



# **Risk Assessment Process for Bio-hazardous Agents and Materials**

2020

# Objectives



- Understand risk assessment
- Differentiate between WHO Risk groups and Bio-safety levels
- Describe the process of risk assessment using the CDC/NIH Biosafety in Microbiology and Biomedical Laboratories (BMBL), 5th ed.

# Laboratory Risk Assessment Process



- Reduces the worker's and environment's risk of exposure.
- The Risk is never zero
- Also call a “Hazard Assessment”

# Lab Biohazard Risk Assessment



A biohazard risk assessment is a process which:

- Performs a site-specific evaluation
- Evaluates risk posed by the:
  - **Agent**
  - **Activities/Procedure(s)**
  - **Worker**
  - **Environment**
  - **Community**
- There are numerous ways to perform this process

# Risk Assessment



- Is a critical and productive exercise, for identifying potential hazardous laboratory activities involving infectious materials or lab exercises.
- The risk assessment process is the basis for assigning the Biosafety Levels (facilities, equipment, practices, & occ. health program).
- Goal to minimize worker's and the environment's risk of exposure to the agent.

# Risk Assessment BMBL 5<sup>th</sup> edition



- There are many ways to perform a Hazard Risk Assessment
- This presentation uses a 5-step process outlined in the US publication entitled:
  - *CDC/NIH Microbiology in Biomedical Laboratories (BMBL), 5th ed.*



## 5-Step Biosafety Risk Assessment:

1. Identify – Agent hazards (biological properties)
2. Identify – Work Activity hazards (associated with lab work)
3. Determine - Preliminary Biosafety Level
  - Facilities, Equipment, Occ Health Programs, Practices



## 4. Evaluate Worker

- Training & Experience
- Occupational Health Programs

## 5. Review the Risk Assessment with:

- Biosafety Professional or Biosafety Committee
- Investigator / Researcher/ Subject-Matter-Expert
- Attending Occupational Health Physician



# Step 1: Risk Assessment Process

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## Agent Based - Risk Assessment

# Evaluate – Agent's Basic Properties



- Origin
- Pathogenicity
- Route of transmission
- Infectious dose
- Agent stability
- Concentration
- Animal study data
- Prophylaxis available (Pre/Post)



# **Biosafety Level vs. Risk Groups**



- Risk Groups & Biosafety Levels – NOT THE SAME
- Risk Group 1-4  $\neq$  BSL 1-4
- Risk-Group profile is a component of determining the Biosafety Level



## WHO Risk Groups 1-4:

### Considers biological properties of the organism

- Pathogenicity / Severity of disease
- Mode of transmission and host range
- Availability of preventive measures (Ex. vaccines)
- Availability of effective treatment (Ex. antibiotics)
- Other factors

# WHO Guidelines – Risk Groups



**RG 1**

**RG 2**

**RG 3**

**RG 4**

| Agents that are not associated with disease in healthy adult humans | Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available | Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions <i>may be</i> available (high individual risk but low community risk) | Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are <i>not usually</i> available (high individual risk and high community risk) |
|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



# **Criteria For Laboratory Biosafety Level (BSL) & Animal Biosafety Levels (ABSLs)**

# 4- Components of a Biosafety Level (BSL & ABSL)\*



- (1) Work Practices & Procedures
- (2) Special Practices (Occupational Health Programs)
- (3) Safety Equipment (Lab equipment & PPE)
- (4) Laboratory Facilities

## Ref:

- WHO Laboratory Biosafety Manual (LBM) 3<sup>rd</sup> ed.
- CDC/NIH Biosafety In Microbiological and Biomedical Laboratories (BMBL)



# Biosafety Level Information (BMBL)



- BSL-1 / ABSL-1,
- BSL-2 / ABSL-2
- BSL-3 / ABSL-3
- BSL-4 / ABSL-4

BSL-3Ag (Large Animals)

# Biosafety Level Information (LBM & BMBL)



- BSL-1: Absence of disease in immuno-competent adult humans (health adults).
- BSL-2: Low to high severity of disease, and low transmissibility
  - Low to moderate infectivity (high infectious dose).

# Biosafety Level information (LBM & BMBL)



- BSL-3: Moderate to high severity of disease, moderate to high transmissibility by infectious aerosols, and indigenous or exotic origin. Medical treatments usually available.
  - *Moderate to high infectivity (low infectious dose)*
- BSL-4: Severe life-threatening disease, moderate to high transmissibility by infectious aerosols, and usually exotic origin. Medical treatments may not be available.
  - *Moderate to high infectivity (low infectious dose)*

# The Risk Assessment Process



- Institutions must perform a site-specific risk assessments for both agents and procedures within their institutions.
  - No two institutions or laboratories are alike.
  - Every lab is unique.
- It may be necessary to use several scientific references / publications to assist in performing the risk assessment, evaluating the agent, and activities.

