DEVELOPING A BIOSAFETY RISK ASSESSMENT METHODOLOGY (Biosafety-RAM)

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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

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
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

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<th>Goal</th>
<th>Milestone</th>
<th>Completion Date</th>
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<td>Outline Methodology</td>
<td>Review method with SMEs</td>
<td>03/2008</td>
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<tr>
<td>Establish criteria</td>
<td>Agent hazard criteria</td>
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<td>Laboratory hazard criteria</td>
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<td>Hazard mitigation criteria</td>
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<td>Determine relative importance among criteria</td>
<td>Determine relationship among the criteria</td>
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<td>Weight the criteria</td>
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<td>Create prototype model</td>
<td>Create prototype model</td>
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<td>Test model with SMEs</td>
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<td>Present overall methodology/model for peer review</td>
<td>03/2009</td>
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<td>Develop software tool</td>
<td>Develop alpha software tool to implement model</td>
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<td>Validate software tool</td>
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<td>Finalize software tool and implement revisions</td>
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<td>09/2010</td>
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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
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