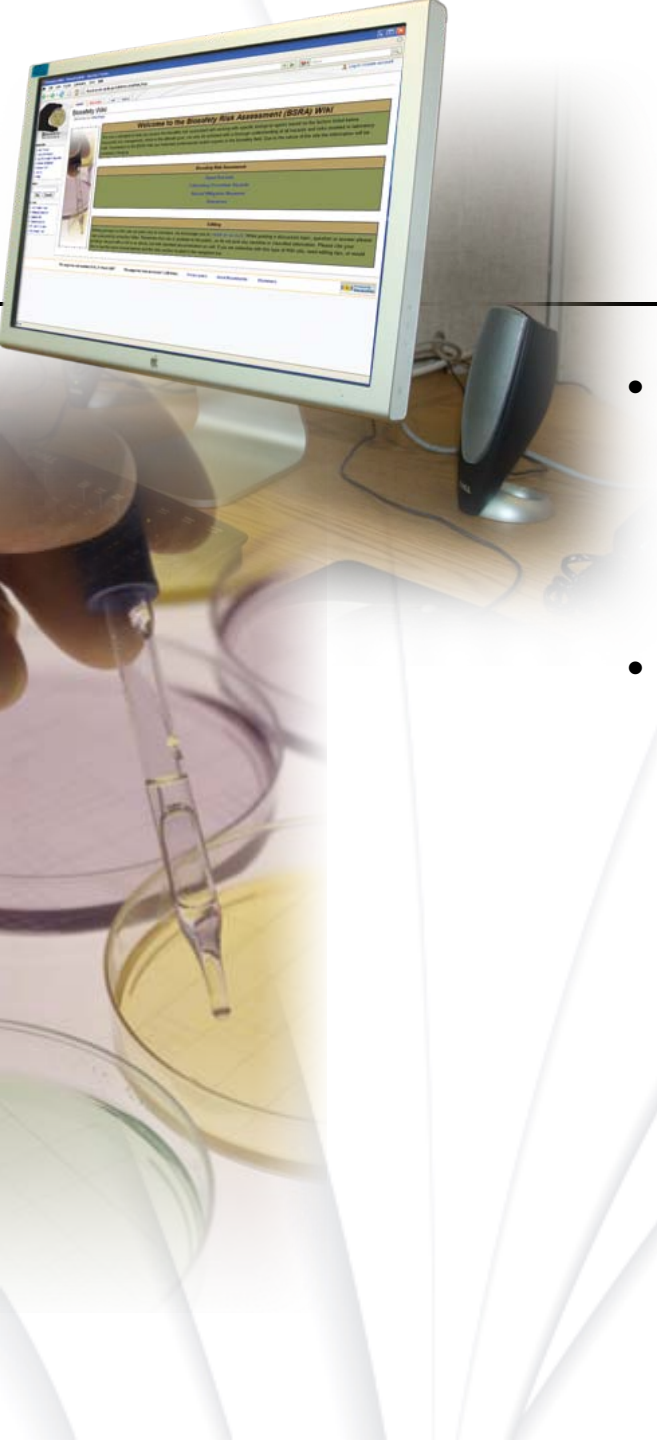
THE WIKIPEDIA OF BIOSAFETY

www.BiosafetyRiskAssessment.org

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy's National Nuclear Security Administration under Contract DE-AC04-94AL85000.
SAND 2007-5956P

Biosafety Risk Assessment Wiki

- The Biosafety Risk Assessment Wiki website is designed to help assess the biosafety risk of working with specific biological agents by collaborating with colleagues and other experts in the field
- Risk assessment is the foundation of a good biosafety program
  - No widely accepted set of qualitative or quantitative tools to help biosafety professionals conduct assessments
  - Critical information that is pertinent to biosafety risk assessments is often hard to find and is not consolidated
- The Biosafety Risk Assessment Wiki aims to assemble this information in a coherent fashion and present it alongside contributions by subject matter experts
- Successful risk management can only be achieved with a thorough understanding of all hazards and risks involved in laboratory work



What Is A Wiki?

