Risk Assessment Process and Methodology

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Biosafety Management Systems Seminar
May 6, 2009
Winnipeg, Canada

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SAND No. 2009-1874P
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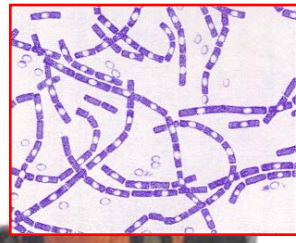
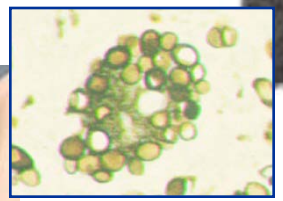
Why Risk Assessment?

- **Why incur risk?**
  - Risks not taken for the sake of risk but because they are inherent in the activity that serves a human need or purpose

- **Laboratory work with pathogens will always involve some level of safety and security risk**
  - Distinguish between “acceptable” and “unacceptable” risks
  - Cannot protect against every conceivable adverse event

- **Resources for risk mitigation are not infinite**
  - Existing resources should be used efficiently





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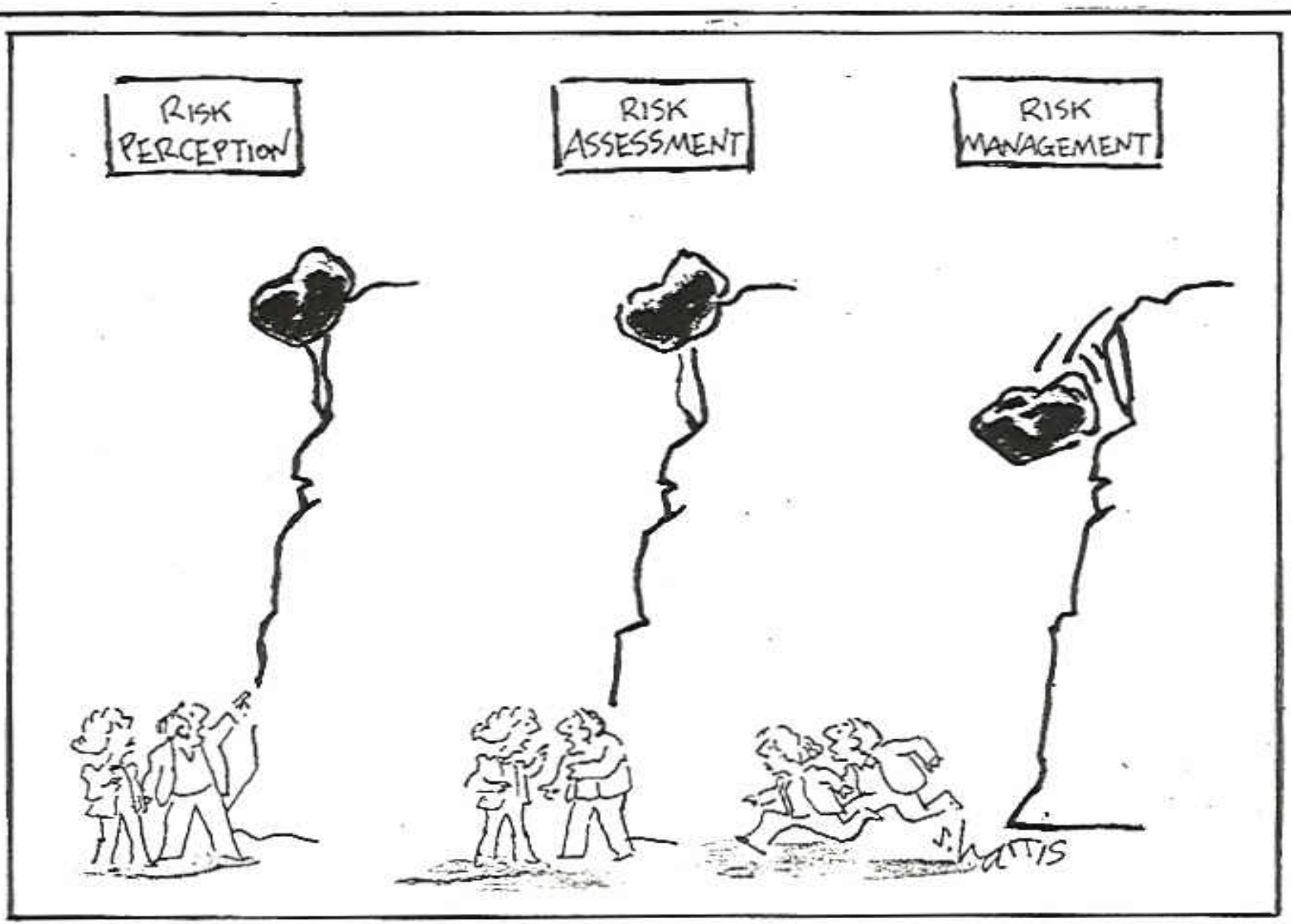
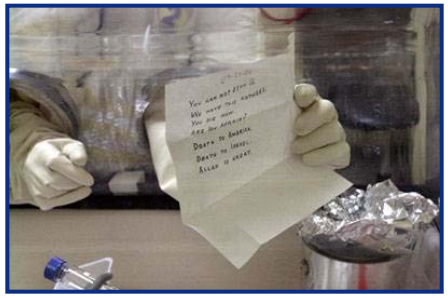

RISK PERCEPTION
RISK ASSESSMENT
RISK MANAGEMENT
V. HARRIS

Discussion: Risk Perceptions

Biosafety Risks

Biosecurity Risks



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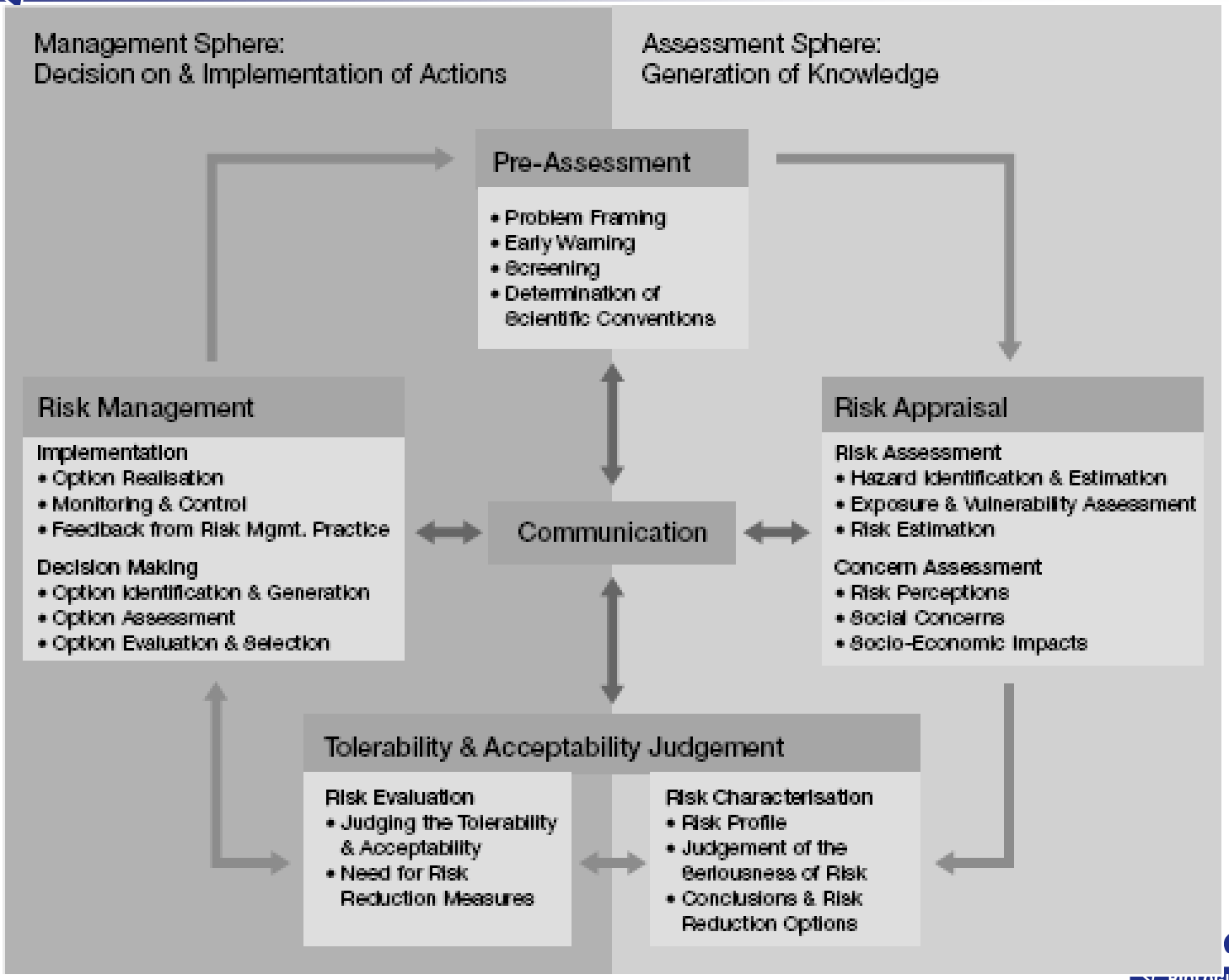
Risk Definitions

