International
BIOLOGICAL THREAT REDUCTION

Biological Risks and Risk Management – An Introduction to Laboratory Biosafety and Biosecurity

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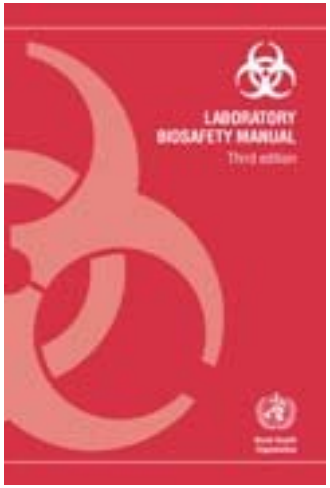
Guidance and Regulations for Bioscience Laboratories

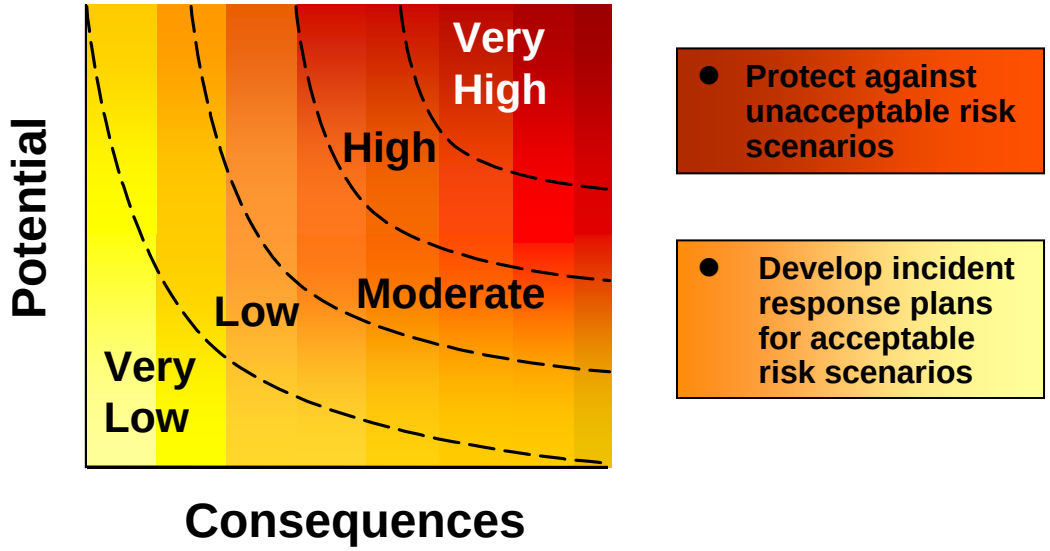
- **Performance-based vs. prescriptive**
  - **A performance approach generally defines what result is intended, leaving how to achieve the result up to the user.**
  - **Prescriptive approaches outline specific requirements that must be done.**

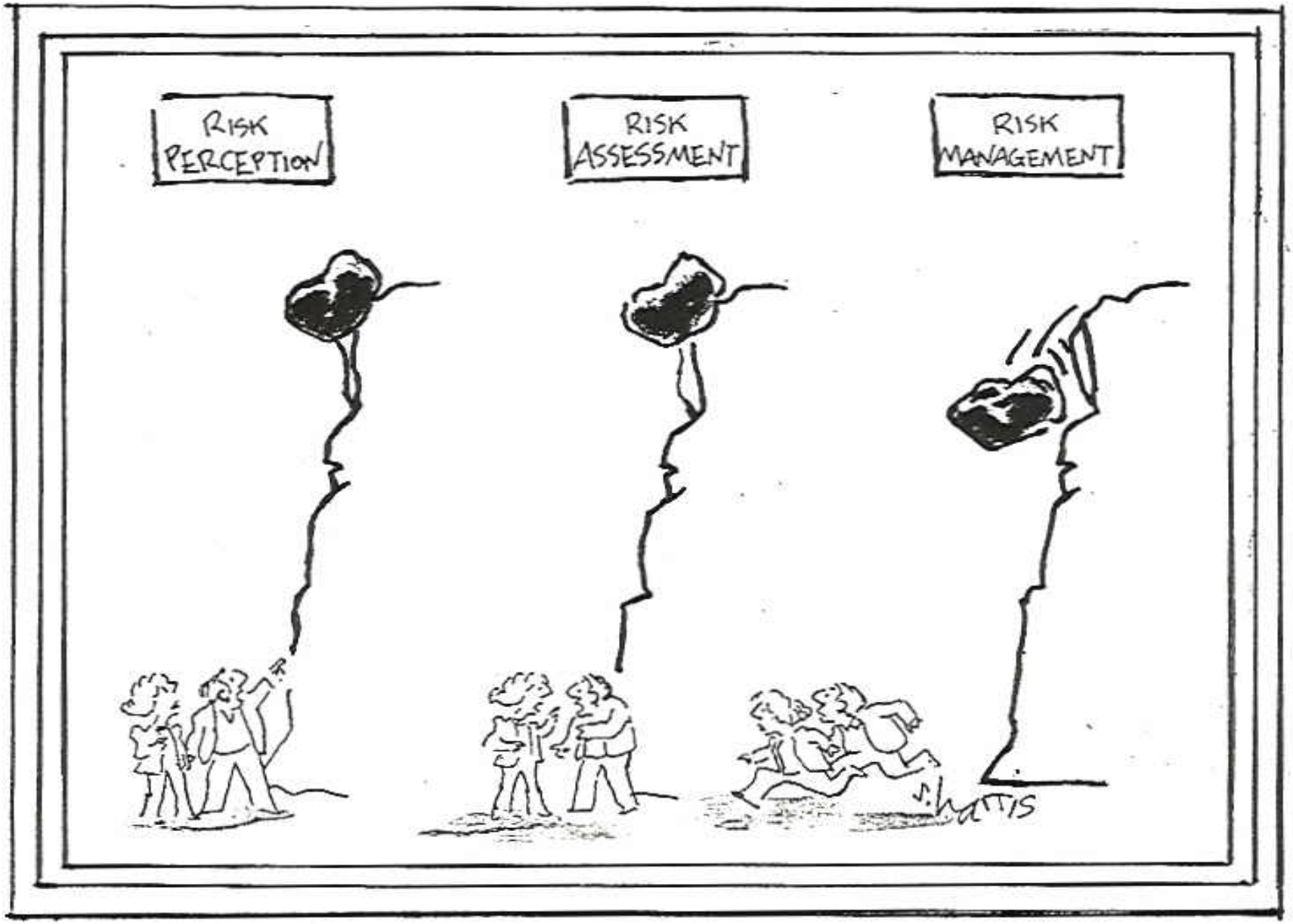
- **WHO *Laboratory Biosafety Manual* – 3rd edition**
- **WHO *Biorisk management: Laboratory biosecurity guidance, September 2006***