- A wiki is a website for facilitating collaboration among peers to produce a consensus text
  - Wikis also provide a central point for sharing information and discussing ideas through text, links, and references
- The Biosafety Risk Assessment Wiki is a repository of risk assessment data, publications, and links for the biosafety community.
  - Contributors are interested professionals and experts in the biosafety field
  - The site is available to the public, but to ensure that the information on the wiki is as accurate and reliable as possible, only those with biosafety expertise will be given editing privileges
  - The site is managed and content controlled by the International Biological Threat Reduction program at Sandia National Laboratories

Content

- Agent Hazards
  - Fact-based information regarding a specific agent's risk that contribute to the probability and consequence of exposure
    - Bacteria
    - Viruses
    - Proteins
    - Rickettsia
    - Fungi
    - Parasites

- Laboratory Procedure Hazards and Hazard Mitigation Measures
  - Discussion-oriented sections to include different laboratory procedure hazards and mitigation measures
- Agent and Laboratory information is outlined based upon a template designed by a biosafety experts panel
  - This template follows a biosafety risk assessment methodology currently in development

Agent Hazards

BIOSAFETY
Risk Assessment

navigation

- Main Page
- Agent Hazards
- Lab Procedure Hazards
- Hazard Mitigation
- Resources
- Apply
- Help

search

Go Search

toolbox

- What links here
- Related changes
- Upload file
- Special pages
- Printable version
- Permanent link

Agent Hazards

Biosafety Wiki main page

These pages lay out agent-specific information to help you evaluate biosafety risks associated with the agents. Since these agents are living organisms, it can be hard to fit them into rigid categories describing their risk; which can vary depending on aspects of the human and animal population in the region, complex human-pathogen interactions, and the variables you want to consider in your assessment. However, relative risk is important to ascertain to protect human and environmental safety. The agents we have already listed are just a starting point, feel free to add more agents and more information than the current template asks for.

Agent Groups [edit

Bacteria	Fungi	Viruses
Proteins	Parasites	Rickettsia

Definitions [edit

Select Agent List

European Economic Community Guidelines

NIH Guidelines on Recombinant DNA

Canadian Laboratory Biosafety Guidelines

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories

Risk Classification Criteria for World Health Organization, Australia, Canada, European Union (EU), USA CDC/NIH and NIH for RDNA.

BIOSAFETY
Risk Assessment

navigation
- Main Page
- Agent Hazards
- Lab Procedure Hazards
- Hazard Mitigation
- Resources
- Apply
- Help

search
Go Search

toolbox
- What links here
- Related changes
- Upload file
- Special pages
- Printable version
- Permanent link

Clostridium tetani

back to Bacteria

Contents [hide]

Background [edit]

Gram positive sporeforming rod; single, spheric, terminal endospore; clubbed appearance; strict anaerobe; swarming on blood agar grown anaerobically; produces an exotoxin (tetanospasmin)

Agent Criteria [edit]

Infectious Dose: Toxin is extremely potent

Latency:

Colonization Potential:

Stability: Spores are resistant to many disinfectants; moderately susceptible to sodium hypochlorite; susceptible to high level disinfectants such as glutaraldehyde with a prolonged contact time

Laboratory Procedure Hazards

BIOSAFETY
Risk Assessment

igation
Main Page
Agent Hazards
Lab Procedure
Hazards
Hazard Mitigation
Resources
Apply
Help

rch
Go Search

box
What links here
Related changes
Upload file
Special pages
Printable version
Permanent link

Laboratory Procedure Hazards

Biosafety Wiki main page

These pages will discuss different laboratory procedure hazards that can affect risk, they are divided up by exposure route. To complete a comprehensive risk assessment it is vital to assess all of the hazards that are generated. Once the lab's hazard assessment is complete, you can begin to look at how to mitigate those hazards.

Inhalation

Procedures that may produce droplets which could be inhaled into the upper respiratory or lower respiratory tract.

