

A complex network diagram with nodes of various sizes and colors (dark green, light green, blue) connected by thin lines. The nodes are scattered across the frame, with some larger nodes acting as hubs. The background has a light green gradient.

2023 Cambridge Biosafety Forum

RISK ASSESSMENT ON AN IBC

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WHAT and WHY – answered in the “LAY Description Section”

Example....

WHAT: This is the study of XYZ pathway in: {ex: brain cancer, bacteria, cells}

WHY: If there is no explanation – just ask.

It could be:

It may lead to a better understanding of the role of XYZ in immune system, or neural pathways, or....whatever...

Questions on an IBC Registration form

The Safety Precautions are listed, and the person in charge has signed the registration the IBC reviews.

Name _____

Signature _____

Date _____



Biosafety Levels –Work Practices, Special Practices, Facility requirements

Recombinant work: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf Practices for labs at BL 1-4; animal facilities 1-4, greenhouses, insectaries, large-scale culture.

Also: Risk Groups for Infectious Agents.

CDC-NIH Biosafety in Microbiological and Biomedical Laboratories, 6th edition.
Comprehensive guidance on every aspect of biosafety.

<https://www.cdc.gov/labs/BMBL.html>

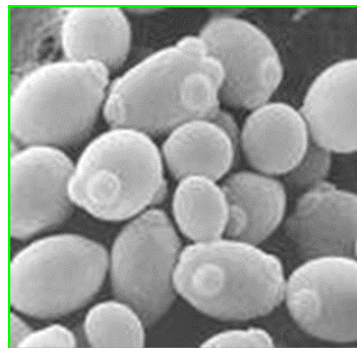
Biosafety Levels BSL1- BSL4.

Agent Summary Statements - describe laboratory acquired infections.

Examples of research materials used at:

BSL1

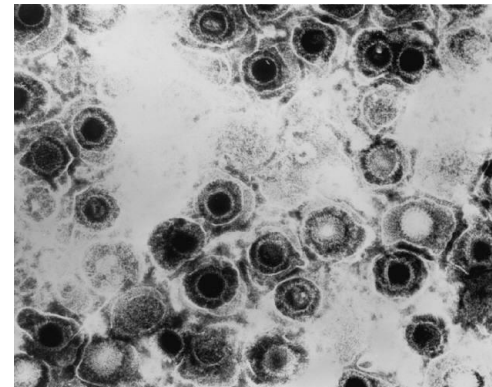
- Expression of proteins in E. coli K12 or **non-pathogenic** strains of yeast
- Work with **uninfected** mice, cell lines of non-human or non-monkey origin
- Work with **fixed** material



BSL2

Human samples, primary cultures

- blood, **unfixed tissue**, body fluids, etc.
- Cell lines of human or monkey origin
- Experiments using **viral vectors** that infect human cells
- Certain BSL2 **pathogens** (e.g. Herpes simplex 1)



RISK Management in 6 Steps

CDC: BMBL
6th
pp.10-19.

- 1. Identify the Hazard, and how it is transmitted.
- 2. Identify the Laboratory Procedure Hazards
- 3. Determine the appropriate Biosafety Level and Additional Special Precautions.
- 4. Risk assessment review with biosafety, a subject matter expert, and IBC.
- 5. Evaluate proficiency re: safety practices and integrity of safety equipment.
- 6. Revisit the risk assessment; revise as necessary.

Step 1. Identify the Hazard

Microorganisms

“Inherent Risk”

- Infectivity – capability of infecting a susceptible host
- Virulence – severity of disease
- Unique features may be present in the organism to be studied: attenuation or gene deletion, for example, could decrease the risk.

Classification of Infectious Microorganisms by Risk Group

Risk Group Classification	NIH Guidelines for Research involving Recombinant DNA Molecules 2002²
Risk Group 1	Agents not associated with disease in healthy adult humans.
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available.
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).
Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).