Bio Risk Management

- Is a function of the likelihood an adverse event will occur and its potential consequences
- Work with pathogens will always involve some level of safety and security risk
- Resources for risk mitigation are not infinite
  - Existing resources should be used efficiently
  - Cannot protect against every conceivable adverse event
- Most biological materials occur in nature and can be isolated from nature
- Critical not to compromise legitimate operations
- Management must distinguish between “acceptable” and “unacceptable” risks




RISK PERCEPTION
RISK ASSESSMENT
RISK MANAGEMENT

Risk Perception in Laboratories

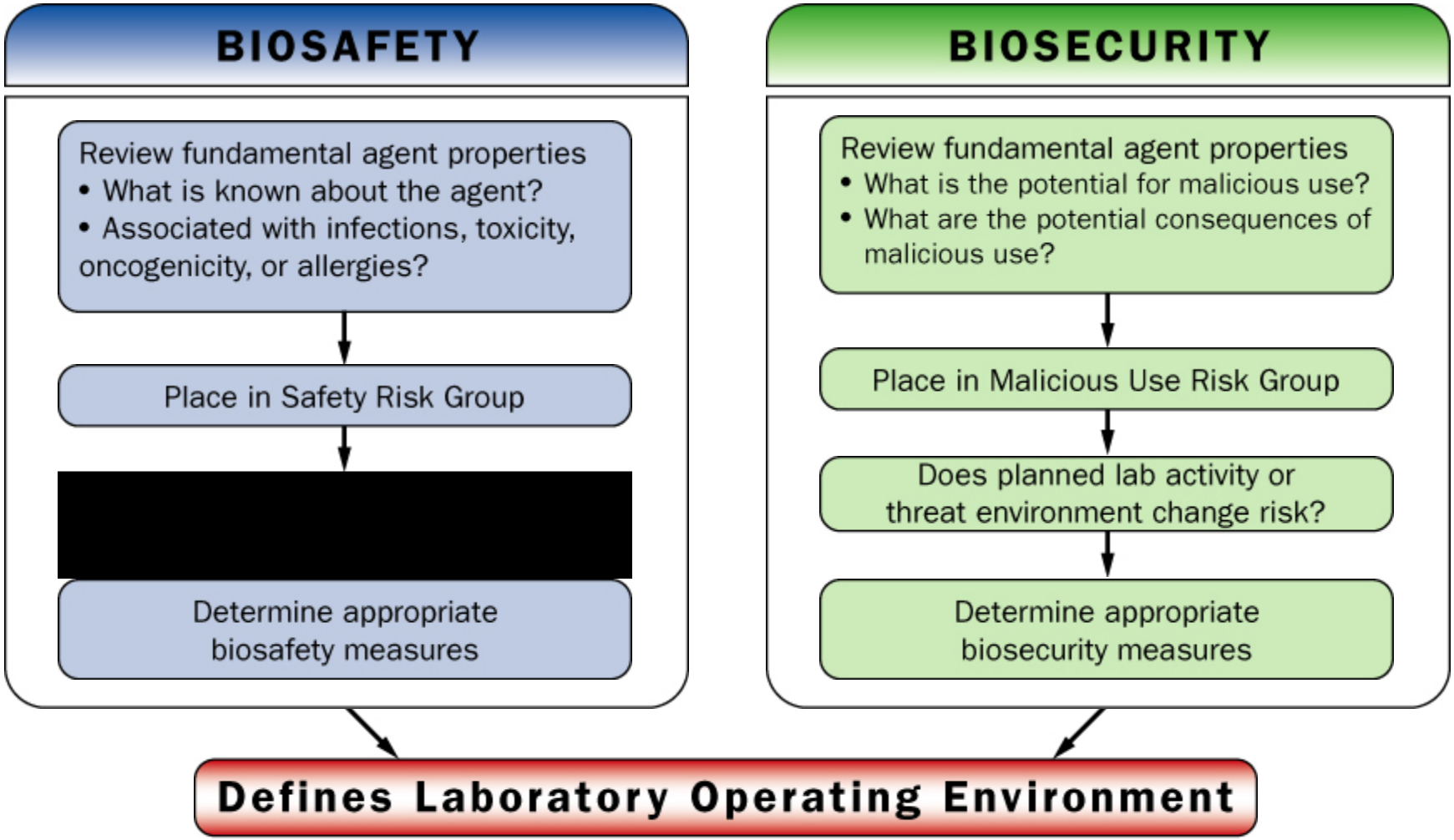
Biosafety risks: laboratory-acquired infections

- History of lab-acquired infections
  - Often attributed to carelessness or poor technique
  - Relatively few cases can be attributed to direct accident (mouth pipetting and sharps injuries)
  - Exposure to airborne pathogens generally presumed to be most plausible cause
  - Brucellosis is most common
- Sporadic infections in community as a result
  - 1973 and 1978—England had 3 secondary cases of smallpox
  - 1950—2 cases of Q fever in household of scientist
  - 1990—1 documented case of Monkey B virus from animal handler to wife
  - SARS—including 3 generations (9 cases)

Biosecurity risks: laboratories as sources of material for malicious use

- Bioterrorism has emerged as a threat to international security
  - 1984 Rajneeshee religious cult attacks
  - 1990s Aum Shinrikyo attempts
  - 2001 Anthrax attacks in the US
- Examples of illicit acquisition
  - 1990s—Aum Shinrikyo ordered *Clostridium botulinum* from a pharmaceutical company
  - 1995—Larry Wayne Harris, a white-supremacist, ordered 3 vials of *Yersinia pestis* from the ATCC
  - 1995—Laboratory technician Diane Thompson removed *Shigella dysenteriae* Type 2 from hospital's collection and infected co-workers

Risk Assessment: Integrated Biosafety and Biosecurity



Risk Assessment

- **Enables the professional (e.g., biosafety officer, responsible official) to:**
  - **Become familiar with the proposed work activities (procedures, equipment, personnel)**
  - **Be a knowledgeable and credible partner with the investigator to develop a safe and secure environment for the work**

- **Review all activities associated with infectious materials**
  - **Proposed work activities**
  - **Personnel**
  - **Storage**
  - **Transfer and transport**
  - **Destruction**

Biosafety Risk Assessment: Safety Risk Group Evaluation

- **What is known about the agent?**
  - **Pathogenicity – ability to cause disease**
  - **Virulence – degree of pathogenicity**
  - **Host range – restricted or broad, human, animals, plants**
  - **Communicability – are there reports of epidemics? Of laboratory infections?**
  - **Transmission – means (e.g., direct contact, vector borne) and routes (e.g., ingestion, inhalation)**
  - **Environmental stability – e.g., resistance to disinfection**
- **Additional agent factors:**
  - **Toxicity**
  - **Is the agent associated with cancer (e.g., Hepatitis B virus associated with liver cancer)?**
  - **Does the agent or by-products induce allergic reactions (e.g., Penicillin)?**