# Example Reference Materials



- Ref: BMBL - Agent Summary Statements are broken down into the following categories:
  - Introduction
  - Occupational Infections
  - Natural Modes of Infection
  - Laboratory Safety
  - Containment Recommendations
  - Special Issues
  - Vaccines
  - Transfer of Agent

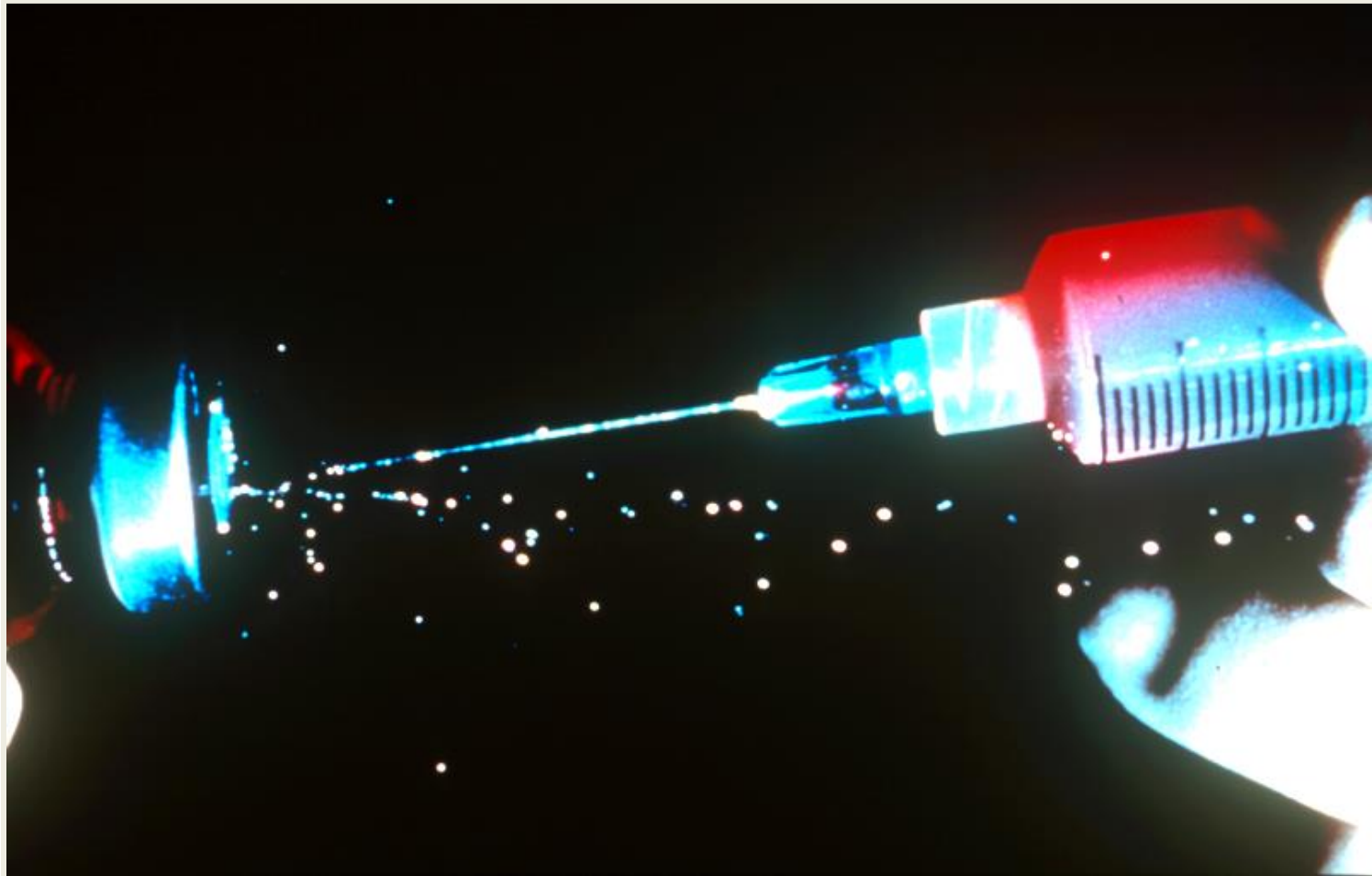
# Step 2: Risk Assessment Process



## Evaluate Work Activities & Laboratory Procedures (for potential safety hazards)

- Next slides provide examples of various work activities

# a. Example - Needle Hazards



## b. Example - Splash and Splatter





## c. Example: Inhalation Exposure to Infectious Aerosols



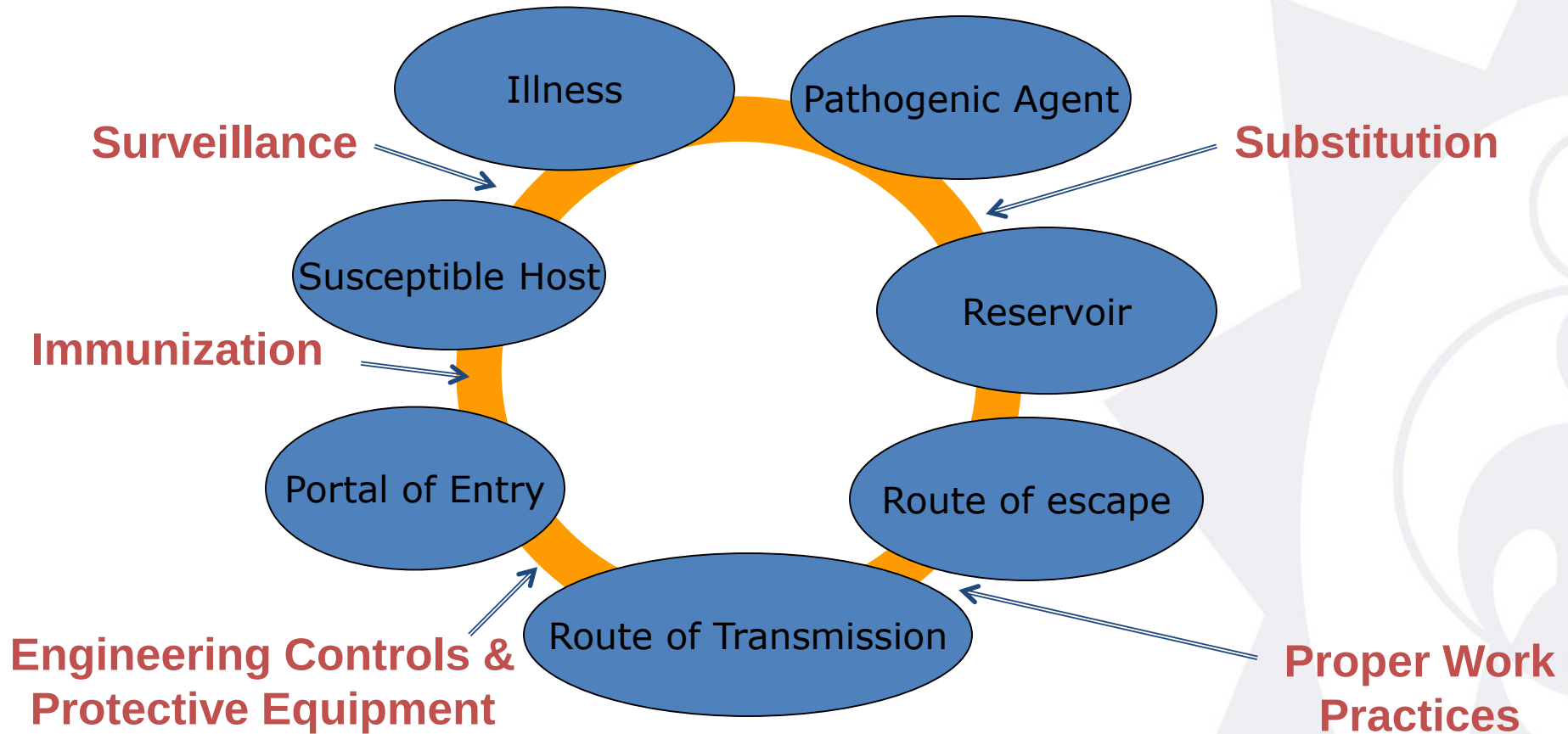
## d. Example - Animal Bites and Scratches



## e. Example: Cleaning & Maintenance Duties



# The Chain of Infection



# Procedures that Increase Risk



- Non-routine activities that require new skills
- Extremely repetitive or boring activities
- Larger scale work, scale up from pilot plant to production; larger volume adds to risk
- Higher concentration of agent adds to risk



# Bio-hazard Risk Assessment



- Exposure to infectious droplets requires as much attention as does the respirable component of aerosols
- Infectious droplets can contaminate gloves, surfaces and mucous membranes resulting in LAIs without associated incidents.

# Step 3: Risk Assessment Process

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Preliminary Determination of  
Biosafety Level and/or ABSL  
and Additional Precautions

# Biohazard Risk Assessment



- Preliminary biosafety level and additional precautions.
  - Facilities
  - Equipment
  - Work practices - Work activities
  - Employee occupational health programs
- Note – This evaluation require comprehensive understanding of the practices, safety equipment, and laboratory facility safeguards.



