

## Risk Assessment Summary

Risk Assessment = Risk Characterization + Risk Evaluation

### Risk Characterization:

Risk characterization is the process of identifying hazards and measuring risk through quantifying likelihood and consequences.

What is a hazard?

A hazard is the potential for harm. A hazard can be a physical object (e.g. needle, scalpel), chemical, biological agent, noise, radiation, extreme heat or cold, electrical energy or anything else that has the potential to cause harm.

What is a threat?

Used in the context of a biosecurity risk assessment, a threat is a person (or group of people) who have intent to steal or misuse laboratory assets (biohazardous agents) for illicit profit/gain or to cause harm or injury.

Not all hazards/threats are risks. Only when the likelihood and consequences are considered from a hazard/threat in a given situation or context does a hazard/threat become a risk. For example, while a shark is a hazard it is not a risk unless one goes in the ocean. A hazard is an object or incident with potential to cause harm whereas risk is a measurement of likelihood and consequences involving a hazard.

Risk is a function of likelihood and consequences. Here is a simple risk assessment matrix:

		Consequences			
		1 - Negligible	2 - Marginal	3 - Critical	4 - Catastrophic
Likelihood	IV - Frequent	Low/Moderate Risk	High Risk	Very High Risk	Extreme Risk
	III - Occasional	Low Risk	Moderate Risk	High Risk	Very High Risk
	II - Remote	Very Low Risk	Low Risk	Moderate Risk	High Risk
	I - Improbable	Very Low Risk	Very Low Risk	Low Risk	Moderate Risk

## Severity/Consequences

4 - Catastrophic: Very serious human or animal disease; causes death or permanent disability in most cases; readily transmitted; limited or no effective treatments or preventative measures; extreme financial loss/cost; exotic and rare agents that are not found in the environment

3 – Critical: Serious human or animal disease; effective treatments available; probability of death or permanent disability is low; however, extended inpatient hospitalization or treatment will be lengthy; does not readily transmit from individual to individual; moderate economic loss; may be found in the environment outside the lab but is not common

2 – Marginal: Causes human or animal disease but disease is rarely severe or life threatening; unlikely to be a serious hazard to lab workers, the community, livestock or the environment. Found commonly in the environment; little to no economic loss or impact if released; treatment if necessary done by medical professionals in outpatient setting.

1 – Negligible: Unlikely to cause human or animal disease; if infected, disease is limited and easily treated; can be dealt with by in-house first aid; etc.

## Likelihood/Probability

IV – Frequent: Likely to occur immediately; occurrences happen regularly; almost certain to occur in most circumstances

III – Occasional: Probably will occur in time

II – Remote: May occur in time; unlikely to occur but could happen

I – Improbable: May occur but only in rare and exceptional circumstances

Examples of typical Laboratory Biorisk Assessments:

**Workplace characterization:** is a description of the processes and operations in the workplace, with particular attention paid to those areas and activities within the lab for potential exposures. This is usually accomplished through inspections or visits of worksites and is usually done by lab managers with the assistance of the BRMA. An all hazards approach is usually taken looking at not just biohazards but chemical, radioactive, fire and life safety hazards and also regulatory compliance issues as well.

**Workforce characterization:** groups and describes employees with similar work duties or job classifications. Particular attention is paid to individuals who may be more susceptible to biohazards in the workplace and to those groups that may have particular exposures based on

their job duties. This activity is usually done by trained occupational health professionals with assistance from the BRMA.

**Project/protocol registration/approval:** Information about a research project or proposal associated with a single laboratory (or Principal Investigator, PI) is collected and reviewed by an Institutional Biosafety Committee. The focus is on regulatory compliance. The type of information collected includes information about the laboratory location and containment practices, training records for individuals, agents used in the laboratory, potentially hazardous procedures and mitigation controls in place. A visit or inspection of the laboratory is usually done as part of the IBC approval process. Risk assessment is a joint effort between the PI, lab manager, biorisk management advisors and IBC.

**Agent characterization:** is creating an inventory of all the biohazardous agents in the workplace. The focus is on their potential adverse health effects, routes of exposure, how they are used, how much they are used and the potential consequences of an exposure. This activity is usually done by the BRMA or Biosafety Officer.