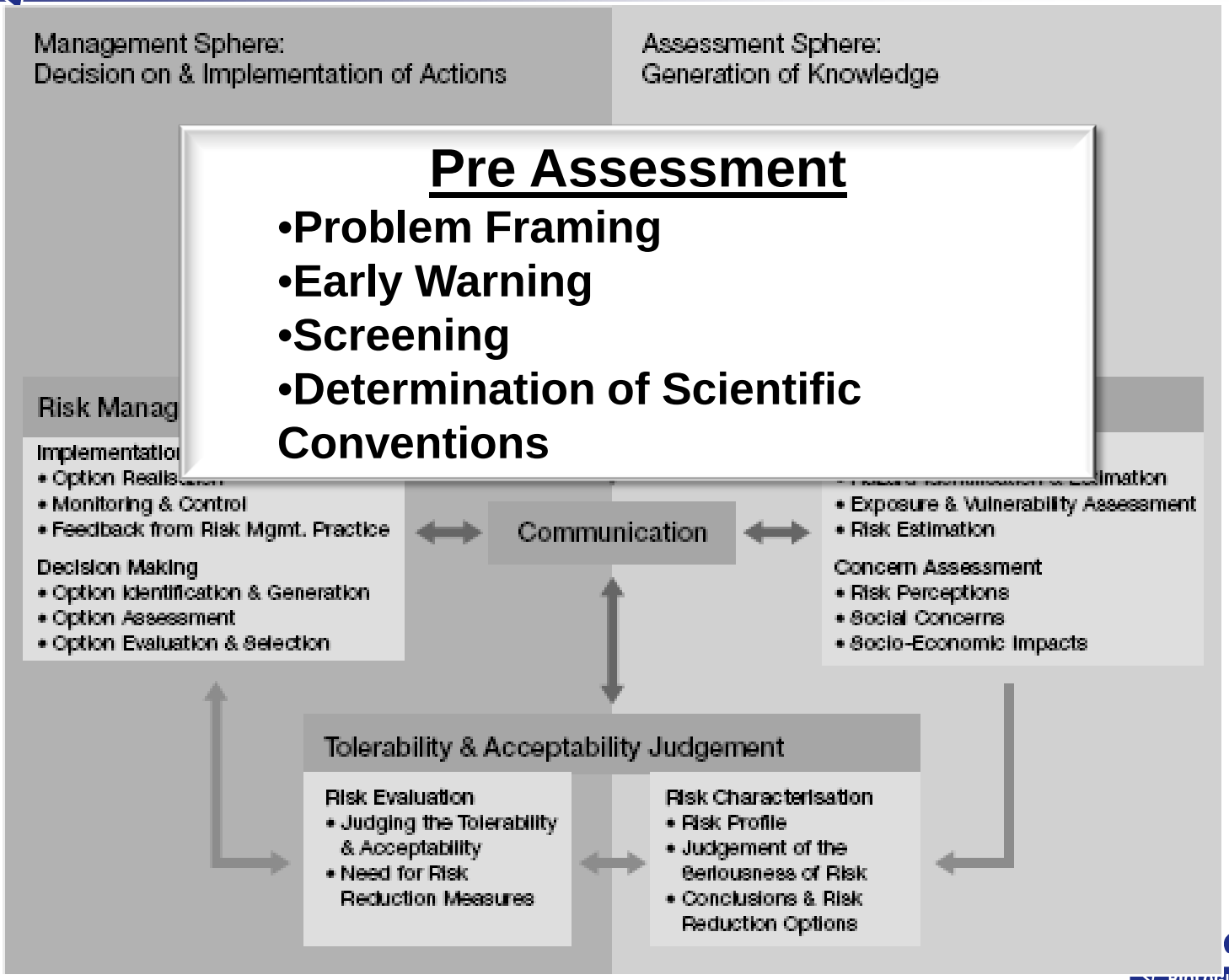
- **Hazard:**
  - The potential for harm or other adverse consequences
- **Risk:**
  - The likelihood of potential consequences AND the severity of those consequences
- **Risk Assessment**
  - Identifying and exploring, preferably in quantified terms, the types, intensities and likelihood of the consequences 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

Risk Governance Framework



International Risk Governance Council: White Paper on Risk Governance, 2005

Risk Governance Framework



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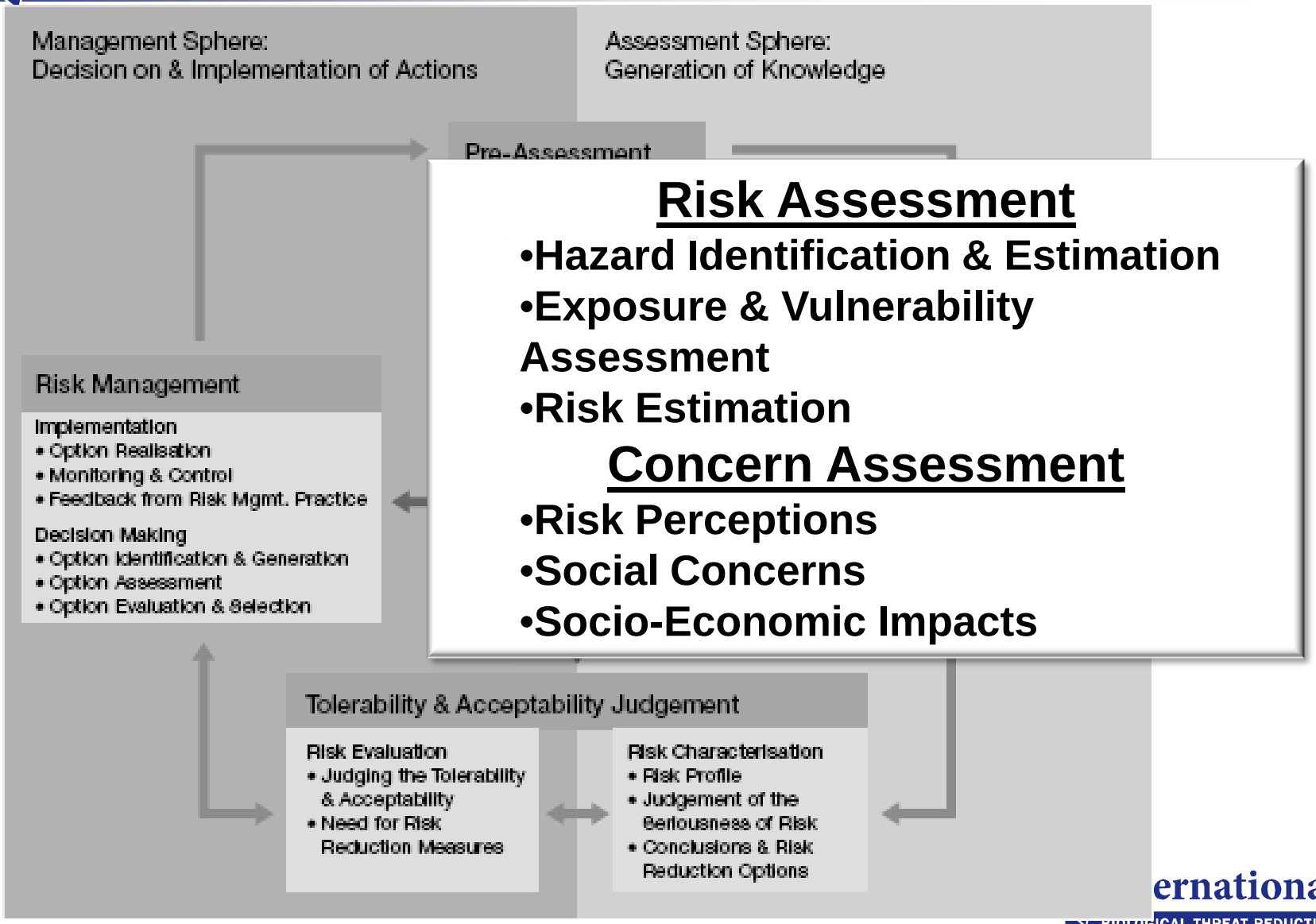