Sources of Information about Laboratory Acquired Infections

CDC BMBL, 6th edition. Agent Summary Statements

<https://www.cdc.gov/labs/BMBL.html>

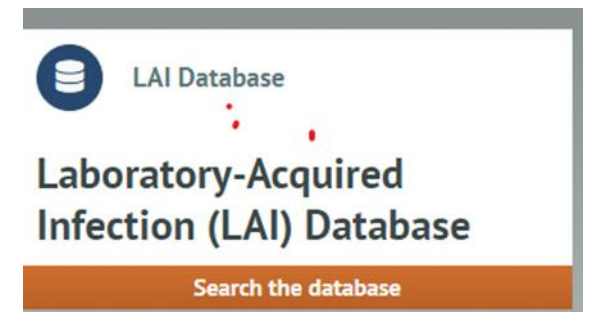
Canadian Pathogen Safety Data sheets

<https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html>



www.absa.org

Open to public



ROUTES OF TRANSMISSION FOR LABORATORY-ACQUIRED INFECTION


20%

- Parenteral: syringe needles or other contaminated sharps
- Mucocutaneous: Spills and splashes onto skin and mucous membranes
- Ingestion or exposure through mouth
- Pipetting or touching mouth or eyes

• 80%

- AEROSOLS AND
- DROPLETS
- DIRECTLY OR BY HAND CONTAMINATION

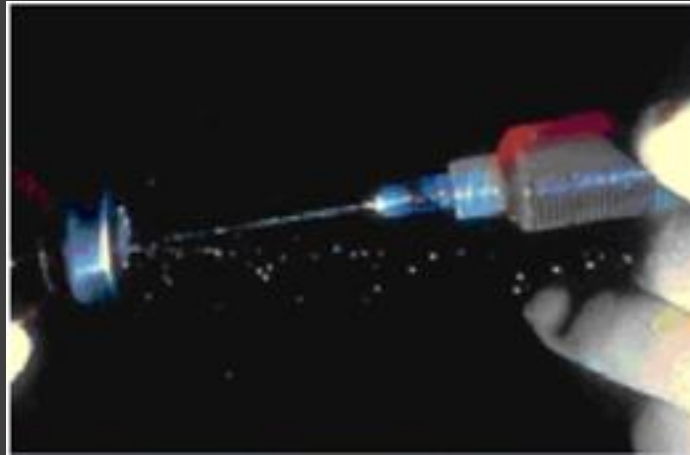
MMWR Supplement Vol. 61(01):1-101



STEP 2: Laboratory
Procedure Hazards

STEP 3: Biosafety Level
Assignment to minimize
biorisk





Lab Activities that can
generate droplets or
aerosols



Move to
biosafety
cabinet

ENGINEERING CONTROLS



Disinfectant
Appropriate for
Biological agent
Used

Centrifuging at BSL2,3,4



- Safety cups and/or O-rings on rotor lids required
 - Spill clean-up is safer, easier since broken tube stays in bucket.
 - Aerosols contained.
 - Check with centrifuge vendor for appropriate cat#.
- containment covers required for plate centrifugation

Sharps Precautions

Required
Biosafety Level

1-4.

Use substitutions or safety-engineered products as feasible.

Needles & Sharps Precautions

- Use sharps containers
- DON'T break, bend, re-sheath or reuse syringes or needles



- Use Safety Scalpels with safety covers or retractable blades



Required BSL1-3.

Handwashing
supplies



Minimize use of glass
as feasible

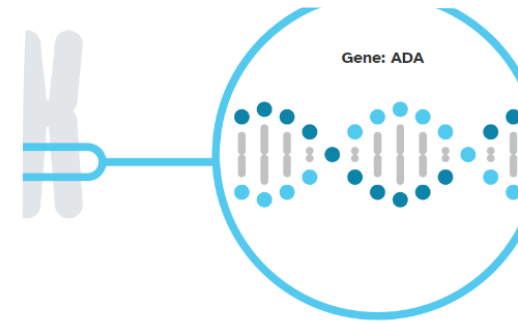
Risk Reduction: Disinfection of work surfaces, spills.

Inactivating chemicals

Appendix K BMBL, 6th ed.

- EPA registered disinfectant labels list required concentration, contact time required to achieve product claims as bactericidal, virucidal, etc.
- Descending order of Resistance:
 - Prions
 - Bacterial spores
 - Mycobacteria
 - Non-enveloped small viruses: polio, coxsackievirus
 - Fungi
 - Vegetative bacteria
 - Enveloped or Medium-sized viruses
 - Herpes simplex, CMV, RSV, HBV,
 - HCV, Hantavirus, Ebola.

Chaotropic Chemicals and Oxidizing Agents required for sample analysis also inactivate infectious potential of sample.



