Training on Medical Waste Management

in Collaboration with
Al-Essa Medical and Scientific Equipment Co. W.L.L

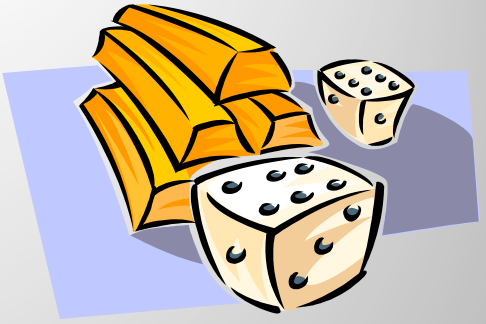
Risk Assessments – Biosafety Levels

Kuwait University
Health Science Center
29 January – 1 February, 2012

Risk Assessment/Risk Management

- **Risk Identification**
  - Adverse events?
- **Risk Estimation**
  - Probability of adverse event?
- **Risk Management**
  - Control measures?

Risk (Definitions)



- **“Possibility of loss, injury, disease, or death.”**
  Webster's Medical Desk Dictionary (1986)
- **“The probability that exposure to a hazard will lead to a negative consequence.”**
  David Ropeik, George Gray (2002)
- **“To risk living is to risk dying.”**
  Anonymous

Risk Assessment

- The emergent science based on toxicology, epidemiology and statistics that utilizes qualitative and quantitative hazard analysis to provide the public with a reasonable estimate of probability of harm.
- "Not a scalpel, but a crude tool that allows you to make estimates." Peter Preuss, US EPA

Find the Balance

Laboratory Hazards

- Biological organisms
- Animals
- Chemicals
- Radiation
- Physical

Risk Assessment

- Difficult process
  (expertise of many fields needed)
- Involves uncertainty
- Range provided (not a specific number)
- Estimates for society (individual risk may vary)
- “Reasonable worst-case estimate” (better to overestimate than underestimate risk)
- Costs and benefits of proposed actions helpful

4 Steps in Risk Assessment (Jeff Wheelwright, 1996)

- 1) Identify health hazard
- 2) Quantify hazard
- 3) Exposure assessment

  (from source to at risk person)
- 4) Determine probability of disease

  (based on exposure estimate and potency of agent)

Biohazard Epidemiology

- **Incidence of Hepatitis among Danish clinical chemistry workers 7X higher than general population**

  (Skinholj, 1974)

- **Risk of acquiring TB 5X greater among medical lab workers in England than general population**

  (Harrington & Shannon, 1976)

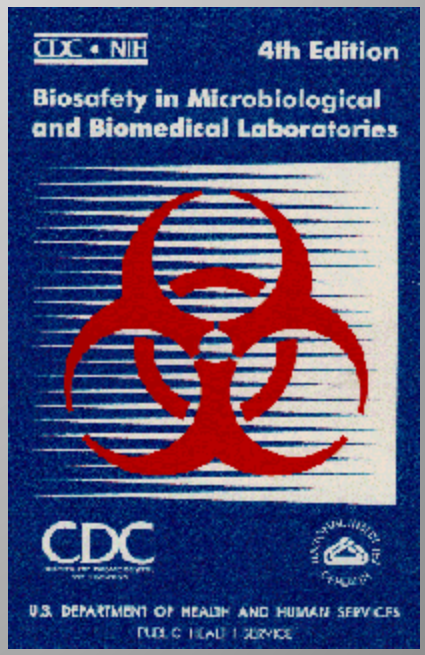
Hierarchy of Controls

- **Anticipation**
- **Recognition**
- **Evaluation**
- **Control**
  - substitution
  - administrative
  - engineering
  - work practices
  - personal protective clothing
  - facility features

Infectious Agents are Classified by Level of Hazard

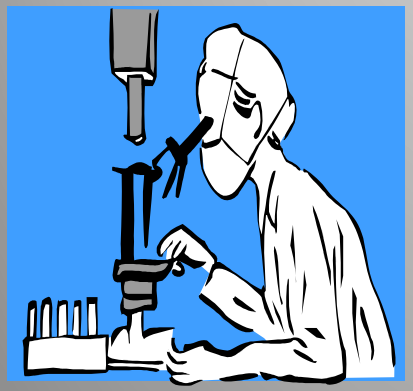
4 Agent Risk Group Classifications

RG1	RG2	RG3	RG4
Low individual risk	Moderate individual risk	High individual risk	
No risk to community	Low risk to community		High risk to community



Risk Groups (RG)

- **RG1**
  - Not infectious to healthy adults
  - e.g. E. coli K12 strains, B. subtilis, S. cerevisiae
- **RG2**



  - Infectious agents of varying severity, treatment usually available, predominantly bloodborne, ingestion, and mucous membrane routes of exposure
  - e.g. Salmonella, Shigella, Vibrio, Plasmodium, Hepatitis B Virus, Cryptococcus neoformans

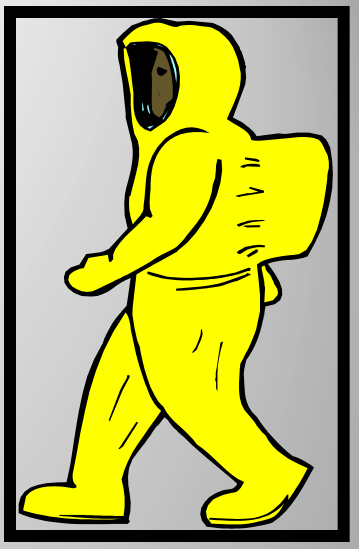
– **Both RG1/RG2 can be used in a basic lab**