Ingestion

Procedures that may increase the possibility of material in the laboratory coming into contact with the GI tract.

Percutaneous

Procedures that include a risk of puncturing or cutting the skin.

Contact

Procedures that would be a risk to someone with broken skin or skin abrasions.

BIOSAFETY
Risk Assessment

igation
Main Page
Agent Hazards
Lab Procedure
Hazards
Hazard Mitigation
Resources
Apply
Help
rch
Go Search
box
What links here
Related changes
Upload file
Special pages
Printable version
Permanent link

Inhalation Procedure Hazards

back to Laboratory Procedure Hazards

Aerosol generating procedures as byproduct of procedure

- Vortex
- Pipetting
- Aerosol Chamber

Accidental aerosol release

- Centrifuge
- Aerosol Chamber

Equipment maintenance

- Centrifuge

Animals

- Animal Cages

Aerosolization experiments - Intentional generation of aerosols

Resources [edi

Aerosol generating processes and small scale accidents:

- Bennett, A. and S. Parks (2006). "Microbial aerosol generation during laboratory accidents and subsequent risk assessment." Journal of Applied Microbiology 100(4): 658-663. Link

Hazard Mitigation Measures

BIOSAFETY
Risk Assessment

navigation

- Main Page
- Agent Hazards
- Lab Procedure Hazards
- Hazard Mitigation
- Resources
- Apply
- Help

search

Go Search

toolbox

- What links here
- Related changes
- Upload file
- Special pages
- Printable version
- Permanent link

Hazard Mitigation Measures

Biosafety Wiki main page

These pages will discuss the different methods of mitigating risk in the laboratory through the planning and use of safety equipment, safety procedures and facility design. It is important to weigh different methods and barriers that will mitigate hazards in your laboratory and make the decision based on risk assessments and the unique needs of your facility. Practices and procedures, primary containment barriers and secondary containment barriers all need to work in concert to create a safe environment in the laboratory. Mitigation measures are divided up below based on routes of exposure.

Inhalation

Measures that may reduce the risk of producing droplets which could be inhaled into the upper respiratory or lower respiratory tract.

Ingestion

Measures that may decrease the possibility of material in the laboratory coming into contact with the GI tract.

Percutaneous

Measures that reduce the risk of puncturing or cutting the skin.

Contact

Measures that would reduce the risk to someone with broken skin or skin abrasions.

BIOSAFETY
Risk Assessment

navigation

- Main Page
- Agent Hazards
- Lab Procedure Hazards
- Hazard Mitigation
- Resources
- Apply
- Help

search

Go Search

toolbox

- What links here
- Related changes
- Upload file
- Special pages
- Printable version
- Permanent link

Inhalation Mitigation Measures

back to Hazard Mitigation Measures

Engineering Controls

- Primary containment
  - Transport Containers
- Primary containment of animals
  - IVC Animal Caging
- Partial containment with airflow and possible filtration
  - Biosafety Cabinet
  - Centrifuge

PPE

- Respiratory protection (accepted and no typically accepted)
  - PAPR (Powered Air Purifying Respirator)
  - Respirators

Procedural / Administrative

- Proper PPE procedures (Donning/Doffing, Selection, Fitting, Integrity)
- Proper fluid handling techniques which reduce/eliminate aerosol
- Proper culture handling techniques which reduce/eliminate aerosol
- Immunization
- Decontamination and waste handling (verified effective against agent)
  - Autoclave

CONCLUSION

- Goal: To become a valuable risk assessment resource for the biosafety community
- This site is still only a skeleton
  - It will require expert input before it can truly become **the *Wikipedia* of Biosafety**
- Thanks to the 2nd International Biorisk Management Workshop at the Canadian Science Center for Human and Animal Health in Winnipeg

The Wikipedia Of Biosafety

www.BiosafetyRiskAssessment.org

Contact:
Jacqueline Smith at jacsmit@sandia.gov

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Biosecurity Risk Assessment Methodology (BioRAM)