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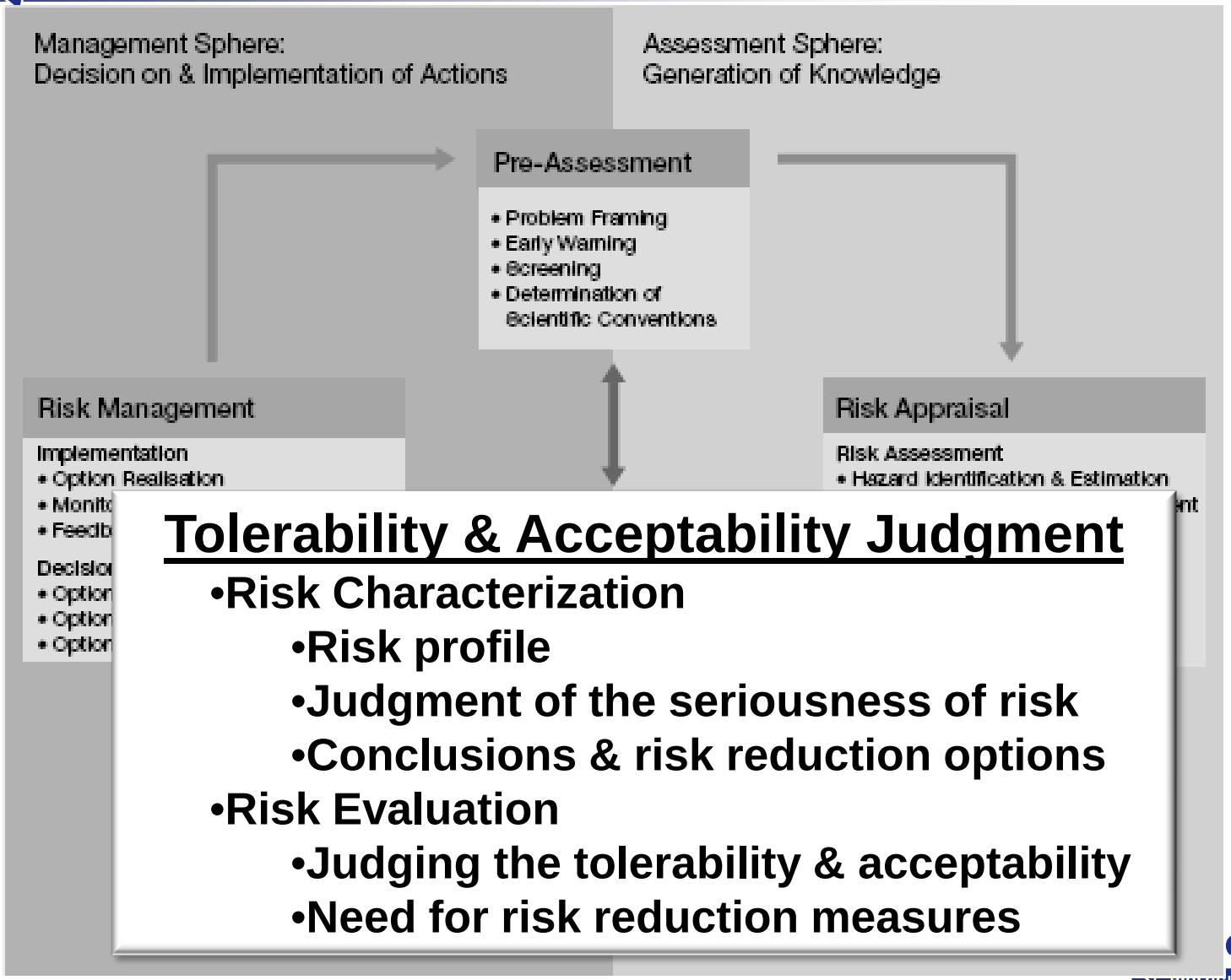

Tolerability & Acceptability Judgment

- Risk Characterization
  - Risk profile
  - Judgment of the seriousness of risk
  - Conclusions & risk reduction options
- Risk Evaluation
  - Judging the tolerability & acceptability
  - Need for risk reduction measures

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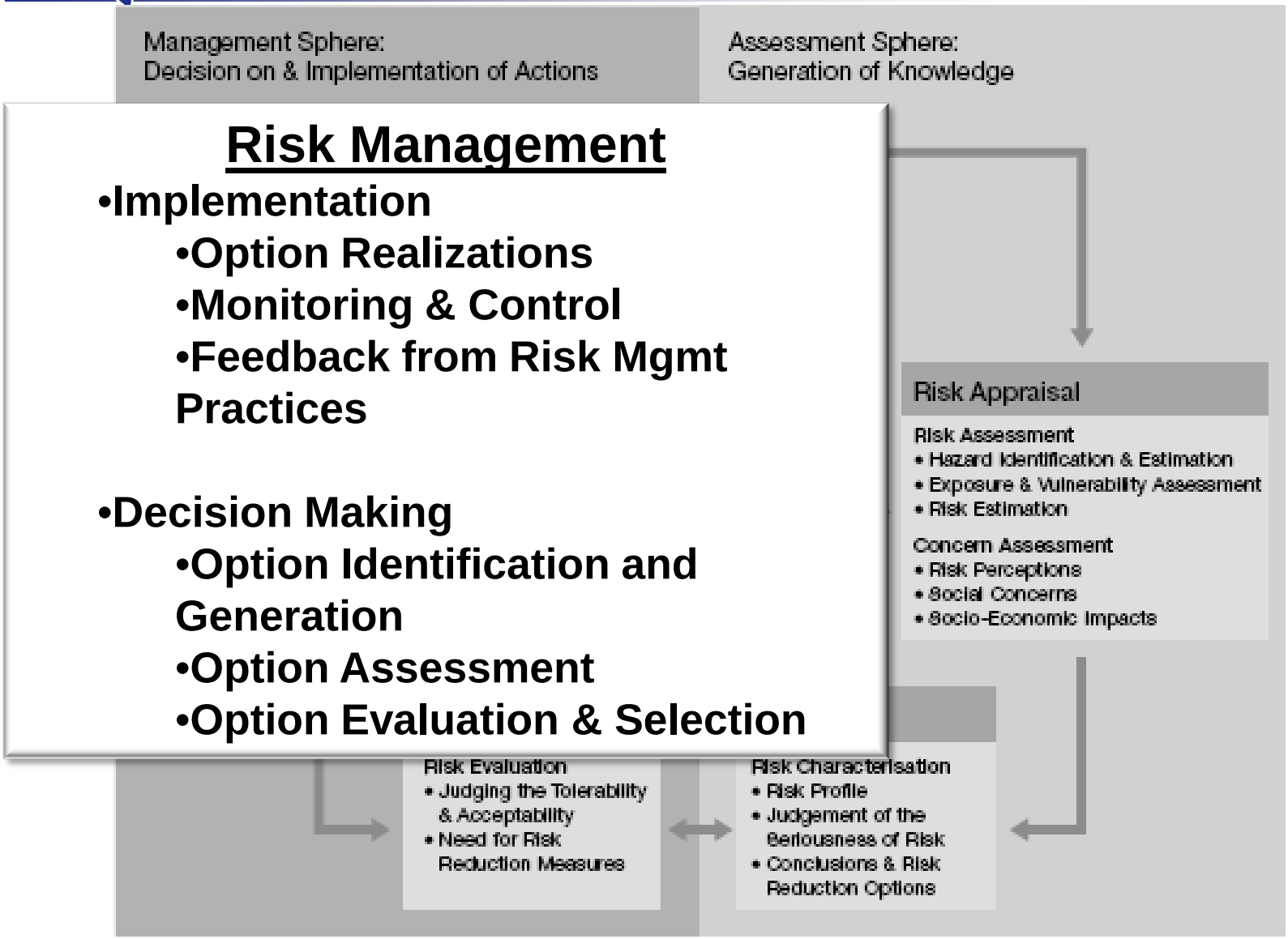
Risk Governance Framework