- containment equipment to contain aerosols

Risk Groups (RG)

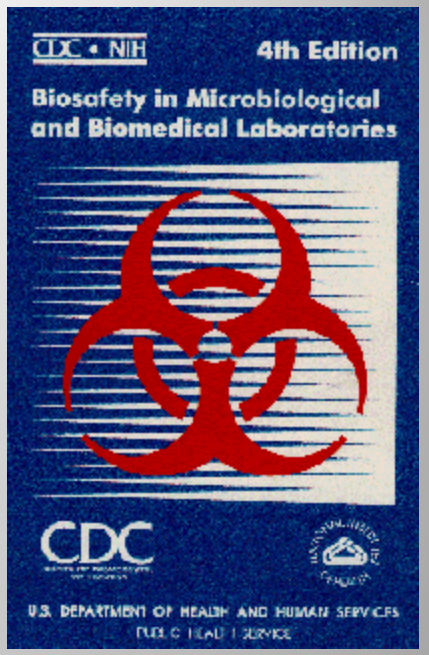
- **RG3**
  - potential to cause serious or lethal disease, airborne route of exposure (and others), treatment generally not available, lower infectious dose.
  - Containment Lab 2 doors off general corridor, dedicated air handler, controlled airflow, all work contained.
  - e.g. TB, Vesicular Stomatitis Virus, Yellow Fever Virus, Coxiella burneti, Francisella tularensis.

Risk Groups (RG)



- **RG4**
  - Dangerous, exotic agents with high risk to individual and community. Aerosol transmission along with all other routes. Very low infectious dose, high mortality rates.
  - Building within building approach for research purposes.
  - e.g. Ebola virus, Marburg virus, Junin, Lassa, Machupo, Sabia, Equine Morbillivirus (Hendra-like viruses), Tick-Borne Encephalitis Viruses

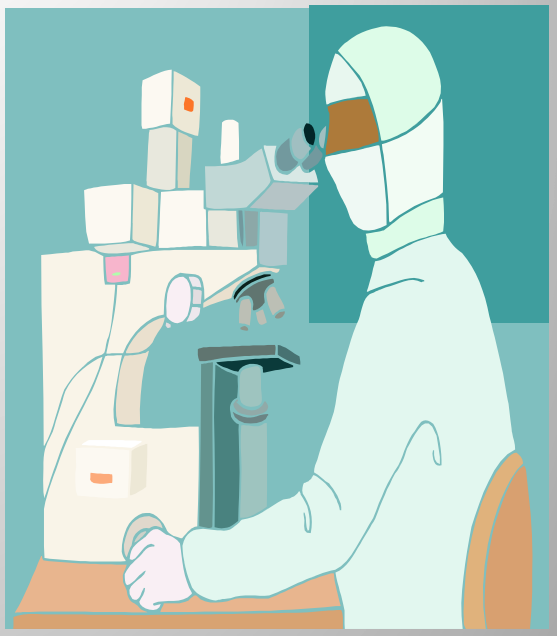
Laboratory Safety Containment Levels



4 Laboratory Biosafety Levels

BSL1 BSL2	BSL3	BSL4
Basic laboratory, confine aerosols in biosafety cabinet if needed	Containment lab, 2 door separation from general traffic, negative air flow, alarms	Maximum containment lab, building w/in building, all features isolated, pos. pressure suits, glove box type isolation

Hybrid Biosafety Level



- **BSL2/BSL3 (BL2+)**
  - Creutzfeld Jacob
  - HIV
  - High risk clinical specimens
- **BSL3-Enhanced (HEPA filtered exhaust Lab)**
  - Yellow Fever, Rift Valley Fever Virus, VEE
  - Rickettsia rickettsii

Unknown Specimens

- **Facility Evaluation (highest level of protection available)**
- **“B.A.R.E”**
  - **Block All Routes of Exposure**

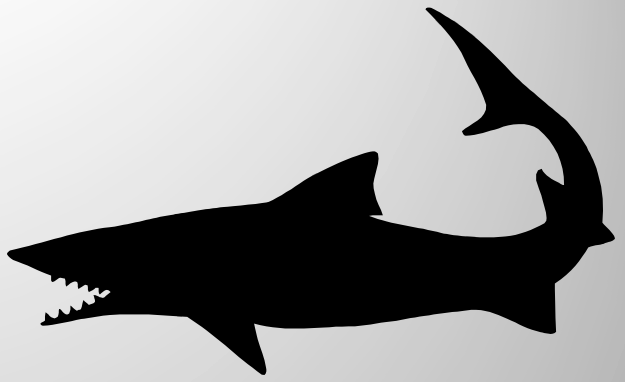
Containment achieved with:

- Good Microbiological practices
- Safety Equipment
- Facility Design

Risk Assessment & Risk Management

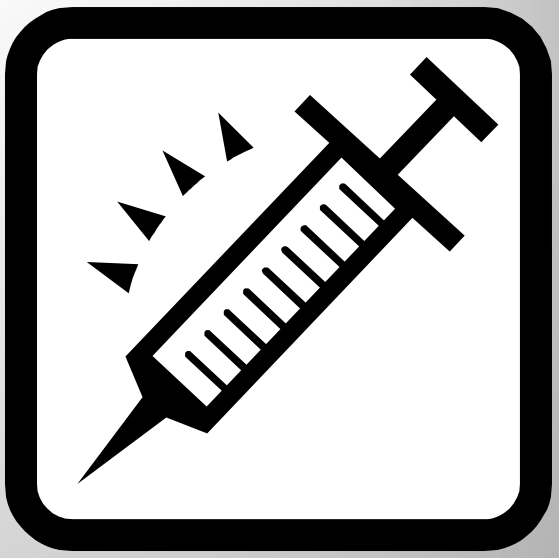
Prior Planning Prevents Poor Performance

Risk Assessment & Risk Management



- Pathogen (Agent)
- Procedures (Protocol)
- Personnel
- Protective Equipment
- Place (Proposed lab facility)

Immunizations



- Vaccinia
- Tetanus
- Meningococcal
- Typhoid
- Botulinum
- Hepatitis B virus, Hepatitis A virus
- Yellow Fever, EEE
- Rabies

Protective Equipment

- Personal Protective Equipment (clothing)
- Containment Equipment
  - Biological safety cabinets
  - Safety centrifuges
  - Sealed sonicators, blenders, homogenizers
  - Sealed tubes, transport carriers
  - Safe sharps, needleboxes, medical waste bags, tongs, forceps, etc.


CORROSIVE
8
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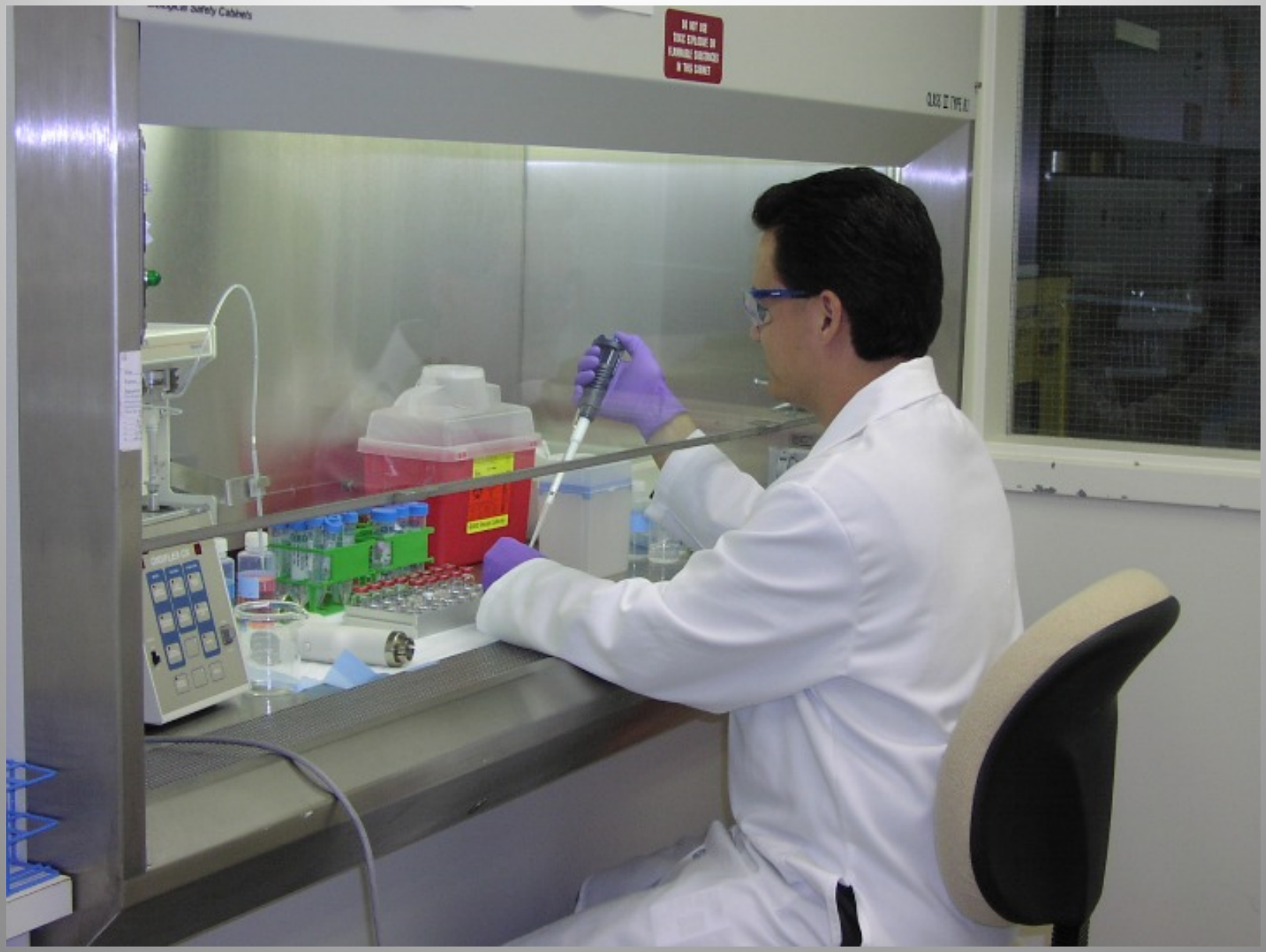


