

國際生物安全管理現況與規範

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9/24/2013

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What is Biosafety?



Sunday, Sep. 20, 2009

Did the Plague Kill Illinois Scientist?

By AP

(AP / CHICAGO) — The University of Chicago Medical Center says the infection that killed a scientist may be connected to bacteria he researched that causes the plague.

The university said Saturday that its researcher studied the genetics of harmful bacteria including *Yersinia pestis*, which causes the illness. He died Sept. 13. His name and age haven't been released

The medical center says the bacteria he worked with was a weakened strain that isn't known to cause illness in healthy adults. The strain was approved by the Centers for Disease Control and Prevention for laboratory studies.

An autopsy found no obvious cause of death but did find the presence of the bacteria. More tests are planned. No other illnesses have been reported.

Definition

Biosafety

The application of combinations of laboratory practice and procedure, laboratory facilities, and safety equipment when working with potentially infectious microorganisms.



Concern for Biosafety

- Ensure that biological research is conducted in a safe fashion.
- Ensure that biological research meets regulatory requirements.
- Ensure all facilities and equipments that are safe enough to operate biological research.
- Surveyed by the Organizational Biological Safety Committee

Examples of Biohazardous Materials

- Recombinant DNA molecules
- Microorganisms containing recombinant DNA molecules
- Microorganisms classified as risk group 2 (RG-2), RG-3, or RG-4
- Biological products derived from RG-2, RG-3, or RG-4 organisms
- Diagnostic specimens known or reasonably expected to contain RG-2, RG-3, or RG-4 organisms.
- Clinical/ medical waste derived from the medical treatment of humans or animals or from biomedical research.