Risk Management

- Implementation
  - Option Realizations
  - Monitoring & Control
  - Feedback from Risk Mgmt Practices
- Decision Making
  - Option Identification and Generation
  - Option Assessment
  - Option Evaluation & Selection

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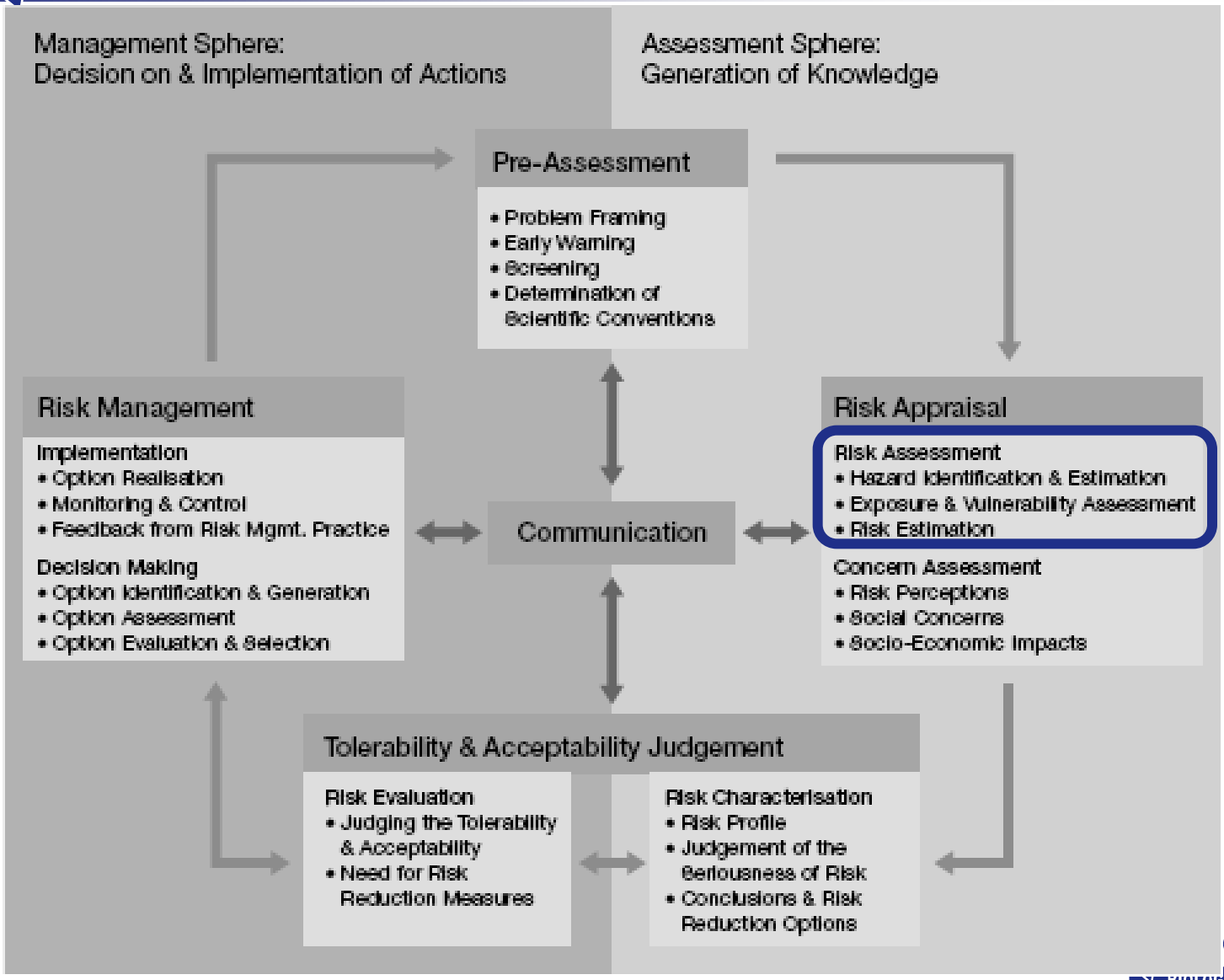
Risk Governance Framework



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Pre-Assessment: Framing

- **Framing – selection of the relevant risks**
  - Consider risks from perspectives of all major actors
    - **Government, scientific community, institution, general public**
  - In selecting risks, do all actors agree on:
    - **Underlying goal?**
    - **Do the identified hazards impact the desired goal? To what extent?**
  - Could be disagreement between actors on:
    - **Goals**
    - **Relevance of evidence**
    - **Is it a risk or an opportunity?**

- **Discussion: Framing biorisks at a bioscience institution**
  - Who are the actors?
  - What is the underlying goal?
  - Any government agencies defining risks?
  - Examples of disagreements between actors?

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Pre-Assessment: Early Warning

- **Early warning – systematic search for new hazards**
  - How does an institution collect and interpret signs of risk?
    - **Who looks for risks and who acts on them?**
  - Indicators of new hazards include:
    - **Unusual events or phenomena**
    - **Systematic comparison between modeled and observed phenomena**
    - **Novel activities or events**

- **Discussion: Early warning for biorisks at a bioscience institution**
  - Consider role of incident reporting (including near misses)

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Pre-Assessment: Risk Screening

- **Risk screening – determining the risk assessment process**
  - Is it reasonable to cut short the assessment process?
  - Categorizing the risks
    - **Different risk categories need different risk assessment approaches, risk management strategies, stakeholder engagement, and tools**
- **Categorizing the risks based on state of knowledge about risks**
  - What is the difficulty in establishing a relationship between the probability and consequences?
    - **Simple**
      - Ex: health risks from smoking
    - **Complexity**
      - Ex: failure risk of interconnected electrical grid
    - **Uncertainty**
      - Ex: international terrorism
    - **Ambiguity**
      - Ex: long term health effects of nanotechnology
- **Discussion: What category(ies) best describe biorisks?**

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Pre-Assessment: Selection of Conventions

- **Selection of applicable scientific conventions – what is needed for a valid, scientific risk assessment**
  - What is adverse?
  - How to combine effects on one scale?
  - Selection of applicable models, definitions, etc
  - Must document assumptions, decisions to ensure stakeholders understand constraints on interpreting assessment results

- **Discussion: Examples of judgments that must be made in assessing biorisks**

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Risk Appraisal: Risk Assessment

- **Purpose: understand uncertain but possible consequences associated with specific hazards**
- **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**

- **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?