Personal Protective Equipment

- **Protect:** skin
  clothing
  mucous membranes
  respiratory system
- **Use:** gloves (double, kevlar)
  lab coats, solid-front gowns
  sleeve covers
  full face protection
  respiratory protection


NALGENE
4000 mL
3500
3000
2500
2000
1500
1000
500

Personal Protective Equipment

- **Disposable**
- **Decontamination**
- **Dedicated to area**
- **Donning/Doffing**
  - Compromised (wet/contaminated/torn)
  - Respiratory Protection Program

Place (Facility Design)

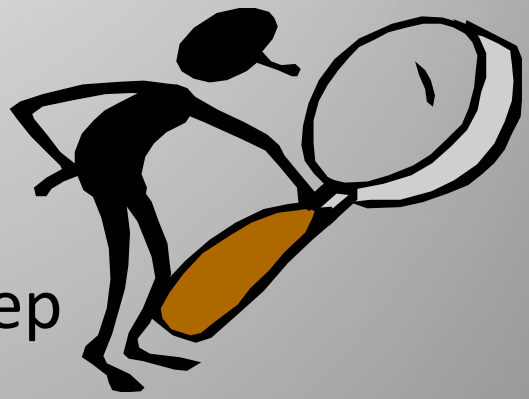
- Restricted access/Door sign
- Easily cleanable
- Hand washing sinks (near exit door)
- Eye wash
- Autoclave
- Vacuum system protection
- Biosafety Cabinet

Place (Facility Design)

- Anteroom
- Negative pressure gradient
- Airflow monitor
- Air changes per hour (10-15)
- Sealed penetrations, coved flooring
- Facility alarms/interlocks
- Communication outside the lab

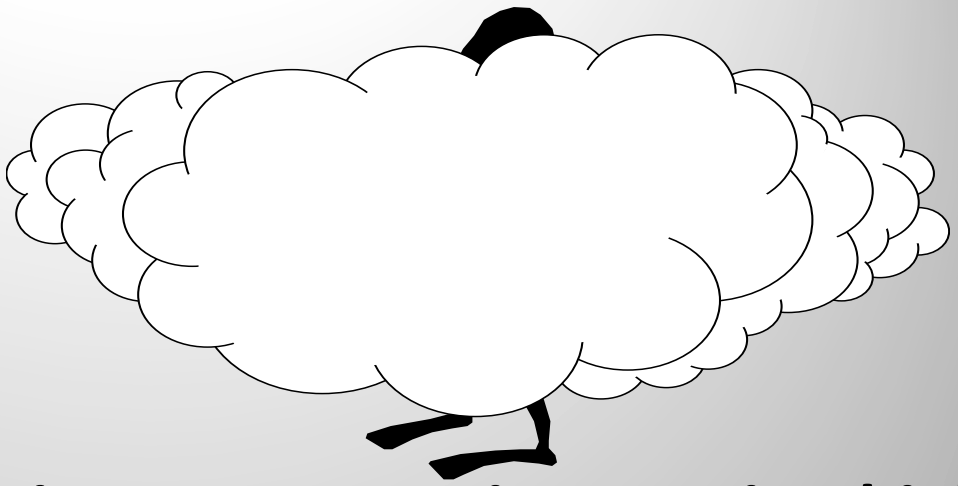
Procedures

- **Develop standard written practices (SOP's) for handling pathogens**
- **Job Safety Analysis (JSA)**
  - identify each task
  - describe all steps
  - hazard assessment at each step
  - incorporate safety



- **Focus on containing aerosol generating procedures and equipment**

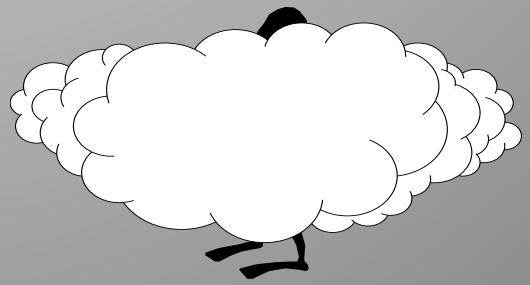
Aerosols



- **Procedures that impart energy into a microbial suspension are a potential source of aerosol (Chatigny, 1974)**
- **Many common lab procedures and accidents have capability of releasing aerosols**
  - homogenization, sonication, blending, mixing, grinding, shaking, vortexing, spills, opening vials, pipetting, animals excreting agent, opening vials under pressure, etc.

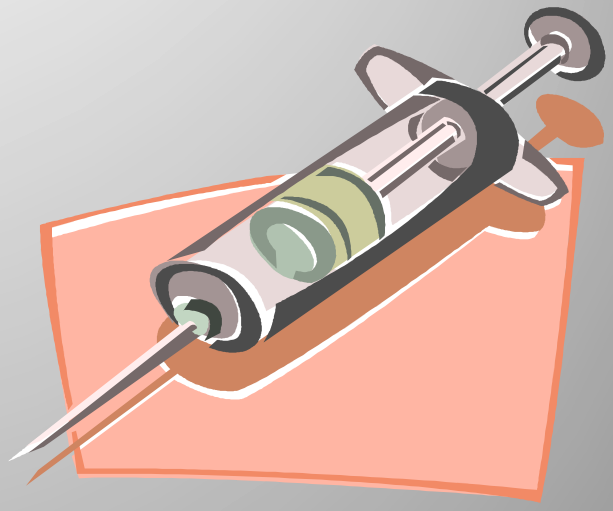
Viable Particles Recovered from Air (Chatigny, 1974)