# Biohazard Risk Assessment



- Intended use of an agent may require greater precautions than those outlined in the agent's summary statement
- Careful selection of additional precautions is often warranted

## Recap:

### **Step-3: Determine Preliminary Biosafety Level**



- Preliminary biosafety level will provide necessary:
  1. Facilities
  2. Equipment
  3. Work practices - Work activities
  4. Employee occupational health programs

# Step 4: Risk Assessment Process

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## Worker Assessment

- (1) Training & Experience
- (2) Occupational Health Needs

# Worker Assessment



- Focus on identifying gaps:
- Worker Training & Experience
  - Working with delegated agent
  - Working at Biosafety Level (or ABSL).
- Worker Occupational Health Programs
  - Includes medical surveillance
  - Respiratory protection programs
  - Pre & Post exposure programs

# Worker Training Experience



- Previous training and experience
- Expertise in specific protocols
- Work experience at delegated Biosafety Level (or ABSL)
- Good microbiological practices
- Attitude toward use of safe practices, PPE
- Occupational Health concerns & needs

# Worker Assessment

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Employee Occupational Health Program

– Also called:

Medical Surveillance Program

# Medical Surveillance Program Occurs Before Work Begins



## Consider need for:

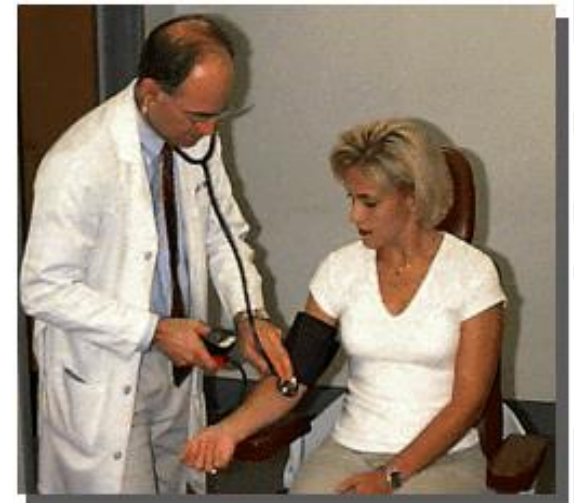
- Pre-placement medical history
- Medical assessments and interventions
- Training and Education enhances self-surveillance efforts:
  - Work-specific
  - Species-specific
  - Agent-specific
  - Method-specific



# Pre-Study/ Pre-Exposure Considerations



- Discuss / review research protocol with Occupational Health physician or services
- Adult vaccines (insure up to date)
  - Examples: MMR, Tetanus, Hepatitis A & B, Influenza, etc
- Current & Past Medical History







# Pre-Study / Pre-Exposure Considerations

- Discuss additional Occupational Health Program needs
  - Determined by risk assessment
  - Respiratory protection program
  - Vaccinations or titers
  - Rabies vaccine (is this standard for your animal facility)
  - Discuss need for serum storage
  - Pre-exposure prophylaxis or medications
- Procure / purchase necessary post-exposure prophylaxis & medications
- Doctor's examinations (immediate care, follow-up care, long-term care)



# First Aid Interventions & Follow-up Care

## Develop exposure control plan (post-exposure plan)



- First-aid protocols
- Location of first-aid kit; stocking & rotating of content
- Assure awareness of first-aid and decontamination activities
- Assure availability of prompt medical evaluation and follow-up as necessary
- Pre-plan for consultations with experts if needed
- Plan for “observation” needs of workers
- Assure timely incident investigation and remediation if required



# Step 5: Risk Assessment Process

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## Review – Results of Risk Assessment

# Review the Risk Assessment with:



- Biosafety Professional or Biosafety Committee
- Investigator / Researcher/ Subject-Matter-Expert
- Attending Occupational Health Physician
- Review is often required by regulatory or funding agencies such as the case outlined in the NIH Guidelines

# Assessing Biosafety Risks and Selecting Safeguards



- Re-evaluate and modify:
  - Biosafety risk assessment
  - Biosafety program / plan.
- Reinforce:
  - Implementation, training, and reevaluation of the biosafety program **ANNUALLY** and **AFTER** any biosafety related incident.

# Key Messages



- A Risk Group is not the same as a Biosafety Level
- Containment conditions do not have to follow a single biosafety level.
- An agent classified in a particular risk group may need to be handled at either a higher or a lower biosafety level.

# Key Messages

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Risk assessment needs and containment decisions require information about:

- Agent
- Worker
- Activities
- Facilities

# Additional Safety Considerations



- Waste Management
- Chemical Hygiene
- Electrical Safety
- Fire Safety
- Radiation Safety
- Emergency Preparedness & Response Programs





# ***Work Safely & Questions***



# Acknowledgement

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- Elsie van Schalkwyk, ACILT –South Africa
- CDC/NIH Biosafety In Microbiological and Biomedical Laboratories (BMBL)