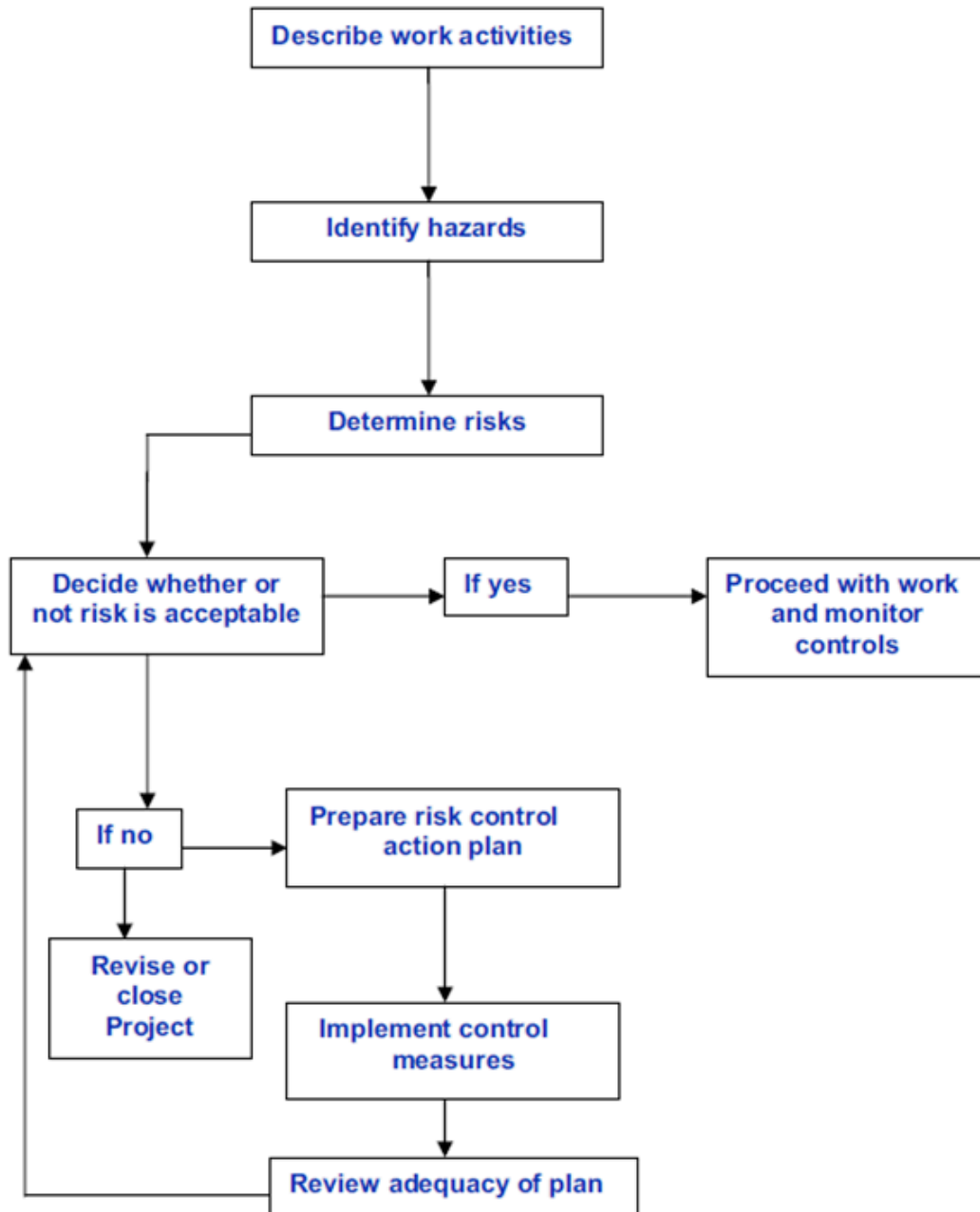
**Job hazard analysis:** a systematic review of a specific procedure (job) usually done by the worker to break the job down into component parts (steps), analyzing each step for potential hazards and developing or suggesting solutions (controls) to mitigate the risk. JHA focuses on what could go wrong in each step (what are the hazards); what are the potential consequences; how likely is it to occur and what are contributing factors and finally, what can be done to eliminate or minimize the hazard? Particular attention should be paid to any procedures that impart energy to a microbial suspension or other activity that could generate aerosols; the use of sharps objects or potential sharps (e.g. glass); potential hazards associated with work practices or carelessness; proper use of safety equipment; proper functioning of safe guards, etc. Often JHAs are included in the process of developing SOPs.

### **Risk Evaluation:**

Risk evaluation is the process of determining the acceptability of risk. It involves both personal and social value judgments. While risk characterization is the process of measuring risk, it does not determine whether something is safe or not. Judging whether or not something is “safe” involves a value judgment. While the level of a risk might remain the same, the acceptability of that risk will vary from individual to individual and over time. Once a determination of the level of risk is made, those who own the risk must make an evaluation and determine whether or not the risk is acceptable to them. Owners of risk include lab workers, management, oversight committees, government regulators, and ultimately the public at large. Lab workers must decide whether or not to do the work given the risk. Management must take responsibility for placing workers at risk. Oversight committees usually give approval for research activities based on acceptable mitigation after a review of the risk. Governments establish regulations that put bounds on what risks the public will accept. If a risk is found to be acceptable, work can proceed with monitoring of controls (risk mitigation). If Risk is found to be unacceptable, then two choices remain: 1. Close the project or don't do the work; or 2. prepare a risk

mitigation control plan and implement additional control measures. Of course, after proposing new or additional mitigation, the risk must be re-characterized and evaluated. A decision again is made whether or not the risk is now acceptable given the additional mitigation.

Example Risk Assessment Process from CEN Biorisk Management Workshop Agreement:



**Risk Assessment Strategy from CWA 15793:2011**

Your name:

## **Risk Assessment Questions**

Define "Risk" in your own terms. How is risk different from hazard or threat? When you think of "risk" what comes to mind.

Are all hazards/threats risks? Why or why not.

Why is doing a risk assessment important?

What kind of information would you need to collect to do a biosafety risk assessment?

What would be some advantages of using a robust, structured, standard risk assessment process?

Why is risk evaluation subjective and what are factors/considerations when determining whether a risk is acceptable or not?

Outline the steps you would take to do a biosafety risk assessment