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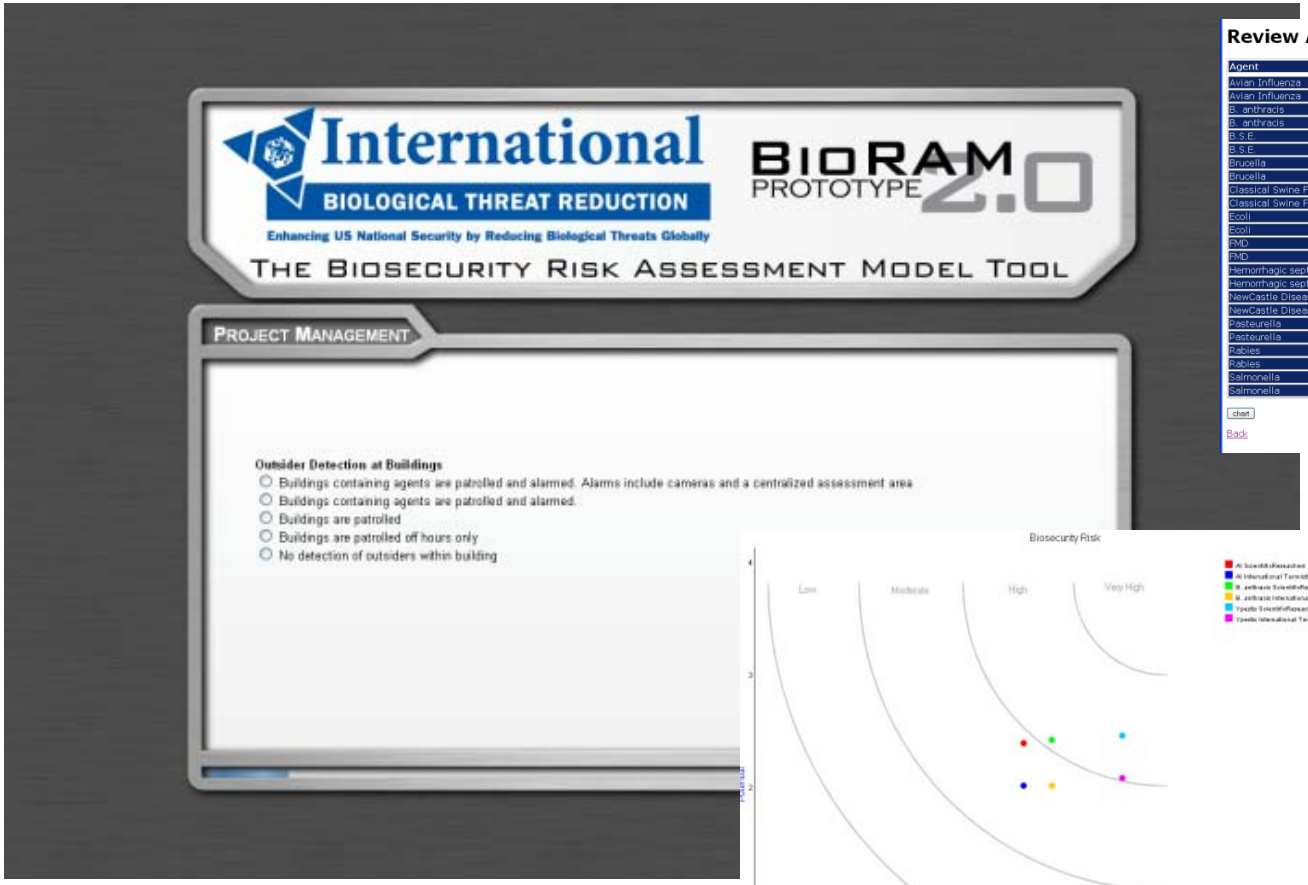
BioRAM 2.0 Software Tool