Biosafety in Various Disciplines

Biosafety is related to several fields

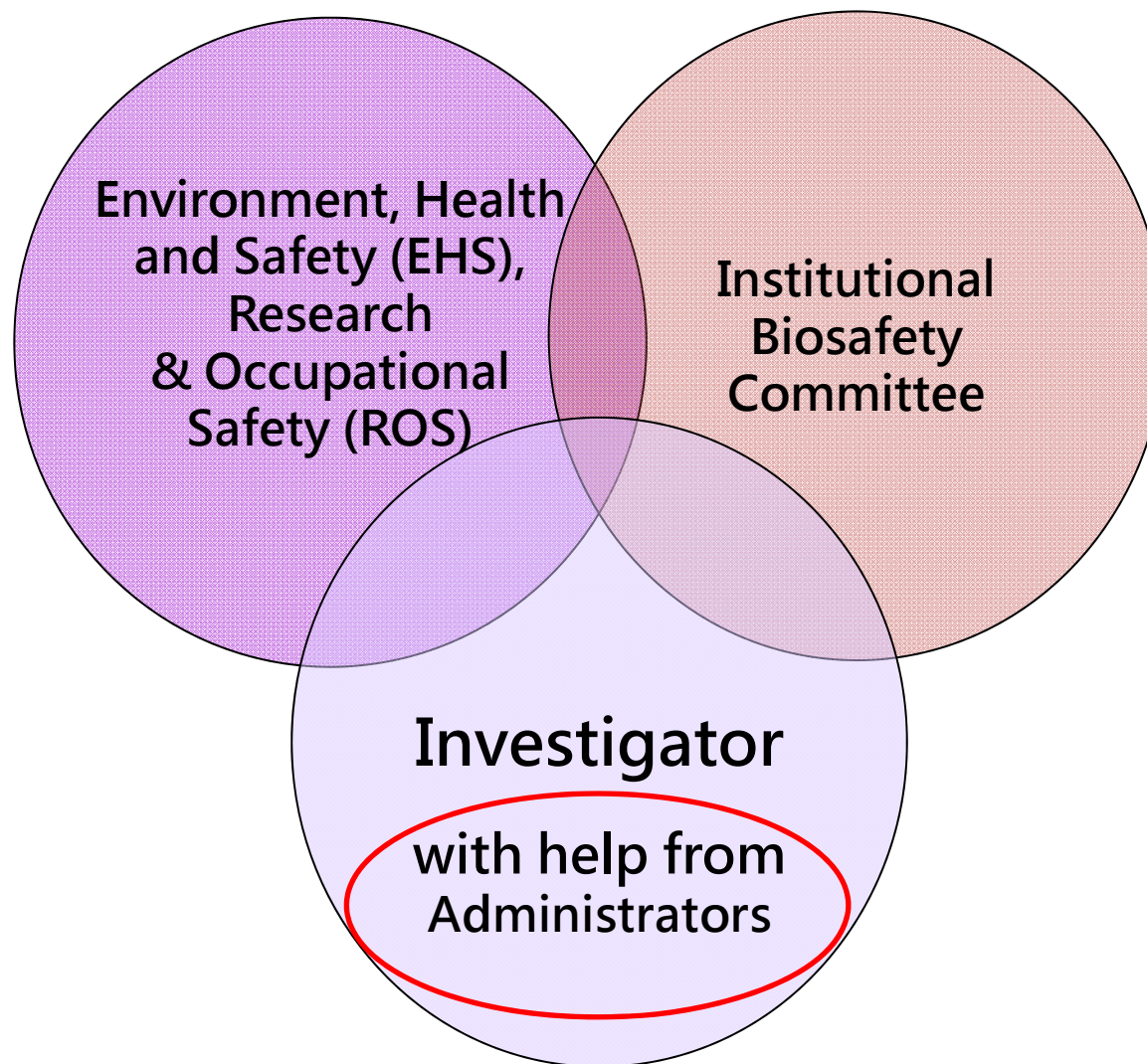
- **ECOLOGY:** referring to imported life forms not indigenous to the region (Reggie the alligator)
- **AGRICULTURE:** reducing the risk of alien viral or transgenic genes, or prions such as BSE/"MadCow "; reducing the risk of food bacterial contamination
- **MEDICINE:** referring to organs or tissues from biological origin, or genetic therapy products, virus; levels of lab containment protocols BSL-1, 2, 3, 4 in rising order of danger
- **CHEMISTRY:** i.e., nitrates in water, PCB levels affecting fertility
- **EXOBIOLOGY:** i.e., NASA's policy for containing alien microbes that may exist on space samples - sometimes called "[biosafety level 5](#)"

Types of Biohazardous Research

- Infectious agents
 - Microorganisms (E. coli → Tuberculosis)
 - Viruses (AAV → HIV)
 - All human source materials (including cell lines)
- Recombinant DNA
 - Transfer DNA/RNA to or from microorganisms or any living cells
 - Transgenic mice
 - Transgenic plants
 - Clinical gene therapy trials
 - Synthetic DNA (PCR, sequencing, etc...)
- Select Agents (high security)
- Laboratory settings
- Live animals
- Clinical trials & Field tests

Oversight of Biohazardous Research

a team approach -



EHS & ROS

- Staffed by biosafety professionals
- Responsible for administering biosafety programs and monitoring compliance with applicable regulations & policies.
- Key Functions:
 - Facility design and approval authority
 - Review research protocols and identify hazards
 - Provide training, consultation, clearances and set OH requirements
 - Site assessments/inspections
 - Biohazard Safety Manual
 - Support IBC

Institutional Biosafety Committee

- Composed of faculty, staff, and community members
- Committee meetings open to public - public trust!
- Key Functions:
 - Review & recommend institutional policies for research involving rDNA and biological agents.
 - Review individual research proposals for compliance with Federal, State, local, and institutional regulations:
 - Biosafety containment levels (BSL1, 2, 3)
 - Adequacy of facilities, SOPs, training
 - Independent approval authority for specific proposals.
 - Monitor and assure compliance with the *Guidelines*

National Authority for IBC

- Institutions h must assure that ALL research is carried out in compliance with the *Guidelines for Research Involving Recombinant DNA & Infectious Agents*.
- Assurance of compliance is accomplished through the Institutional Biosafety Committee (IBC) in collaboration with the Institutional Health and Safety Departments.