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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**

- **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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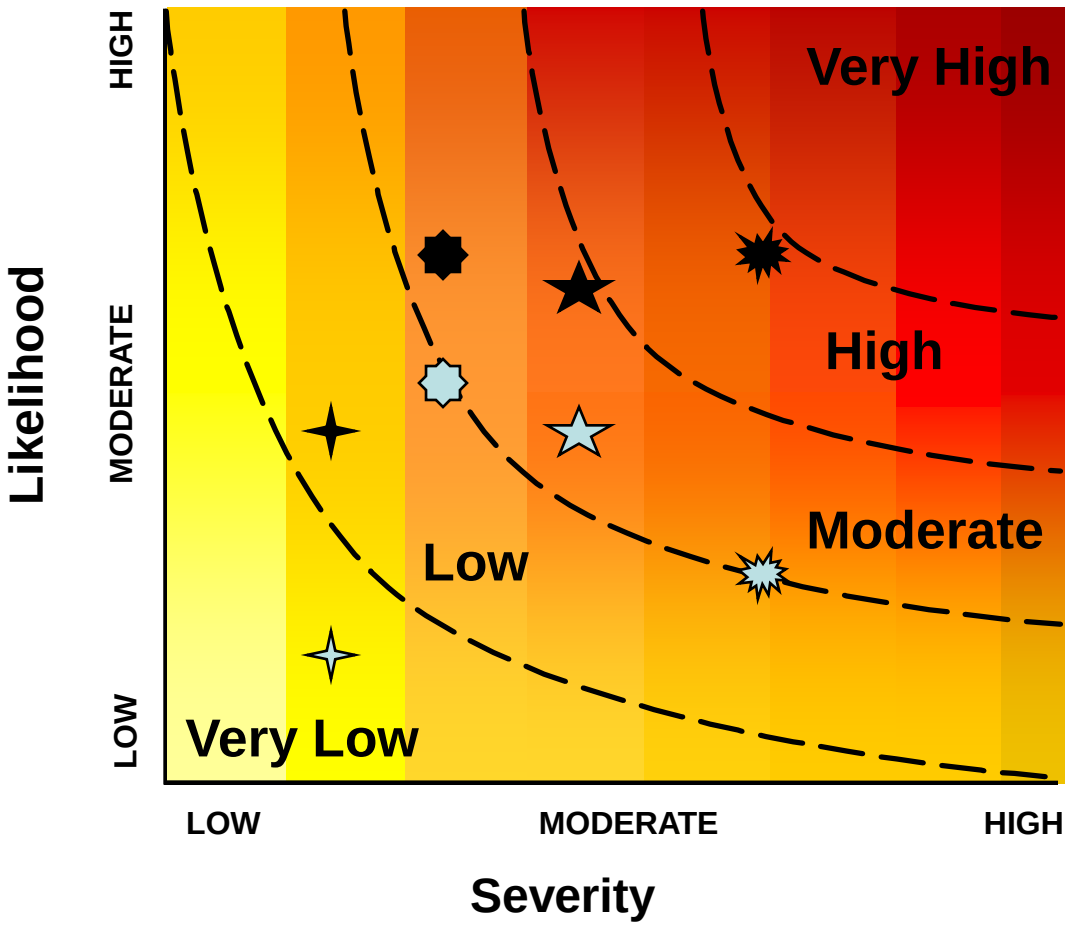
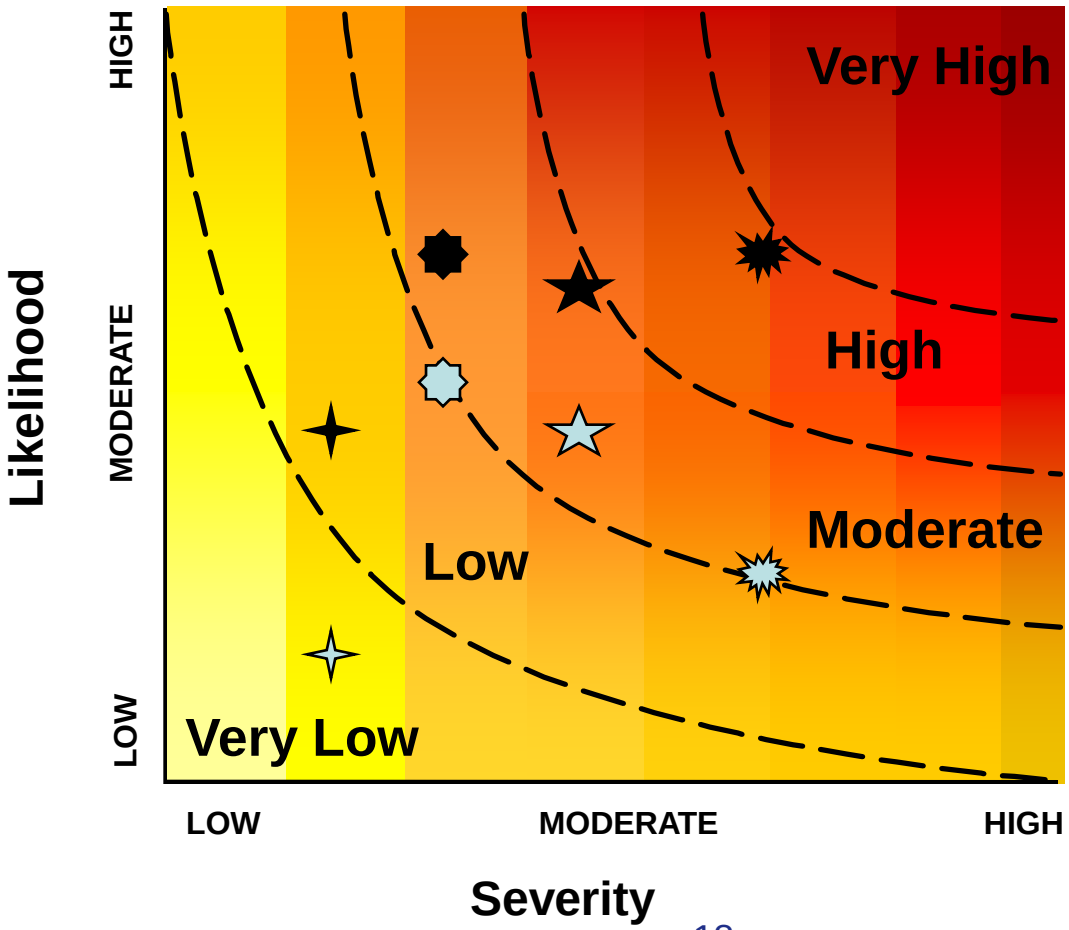
Tolerability & Acceptability Judgment: Risk Characterization

- **Evidence-based**



Tolerability & Acceptability Judgment: Risk Evaluation

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



- **Protect against unacceptable risk scenarios**

- **Develop incident response plans for acceptable risk scenarios**

Risk Management: Decision Making

- **Option generation**
  - Identification of potential risk handling options:
    - **Prevention, adaptation and mitigation, risk avoidance, transfer and retention**
- **Option assessment**
  - Investigations of impacts of each option
    - **Economic, technical, social, political, cultural**
  - Evaluation of trade-offs
- **Option selection**

- **Discussion: Decision-making for biorisks**
  - Who should generate options for managing biorisks?
  - Who should assess options?
  - Who should select?