- **Procedure**
  - sonic oscillator
  - mixing w/ pipette
  - overflow from mixer
  - opening lyophilized vial
  - top removed after blending
  - dropping flask of culture
  - dropping lyophilized culture
- **# Particles/ft^3 of air**
  - 6
  - 7
  - 9
  - 135
  - 1500
  - 1551
  - 4839



Procedures - Sharps Hazards

- **Syringe/Needle**
  - adjusting volume
  - withdrawal from stopper
  - separation from syringe
  - leaking syringe
  - leakage from injection site
  - inappropriate disposal
  - poor work practices



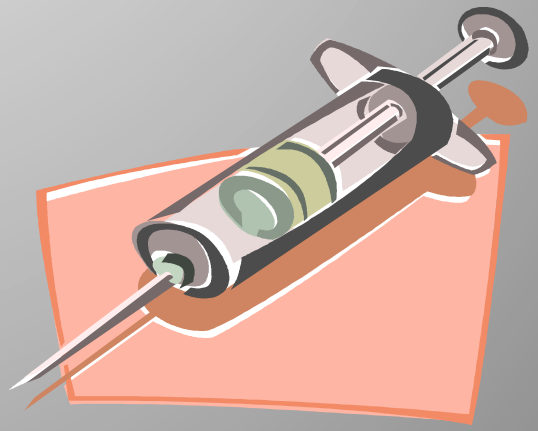
Metal

Glass

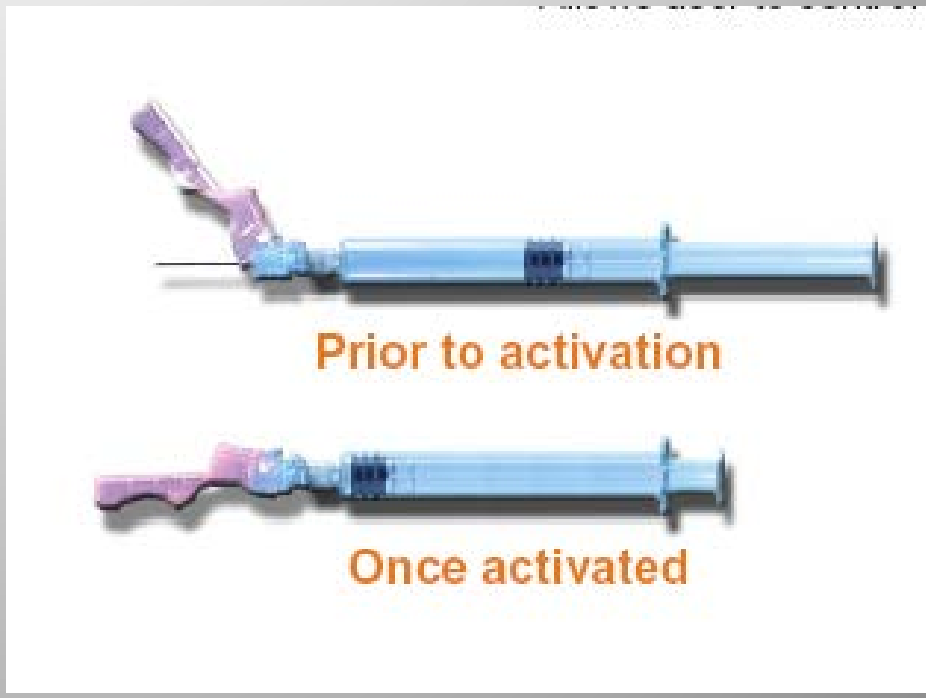
Plastic

Procedures - Sharps Precautions

- **Syringe/Needle**
  - use needle-locking syringes
  - cover with disinfectant soaked gauze
  - animal restraints
  - cleanse inoculation site
  - safe needle practices
  - immediate collection/disposal



BD Eclipse Shielding Hypodermic Needle

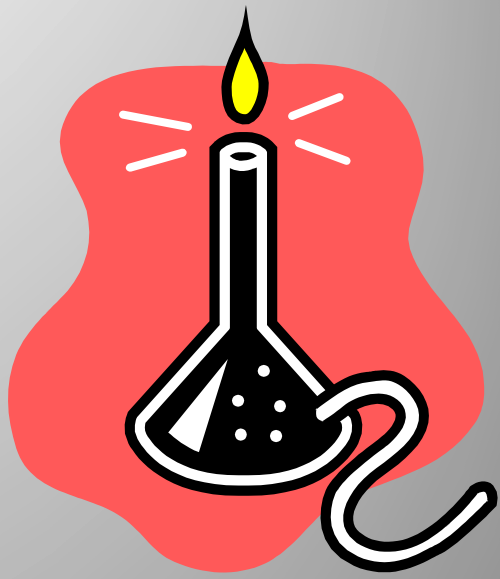


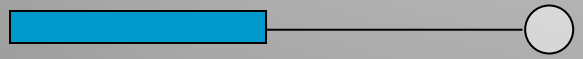
Procedures - Sharps Precautions

- **Needle / Syringe**
  - removal of needle from syringe (hemostat)
  - no recapping, bending, breaking, etc.
  - immediate disposal of intact needle/syringe
  - location of needlebox (vicinity, height)
  - replacement of needleboxes
  - eliminate/minimize use/safe sharp devices
  - avoid glass Pasteur pipettes