Biosafety Standards

Biosafety standards are defined and codified:

- Institution (Administrative Policy, EH&S/ROS, IBC)
- *Guidelines*
- CDC/NIH BMBL *Biosafety in Microbiological and Biomedical Laboratories*
- Department of Agriculture
- Select Agent Rule, 42 CFR Part 73
- Occupational Health & Safety Standards
- Bloodborne Pathogens Standard
- Infectious Waste Management

Biosafety Issues (1/2)

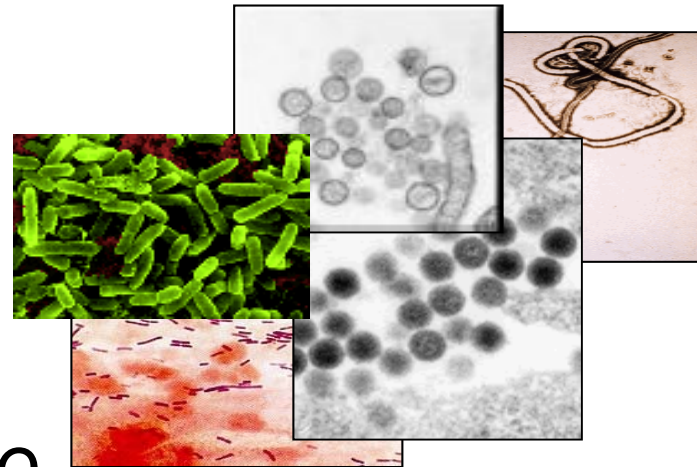
- Laboratory Safety
- Bloodborne pathogens (BBP)
- Recombinant DNA (rDNA)
- Biological waste disposal
- Infectious substance and
diagnostic specimen shipping

Biosafety Issues (2/2)

- Respiratory Protection
- Bioterrorism and Select agents
- Mold and indoor air quality
- Occupational safety and health in the use of research animals
- Biohazards used in animal models

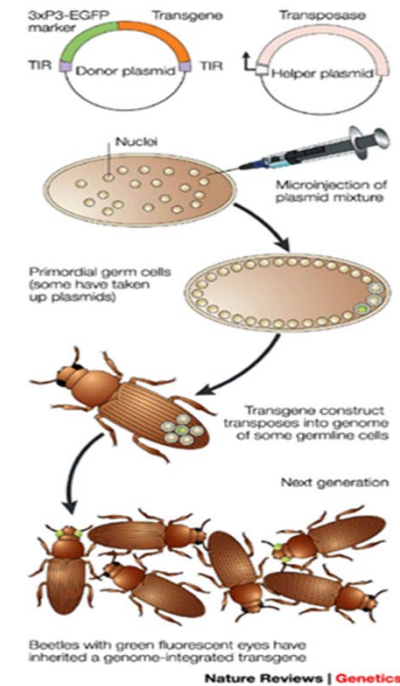
Biohazardous Materials (1/3)

- Viruses
- Bacteria
- Fungi
- Chlamydiae/Rickettsiae
- Prions
- Recombinant DNA



Biohazardous Materials (2/3)

- Transgenic Plants, Animals and Insects



Biohazardous Materials (3/3)