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Risk Management: Implementation

- **Option realization**
- **Monitoring and control**
  - Accountability, consistency, effectiveness
- **Feedback**
  - Intended impacts, unintended impacts

- **Biorisk Management – CEN Workshop Agreement**
  - **Plan** – Pre-assessment, Risk Appraisal, Tolerability & Acceptability Judgment
  - **Do** – Option realization
  - **Check** – Monitoring and control
  - **Act** - Feedback

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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Risk

- Is a function of the likelihood of potential consequences
  - Likelihood (L)
- And the severity of those consequences
  - Consequences (C)

$$\text{Risk} = f\,(L, C)$$

Risk Assessment Principles

- **Define the problem**
- **The problem should drive the method**
- **The 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 schemes**

Steps for Conducting a Risk Assessment

1. State the Problem
2. Formulate the approach – determine the method(s)
3. Collect data / Interview experts
4. Build the model
5. Run base case in the model
6. Conduct sensitivity analysis
7. Record results
8. Document model

"We've considered every potential risk except the risks of avoiding all risks."

Traditional Security Assessment vs. Traditional Safety Assessment

- **Traditional Security Assessment**
  1. Asset Characterization
  2. Threat Characterization
  3. Vulnerability Assessment
  4. Consequence Assessment
  5. Likelihood Assessment
  6. Risk Assessment Results

- **Traditional Safety Assessment**
  1. Hazard Identification
  2. Consequence Assessment
     1. **Direct**
     2. **Indirect**
  3. Likelihood Assessment
  4. Risk Assessment Results

How is likelihood defined?

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

Risk Assessment Schemes

- Qualitative Schemes
- Quantitative Schemes
- Probabilistic
- Relative
- Tree-Based Techniques
- Multi-Criteria Techniques
- Dynamic Systems
- Weighted
- Unweighted
- Expert Judgments
- Collected Data

Quantitative vs. Qualitative Schemes

- **In a quantitative scheme, the risk assessor assigns numerical values to the likelihood and consequences of the adverse event**
  - All data in the model should be quantitative

- **In a qualitative scheme, the risk assessor may rely on linguistic variables to estimate the likelihood and consequences of the adverse event**
  - The model may incorporate both quantitative and qualitative data

Probabilistic vs. Relative Schemes

- **Probabilistic schemes are quantitative assessments of the likelihood**
  - Assign probabilities to the likelihood
    - **E.g. assessing the probability of a small prop airline crashing during a rain storm**
  - Strong quantitative methods also assign numerical values to the magnitude of consequences of the adverse event
  - Weak quantitative methods may make qualitative assessments of the consequences

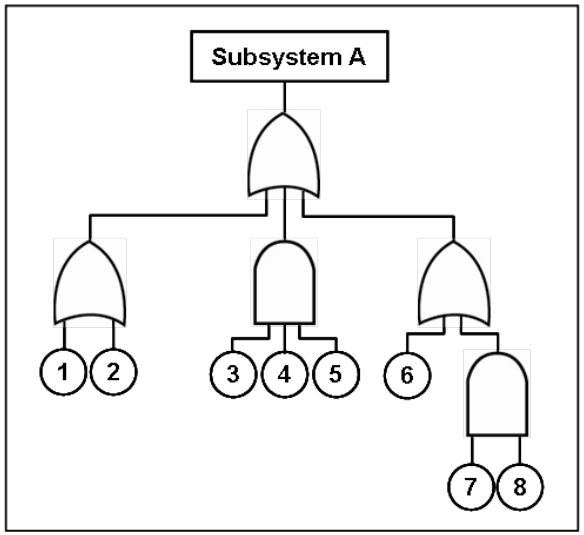
- **Relative schemes are typically qualitative assessments of the likelihood and consequences of an adverse event**
  - Risk result is relative to other possible adverse outcomes or the status quo
    - **E.g. planning the route from home to work**
    - **E.g. prioritizing needed physical security enhancements**

Calculating Probabilities

1. Collection of statistical data relating to the performance of a risk source in the past (actuarial extrapolation);
2. Collection of statistical data relating to components of a hazardous agent or technology. This method requires a synthesis of probability judgments from component failure to system performance (probabilistic risk assessments, PRA);
3. Epidemiological or experimental studies which are aimed at finding statistically significant correlations between an exposure of a hazardous agent and an adverse effect in a defined population sample (probabilistic modelling);
4. Experts', or decision makers' best estimates of probabilities, in particular for events where only insufficient statistical data is available (normally employing Bayesian statistical tools)
5. Scenario techniques by which different plausible pathways from release of a harmful agent to the final loss are modeled on the basis of worst and best cases or estimated likelihood for each consequence at each knot

Tree-Based Techniques (Probabilistic Risk)

- **The adverse event is the top event of the tree**
- **Each situation that could cause that event is added as a branch**
  - The adverse event to be modeled is defined by the tree
  - More detailed situations can be added to each branch
- **Each event and situation is given a probability of success or failure**
  - Modeling software is often used to determine the overall probability of the adverse event based upon analysis of all the possible routes



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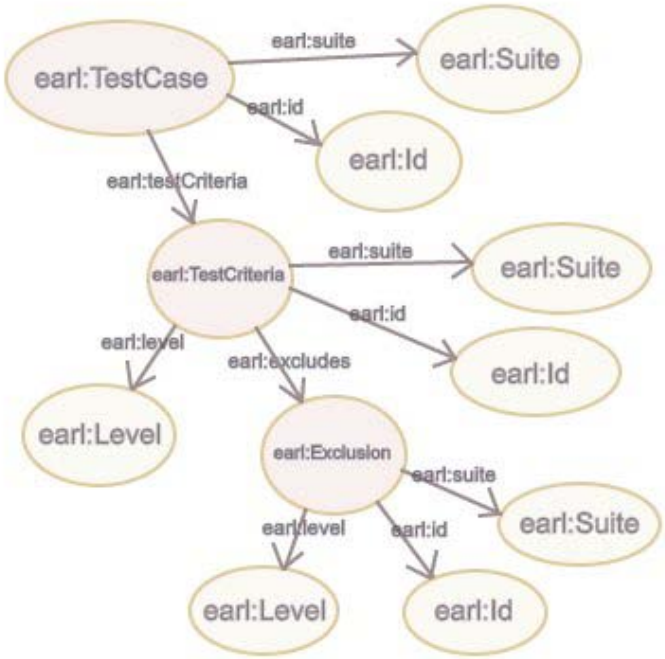
Multi-Criteria Techniques

- **A set of criteria are developed**
  - These criteria form the basis of the assessment, and define the adverse event
- **Detail is built into the model by refining top-level criteria with sub-criteria**
  - The criteria and sub-criteria reflect the attributes that the risk assessor would like to model
  - In the simplest implementation, all criteria contribute equally to the assessment of risk
  - Risk assessors may model unequal contributions to risk by assigning weights to each criterion



Incorporating Expert Judgment in Risk Assessment Models

- **Data for models (e.g. a value for a probability in the event tree or a value for a criterion) can be either a single data point or multiple data points**

- **Single values may be drawn from a recognized value in the scientific literature, a consensus value elicited from a group of experts, or a value assigned by a single individual**
  - Easier to incorporate in the model, but may not be a statistically robust

- **Multiple values may exist when there is uncertainty in the literature, or when separate values are elicited from multiple experts**
  - Risk assessor must decide how to incorporate these multiple values
    - **Simple average**
    - **Distribution functions**
      - Triangle distribution
      - Monte Carlo Integration

Common Language

- **Criteria should be defined in a manner common to those providing the data**

- **Ontology is a representation of a set of concepts and the relationship between those concepts**
  - Domains
    - **Classes**
      - Elements
        - **Attributes**
        - **Relationships**
- **Taxonomy are the hierarchical structure things are defined based upon relationships**
  - Parent-Child relationships

Examples Of Risk Assessment Models

- **CARVER + Shock: Criticality, Accessibility, Recuperability, Vulnerability, Effect, Recognizability, Impact (or Shock)**
  - Set criteria, unweighted, expert judgment, assesses relative risk