Procedures presenting risk

- **Microbiological loop**
  - streaking plates
  - spreading material on slides
  - cooling loop in media
  - heating loop in an open flame





Precautions in Bacteriology

- **Microbiological loop**
  - smooth plates
  - disposable plastic loops
  - well formed loops with short staff
  - glass spreaders
  - electric (walled) micro-incinerators
  - work within a biosafety cabinet

Procedures with general risk

- **Pipetting**
  - mouth pipetting
  - glass Pasteur pipettes
  - blow-out pipettes
  - mixing suspensions
  - spill of droplets onto hard surfaces
- **Eating, drinking, smoking, applying cosmetics**

Procedures

- **Pipetting**
  - no mouth pipetting
  - disposable plastic pipettes
  - mark to mark pipettes
  - collect within biosafety cabinet
  - work over disinfectant-wet pad
- **Restrict consumption of food or beverage to well defined break areas**

Procedures

- **Centrifugation**
  - broken/leaking tubes
  - microfuge tubes (snap caps)
  - (flawed/overfilled)
- **Protective Measures**
  - check O-rings on rotors (use O-ring tubes)
  - safety cups/sealed rotors
  - load/unload in a biosafety cabinet

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Canada

Staphylococcus aureus - Material Safety Data Sheets (MSDS)

MATERIAL SAFETY DATA SHEET - INFECTIOUS SUBSTANCES

SECTION I - INFECTIOUS AGENT

NAME: ***Staphylococcus aureus***

SYNONYM OR CROSS REFERENCE: Staphylococcal diseases, impetigo, toxic shock syndrome, food poisoning, intoxication

CHARACTERISTICS: Gram positive cocci, usually in clusters; coagulase positive; non-spore forming; non-motile; many strains produce exotoxins including staphylococcal enterotoxins A,B,C,D,E, toxic shock syndrome toxin (TSST-1) and exfoliative toxins A, and B

SECTION II - HEALTH HAZARD

PATHOGENICITY: Opportunistic pathogen, normal flora; produces a variety of syndromes with a range of clinical manifestations; clinically different in general community, newborns, menstruating women, and hospitalized patients; food intoxication is characterized by abrupt/violent onset, severe nausea, cramps, vomiting, and diarrhea using lasting 1-2days; animal bites can result in localized infections; may cause surface or deep/system infections in both community and hospital settings; surface infections include impetigo, folliculitis, abscesses, boils, infected lacerations; deep infections include endocarditis, meningitis, septic arthritis, pneumonia, osteomyelitis; systemic infection may cause fever, headache malaise, myalgia; newborns are susceptible to scalded skin syndrome (SSS) caused by exfoliative toxins; my be colonized during delivery resulting in sepsis meningitis; toxic shock syndrome is an acute multi-system illness caused by TSST-1 a super antigen; characterized by sudden onset, high fever, vomiting, profuse watery diarrhea, myalgia, hypotension erythematous rash

EPIDEMIOLOGY: Occurs worldwide; particularly in areas where personal hygiene is suboptimal; in hospitals by development of antibiotic-resistant strains

HOST RANGE: Humans; to a lesser extent, warm-blooded animals

INFECTIOUS DOSE: Virulence of strains varies greatly

MODE OF TRANSMISSION: Contact with nasal carriers (30-40% of population); from draining lesions or purulent discharges; spread person-to-person; ingestion of food containing staphylococcal enterotoxin (food may be contaminated by food handlers hands); from mother to neonate during delivery

INCUBATION PERIOD: Variable and indefinite, commonly 4-10 days; disease may not occur until several months after colonization; interval between eating food and onset of symptoms is usually 2-4 hours (30 min to 8 hours)

SECTION III - DISSEMINATION

RESERVOIR: Human; patients with indwelling catheters or IVs act as reservoirs for nosocomial infections; food borne - occasionally cows with infected udders

ZOONOSIS: Yes - direct or indirect contact with infected animals

VECTORS: None

SECTION IV - VIABILITY

DRUG SUSCEPTIBILITY: Many strains are multi-resistant to antibiotics and are of increasing importance; methicillin resistant (MRSA) strains have caused major outbreaks world-wide; Vancomycin resistant (VRSA) are being increasingly isolated; sensitivity must be determined for each strain

SUSCEPTIBILITY TO DISINFECTANTS: Susceptible to many disinfectants - 1% sodium hypochlorite, iodine/alcohol solutions, glutaraldehyde, formaldehyde

PHYSICAL INACTIVATION: Organisms are destroyed by heat (moist heat - 121° C for at least 15 min, dry heat - 160-170° C for at least 1 hour; enterotoxins are heat resistant, stable at boiling temperature

SURVIVAL OUTSIDE HOST: Carcass and organs - up to 42 days; floor - less than 7 days; glass - 46 hours; sunlight - 17 hours; UV - 7 hours; meat products - 60 days; coins - up to 7 days; skin from 30 min to 38 days

SECTION V - MEDICAL

SURVEILLANCE: Monitor for skin inflammation if wounded by a sharp instrument; isolation of organism from wound or blood, CSF, urine; isolation of> 10^5 organisms or enterotoxin from suspected food

FIRST AID/TREATMENT: Fluid replacement for food poisoning; in localized skin infections, drain abscesses; antibiotic therapy for severe infections