PACKAGING BIOLOGICAL WASTE FOR OFF-SITE DECONTAMINATION

MA 105 CMR

**480.000: MINIMUM
REQUIREMENTS FOR
THE MANAGEMENT
OF
MEDICAL OR
BIOLOGICAL WASTE
(STATE SANITARY
CODE CHAPTER VIII)**



IBC reviews plans annually

AUTOCLAVING BIOLOGICAL WASTE PRIOR TO REMOVAL



AUTOCLAVING BL2+ WASTE

NOTE:

- To load / unload the autoclave, full PPE protection is required. Change heat insulating gloves must be worn.
- Radioactive waste requires special measures. Contact Aidsen if you are unfamiliar with radioactive waste procedures.

LOADING THE AUTOCLAVE:

- Close the bags loosely with autoclave tape.
- Use at least one chemical indicator per autoclave run.
- Press the "Open Door" button.
- Load waste - place solid waste into autoclave pass. Place liquid waste into pails.
- ***REMEMBER TO LOOSEN THE CAPS OF LIQUID CONTAINERS*****
- Press the "Close Door" button.
- Record run details in the Autoclave Log Book.

NOTE: Anything blocking the door as it closes will cause the autoclave to go into alarm. Press "Clear Alarm" to reset the alarm, followed by "Close Door".

SELECTING THE CYCLE:

- Choose "Select Cycle" scroll down to either "Gravity" for solid waste, or "Liquid" for liquid waste, and press "Enter". It is important to choose "Enter" and not "OK".
- Make sure that the program that you want to run is loaded correctly, and press "Start".

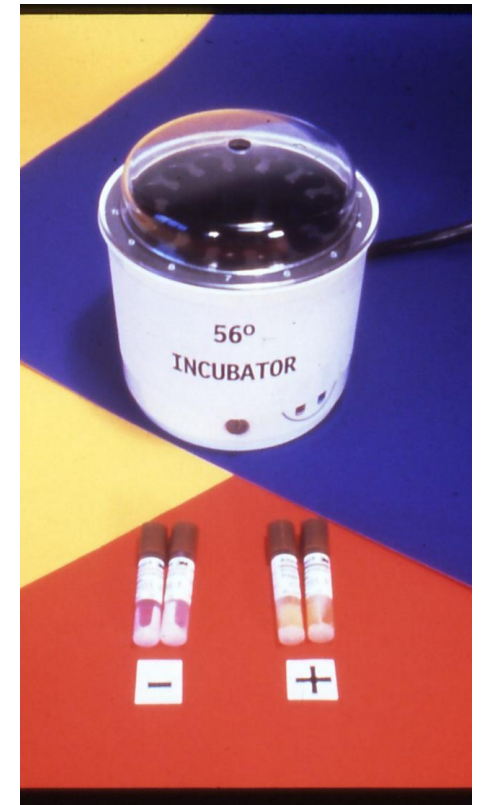
NOTE: Make sure that you choose "Enter" and not "OK" when selecting the program. If you press "OK" the autoclave will default to the previously run program.

*****THIS IS ESPECIALLY IMPORTANT IF YOU ARE RUNNING A DOPED CYCLE*****

INTERPRETING THE CHEMICAL INDICATOR:

- A successful run is indicated when the colored line has moved anywhere into the "ACCEPT" area.
- If the color indicator fails to reach the "ACCEPT" area, the run has failed. Leave waste in autoclave, place a sign on door indicating a failed run, and contact Aidsen immediately.

ACCEPT **REJECT**

A blue autoclave with a control panel and a log book. The control panel has a display and several buttons. The log book is open and shows a list of runs.

5. Evaluate proficiency re: safety practices and integrity of safety equipment

Training records: annual safety training

technical training on equipment

Biosafety cabinet: tested for compliance with NSF49 annually.

Eyewash testing: weekly

Routine service on ultracentrifuges, cell sorters, etc.

Minimize
exposure risk
with training –
enhance
awareness of
personal safety
and safety of
support staff



Immunocompromised staff may be at greater risk

Pregnant staff.

Staff on certain medications – for example, chemotherapy, steroids or TNF blockers (e.g. Humira).

Staff with other medical conditions.

QUESTIONS?
Contact Occupational Health

6. Revisit as Necessary

IBCs have a strong role in building the safety culture

2
2

Reporting- must be routine, fact-based, and non-punitive.

“near-misses” are important.

Fostered by “no fault” reporting.

Response - developed in advance.