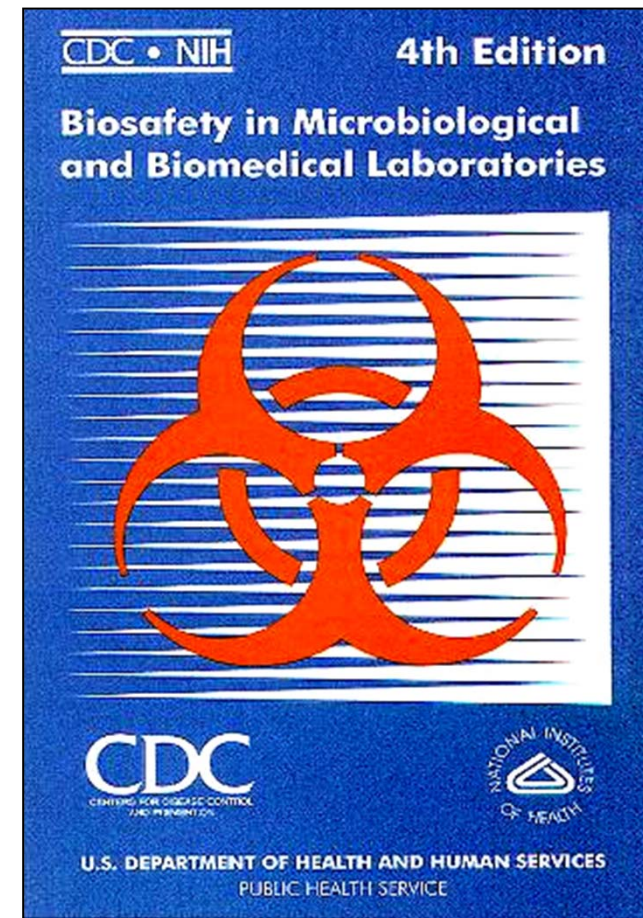
- Human and Primate Cells, Tissues, and Body Fluids
- Brain Tissue from Demented Patients
- Viral Vectors
 - Replication deficient viruses



Biosafety Concepts

Biosafety In Microbiological and Biomedical Laboratories

- "BMBL"
- CDC/NIH Publication
- Safety "Guidelines"
- Regulations of Institution receives NIH funding
 - Code of Practice and "Gold" Standard in Industry and
 - Gold Standard
- Clinical & Research Lab.
- Lab. Animal Facilities