IMMUNIZATION: None

PROPHYLAXIS: None

SECTION VI - LABORATORY HAZARDS

LABORATORY-ACQUIRED INFECTIONS: 29 reported cases up to 1973 with 1 death

SOURCES/SPECIMENS: Clinical specimens - blood, abcesses, lesion exudates, CSF, respiratory specimens, feces, urine

PRIMARY HAZARDS: Injuries from contaminated sharp instruments; ingestion; aerosols

SPECIAL HAZARDS: Direct contact with open cuts and lesions of skin

SECTION VII - RECOMMENDED PRECAUTIONS

CONTAINMENT REQUIREMENTS: Biosafety level 2 practices, containment equipment and facilities for activities with cultures or potentially infectious clinical materials

PROTECTIVE CLOTHING: Laboratory coat: gloves when skin contact is unavoidable

OTHER PRECAUTIONS: Thorough handwashing before leaving the laboratory and after handling infectious materials

SECTION VIII - HANDLING INFORMATION

SPILLS: Allow aerosols to settle; wear protective clothing; gently cover spill with paper towel and apply 1% sodium hypochlorite, starting at perimeter and working towards the centre; allow sufficient contact time (30 min) before clean up

DISPOSAL: Decontaminate before disposal; steam sterilization, chemical disinfection

STORAGE: In sealed containers that are appropriately labelled

Hepatitis B virus - Material Safety Data Sheets (MSDS)

MATERIAL SAFETY DATA SHEET - INFECTIOUS SUBSTANCES

SECTION I - INFECTIOUS AGENT

NAME: ***Hepatitis B virus***

SYNONYM OR CROSS REFERENCE: Serum hepatitis, type B hepatitis, homologous serum jaundice, Australia antigen hepatitis, HBV, viral hepatitis B, HB

CHARACTERISTICS: Partially double-stranded DNA, 42-47 nm diameter, enveloped, *Hepadnaviridae*; lipoprotein coat contains the HBsAg

SECTION II - HEALTH HAZARD

PATHOGENICITY: Two major forms: asymptomatic infection and symptomatic hepatitis; onset is insidious with anorexia, vague abdominal discomfort, nausea and vomiting, sometimes arthralgias and rash, often progressing to jaundice; fever may be absent or mild; severity ranges from inapparent cases to fatal acute hepatic necrosis, or becomes chronically infected; low short term case fatality rate in hospitalized patients; long term case fatality rate is 2-3% due to cancer or cirrhosis of the liver; 95% of adult infections are self limited

EPIDEMIOLOGY: Worldwide; endemic with little seasonal variation; commonly in young adults in North America and in infancy or childhood in Africa and Asia; antigen carrier rate in North America is under 1% for the general population and 10-15% in Asia; common in high risk groups - drug abusers, persons in the health care field exposed to blood or serous fluids, sexually promiscuous individuals

HOST RANGE: Humans (chimpanzees are susceptible)

INFECTIOUS DOSE: Not known, however, 1 mL of infected blood may contain from 10^2-10^9 HBV particles

MODE OF TRANSMISSION: Percutaneous or permucosal exposure to infectious body fluids (blood, blood products, cerebral spinal fluid, serum-derived fluids, saliva, semen, vaginal fluids, unfixed tissues and organs), indirect contact with contaminated items in the laboratory; commonly spread by contaminated needles, syringes and other IV equipment; contamination of wounds or lacerations; exposure of mucous membranes; sexual contact, household contact, perinatal transmission from mother to infant, nosocomial exposure

INCUBATION PERIOD: Usually 24-180 days; average 60-90 days; HBsAg can appear in 2 weeks or rarely, 6-9 months, depending on dose, mode of transmission and host factors

COMMUNICABILITY: Blood can be infective weeks before onset of symptoms; remains infective through clinical and chronic carrier states; infectivity of chronically infected individuals varies from highly infectious to sparingly infectious; sera of infected individuals may contain as many as 10^{10} infectious virons per mL

SECTION III - DISSEMINATION

RESERVOIR: Humans, chimpanzees are susceptible, but an animal reservoir in nature has not been recognized

ZOONOSIS: None

VECTORS: None

SECTION IV - VIABILITY

DRUG SUSCEPTIBILITY: No specific antivirals

SUSCEPTIBILITY TO DISINFECTANTS: Susceptible to many disinfectants; 1% sodium hypochlorite, 70% ethanol, 2% alkalinized glutaraldehyde, formaldehyde

PHYSICAL INACTIVATION: Stable at 37°C for 60 minutes and 56° C for 30 minutes but not at temperatures above 60°C; stable at pH 2.4 for up to 6 hours (some infectivity is lost); HBsAg not destroyed by UV of blood products; stable for years at -70° C

SURVIVAL OUTSIDE HOST: Survives in dried blood for long periods (weeks), stable on environmental surfaces for a least 7 days at 25° C

SECTION V - MEDICAL

SURVEILLANCE: Testing of blood samples for the presence of HBsAg, EIA, RIA, PCR

FIRST AID/TREATMENT: Alpha interferon licensed for treatment of chronic infection. About 30% effective in elimination of "e" antigenemia; Lavivudine (reverse transcriptase inhibitor) is being investigated for chronic infections

IMMUNIZATION: Inactivated vaccine is available and recommended for those of increased risk such as laboratory workers and other health care workers exposed to blood

PROPHYLAXIS: Hepatitis B immunoglobulin (HBIG)