Review Assessment for BAI Post Upgrade

Agent	Adversary	Consequences	Threat Potential
Avian Influenza	ScientificReseachers	1.61	2.77
Avian Influenza	International Terrorist Group	1.61	2.39
B. anthracis	ScientificReseachers	2.74	2.75
B. anthracis	International Terrorist Group	2.74	2.33
B.S.E.	ScientificReseachers	1.49	2.66
B.S.E.	International Terrorist Group	1.49	2.23
Brucella	ScientificReseachers	1.62	2.84
Brucella	International Terrorist Group	1.62	2.41
Classical Swine Fever	ScientificReseachers	2.16	2.86
Classical Swine Fever	International Terrorist Group	2.16	2.48
Ecoli	ScientificReseachers	0.73	2.73
Ecoli	International Terrorist Group	0.73	2.3
FMD	ScientificReseachers	2.3	3.04
FMD	International Terrorist Group	2.3	2.63
Hemorrhagic septicemia	ScientificReseachers	1.89	2.81
Hemorrhagic septicemia	International Terrorist Group	1.89	2.38
NewCastle Disease Virus	ScientificReseachers	2.84	2.76
NewCastle Disease Virus	International Terrorist Group	2.84	2.34
Pasteurella	ScientificReseachers	1.1	2.73
Pasteurella	International Terrorist Group	1.1	2.31
Rabies	ScientificReseachers	2.16	2.64
Rabies	International Terrorist Group	2.16	2.21
Salmonella	ScientificReseachers	1.34	2.78
Salmonella	International Terrorist Group	1.34	2.35

chart

Back

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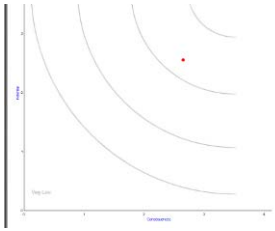
Asset Assessment

- **Assess value of the agents from an adversary's perspective**
  - Consequences
    - **Population**
      - **Transmissibility**
      - **Mortality**
      - **Morbidity**
    - **Economic**
    - **Psychological**
  - Task Complexity
    - **Acquisition**
      - **Natural**
      - **Laboratory**
      - **Synthetic biology**
    - **Production**
      - **R&D**
      - **Covert production**
      - **Ease of storage**
    - **Dissemination**
      - **Route of infection (e.g. aerosol, ingestion)**
      - **Environmental hardiness**

AGENTS | ADVERSARIES | ASSESSMENTS | SITES | MAIN

Agent Name	B. anthracis		
Strain			
The Consequences of Malicious Release of Agent			
	Population Impact		
		Transmissibility	0
		Morbidity	3
		Mortality	3
		Pre-Exposure Treatment	3
		Post-Exposure Treatment	1
	Economic Impact		
		Economic Fluctuation	3
		Long-Term Economic Impact Due to Release of Agent	3
	Social or Psychological Impact		
		Agent Endemic in Area	3
		History of Biological Weapons Use of This Agent	4
		Behavioral Impact to the General Population	4
Total Weighted Consequence Score			2.74
Agents Desirability for Malicious Use			
	Acquisition		
		International or National Regulations on Agent	3
		Agent Common in Laboratories	0
		Isolation from Natural Sources	2
		Synthetic Production	4
	Production		
		Easy of Agent Growth	3
		Laboratory Requirements for Growth	3
		Agent Stability	3
		Preprocessing Prior to Dissemination Required	0
	Dissemination		
		Infectious Dose of Agent	0
		Environmental Stability	4
		Dissemination Methods	4
Total Weighted Desirability Score			2.6375