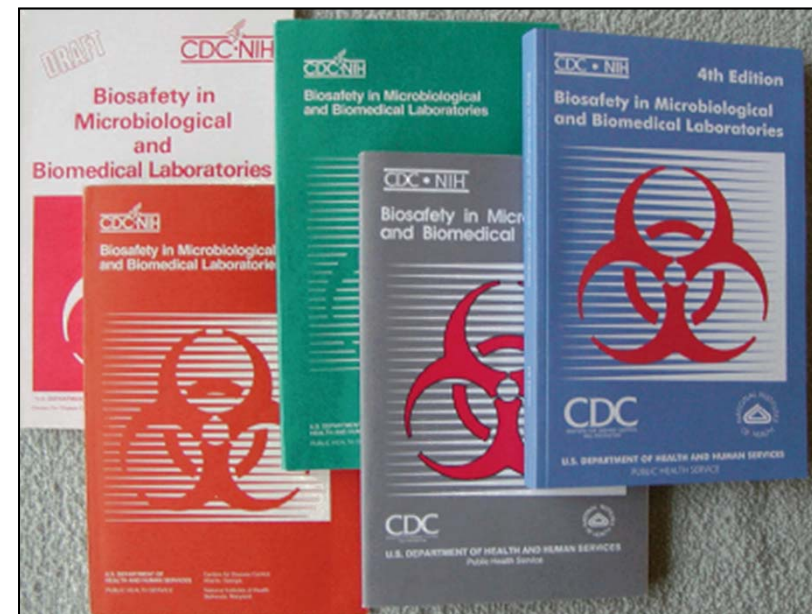


Biosafety Concepts *The BMBL*

The BMBL continues
to be published by
the CDC and the NIH

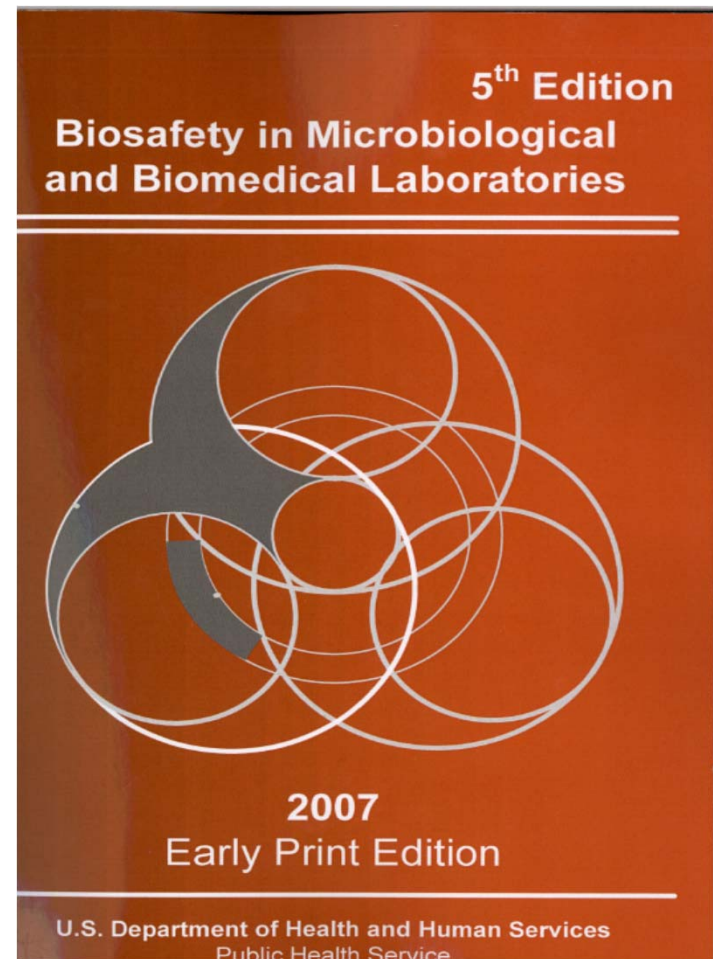
5th edition is now at
the printers

<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>



The New BMBL

- Early print edition....
- Emphasis on “Risk & Containment”



Biosafety Concepts from the BMBL

Principles of Biosafety

- Practice and Procedures
 - Standard Practices
 - Special Practices & Considerations
- Safety Equipment
- Facility Design and Construction
- Increasing levels of protection



Principles of Biosafety

Biosafety Levels 1-4 (BSL)

- Increasing levels of employee and environmental protection
- Guidelines for working safely in research & medical laboratory facilities

Animal Biosafety Levels 1- 4 (ABSL)

- Laboratory animal facilities
- Animal models that support research
- Guidelines for working safely in animal research facilities



Biosafety Concepts

The BMBL

(1) Standard Microbiological Practices

- Most important concept / Strict adherence
- Aware of potential hazard
- Trained & proficient in technique
- Supervisors responsible for:
 - Appropriate Laboratory facilities
 - Personnel & Training
- Special practices & precautions
 - Occupational Health Programs



Biosafety Issues

The BMBL

(2) Safety Equipment

- Primary Containment Barrier
- Minimize exposure to hazard
 - Prevent contact / Contain aerosols
- Engineering controls/ equipment
- Personal Protective Equipment (PPE)
 - Gloves, gowns, Respirator, Face shield, Booties
- Biological Safety Cabinets
- Covered or ventilated animal cage systems



Biosafety Concepts

The BMBL

(3) Facility Design and Construction

- Secondary Barrier/ Engineering controls
- Contributes to worker protection
- Protects outside the laboratory
 - Environment & Neighborhood
- Ex. Building & Lab design, Ventilation, Autoclaves, Cage wash facilities, etc.