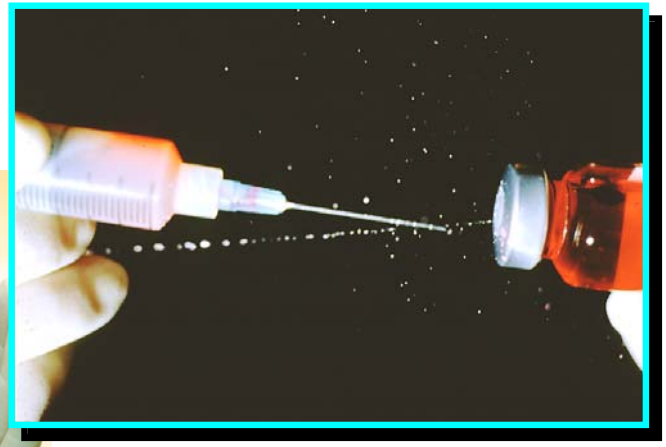
Biosafety Risk Assessment: Safety Risk Groups

WORLD HEALTH ORGANIZATION

- **Risk Group 1**
  - **No or low individual and community risk**
  - **Unlikely to cause human or animal disease**
- **Risk Group 2**
  - **Moderate individual risk, low community risk**
  - **Can cause disease but unlikely to be a serious hazard. Lab exposures may cause serious infection, but effective treatment and preventative measures are available and risk of spread of infection is limited**
- **Risk Group 3**
  - **High individual risk, low community risk**
  - **Usually causes serious human or animal disease but does not ordinarily spread. Effective treatment and preventative measures are available.**
- **Risk Group 4**
  - **High individual and community risk**
  - **Usually causes serious human or animal disease and can be readily transmitted. Effective treatment and preventative measures are not usually available**

Biosafety Risk Assessment: Elements That May Modify Risk

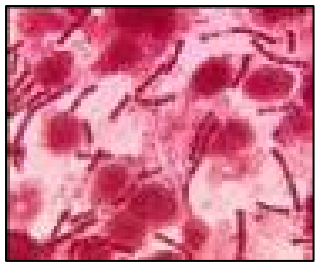
- Does the environment or activity change the risk?
  - Laboratory versus field studies
  - Animal studies?
  - Procedures
    - Do planned experiment have the potential to generate aerosols?
  - Equipment
    - Needles
    - Centrifuges
    - Homogenizers
    - Pipettes



Biosafety Risk Assessment: Elements That May Modify Risk

- **Are their host factors that change the risk?**
  - **Deficiencies in host defenses**
    - **Pre-existing medical conditions – for example:**
      - **Asplenia, eczema**
  - **Reproductive hazards**
    - **Pregnancy, teratogens, mutagens – for example:**
      - **Rubella, *Toxoplasma*, *Chlamydia***
  - **Allergies**
    - **Foreign proteins, vaccine constituents, antimicrobial therapies – for example:**
      - **Animal dander, egg proteins, latex**
  - **Immunization status**
    - **Immunization against workplace pathogens but …**
      - **Not always the answer (vaccine efficacy, safety issues)**
  - **Behavioral elements**
    - **Education, training, experience, motivation, attentiveness**

Biosecurity Risk Assessment



1. **Evaluate assets (agent assessment)**
2. **Evaluate laboratory activity**
3. **Evaluate threat environment**

Biosecurity Risk Assessment: Malicious Use Risk Group Evaluation

- **Assess value of the agents from an adversary's perspective**
  - **Consequences**
    - **Population**
      - Transmissibility
      - Mortality
      - Morbidity
    - **Economic**
    - **Psychological**
  - **Weaponization potential**
    - **Acquisition**
      - Natural
      - Laboratory
      - Synthetic biology
    - **Production**
      - R&D
      - Covert production
      - Ease of storage
    - **Dissemination**
      - Route of infection (e.g., aerosol, ingestion)
      - Environmental hardiness

REPORTS

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*

9 AUGUST 2002 VOL 297 SCIENCE www.sciencemag.org

JOURNAL OF VIROLOGY, Feb. 2001, p. 1205–1210 Vol. 75, No. 3
0022-538X/01/$04.00+0 DOI: 10.1128/JVI.75.3.1205–1210.2001
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Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

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Biosecurity Risk Assessment: Malicious Use Risk Groups

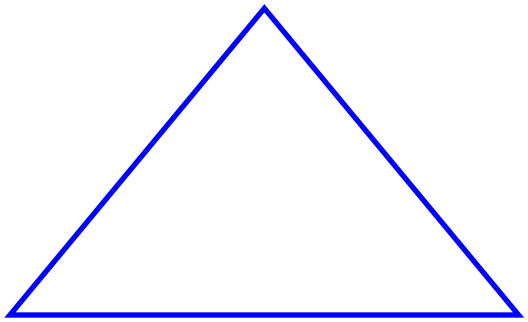
- **Nonpathogenic**
  - Malicious use would have insignificant or no consequences
- **Low**
  - Difficult to deploy, and/or
  - Malicious use would have few consequences
- **Moderate**
  - Relatively difficult to deploy, and
  - Malicious use would have localized consequences with low to moderate casualties and/or economic damage, and potentially cause pervasive anxiety
- **High**
  - Not particularly difficult to deploy, and
  - Malicious use could have national or international consequences, causing moderate to high casualties and/or economic damage, and the potential to cause mass panic and significant social disruption
- **Extreme**
  - Would normally be classified as highly attractive, except that they are not found in nature (eradicated)
  - Could include genetically engineered agents, if they would otherwise be classified as highly attractive

Biosecurity Risk Assessment: Elements That May Modify Risk

- **Adversary Classes**
  - **Terrorist**
  - **Extremist**
  - **Criminal**
- **Insiders**
  - **Authorized access to the facility, dangerous pathogens, and/or restricted information**
  - **Distinguish Insiders by level of authorized access**
    - **Site**
    - **Building**
    - **Asset**
  - **Facility management, site security, and local law enforcement interviews**
- **Outsiders**
  - **No authorized access**
  - **Local law enforcement, site security, and intelligence community interviews**

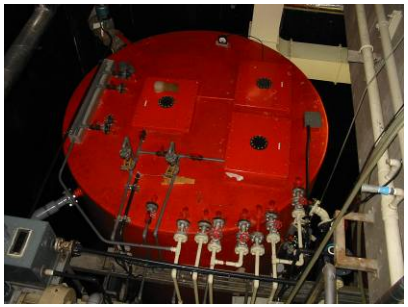
Risk Management: Implementation of Biosafety