SECTION VI - LABORATORY HAZARDS

LABORATORY-ACQUIRED INFECTIONS: The most frequently occurring laboratory-associated infection; incidence in some categories of laboratory workers is 7 times greater that of the general population; 234 reported cases up to 1974 with one death (3921 total infections surveyed); 26 reported cases in UK laboratories from 1980-1987

SOURCES/SPECIMENS: Blood and blood products, urine, semen, CSF, and saliva

PRIMARY HAZARDS: Parenteral inoculation; droplet exposure of mucous membranes; contact exposure of broken skin

SPECIAL HAZARDS: Needle stick with infected blood

SECTION VII - RECOMMENDED PRECAUTIONS

CONTAINMENT REQUIREMENTS: Biosafety level 2 practices and containment for activities utilizing infectious body fluids and tissues; biosafety level 3 primary containment and personnel precautions for activities with high potential for droplet or aerosol production and high production quantities or

concentrations; animal biosafety level 2 for work with non-human primates

PROTECTIVE CLOTHING: Laboratory coat; gloves when skin contact is unavoidable and when working with animals; wrap-around gown and gloves for work in biosafety cabinet

OTHER PRECAUTIONS: General needle safety precautions important - do not bend, break or recap needles; dispose directly into puncture-proof container, universal precaution for blood, blood products or specimens containing or contaminated with blood

SECTION VIII - HANDLING INFORMATION

SPILLS: Allow aerosols to settle; wearing protective clothing, gently cover spill with absorbent paper towel and apply 1% sodium hypochlorite, starting at perimeter and working towards the centre; allow sufficient contact time (30 min) before clean up

DISPOSAL: Decontaminate before disposal; steam sterilization, chemical disinfection, incineration

STORAGE: In sealed containers that are appropriately labelled

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HPV

HUMAN PAPILLOMARVIRUS

PATHOGEN SAFETY DATA SHEET - INFECTIOUS SUBSTANCES

SECTION I - INFECTIOUS AGENT

NAME: Human papillomavirus

SYNONYM OR CROSS REFERENCE: HPV, cervical cancer, cervical and uterine carcinoma, cervical dysplasia, genital warts (condyloma acuminatum, venereal warts, anal and anogenital warts), the common wart (*verruca vulgaris*), papilloma venereum, the common types are 6, 11, 16, 18, 31, 45, and 58.

CHARACTERISTICS: Part of the Papillomaviridae family, HPV is a closed circular double-stranded DNA virus located in a non-enveloped, icosahedral capsid that is 55 nm in diameter[1,2]. Over 100 types of HPV have been identified, 80 types have been sequenced, and it is believed that over 200 types exist based on partially sequenced fragments[3]. It is a very common sexually transmitted disease, with over 50 different types causing anogenital infections[4]. Of those, 25 are proven or likely human carcinogens[5].

SECTION VI - LABORATORY HAZARDS

LABORATORY –ACQUIRED INFECTIONS : None reported to date.

SOURCES/SPECIMENS: Warts on perianal or common skin infected outer skin tissues, and melanoma biopsy tissues[9,20].

PRIMARY HAZARDS: Accidental skin contact with infected wart tissue may lead to development of common wart (*verruca vulgaris*), due to benign cutaneous HPV types[21]. Accidental transmission of genital HPVs from clinical specimens has not been reported and it should be considered very unlikely.

SPECIAL HAZARDS: None.

SECOND VII - EXPOSURE CONTROLS / PERSONAL PROTECTION

RISK GROUP CLASSIFICATION: Risk Group 2[22].

CONTAINMENT REQUIREMENTS: Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials, animals, or cultures.

PROTECTIVE CLOTHING: Lab coat. Gloves when direct skin contact with infected materials or animals is unavoidable. Eye protection must be used where there is a known or potential risk of exposure to splashes[23].

OTHER PRECAUTIONS: All procedures that may produce aerosols, or involve high concentrations or large volumes should be conducted in a biological safety cabinet (BSC). The use of needles, syringes, and other sharp objects should be strictly limited. Additional precautions should be considered with work involving animals or large scale activities[23].

Issues with Infectious/Clinical Waste

- **Transmission of *Mycobacterium tuberculosis* From Medical Waste Kammy R. Johnson, DVM, PhD; et al**

  JAMA. 2000; 284:1683-1688.

  ABSTRACT

  Context Washington State has a relatively low incidence rate of tuberculosis (TB) infection. However, from May to September 1997, 3 cases of pulmonary TB were reported among medical waste treatment workers at 1 facility in Washington. There is no previous documentation of *Mycobacterium tuberculosis* transmission as a result of processing medical waste.

CalOSHA report faults UCLA, professor in lab death January 12, 2012

LOS ANGELES (KABC) -- A new report by the California Division of Occupational Safety and Health blames a UCLA professor and the university for a lab accident in 2008 that killed a staff research assistant.

The criminal investigation report obtained by the Los Angeles Times stated that 23-year-old Sheharbano "Sheri" Sangji wasn't experienced or well-trained, if not trained at all, to handle the chemicals that killed her.

Sangji was severely burned over nearly half her body when air-sensitive chemicals burst into flames and ignited her clothes at a campus lab in December 2008. She died 18 days later.

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Supplement / Vol. 61
January 6, 2012

Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories

Recommendations of a CDC-convened, Biosafety Blue Ribbon Panel

http://www.cdc.gov/mmwr/pdf/other/su6101.pdf