- **Multi-Criteria Decision Analysis (MCDA)**
  - Multiple criteria, weighted, expert judgment and collected data, qualitative or quantitative, assesses relative risk

- **Probabilistic Risk Assessment (PRA)**
  - Multiple criteria, can be weighted, requires probability data, quantitative, assesses probabilities, also needs to be paired with consequence modeling to assess risk

More Examples of Risk Assessment Models

- **Failure Mode and Effects Analysis (FMEA)**
  - Matrix model of system, probability of failure at each index in matrix, unweighted, assesses probability of overall system failure
- **Fault Tree Analysis (FTA) or Event Tree Analysis (ETA)**
  - Multiple criteria (in hierarchical structure), unweighted, uses Boolean logic (and/or), requires probabilities, assesses probabilistic risk
  - Often used in PRA to define structure of model
- **Dynamic Models**
  - Use time explicitly
  - Often can have multiple states and feedback loops
- **Fuzzy Logic**
  - Uses approximate yet effective means to describe situations which are too complex or ill-defined to allow precise mathematical values

Risk Assessment Layers

- **Multiple Risk Assessments can be combine or layered to address more complex questions**
  - Hazard based Risk Assessment
  - Threat based Risk Assessment

Summary

Risk = f (Likelihood, Consequence)

- **For security assessments, the likelihood of the adverse event, often referred to as the Threat Potential, includes the <u>Threat</u>**

- **For safety assessments, the likelihood of the adverse event <u>does not</u> incorporate the Threat**

- **The problem should drive the method**
- **The method should be as simple as possible, but not oversimplified**
- **The model is only as good as the data (Garbage in Garbage out)**

  - **State the Problem**
  - **Formulate the approach**
  - **Collect data/Interview Experts**
  - **Build the model**
  - **Run base case in the model**
  - **Conduct sensitivity analysis**
  - **Record results and document model**

Risk Assessment Flow Chart

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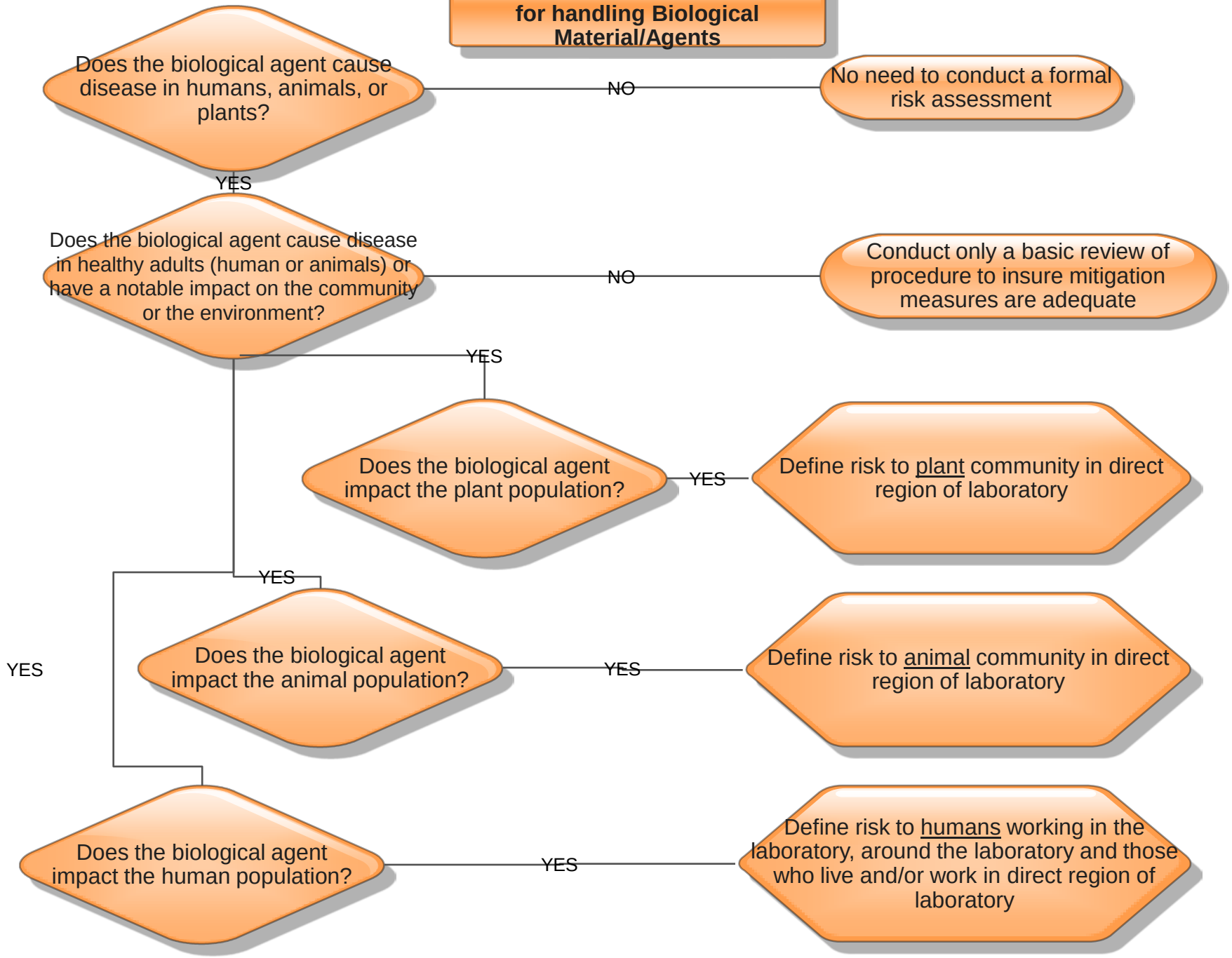
Risk Assessment Model for handling Biological Material/Agents



For each defined risk:
Plant, Human, Animal

Define factors
about the biological agent which scale the consequence of disease to each population

Biological Agent Factors
Agent Characteristics (allergenic, carcinogenic, toxin production, abortogenic)
Morbidity (Duration of illness, severity of illness, duration of infection, sequelae)
Mortality (untreated mortality)
Treatment options (diagnostic tests, anti-microbials, vaccines)

Define factors
about the biological agent which scale the likelihood of infection to each population

Biological Agent Factors
Route of Infection
Infectious Dose
Stability
Existence of prophylaxis

For each research project:
Accidental exposure risk to individuals performing direct manipulation of the agent

Define factors
about the research which scale the likelihood for exposure

Laboratory Factors
Inhalation potential (aerosol generating procedures, animal, experiments)
Percutaneous or direct contact potential (animals, needles, other sharps, splashes and spills)
Ingestion potential (splashes)
Quantity and Quality of infectious material

Define factors
about the research which **reduce** the likelihood for exposure

Biosafety Measures
Management oversight
Primary Containment
PPE
Procedural/administrative

For each research project:
Risks to human, animal, and or plant communities of accidental exposure

Define factors
about the research which scale the likelihood for exposure

Laboratory Factors
Inhalation (contaminated air entering clean space)
Percutaneous (contaminated animals or sharps entering clean space)
Contact (contaminated solids/liquids, animals or people entering clean space)
Ingestion (contaminated solid/liquid entering clean space)
Quantity and Quality of infectious material

Define factors
about the research which **reduce** the likelihood for exposure

Biosafety Measures
Management oversight
Secondary Containment
Procedural/administrative

Risk of theft of biological material from laboratory for malicious use

Define factors about the potential adversaries to the laboratory

Adversaries
Insiders with direct access
Insiders without direct access
Visitors
Outsiders with criminal intent
Outsiders with terrorist intent

Define factors about the laboratory which can **reduce** the potential of the adversaries to acquire the biological agent

Biosecurity Measures
Management oversight
Physical security
Personnel security
Transport security
Material control
Information security