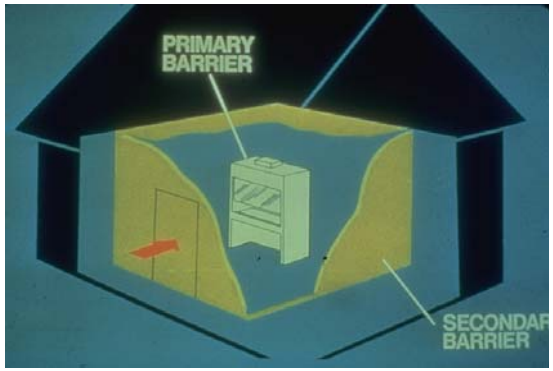
Practices & procedures



Primary barriers

Secondary barriers





Practices & Procedures

- All procedures with live agents and toxins performed inside the biosafety cabinet
- No work with open vessels on open bench
- Use of paper covering on work surface assists clean-up
- Use of appropriate disinfectant in cabinet
- Substitute plastic for glass
- Careful pipetting techniques
- Wash hands often
- No mouth pipetting
- No eating or drinking in lab
- Minimize aerosol generation
- Decontaminate work surfaces
- Safe sharps handling
- Wear applicable PPE

Practices & Procedures: Pipetting

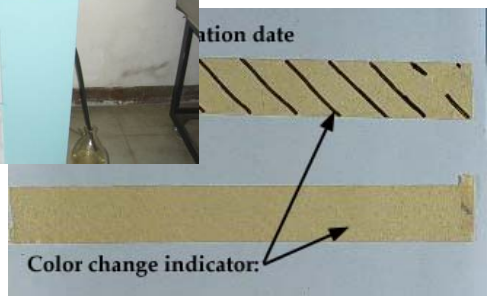
- Use careful pipetting practices
- Avoid drops onto hard surfaces
- Never blow out last drop in pipette
- Use pipetting aids
- Never mix by suction + expulsion
- Discharge liquid down side of container, using tip-to-wall contact
- Deliver as close as possible to contents
- Work over plastic-backed absorbent matting

Practices & Procedures: Sharps

- Sharps includes needles, scalpels, blades and wires, anything that can cut or puncture
- Percutaneous and aerosol exposure risks
  - Employ safe work practices
  - Only use sharps if absolutely required as part of a process
- Utilize safe sharp devices
- Keep hands away from needles
- Never bend, recap or manipulate sharps by hand.
- Dispose of entire unit into sharps container
- Collect reusable sharps in labeled, leak-proof container

Practices & Procedures: Decontamination

- **Effectiveness of decontamination depends on:**
  - **Type and concentration of agent**
  - **Type and concentration of germicide**
  - **Contact time**
  - **Environmental conditions**
- **Surface disinfection**
  - **Examples: Ethanol, Sodium hypochlorite, Lysol, quaternary ammonium compounds**
- **Autoclaves**
  - **Direct exposure of each item to steam at the required <u>temperature</u> and <u>pressure</u> for a specific time**
  - **Properly used autoclaves may be used to sterilize instruments, other media, and biohazard waste**
  - **Require record keeping, validation, verification**
- **Area decontamination**
  - **Formaldehyde vapor**
  - **Vapor phase hydrogen peroxide (VHP)**
  - **Chlorine dioxide**
  - **Requires validation, verification**



Practices & Procedures: Waste Handling

- Types of waste
  - Solid, non-sharp waste
  - Liquids
  - Sharps

- Treatment
  - Intermediate
    - Performed for worker protection, on-site before transport
    - Standard microbiology lab practice
    - Autoclaving most common
  - Final
    - On-site treatment by facility staff
    - Off-site treatment by disposal contractor

Primary Barriers: Personal Protective Equipment (PPE)

- Types of PPE
  - Gloves
  - Gowns, laboratory coats, coveralls, scrubs
  - Goggles, safety glasses with side shields, face shield
  - Booties, closed toe shoes (no sandals)
  - Respirators
- Limitations:
  - Does not eliminate the hazard
  - Integrity wanes with use (change gloves frequently)
  - Not all gloves created equal - select best glove for the task
- Contaminated PPE is NOT laundered off-site – autoclave on-site first
- PPE should not be worn outside of the laboratory
- Staff must be trained in aseptic removal procedures- gloves last
- Respirators use a filter medium to remove contaminant
  - Reduces aerosol exposure
  - N95
  - Powered Air Purifying Respirator (PAPR)
  - Surgical masks are not respirators

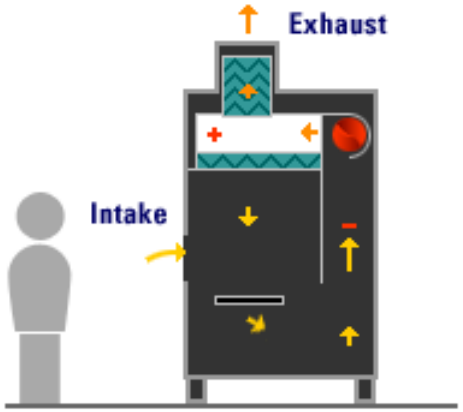
Primary Barriers: Biosafety Cabinets

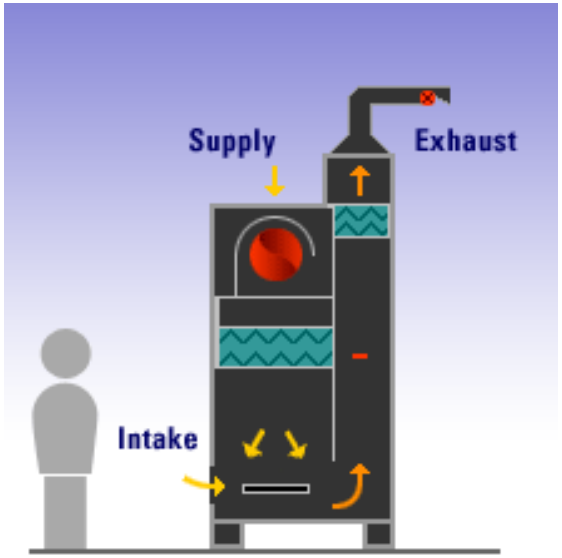
- Primary means of containment
- Designed to provide protection for
  - Personnel
  - Product
  - Environment
- Three design types
  - Class I
  - Class II – Types A1, A2, B1, and B2
  - Class III
- Rely on High Efficiency Particulate Air (HEPA) filters
  - <u>Minimum</u> efficiency of 99.97% removal of 0.3 micron particles
  - HEPA filters do not filter out gases and vapors; they only filter out particulates
- BSCs must be certified prior to initial use, annually, and after any repairs or moving

