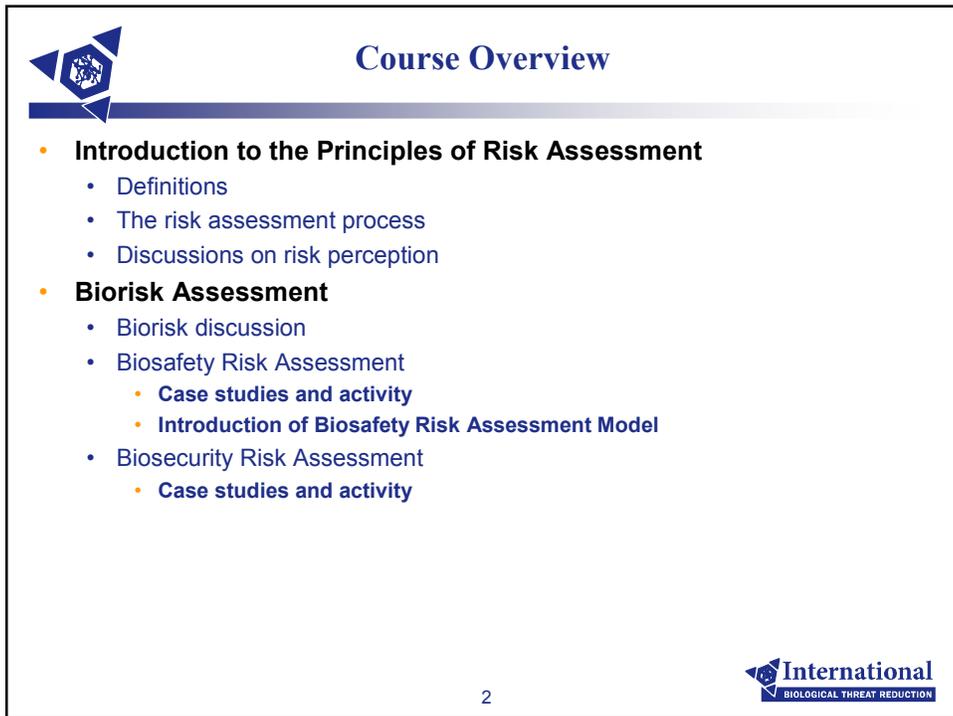


**Biorisk Assessment Methodologies and Models**

[www.biosecurity.sandia.gov](http://www.biosecurity.sandia.gov)

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Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,  
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## Course Overview

- **Introduction to the Principles of Risk Assessment**
  - Definitions
  - The risk assessment process
  - Discussions on risk perception
- **Biorisk Assessment**
  - Biorisk discussion
  - Biosafety Risk Assessment
    - **Case studies and activity**
    - **Introduction of Biosafety Risk Assessment Model**
  - Biosecurity Risk Assessment
    - **Case studies and activity**

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## Risk Definitions

- **Risk Assessment**
  - Identifying and exploring, preferably in quantified terms, the types, intensities and likelihood of the consequences related to a risk. Risk assessment comprises hazard identification and estimation, exposure and vulnerability assessment and risk estimation
- **Risk Analysis**
  - Risk assessment, risk management, and risk communication
- **Risk Prevention**
  - Measures to stop a risk being realized; typically means stopping the activity giving rise to the risk
- **Risk Reduction**
  - Measures to reduce the level of risk, for example by reducing the likelihood of the risk being realized or reducing the impact of the risk



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## Risk = $f$ (Likelihood, Consequence)



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## Using a Risk Assessment Process

- **A standardized biological risk assessment process allows the risk assessments to be:**
  - Repeatable
  - Quantifiable
- **A systematic, standardized approach should include:**
  - Accepted criteria for assessing the risk
  - A standardized approach for evaluating the situation against the criteria (“scoring system”)
- **Ideally this process results in a system that:**
  - Allows analysis of the risk to identify driving factors and allow better realization of mitigation measures
  - Enables better communication of risk
    - **Help to define what is acceptable risk**



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## 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**



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## Stages of Risk Governance