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Risk Group Classification for Infectious Agents

In many countries, including the United States, infectious agents are categorized in risk groups based on their relative risk. Depending on the country and/or organization, this classification system might take the following factors into consideration:

- Pathogenicity of the organism
- Mode of transmission and host range
- Availability of effective preventive measures (e.g., vaccines)
- Availability of effective treatment (e.g., antibiotics)
- Other factors

Risk Group Database

[Search Bacteria](#)

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Risk Group and Biosafety Level Definitions

Risk group classifications are primarily used in the research environment as part of a comprehensive biosafety risk assessment.

Risk Classification Criteria for World Health Organization, Australia, Canada, European Union (EU), USA CDC/NIH and NIH for RDNA.

1. WHO Classification of Infective Microorganisms by Risk Group (2004)

WHO Basis for Risk Grouping: Each country classifies the agents in that country by risk group based on pathogenicity of the organism, mode of transmission and host range of the organism. These may be influenced by existing levels of immunity, density and movement of host population presence of appropriate vectors and standards of environmental hygiene.



TRSA

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)

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.

Risk

- Based on what you know about Biosafety Levels, Practices and Operational Controls, what are some discussion issues for conducting Biohazard risk assessments?
- How do you approach risks when addressing a particular organism?

The December 2003 Laboratory-acquired SARS Case at the Institute of Preventive Medicine of the National Defense Medical Center



The First Confirmed Indigenous Case of Dengue Fever Type I Onset on April 22, 2004

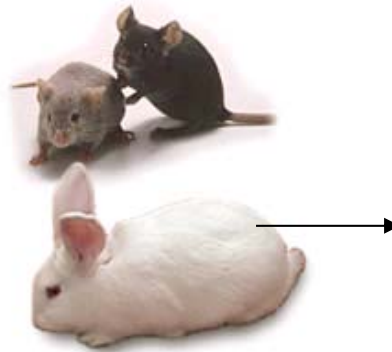
- According to the interview record, the patient was bitten by *Aedes albopictus* while conducting a field trip of collecting *Forcipomyia taiwana* in the JuShan and LuGu area of Nantou County in central Taiwan, five days before the onset of the disease.
- Besides, there were dengue-related projects ongoing at the laboratory the patient worked in early April.



Risk Assessment



In-Vitro



In-Vivo



Human Clinical
Trial

Addressing Risk Assessments

- What is the organism?
- Is it Wild-type, attenuated, irradiated, or chemically treated? Look at kill data or kill curves.
- What is the max. concentration, volume, infectious dose?
- What is the work space like?
- Aerosolizing procedures? How do they contain their aerosols?

Risk Assessment

- Are personnel trained?
- Do personnel understand the organism, infectious dose and symptoms?
- What are their experimental procedures?
- Will they be transporting the material? Shipping intra, inter-state or international?
- Are they doing tissue culture?
- Do they have adequate containment equipment?



Risk Assessment

- Are they doing this work in-vivo?
- Have you consulted and discussed this with the Vets and IACUC to determine special needs and housing?
- Waste issues addressed?
- Pregnancy issues with the organisms?





Risk Assessment

- Do they share their Tissue Culture room?
- Do they have more than 1 Biosafety Cabinet?
- Occupational Health informed and set up to receive patient or offer counseling?

9/24/2013



What Helps?

 BIOHAZARD ABSL 2	 CAUTION BLOODBORN PATHOGEN RISK This room contains animals with human primary and established cell line xenographs. All cages must be opened only in cage changing station. Individuals who handle the identified animals must be enrolled in the bloodborne pathogen program. MCCT specific attire is adequate protection. Emergency Contacts: Amy Harpin: (858) 688-2720 Isidro Lonzano: (858) 245-5216
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**You must
look like this**