BIOSAFETY RISK
For each defined risk:
Plant, Human, Animal

Score
likelihood of infection to
the individual or community

Score
likelihood for exposure

Score the measures to
reduce the likelihood for exposure
(subtract this score from the likelihood for exposure score)

Overall score of likelihood of exposure and likelihood of infection via that exposure

Score
consequence of disease
the individual or community

Overall score consequence of disease

BIOSECURITY RISK
For each defined risk:
Plant, Human, Animal

Score
likelihood of infection
of the community

Score
the potential adversaries means, motive to steal from
the laboratory

Score the factors
about the laboratory which can **reduce** the potential of
the adversaries to acquire the biological agent

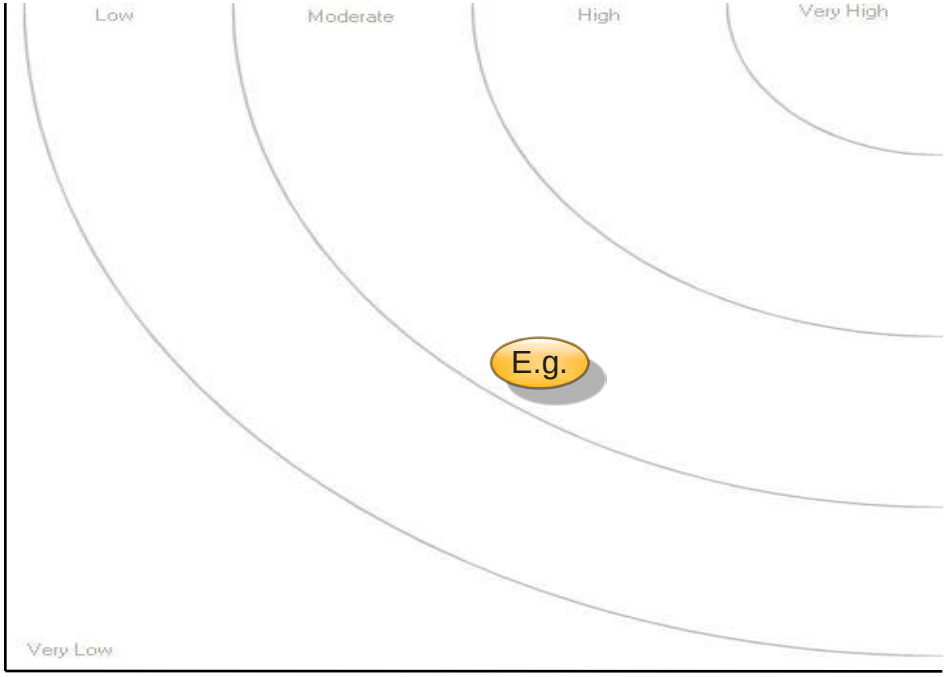
Overall score of likelihood of targeting and theft of a biological agent from the laboratory

Score
consequence of disease
to the community

Overall score consequence of disease

RISK
For each defined risk (biosafety and biosecurity):
Plant, Human, Animal

Overall score of likelihood



Overall score consequence of disease

Biosafety Risk Variables

Biosafety Risk = F (Likelihood)(Consequence of Disease)

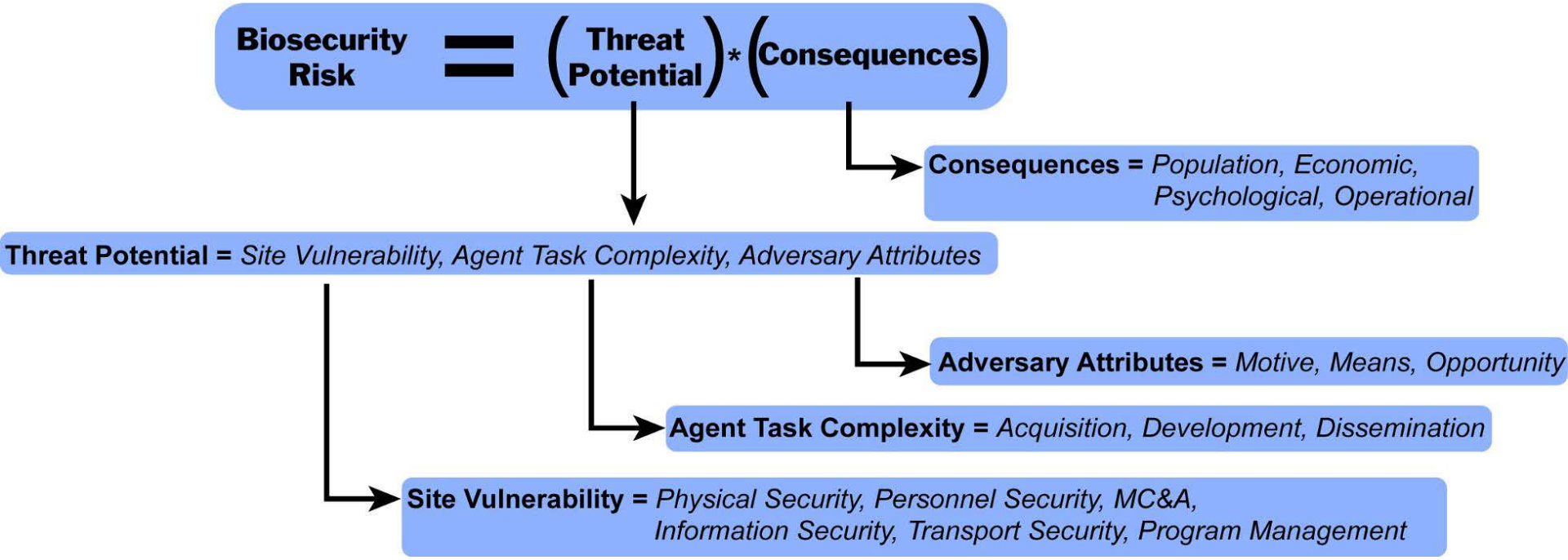
Consequence of Disease = F (Biological Properties of Agent) (Mitigation Measures)

Likelihood = F (Likelihood of Exposure)(Likelihood of Infection)

Likelihood of infection = F (Biological Properties of Agent)

Likelihood of Exposure = F (Laboratory Hazards)(Biosafety Practices)

Biosecurity Risk Variables



Reference: Laboratory Biosecurity Handbook,
by Reynolds M. Salerno, Jennifer Gaudioso
CRC; 1 edition (June 20, 2007) ISBN-10: 0849364752

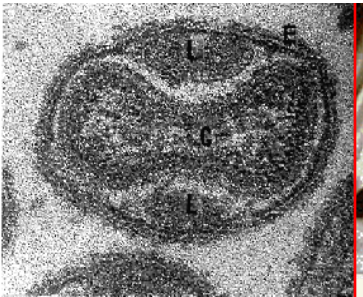
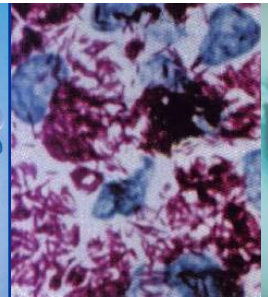
Risk Assessment Usually Not the Only Input for Risk Management

- **Mitigation strategies for risk are based on several factors:**
  - Science (the risk assessment)
  - Technical limitations
  - Economic constraints
  - Politics
  - Legal implications
  - Health
  - Social

Conclusions

- **Need to integrate biosafety and biosecurity considerations into decisions about laboratory operations**

- **Biological facility risk assessment provides an opportunity to concentrate resources on the highest risks**
  - Tiered system of protection based on risk assessment and risk management methodologies
  - Risk assessment is a fundamental resource allocation tool for making decisions about which risks need to be protected against

- **Parallels exist between safety and security risk assessment processes**

- **Risk assessment and risk decision are the critical foundations for the design of a laboratory biosafety and biosecurity program**