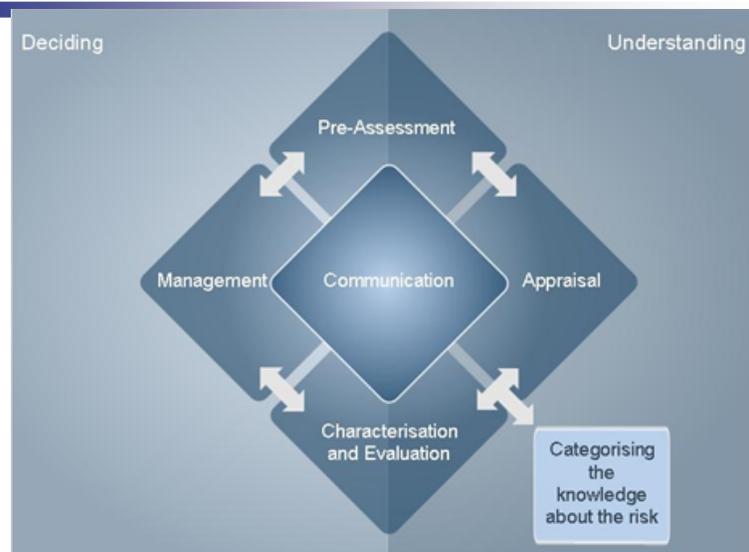
- **Risk Pre-assessment**
  - Early warning and "framing" the risk in order to provide a structured definition of the problem, of how it is framed by different stakeholders, and of how it may best be handled
- **Risk Appraisal**
  - Combining a scientific risk assessment (of the hazard and its probability) with a systematic concern assessment (of public concerns and perceptions) to provide the knowledge base for subsequent decisions
- **Characterization and Evaluation**
  - In which the scientific data and a thorough understanding of social values affected by the risk are used to evaluate the risk as acceptable, tolerable (requiring mitigation), or intolerable (unacceptable)
- **Risk Management**
  - The actions and remedies needed to avoid, reduce transfer or retain the risk
- **Risk Communication**
  - How stakeholders and civil society understand the risk and participate in the risk governance process



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## Risk Governance Process



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## Risk Appraisal: Risk Assessment

- **Purpose: understand uncertain but possible consequences associated with specific hazards and their potential**
- **Goal: estimation of the risk in terms of a probability distribution of the modeled consequences**
  - Systematic use of analytical methods
- **Components:**
  - Hazard identification and estimation
  - Assessment of exposure and/or vulnerability
  - Estimate of risk based on hazards and exposure/vulnerability assessment
    - **Combining likelihood and severity of selected consequences**
    - **Quantitative or qualitative**



## Risk Appraisal: Concern Assessment

- **Considers social and economic implications of the risks, including**
  - Stakeholders' concerns and questions
  - Financial and legal implications
  - Secondary social and economic consequences
    - **Events related to the hazards can heighten or attenuate individual and social perceptions of risk that can lead to significant secondary impacts**
- **Examples**
  - The community concerns associated with working on a hemorrhagic fever virus
  - The use of an armed guard at the front of a building





## Risk Appraisal Discussion

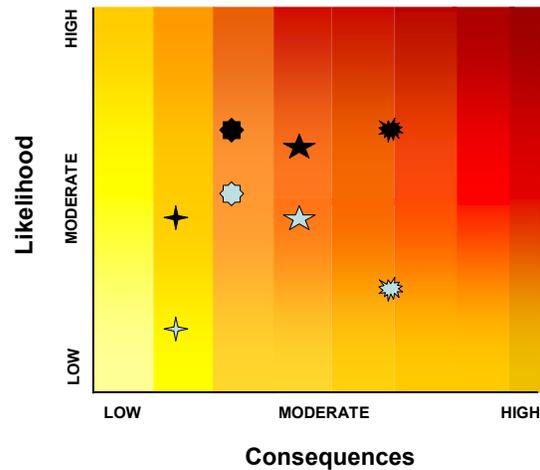
- **Discussion: Current risk assessment methods used for biorisks**
  - How are hazards identified and estimated?
  - How are exposures and vulnerabilities assessed?
  - How are the likelihood and severity of consequences determined?
- **Discussion: Biorisks and concern assessment**
  - What is the public familiarity and experience with the hazards?
  - What do they understand about the nature of the hazard and its potential impacts?
  - What are the public perceptions of fear and dread for the biorisks?
  - What is the public's perception of institutional control to manage the risks?
  - How much does the public trust the risk managers?