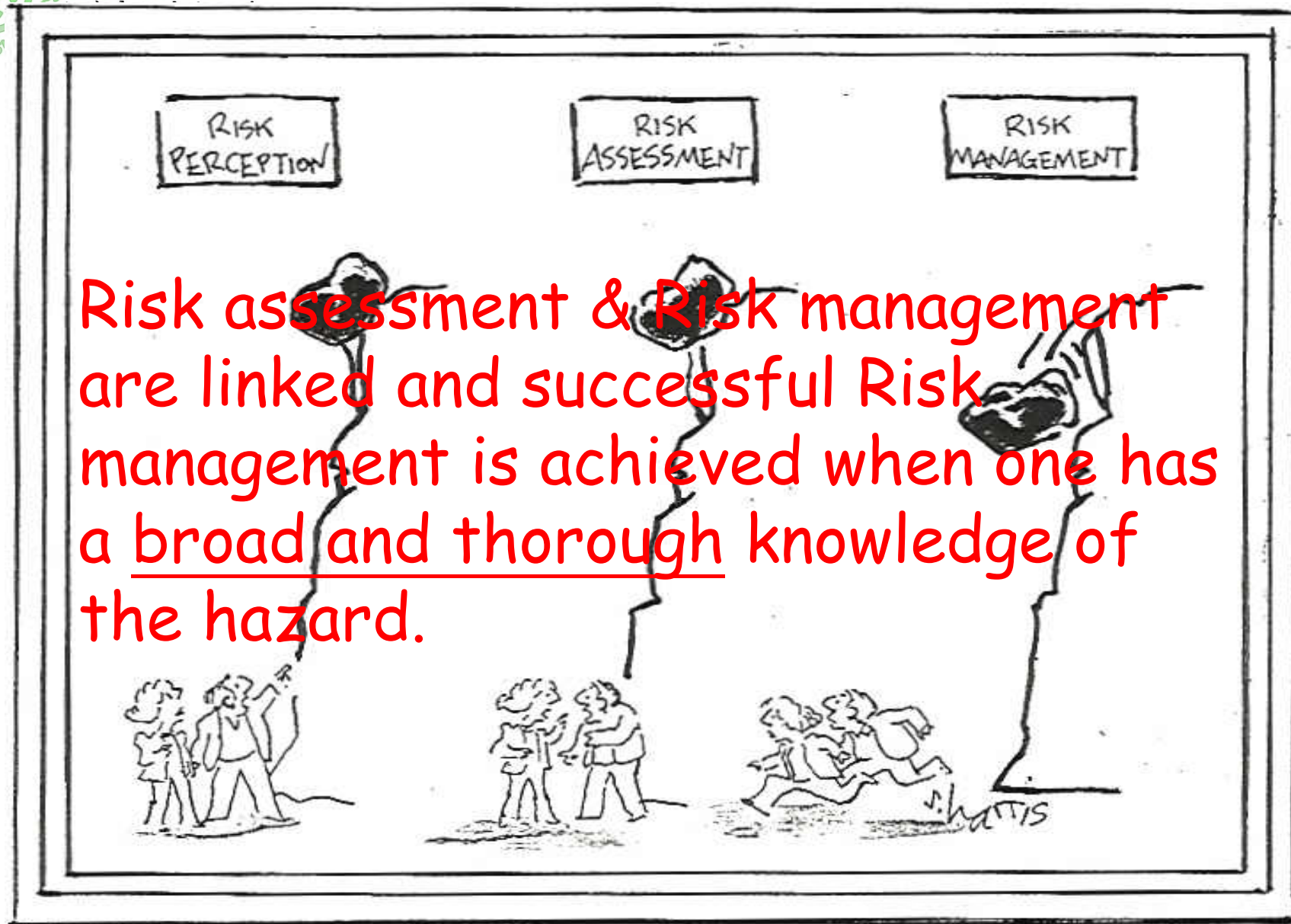
Street Clothes

OR

**Like this
to enter**



Scrubs



Risk assessment & Risk management are linked and successful Risk management is achieved when one has a broad and thorough knowledge of the hazard.