Primary Barriers: Biosafety Cabinets

- Class I
  - Provides personnel and environmental protection but no product protection
  - Typical applications include: Housing centrifuges, fermenters, cage dumping in an animal lab
- Class II
  - Provides personnel, environmental, and product protection
  - Type A2
    - Exhaust to room or outside through thimble connection
    - 30% recirculated, 70% exhausted
  - Type B2
    - Must be hard ducted to outside
    - Total exhaust (100%)
    - Pro: may be used with volatile chemicals
    - Con: more expensive to operate, harder to balance airflows in lab
- Class III
  - Gas tight, absolute containment enclosure

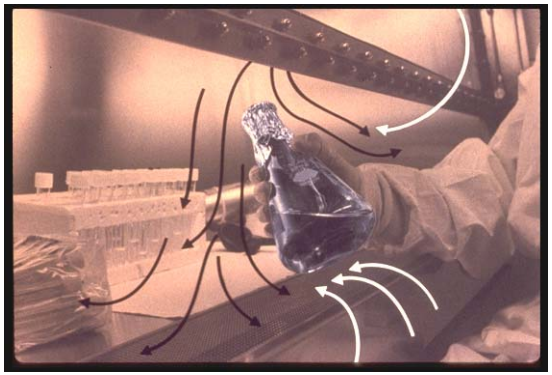
Type A2 Cabinet without canopy

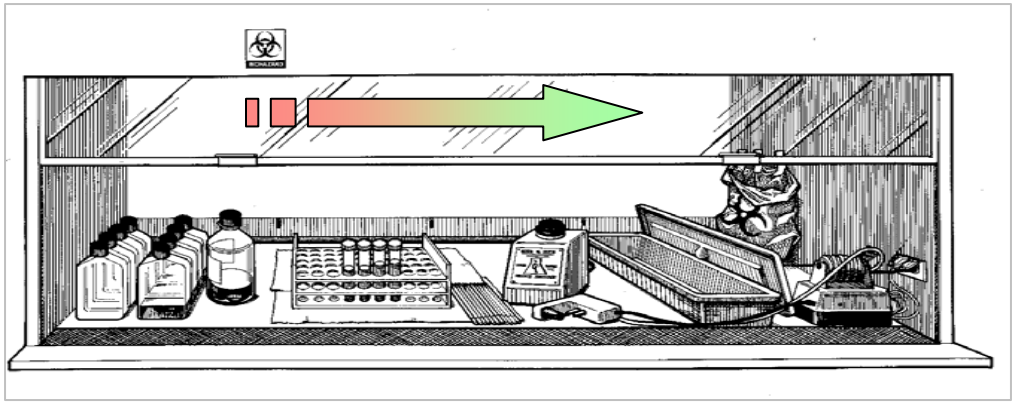




Primary Barriers: Working in Biosafety Cabinets

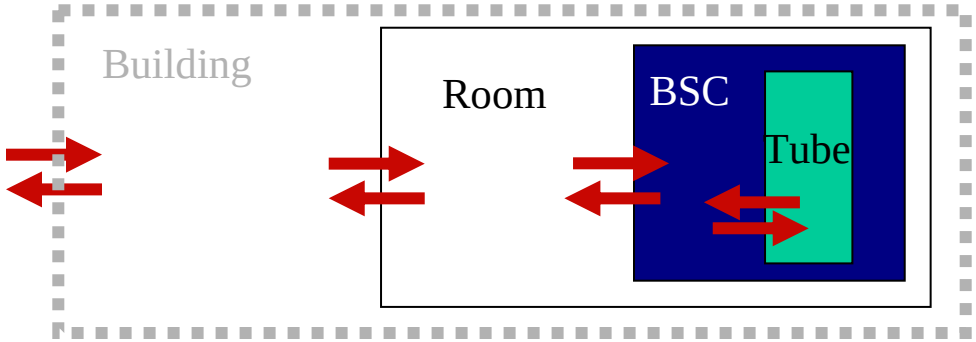
- **Proper technique is critical to maintaining personnel and product protection!**
- **Elements**
  - **Decontamination**
  - **Setup**
  - **Work flow**
  - **Locations of supplies and waste containers**
  - **Movement in and out**
  - **Others**
- **Workflow from clean to contaminated ("dirty")**





Secondary Barriers

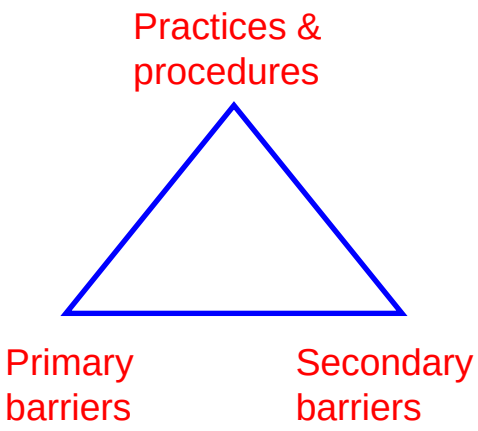
- **Contain the agent within the room or facility *in case an agent escapes from the primary barriers***
  - **Building & Room Construction**
    - **Separated from public areas**
    - **Easily cleaned**
    - **For containment laboratories:**
      - **Room pentrations sealed**
      - **Double-door entry**
  - **HVAC Issues:**
    - **Directional airflow**
    - **Exhaust filtration**
  - **Other Engineering Controls:**
    - **Solid waste treatment**
    - **Wastewater treatment**



Biosafety Levels

- **Biosafety Levels**
  - **Four biosafety levels provide increasing degrees of protection**
  - **What's the right balance of practices & procedures, primary barriers and secondary barriers?**

- **Applications:**
  - **Laboratories (BSL-1, 2, 3, 4)**
  - **(Small) Animal Containment (ABSL-1, 2, 3, 4)**
  - **Large Animal Containment ("BSL-3 AG")**
  - **Plant Containment (BSL-1P, 2P, 3P, 4P)**



Biosafety Levels 1 and 2

- **Biosafety Level 1**
  - **Suitable for work involving well-characterized agents not known to cause disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment.**
  - **Examples:**
    - ***Bacillus subtilis***
    - ***Naegleria gruberi***
    - **Infectious canine hepatitis virus**
    - ***E. coli***
- **Biosafety Level 2**
  - **Suitable for work involving agents of moderate potential hazard to personnel and the environment**
  - **Examples:**
    - **Measles virus**
    - **Salmonellae**
    - ***Toxoplasma* species**
    - **Hepatitis B virus**

Biosafety Levels 3 and 4

- **Biosafety Level 3**
  - **Suitable for work with infectious agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.**
  - **Examples:**
    - ***Mycobacterium tuberculosis***
    - **St. Louis encephalitis virus**
    - ***Coxiella burnetii***
- **Biosafety Level 4**
  - **Suitable for work with dangerous and exotic agents that pose a high individual risk of aerosol transmitted laboratory infections and life-threatening disease.**
  - **Examples:**
    - **Ebola Zaire virus**
    - **Rift Valley Fever virus**

Summary of Biosafety Level Requirements

Table 3. ***Summary of biosafety level requirements***

	BIOSAFETY LEVEL			
	1	**2**	**3**	**4**
Isolation[a] of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
— inward airflow	No	Desirable	Yes	Yes
— controlled ventilating system	No	Desirable	Yes	Yes
— HEPA-filtered air exhaust	No	No	Yes/No[b]	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	—
Anteroom with shower	No	No	Yes/No[c]	No
Effluent treatment	No	No	Yes/No[c]	Yes
Autoclave:				
— on site	No	Desirable	Yes	Yes
— in laboratory room	No	No	Desirable	Yes
— double-ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability[d]	No	No	Desirable	Yes

[a] Environmental and functional isolation from general traffic.
[b] Dependent on location of exhaust (see Chapter 4).
[c] Dependent on agent(s) used in the laboratory.
[d] For example, window, closed-circuit television, two-way communication.

