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Biological Risk Assessment

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Biohazard Risk Assessment

What is it?

- Agent-based **qualitative risk estimate**.
 - Safe when risk associated with task is considered to be acceptable.

What needs to be reviewed?

- From accessioning to waste disposal.

Most important component is professional judgement.



Why do it and document it?

Standards and guidelines driving biohazard risk assessments:

OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030

- The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to **reflect new or revised employee positions with occupational exposure.**
- Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to **eliminate or minimize occupational exposure.**



Why do it and document it?

Standards and guidelines driving biohazard risk assessments:

- OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030
- The CDC/NIH Booklet *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 6th Edition, June 2020



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Why do it and document it?

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CDC/NIH Booklet *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition 2020

NYS DOH CLEP Safety Standards 2021

- Consistent with BMBL

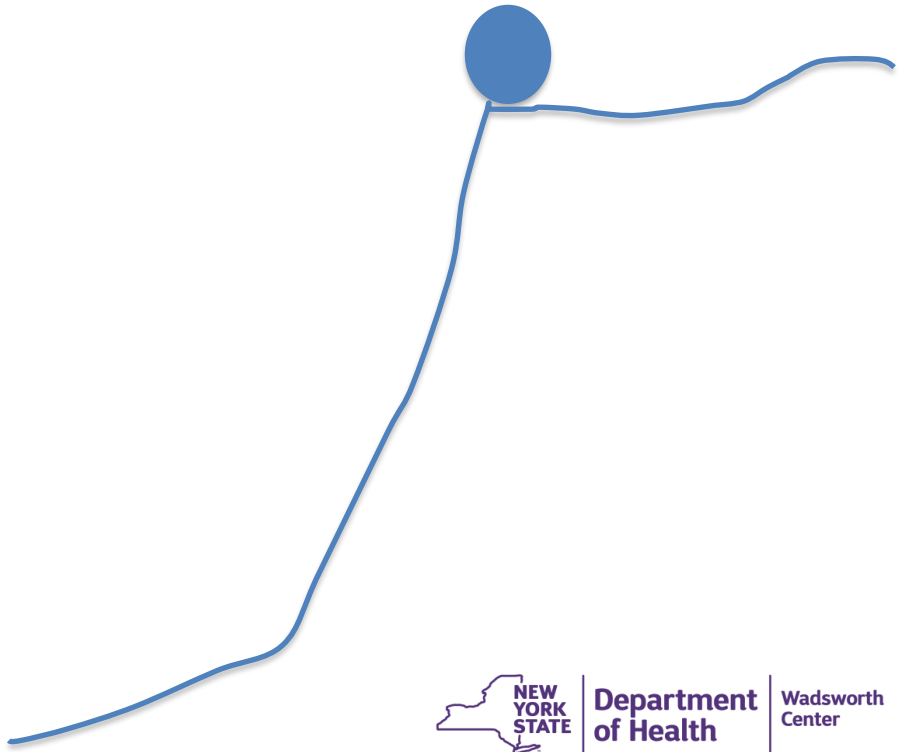
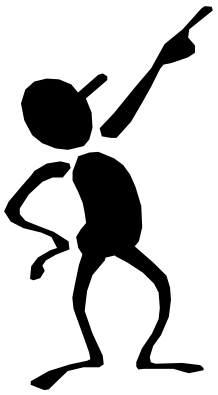
42 CFR Part 73 Select Agents and Toxins.



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Risk Assessment



5 Steps of Biosafety Risk Assessment and Management

Risk Assessment

1. Perform comprehensive hazard evaluation and determine initial biosafety level (BSL).
2. Identify laboratory procedure hazards
 - Determine risk
 - Determine acceptability of risk

Risk Management

3. Determine final containment (BSL) with any additional safety enhancements
4. Evaluate staff proficiency and safety equipment integrity
5. Review with knowledgeable individuals

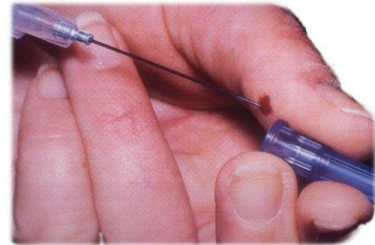
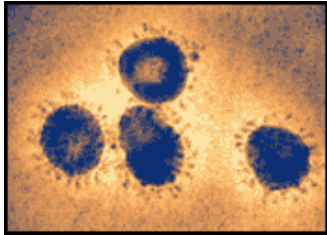


Biosafety Risk Assessment

Agent Hazards

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Lab Procedure Hazards



Agent Hazards

What are the principle hazardous characteristics of an agent?

- Its capability to infect and cause disease
- The severity of the disease
- Availability of preventative measures and treatments for the disease
- Route of transmission
 - Transmission via aerosol is most serious hazard.
 - Infective dose and agent stability key factors.
- History of laboratory-acquired infection (LAI)



Determine the proper risk group

Risk Group 1:

- Agents are not associated with disease in healthy human adults.

Risk Group 2:

- Agents associated with human diseases that are rarely serious. Effective preventive or treatment options are often available.

Risk Group 3:

- Agents are associated with serious or potentially lethal diseases for which effective preventive or treatment options may be available.

Risk Group 4:

- Agents are likely to cause serious or lethal disease. Effective preventive or treatment options are not usually available.



Section VIII Agent Summary Statements

Good Source of Info:

- Agent
- Occupational Infections
- Natural Modes of Infection
- Laboratory Safety
- Containment Recommendations
- Special Issues
 - Vaccines
 - Select Agent
 - Transfer of Agent
 - Post Exposure Treatment



Pathogen Safety Data Sheets (PSDS)

- Formerly Material Safety Data Sheets for infectious substances
- Produced by Public Health Agency of Canada



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Agent Hazards

What about clinical specimens with unknown risks?

- Past experience
 - Have you seen high risk agents in your lab?
- Medical data on patient if available
- Geographic origin of specimen
- Ad hoc guidelines during outbreaks
 - For example: West Nile Virus, SARS-CoV



Lab Procedure Hazards

- Assess specific tasks within each method or procedure.
- Consider all sources and routes of exposure:
 - Manipulations that produce droplets and aerosols
 - Pipetting, blender, centrifuges without primary containment, sonicators, and vortex mixers
- Manipulations involving sharps
- Manipulations with high potential for spills and splashes
- New/emerging technologies



Lab Procedure Hazards

Assess automated systems and other emerging technology for exposure risks.



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Lab Procedure Hazards

Important to define what constitutes and “exposure incident” or “occupational exposure” in advance of incidents.

Exposure incident (OSHA BBP): “means a specific eye, mouth, or other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM...”

Occupational exposure (CDC/APHIS Select Agent Regulations): “Any event that results in any person...not being appropriately protected in the presence of an agent or toxin...”



Managing Risks

OSHA Bloodborne Pathogen Standard

- Shall establish a written Exposure Control Plan

CDC/NIH BMBL

- A lab-specific biosafety manual must be prepared and adopted as policy
- Four recommended laboratory practices
 - Biosafety levels 1-4

NYS DOH CLEP Standards

- LS S1-The laboratory director, or individual delegated in writing by the director, must review and approve all new and revised safety standard operating procedures and/or policies before implementation.
- LS S7-determination of the appropriate biosafety level and any additional or enhanced precautions needed as indicated by the risk assessment for each section and areas of the laboratory processing biohazardous agents or specimens





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Thank you!

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