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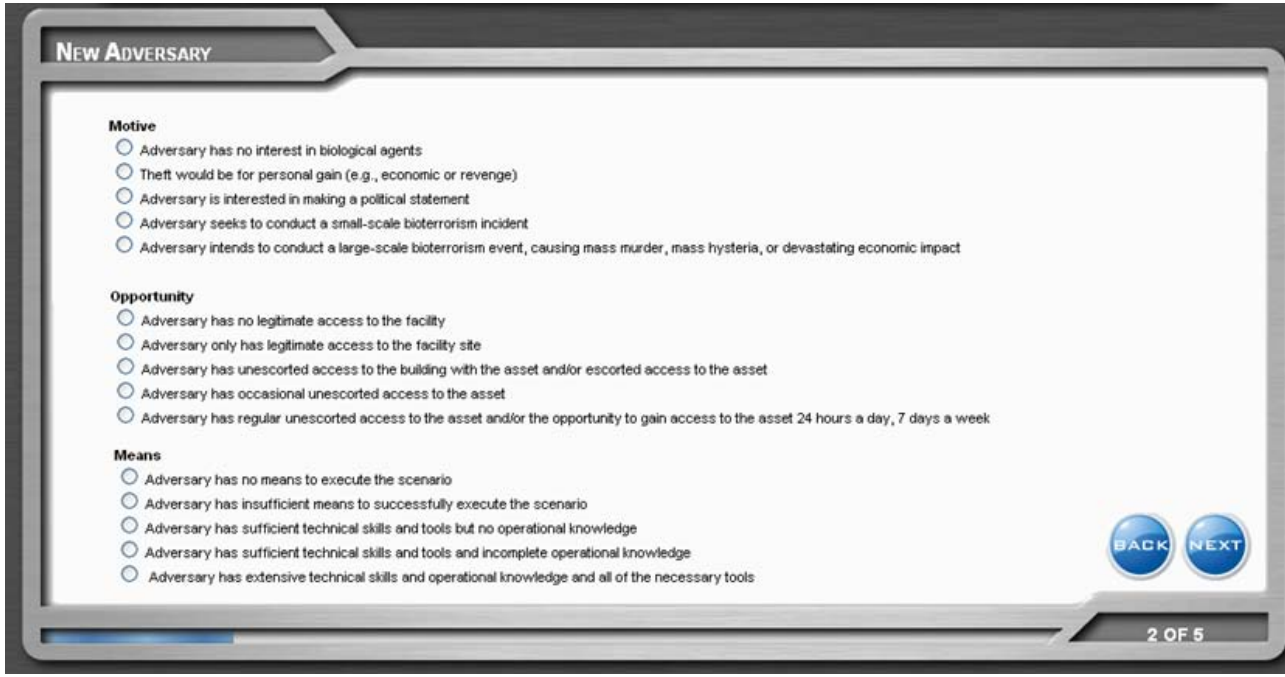
Threat Assessment

- **Adversary Classes**
  - Terrorist
  - Extremist
  - Criminal
- **Insiders**
  - Insiders have authorized access to the facility, agents, and/or restricted information
  - Distinguish Insiders by level of authorized access
    - **Site**
    - **Building**
    - **Asset**
- **Outsiders**
  - Outsiders have no authorized access
  - To assess, interview local law enforcement, site security, and intelligence community