From: WHO LBM 3rd edition

Biosafety Levels, Practices, and Equipment

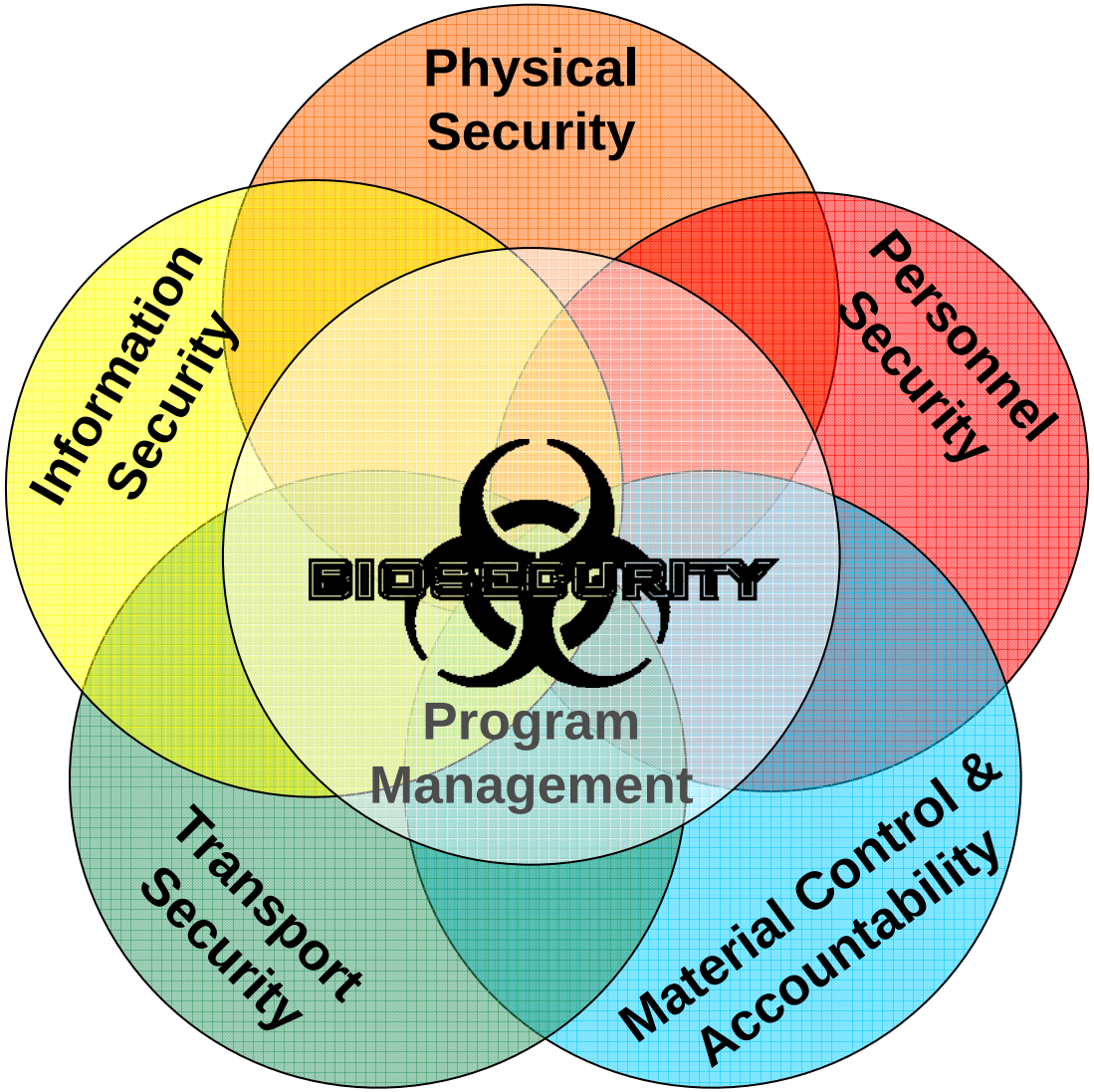
Table 2. ***Relation of risk groups to biosafety levels, practices and equipment***

RISK GROUP	BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
1	Basic – Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Basic – Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	Containment – Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum containment – Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall), filtered air

BSC, biological safety cabinet; GMT, good microbiological techniques (see Part IV of this manual)

From: WHO LBM 3rd edition

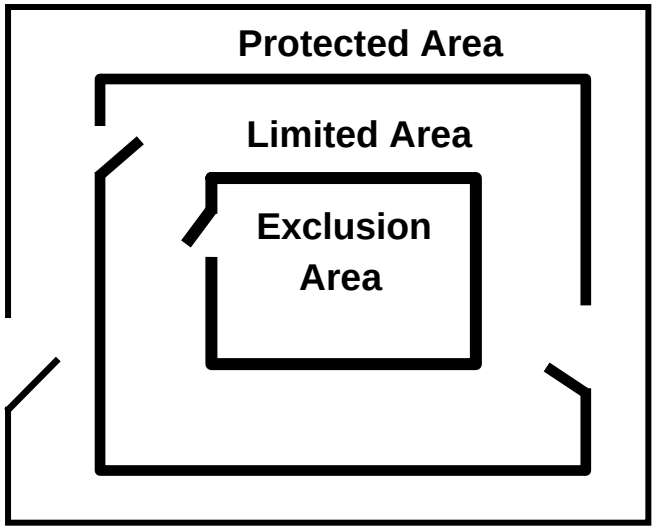
Risk Management: Implementation of Biosecurity



Physical Security

- **Aims to limit access to authorized individuals**

- **Moderate**
  - **Store and use pathogens (and infected animals) within Limited Areas**
  - **Restrict access using controlled keys and secured windows**
  - **Control visitors**



- **High**
  - **Store and use pathogens (and infected animals) within Exclusion Areas**
  - **Electronic Intrusion Detection System and/or guards**
  - **Controlled and authenticated key**
    - **Something you *have* (key) plus something you *know* (PIN)**
  - **Restrict and control visitors**
  - **Maintain records of entry/exit**