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## Risk Characterization

- **Evidence-based**

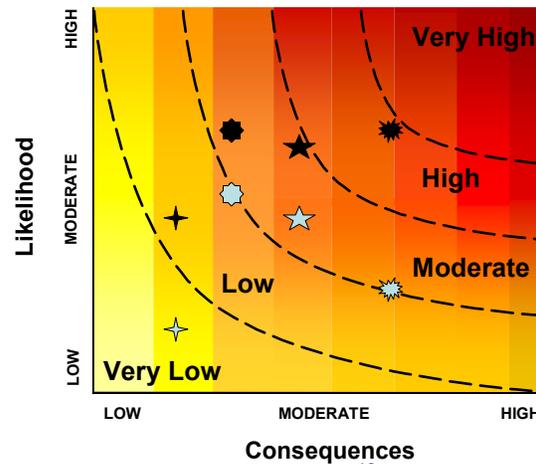


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## Risk Evaluation

- **Value-based**
  - What is acceptable, tolerable, and intolerable?



• Protect against unacceptable risk scenarios

• Develop incident response plans for acceptable risk scenarios



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## Communication

- **Two main audiences:**
  - Those who are central to risk framing, risk appraisal or risk management understand what is happening, how they are to be involved, and, where appropriate, what their responsibilities are
  - Others outside the immediate risk appraisal or risk management process are informed and engaged
- **Four functions:**
  - Education and enlightenment
  - Risk training and inducement of behavioral changes
  - Creation of confidence in institutions responsible for the assessment and management of risk
  - Involvement in risk-related decisions and conflict resolution
- **Strategy for risk management and communication related to type of risk:**
  - Simple, complexity, uncertainty, ambiguity



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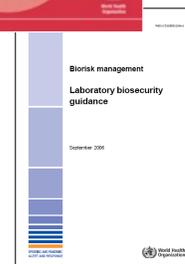
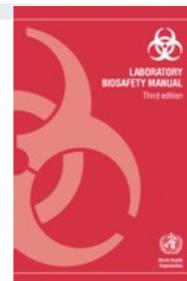
## BioRisk Assessments

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## Why Risk Assessment?

- **Laboratory Biosafety**
  - A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological agent
- **Laboratory Biosecurity**
  - A set of preventive measures designed to reduce the risk of intentional removal (theft) and misuse of a biological agent – intent to cause harm
- **Identification of preventive measures is determined by the RISK ASSESSMENT**



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## Discussion

- **What are the primary reasons/drivers for implementing a biorisk management system?**
  - How do these drivers impact the risk appraisal? Are they part of the risk assessment or the concern assessment or both?
- **Whose role is it to conduct a risk assessment?**
- **Whose role is it to evaluate the risk?**
- **Define the problem; what is the goal of a biosafety or biosecurity risk assessment?**

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## Laboratory Biosafety

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## Laboratory Biosafety Risk



$$\text{Risk} = f(\text{Likelihood, Consequence})$$

- **Likelihood**
  - The likelihood of infection by the agent and the likelihood of exposure through an infectious route based on the procedures and work practices
  
- **Consequences**
  - Of disease from accidental exposure
  
- **Risks**
  - To laboratory workers
    - **Researchers**
    - **Animal care workers**
    - **Technicians**
    - **Engineers**
  - Risk of accidental exposure to community
  - Risk of accidental exposure to animal community

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## Likelihood of Infection



- **Routes of infection of the agent (and infectious dose via that route)**
  - Inhalation
  - Ingestion
  - Contact
  - Percutaneous
  - Vector-Borne
  
- **Stability of the agent**
  
- **Infection mitigation measures (existence of prophylaxis)**

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## Likelihood of Exposure (based on the routes of infection)



- **Potential of inhalation exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures
- **Potential of ingestion exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures
- **Potential of percutaneous exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures
- **Potential of contact exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures