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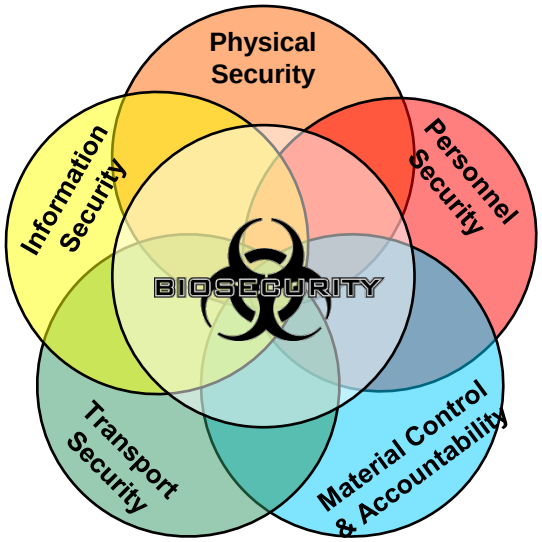
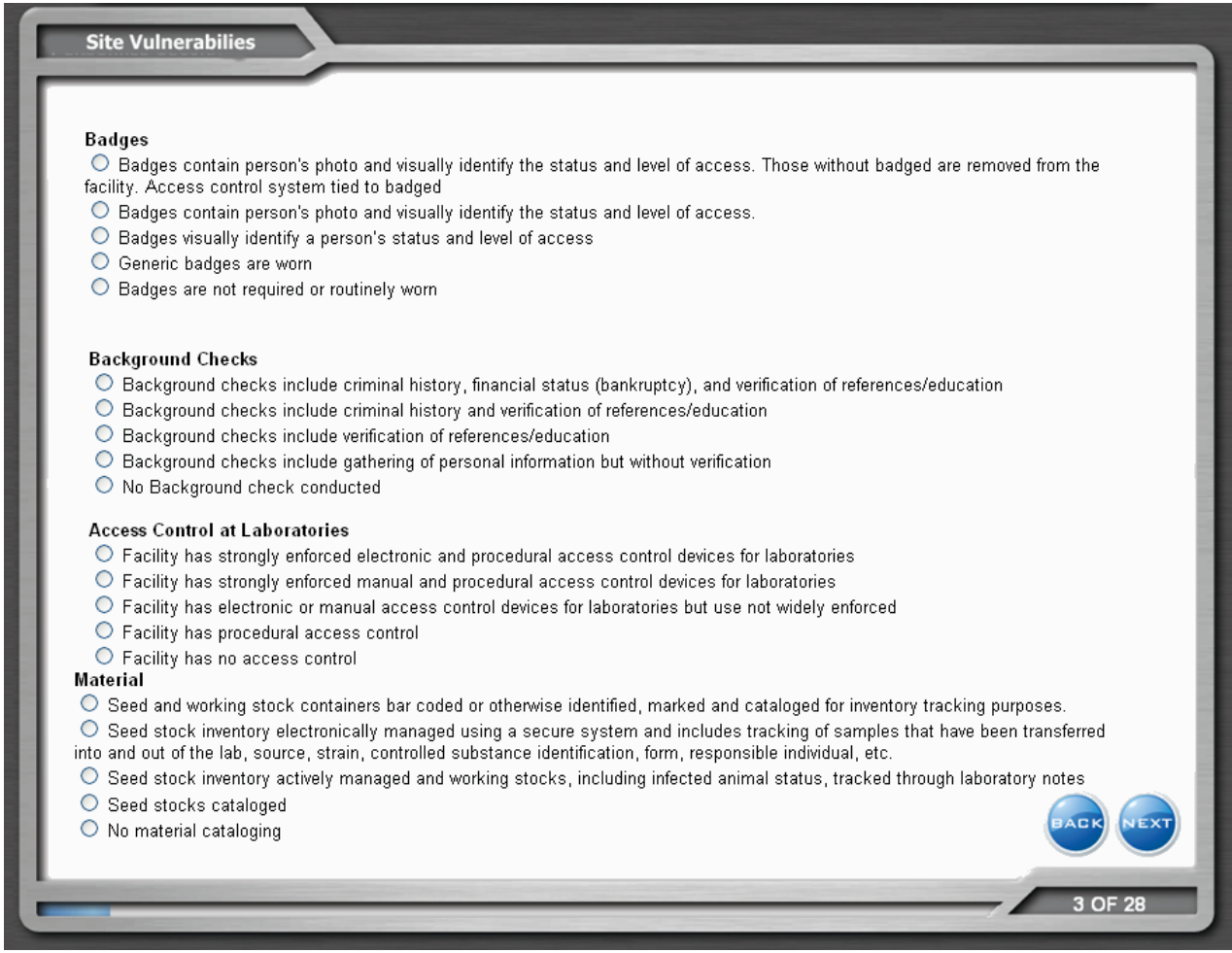
Vulnerability Assessment

- **Evaluate the effectiveness of each of the components of the existing laboratory biosecurity system**