Personnel Security

- **Determines who should be authorized to have access**

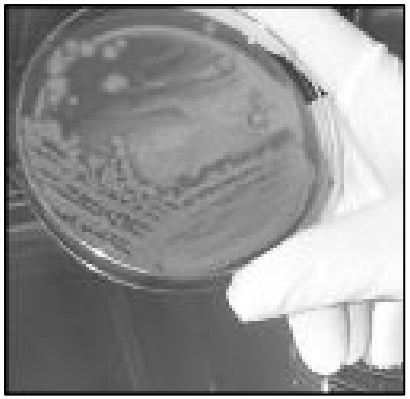
- **Moderate**
  - **Background investigation**
    - **Criminal history**
    - **Verifiable compliance with rules and regulations**
  - **Drug test**

- **High**
  - **Moderate plus**
    - **Personal and associate interviews**
    - **Credit history**
    - **Terrorist/extremist/criminal affiliation**
    - **Periodically reinvestigate**

Material Control & Accountability

- Determine what materials exist, where they are, and who is responsible for those materials

- Moderate
  - Seed stocks cataloged and records stored securely
    - Transfers in and out
    - Source
    - Strain
    - Form
    - Responsible individual
  - Working stocks, including infected animal status, tracked through laboratory notebooks



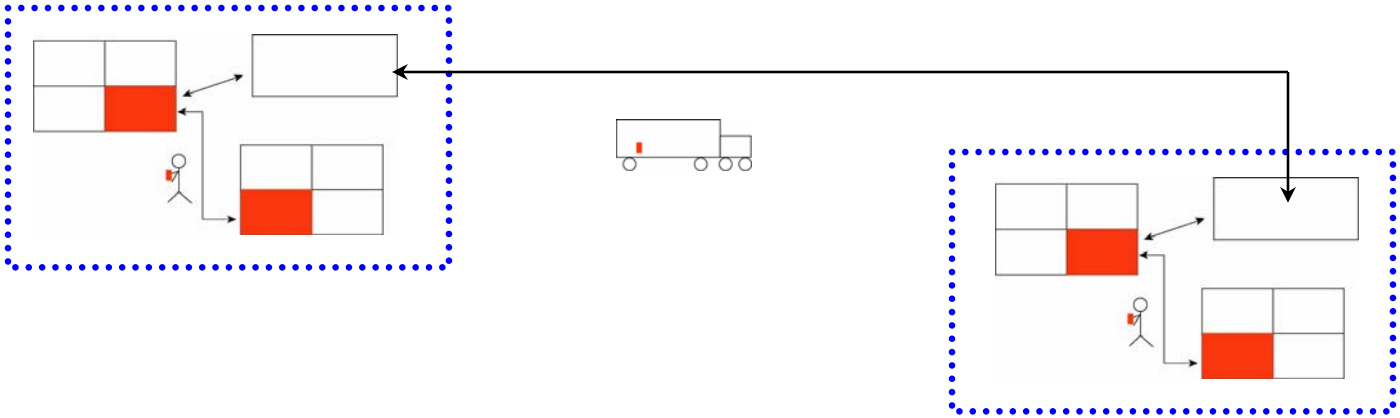
- High
  - Moderate plus
    - Increased control over working stocks
    - Increased verification over destruction

Transport Security

- **Aims to deter theft while materials are outside of laboratories by implementing measures during the transport process**

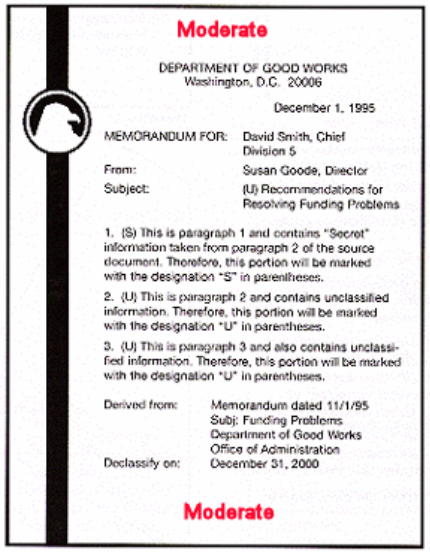
- **Moderate**
  - **Internal transport personnel screened**
  - **Recipient screened for legitimacy**
  - **Safe receipt notification**

- **High**
  - **Moderate plus**
    - **Chain of custody**
    - **Physical controls on storage containers**



Information Security

- Measures to protect information that is too sensitive for public distribution
- Examples include:
  - Risk assessments
  - Access authorizations
  - Security plans
- Identification
  - A review & approval process
- Control
  - Storage
  - Communication security
    - Phone, fax, email
  - Network security
    - User authentication, firewalls, virus protection, layered network access, wireless access
- Marking



Moderate

DEPARTMENT OF GOOD WORKS
Washington, D.C. 20006

December 1, 1995

MEMORANDUM FOR: David Smith, Chief
Division 5

From: Susan Goode, Director

Subject: (U) Recommendations for Resolving Funding Problems

1. (S) This is paragraph 1 and contains "Secret" information taken from paragraph 2 of the source document. Therefore, this portion will be marked with the designation "S" in parentheses.

2. (U) This is paragraph 2 and contains unclassified information. Therefore, this portion will be marked with the designation "U" in parentheses.

3. (U) This is paragraph 3 and also contains unclassified information. Therefore, this portion will be marked with the designation "U" in parentheses.

Derived from: Memorandum dated 11/1/95
Subj: Funding Problems
Department of Good Works
Office of Administration

Declassify on: December 31, 2000

Moderate

Program Management

- Establish program objectives
- Communication
- Institutional support
- Allocate resources
- System design
- Determine standards
- Develop manuals and standard operating procedures (SOPs)
- Emergency response planning
- Conduct exercises
- Maintenance
- Medical surveillance
- Conduct training
- Ensure regulatory compliance
- Reviews and audits

Biosecurity and Biosafety Documentation

- **Goals:**
  - **Demonstrate institutional support**
  - **Document chain of command and responsibilities**
  - **Ensure institutional memory**
- **Types:**
  - **Policy statements**
    - **Guide for staff**
    - **Where is institutional oversight? IBC?**
  - **Manuals**
    - **Big picture documents that are the foundation of your program**
    - **Ex: Biosafety, Biosecurity, Animal care, Waste disposal**
  - **Standard Operating Procedures (SOPs)**
    - **Detailed – an experienced person can read SOP and carry out the operations**
    - **Ex: Equipment maintenance, Spill clean up, transport procedures**