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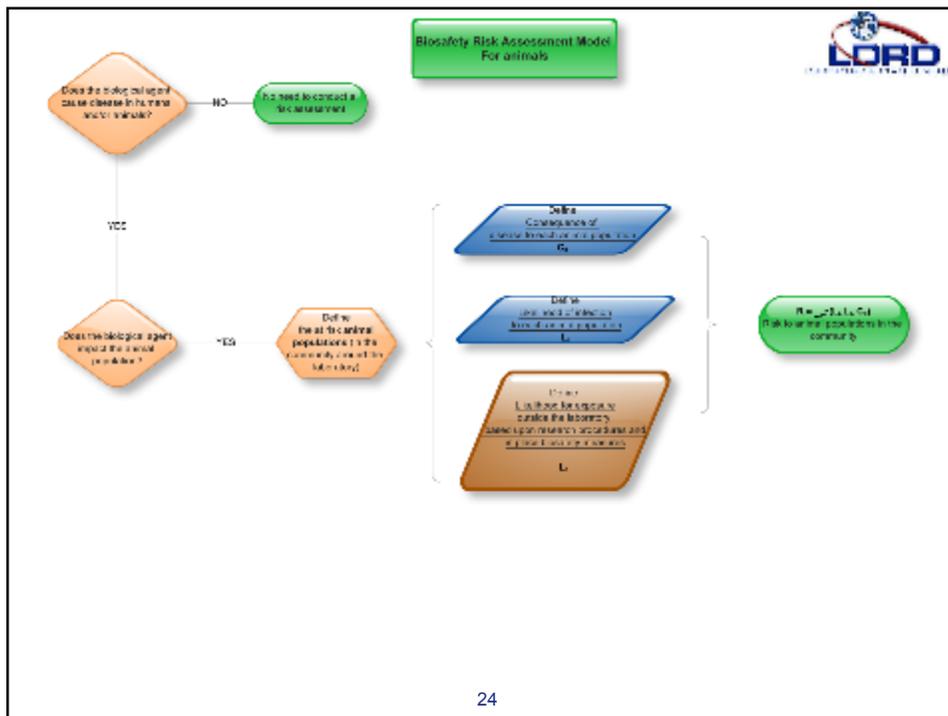
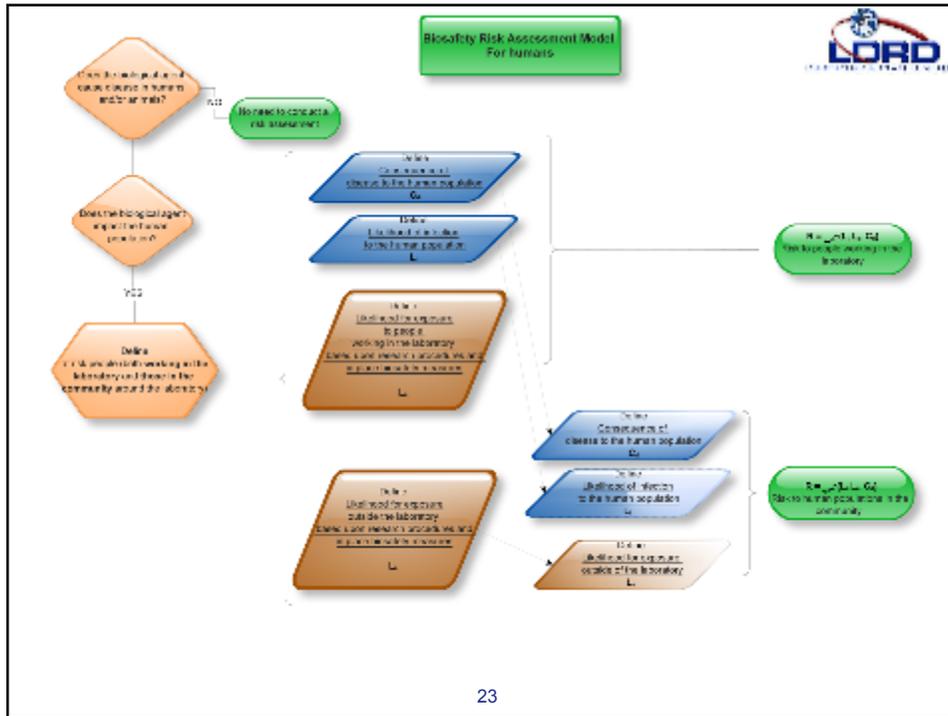
## Consequence of Disease