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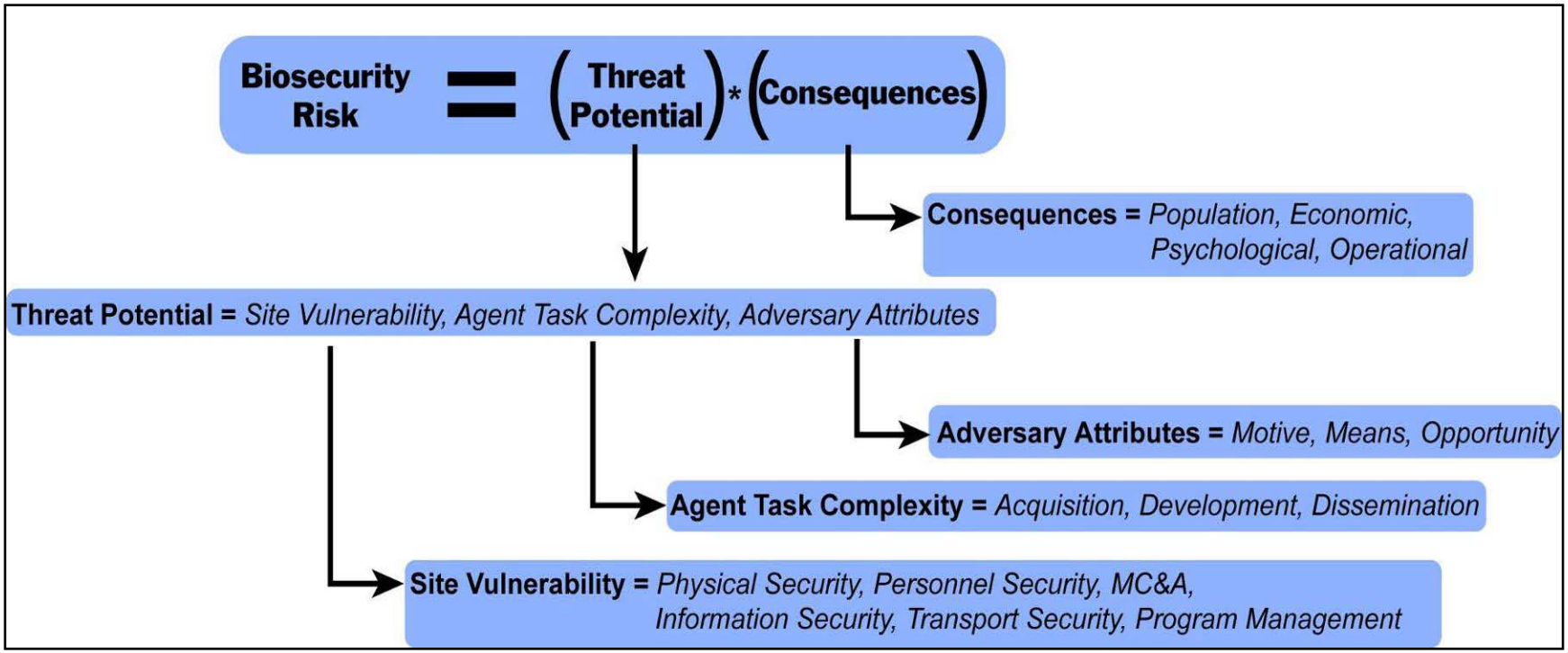
Biosecurity Risk Assessment Methodology



Pilot Studies of Biosecurity Risk Assessment Methodology in Japan

- **Test facilities**
  - Reference laboratories
  - Regional public health laboratory
  - Hospital laboratory
  - University laboratory (one division)

- **Respondents**
  - Senior management vs. Technical chief
  - Different departments in same facility

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BioRAM Next Steps

- **Improvements to methodology – Summer 2009**
  - Based on lessons learned by
    - **Using tool and from developing Biosafety RAM**

- **Create stand-alone CD-ROM version of tool – 2010**

- **In partnership with Japanese National Institute of Infectious Diseases**

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