Laboratory Biosecurity and Biosafety Manuals

- **Develop laboratory biosecurity plan:**
  - **Facility mission and description**
  - **Outlines risks**
  - **Personnel requirements**
  - **Physical security**
  - **Material control and accountability**
  - **Material transport security**
  - **Information security**
  - **Incident response plans and reporting**
  - **Standard Operating Procedures**
  - **Laboratory practices**
  - **Containment equipment**
  - **Special laboratory design**
  - **Animal care and use**
  - **Medical monitoring**
  - **Biosafety and Biosecurity management**
    - **Biosafety Officer roles and responsibilities**
    - **Responsible Official roles and responsibilities**

Standard Operating Procedures (SOPs)

- **Goal: someone who has experience and is familiar with a process can read it should be able to safely and securely do the work**
  - **Balance between too much detail and not enough**
  - **May be a regulatory document and can be problematic if not followed exactly**
- **Areas to address with SOPs**
  - **BSL 3 operation**
  - **Emergency response, including biological and chemical spill clean up**
  - **Equipment maintenance**
  - **Shipping and receiving infectious materials**
  - **Research-specific**
  - **Agent specific**
  - **Animal handling**

Medical Surveillance

- **"The employing authority, through the laboratory director, is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel.**
- **The objective of such surveillance is to monitor for occupationally acquired diseases.**
- **Appropriate activities to achieve these objectives are:**
  - **Provision of active or passive immunization where indicated**
  - **Facilitation of the early detection of laboratory-acquired infections**
  - **Exclusion of highly susceptible individuals (e.g., pregnant women or immunocompromised individuals) from highly hazardous laboratory work**
  - **Provision of effective personal protective equipment and procedures"**

WHO *Laboratory Biosafety Manual*, 3rd edition

Medical Surveillance for BSL 3

- **"Medical examination of all laboratory personnel who work in containment laboratories – Biosafety Level 3 is mandatory.**
- **This should include recording of a detailed medical history and an occupationally-targeted physical examination.**
- **After a satisfactory clinical assessment, the examinee may be provided with a medical contact card stating that he or she is employed in a facility with a containment laboratory – Biosafety Level 3. This card should include a picture of the card holder, be wallet-sized, and always be carried by the holder. The name(s) of the contact persons to be entered will need to be agreed locally but might include the laboratory director, medical adviser and/or biosafety officer."**

WHO *Laboratory Biosafety Manual*, 3rd edition

Recommended Medical Contact Card (front)

ILLNESS SURVEILLANCE NOTICE

Name _____

_____

Card holder's picture

TO THE EMPLOYEE

Keep this card in your possession. In case of unexplained febrile illness, present the card to your physician and notify one of the following in the order listed.

Dr _____ Tel (Work): _____

_____ Tel (Home): _____

Dr _____ Tel (Work): _____

_____ Tel (Home): _____

Recommended Medical Contact Card (back)

TO THE PHYSICIAN

The holder of this card works in an area at _____ in which pathogenic viruses, rickettsia, bacteria, protozoa or helminths are present. In the event of an unexplained febrile illness, please call the employer for information on agents to which this employee may have been exposed.

Name of laboratory: _____

Address: _____

_____

_____

_____

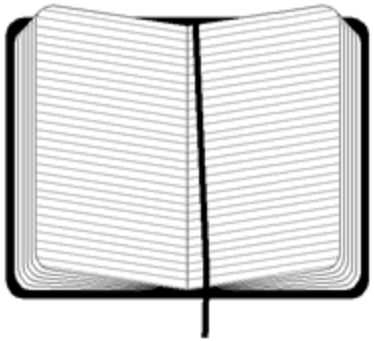
Tel: _____

Occupational Health Program

- Health history, medical clearance
- Respirator clearance
- Screening
- Immunization and testing
- Post-exposure evaluation and response

Training

- Annual training tailored to different audiences
  - New and current employees
  - Managers
  - Emergency responders
  - Guard force
- Topics
  - Applicable manuals, SOPs
  - Statutory requirements
  - Operations and procedures
    - PPE
    - Access control procedures
    - Physical security, personnel security, information security
    - Equipment
    - Spills, general emergency response
    - Appropriate containment
  - Incident reporting
  - Disciplinary actions
  - Media and public requests

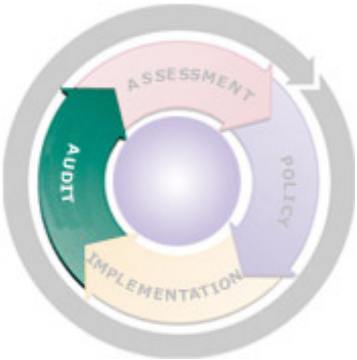


Training

- Task-specific training
  - Critical for biosafety in BSL2 or higher laboratories
  - For example, using biosafety cabinets
- Evaluate effectiveness of training
  - Written evaluations
    - Quizzes and tests
  - Skills evaluations
    - Observations
    - Performance tests with noninfectious substitutes (e.g. water or saline)

Program Evaluations

- Internal and third party
  - Self assessments ensure compliance with standards and evaluate effectiveness of the biosecurity and biosafety programs
    - Regular self-inspections by designated employees (daily/weekly)
    - Supervisor inspections to reinforce employee inspections (weekly/monthly)
  - Management reviews institute corrective and preventive actions, and allocate required resources
    - Inspections by a site team of employees, supervisors, and site management
  - Periodic third party reviews provide an independent assessment

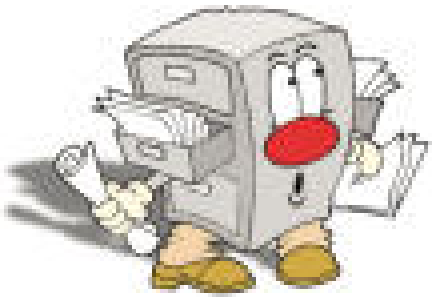


Responding to Inspection / Audit Findings

- Ensure corrective actions are taken to eliminate identified deficiencies
- Assign responsibilities
  - Ensure that a responsible individual is assigned for the identified deficiency or action item
- Implementation schedule
  - Create an implementation schedule with set milestones and follow through to completion
  - Identify a completion date and provide periodic updates against that completion date
- Document completion
  - Document all actions and sign-off when corrective actions are completed

Documentation

- Protocol approvals, registration
  - Signed by investigator, department director, biosafety officer (biosafety coordinator), responsible official (biosecurity coordinator)
- Medical & vaccination records
  - Confidentiality requirements must be addressed
- Policies, Manuals, SOPs
- Training records
  - Document initial training, supervisor training, refresher training
  - Include dates, trainer qualifications, course syllabus, method of evaluation
- Auditing records
  - Include follow up actions
  - Establish a records management system
  - Designate a responsible document control coordinator
  - Define appropriate document retention time
  - Establish procedures for handling sensitive information



Strengthening Biological Risk Management

Vision for Integrated BioRisk Management:

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"

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www.biosecurity.sandia.gov