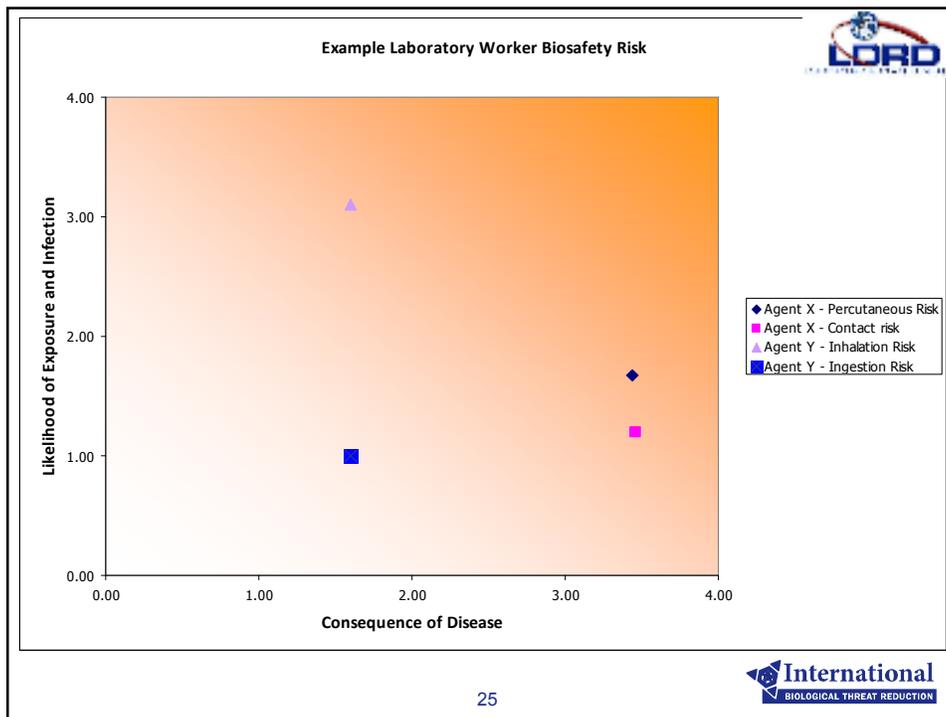


- **Agent properties**
- **Morbidity**
- **Mortality**
- **Consequence mitigation measures**
- **Potential for secondary transmission**
  - Communicability (host to host)
  - Transmissibility (route of infection between hosts)

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## Biosafety Risk Assessment Activity

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- **Assess the biosafety risk to the individual in the laboratory in each of these case studies**
  - [Case Study 1: Marburg virus](#)
  - [Case Study 2: \*Brucella melitensis\*](#)
  - [Case Study 3: MDR - \*Shigella sonnei\*](#)
  - [Case Study 4: SARS](#)
  - [Case Study 5: Highly Pathogenic Avian Influenza \(H5N1\)](#)



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## Biosafety Risk Assessment Model: Key Points

- **This training model is not weighted**
  - Weights allow the model to focus more on the important attributes without losing data
  - The full biosafety risk assessment model has been weighted using expert judgment
- **What risks is this model not addressing?**
- **This model highlights areas for biosafety officers to focus on when doing risk assessments**
- **This training model was designed to teach the process, not as a universally applicable model**
  - You should determine what key factors you need for your assessments, and how those factors should be weighted

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## Laboratory Biosecurity

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## Laboratory Biosecurity Risks for Dangerous Pathogens



**Risk = f(Likelihood, Consequence)**

- **Likelihood**
  - The likelihood of theft from a facility and the likelihood an agent can be used as a weapon
- **Consequences**
  - Of a bioattack with the agent
- **Risks**
  - Persons in area of attack
  - Persons in larger community from secondary exposure
  - Animals in area of attack
  - Animal in larger community from secondary exposure

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## Biosecurity Risk Assessment



- 1. Characterize biological agents and threats**
  - a. Evaluate pathogens and toxins at a facility (Asset Assessment)
  - b. Evaluate adversaries who might attempt to steal those pathogens or toxins (Threat Assessment)
- 2. Characterize the facility**
  - a. Evaluate the likelihood the facility will be targeted
  - b. Evaluate the likelihood of a successful theft (Vulnerability Assessment)
- 3. Characterize the risk**
  - a. Evaluate the overall likelihood and consequences of each scenario
  - b. Determine acceptable and unacceptable risks; develop risk statement



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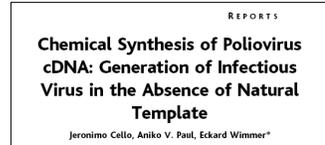




## Characterize the Biological Agents



- Agents potential as a biological weapon
  - **Biological Agent Properties**
    - Transmissibility
    - Stability
    - Awareness of agent's BW potential
  - **Production and dissemination**
- Consequences of a bioattack with agent
  - **Disease consequences**
  - **Socioeconomic consequences**
  - **Secondary exposure consequences**



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## Characterize the Adversaries



- **Adversary Classes**
  - Should be defined in design basis threat
    - **Terrorist**
    - **Extremist**
    - **Criminal**
- **Insiders**
  - Authorized access to the facility, dangerous pathogens, and/or restricted information
  - Distinguish Insiders by level of authorized access
    - **Site**
    - **Building**
    - **Asset**
- **Outsiders**
  - No authorized access



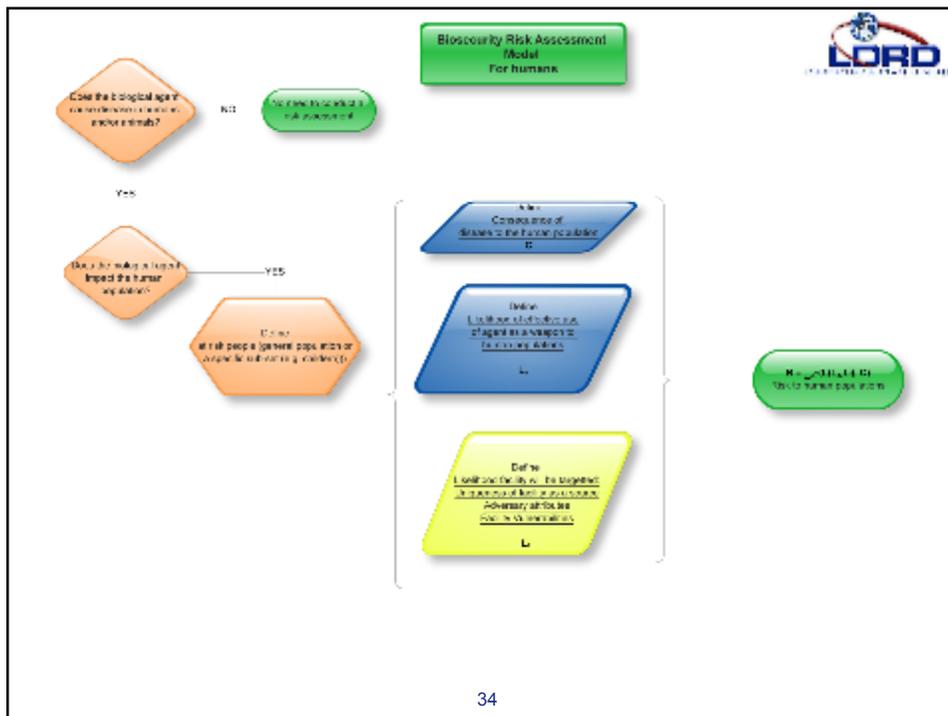
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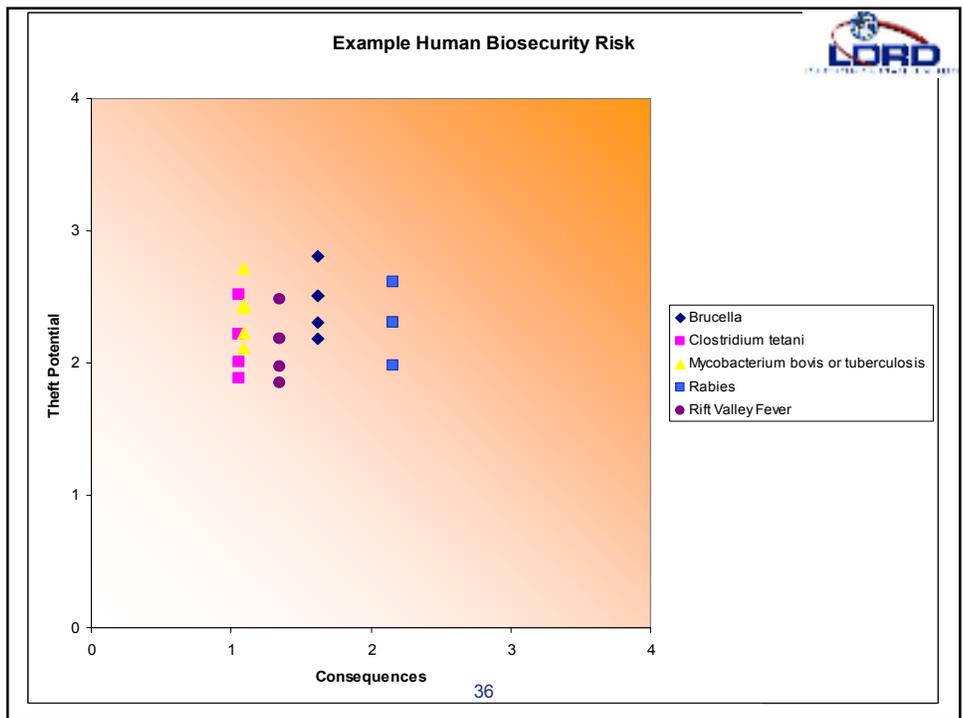
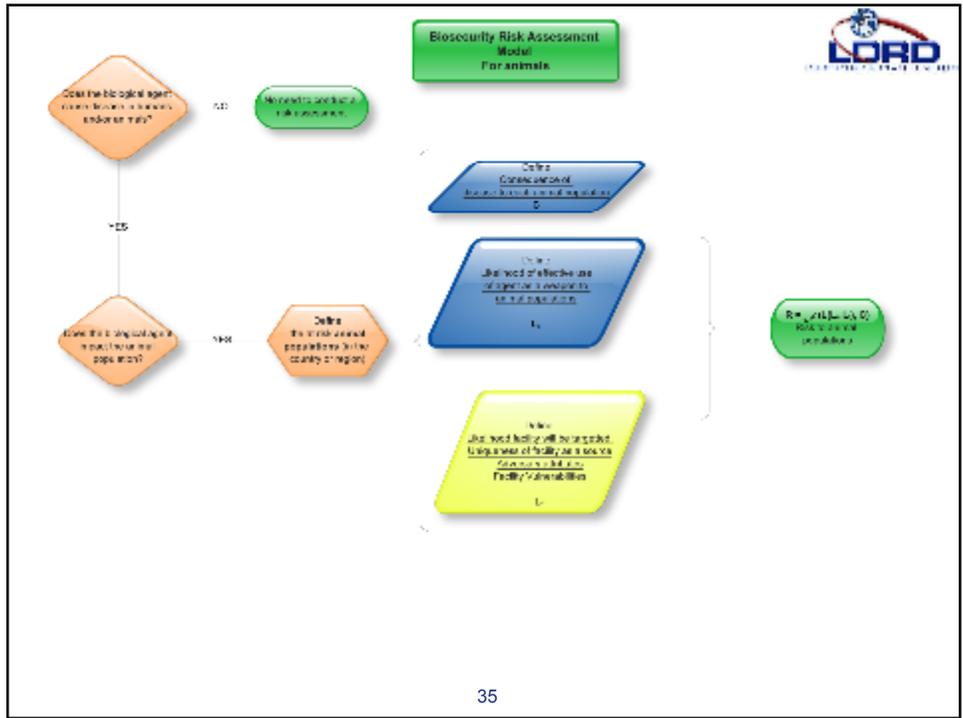


# Characterize the Facility



- **Identify “specific adversaries”**
  - Operational Means
  - Opportunity
  
- **Identify “specific assets”**
  - Uniqueness of asset at facility
  - Location of asset
  - State of asset (e.g. in long-term storage, in active research, type of research, quantity, ...)







## Biosecurity Risk Assessment Activity

- **Assess the biosecurity risk for the facility for each agent and adversary in the case studies**
  - [Case Study 1: Marburg virus](#)
  - [Case Study 2: \*Brucella melitensis\*](#)
  - [Case Study 3: MDR - \*Shigella sonnei\*](#)
  - [Case Study 4: SARS](#)
  - [Case Study 5: Highly Pathogenic Avian Influenza \(H5N1\)](#)

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## Conclusions

- **A systematic, standardized biological risk assessment process enables:**
  - The analysis of the risk to identify driving factors and allow better realization of mitigation measures
  - Enables better communication of risk
    - Help to define what is acceptable risk
- **Biorisk can be strengthened by standard risk governance approaches**
- **Risk assessment and risk decision are the critical foundations for the design of a laboratory biosafety and biosecurity program**



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